

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

F2_R2

C Number: C20007
Lock Date: 03/27/2007
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.2.0

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 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 1

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601481

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Bone Marrow	* Brain
* Esophagus	* Eye	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Mammary Gland	* Parathyroid Gland
* Preputial Gland	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Degeneration Hyperplasia	Cystic, Moderate Minimal
[Degeneration TGLs = 1 - 8]			
* Adrenal Medulla		Pheochromocytoma Benign	
* Epididymis		Mesothelioma Malignant	
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver	Bile Duct	Basophilic Focus Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Lymph Node, Mesenteric		Atrophy	Minimal
* Nose		Inflammation	Minimal
* Pancreas		Atrophy	Mild
* Pituitary Gland	Pars Distalis	Adenoma	
[Adenoma TGLs = 2 - 14]			
* Prostate		Inflammation	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Germinal Epith	Degeneration	Mild

* PROTOCOL REQUIRED TISSUE

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Lab: BAT

ANIMAL NUM: 1

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601481

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Atrophy

Moderate

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 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 2

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601482

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Bone Marrow |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Pancreas |
| * Parathyroid Gland | * Preputial Gland | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|--------------------------|------------------------|-------------------------|
| * Adrenal Cortex | Zona Fascult | Hyperplasia | Minimal |
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Clear Cell Focus | |
| | | Hepatocellular Adenoma | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolar Epith | Hypertrophy | Minimal |
| | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 1 - 8] | | |
| * Prostate | | Inflammation | Mild |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Minimal |
| * Testes | Interstit Cell | Adenoma | |
| | Interstit Cell | Hyperplasia | Minimal |
| * Thymus | | Atrophy | Moderate |
| Tooth | | Malformation | Minimal |

* PROTOCOL REQUIRED TISSUE

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 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 3

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 651
HISTO: 0601483

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Mammary Gland	* Pancreas	* Parathyroid Gland
Peripheral Nerve	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Skin	Spinal Cord	* Stomach, Forestomach	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Leukemia Mononuclear	
* Bone Marrow		Hyperplasia	Moderate
* Eye	Retina	Degeneration	Mild
* Heart		Cardiomyopathy	Mild
* Islets, Pancreatic		Adenoma	
* Kidney		Leukemia Mononuclear	
		Nephropathy	Minimal
* Liver	Bile Duct	Hyperplasia	Minimal
		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 4 - 6+7]		
* Lung		Leukemia Mononuclear	
* Lymph Node, Mesenteric		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 5 - 16]		
Mesentery		Hemorrhage	Moderate
	Note: Hemorrhage is organizing (has areas of fibroplasia).		
	[Hemorrhage TGLs = 3 - 15]		
* Nose		Inflammation	Minimal
* Pituitary Gland		Hemorrhage	Mild
		Leukemia Mononuclear	
	[Hemorrhage TGLs = 1 - 8]		

* PROTOCOL REQUIRED TISSUE

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Lab: BAT

ANIMAL NUM: 3

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 651
HISTO: 0601483

ORGAN AND ACCOUNTABLE SITE STATUS

* Prostate		Inflammation	Moderate
* Spleen		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 2 - 14]		
* Stomach, Glandular		Inflammation	Mild
* Testes	Germinal Epith Interstit Cell	Degeneration Hyperplasia	Minimal Mild
* Thymus		Atrophy	Marked
* Thyroid Gland	C Cell	Adenoma	

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

Animal Note: Spinal cord and sciatic nerve were processed, as per protocol, because this rat had neurologic signs.

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 Lab: BAT

ANIMAL NUM: 4

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601484

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Pancreas	* Parathyroid Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Moderate
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
	[Clear Cell Focus TGLs = 2,3 - 14+15]		
* Nose		Inflammation	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Marked

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
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P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

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 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 5

TMT: 1

SEX: Male

DAY ON TEST: 727

DOSE: 0.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601485

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Hypertrophy	Minimal
* Heart		Cardiomyopathy	Mild
* Intestine Large, Colon		Parasite Metazoan	
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Interstit Cell	Adenoma	
	Interstit Cell	Hyperplasia	Moderate
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Marked
Tooth		Malformation	Minimal

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 Lab: BAT

ANIMAL NUM: 6

TMT: 1

SEX: Male

DAY ON TEST: 610

DOSE: 0.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601486

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Parathyroid Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Marked
* Heart		Cardiomyopathy	Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Hepatodiaphragmatic Nodule	
	Bile Duct	Hyperplasia	Minimal
		Leukemia Mononuclear	
	[Hepatodiaphragmatic Nodule TGLs = 4 - 15]		
	[Leukemia Mononuclear TGLs = 3 - 6+7]		
* Lung	Alveolar Epith	Hypertrophy	Minimal
		Inflammation	Chronic Active, Mild
Mesentery	Fat	Necrosis	Minimal
	Note: Lesion was in fat adjacent to routine section of pancreas (B06).		
* Nose		Inflammation	Minimal
* Pancreas		Atrophy	Mild
* Pituitary Gland	Pars Distalis	Adenoma	
* Spleen		Hemorrhage	Moderate
		Leukemia Mononuclear	
		Necrosis	Mild

* PROTOCOL REQUIRED TISSUE

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First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 6

TMT: 1

SEX: Male

DAY ON TEST: 610

DOSE: 0.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601486

ORGAN AND ACCOUNTABLE SITE STATUS

[Leukemia Mononuclear TGLs = 1 - 15]			
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation Ulcer	Mild Moderate Moderate
[Ulcer TGLs = 5 - 14]			
* Testes	Bilateral, Interstit Cell	Adenoma	
[Adenoma TGLs = 2 - 11]			
* Thymus		Atrophy	Moderate

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

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Date Report Requested: 09/17/2010
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 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 7

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 629
HISTO: 0601487

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| Blood Vessel | * Bone | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Parathyroid Gland |
| * Preputial Gland | * Salivary Glands | * Seminal Vesicle | * Skin |
| * Spleen | * Stomach, Forestomach | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|---|---|-------------------------------|------------------------------|
| * Adrenal Cortex | | Fibrous Histiocytoma | Metastatic (Skeletal Muscle) |
| * Adrenal Medulla | | Hyperplasia | Minimal |
| * Bone Marrow | | Hyperplasia | Moderate |
| * Brain | | Necrosis | Minimal |
| Note: A cluster of fibrous histiocytoma cells is present in a cerebral vessel (but not growing in brain). Such a tumor embolus may be responsible for the necrosis. | | | |
| * Heart | Atrium | Cardiomyopathy | Minimal |
| | | Thrombosis | Mild |
| | [Thrombosis TGLs = 2 - 7] | | |
| * Kidney | | Accumulation, Hyaline Droplet | Minimal |
| | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Fibrous Histiocytoma | Metastatic (Skeletal Muscle) |
| | | Pigmentation | Hemosiderin, Moderate |
| | [Fibrous Histiocytoma TGLs = 4,5,6 - 6+7+16+17] | | |
| * Lung | | Fibrous Histiocytoma | Metastatic (Skeletal Muscle) |
| | | Inflammation | Chronic Active, Mild |
| | | Necrosis | Mild |
| Note: Eosinophilic crystals are present in areas with inflammation and necrosis. | | | |
| | [Fibrous Histiocytoma TGLs = 1 - 3+4] | | |
| * Nose | | Inflammation | Mild |

* PROTOCOL REQUIRED TISSUE

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Lab: BAT

ANIMAL NUM: 7

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 629
HISTO: 0601487

ORGAN AND ACCOUNTABLE SITE STATUS

* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Prostate		Inflammation	Mild
Skeletal Muscle		Fibrous Histiocytoma	
	[Fibrous Histiocytoma TGLs = 7 - 14+15]		
* Stomach, Glandular		Inflammation	Mild
	Epithelium	Necrosis	Mild
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 3 - 11]		
* Thymus		Atrophy	Marked

PRIMARY CAUSE OF DEATH - Skeletal Muscle Fibrous Histiocytoma

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 Lab: BAT

ANIMAL NUM: 8

TMT: 1
 DOSE: 0.0 G/KG

SEX: Male
 DISP: Terminal Sacrifice

DAY ON TEST: 729
 HISTO: 0601488

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| Blood Vessel | * Bone | * Brain | * Epididymis |
| * Esophagus | * Eye | * Harderian Gland | * Intestine Large, Cecum |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Mammary Gland | * Nose | * Pancreas |
| * Parathyroid Gland | * Pituitary Gland | * Preputial Gland | * Prostate |
| * Salivary Glands | * Seminal Vesicle | * Stomach, Forestomach | * Stomach, Glandular |
| * Thyroid Gland | * Trachea | * Urinary Bladder | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--------------------------|---|----------------------|----------|
| * Adrenal Cortex | | Hypertrophy | Mild |
| | | Leukemia Mononuclear | |
| | | Necrosis | Minimal |
| * Adrenal Medulla | | Leukemia Mononuclear | |
| * Bone Marrow | | Hyperplasia | Moderate |
| * Heart | | Cardiomyopathy | Mild |
| * Intestine Large, Colon | | Parasite Metazoan | |
| * Kidney | | Leukemia Mononuclear | |
| | | Mineralization | Minimal |
| * Liver | | Leukemia Mononuclear | |
| | [Leukemia Mononuclear TGLs = 4 - 6+7] | | |
| * Lung | | Leukemia Mononuclear | |
| * Lymph Node, Mesenteric | | Leukemia Mononuclear | |
| * Skin | Subcut Tiss | Fibroma | |
| | [Fibroma TGLs = 1 - 14] | | |
| * Spleen | | Leukemia Mononuclear | |
| | [Leukemia Mononuclear TGLs = 2 - 15] | | |
| * Testes | Interstit Cell | Adenoma | |
| | Interstit Cell | Hyperplasia | Minimal |
| | [Adenoma TGLs = 3 - 11] | | |

* PROTOCOL REQUIRED TISSUE

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Lab: BAT

ANIMAL NUM: 8

TMT: 1

SEX: Male

DAY ON TEST: 729

DOSE: 0.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601488

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Atrophy

Moderate

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 Lab: BAT

ANIMAL NUM: 9

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601489

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Moderate
* Intestine Large, Colon		Parasite Metazoan	
* Islets, Pancreatic		Adenoma	
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
	[Eosinophilic Focus TGLs = 3,4 - 15]		
* Lung	Alveolar Epith	Hyperplasia	Moderate
		Inflammation	Chronic Active, Minimal
	Alveolar Epith	Metaplasia	Squamous, Minimal
* Prostate		Inflammation	Minimal
* Skin	Dermis	Fibroma	
	[Fibroma TGLs = 1 - 14]		
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 2 - 11]		

* PROTOCOL REQUIRED TISSUE

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Lab: BAT

ANIMAL NUM: 9

TMT: 1

SEX: Male

DAY ON TEST: 727

DOSE: 0.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601489

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Atrophy

Moderate

* Thyroid Gland

C Cell

Adenoma

Tooth

Malformation

Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 10

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601490

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Moderate
* Intestine Large, Colon		Parasite Metazoan	
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Mild
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate
* Thyroid Gland	Follicular Cel	Adenoma	
	[Adenoma TGLs = 2 - 8]		

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 11

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601491

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Vacuolization Cytoplasmic	Moderate
* Bone Marrow		Hyperplasia	Minimal
* Eye	Cornea	Fibrosis	Mild
	Retina	Retinal Detachment	Marked
	Iris	Synechia	Marked
	[Fibrosis TGLs = 1 - 10]		
* Heart		Cardiomyopathy	Mild
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Fatty Change	Diffuse, Minimal
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Skin	Subcut Tiss	Fibroma	
	[Fibroma TGLs = 3 - 14]		
* Spleen		Hematopoietic Cell Proliferation	Mild
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 2 - 11]		
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Adenoma	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 12

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 582
HISTO: 0601492

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Parathyroid Gland
* Preputial Gland	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Fatty Change	Diffuse, Minimal
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Lung		Inflammation	Chronic Active, Minimal
* Pancreas	Acinus	Adenoma	
		Atrophy	Minimal
	[Adenoma TGLs = 2 - 14]		
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 3 - 8]		
* Prostate		Inflammation	Mild
* Spleen		Accessory Spleen	
	[Accessory Spleen TGLs = 1 - 14]		
* Testes	Interstit Cell	Adenoma	
	Interstit Cell	Hyperplasia	Mild
* Thymus		Atrophy	Marked

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 12

TMT: 1

SEX: Male

DAY ON TEST: 582

DOSE: 0.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601492

ORGAN AND ACCOUNTABLE SITE STATUS

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 13

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601493

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric | * Mammary Gland |
| * Pancreas | * Parathyroid Gland | * Preputial Gland | * Salivary Glands |
| * Seminal Vesicle | * Skin | * Stomach, Forestomach | * Stomach, Glandular |
| * Thyroid Gland | * Trachea | * Urinary Bladder | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--------------------------------------|--------------------|-------------------------|
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | [Eosinophilic Focus TGLs = 1 - 14] | | |
| * Nose | | Inflammation | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Minimal |
| * Prostate | Epithelium | Hyperplasia | Minimal |
| | | Inflammation | Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 2 - 11] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 14

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601494

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mesenteric
* Mammary Gland	* Pancreas	* Parathyroid Gland	* Preputial Gland
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Islets, Pancreatic		Adenoma	
* Kidney		Mineralization	Minimal
* Liver		Clear Cell Focus	
	Bile Duct	Eosinophilic Focus	
		Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
	[Eosinophilic Focus TGLs = 3 - 6+7+14]		
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Nose		Inflammation	Mild
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 1 - 15]		
* Prostate	Epithelium	Hyperplasia	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 2 - 11]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 15

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601495

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Parathyroid Gland | * Preputial Gland | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---------------------------|------------------------------|-------------------------|
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Clear Cell Focus | |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | | Alveolar/Bronchiolar Adenoma | |
| | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Moderate |
| * Prostate | | Inflammation | Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Moderate |
| * Urinary Bladder | Transit Epithe | Hyperplasia | Mild |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 16

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 504
HISTO: 0601496

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Heart | * Intestine Large, Cecum |
| * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric |
| * Mammary Gland | * Nose | * Pancreas | * Preputial Gland |
| * Salivary Glands | * Seminal Vesicle | * Skin | * Stomach, Glandular |
| * Testes | * Thyroid Gland | * Trachea | * Urinary Bladder |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|--------------------------|----------------|-------------------|
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Moderate |
| * Liver | | Fatty Change | Diffuse, Moderate |
| * Parathyroid Gland | | Hyperplasia | Mild |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 1 - 8] | | |
| * Prostate | | Inflammation | Moderate |
| * Spleen | | Pigmentation | Hemosiderin, Mild |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Moderate |
| | | Inflammation | Moderate |
| | | Ulcer | Mild |
| * Thymus | | Atrophy | Moderate |

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 17

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601497

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric | * Mammary Gland |
| * Pancreas | * Parathyroid Gland | * Preputial Gland | * Salivary Glands |
| * Seminal Vesicle | * Skin | * Stomach, Forestomach | * Stomach, Glandular |
| * Thyroid Gland | * Trachea | * Urinary Bladder | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--|---------------------------|------------------|-------------------------|
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Moderate |
| * Liver | | Basophilic Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Nose | Respirat Epith | Hyperplasia | Mild |
| | | Inflammation | Mild |
| Note: Hyperplasia of respiratory epithelium was diagnosed because it was more extensive than the degree of inflammation appeared to justify. | | | |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| * Prostate | Epithelium | Hyperplasia | Minimal |
| | | Inflammation | Moderate |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Interstit Cell | Adenoma | |
| | Interstit Cell | Hyperplasia | Moderate |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 18

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601498

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Mammary Gland	* Nose
* Parathyroid Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Stomach, Glandular	* Trachea	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Leukemia Mononuclear	
* Bone Marrow		Hyperplasia	Moderate
* Eye	Retina	Degeneration	Minimal
* Heart		Cardiomyopathy	Minimal
		Leukemia Mononuclear	
* Kidney	Cortex	Cyst	Mild
		Infarct	Mild
		Leukemia Mononuclear	
		Mineralization	Minimal
		Nephropathy	Minimal
	[Infarct TGLs = 6 - 18]		
* Liver	Bile Duct	Hyperplasia	Mild
		Leukemia Mononuclear	
* Lung		Inflammation	Chronic Active, Mild
Lymph Node	Deep Cervical	Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 5 - 17]		
* Lymph Node, Mesenteric		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 4 - 16]		
* Pancreas		Atrophy	Minimal
		Leukemia Mononuclear	
* Pituitary Gland	Pars Distalis	Adenoma	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 18

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601498

ORGAN AND ACCOUNTABLE SITE STATUS

* Skin	Subcut Tiss	Fibroma	
[Fibroma TGLs = 1 - 14]			
* Spleen		Leukemia Mononuclear	
[Leukemia Mononuclear TGLs = 2 - 15]			
* Stomach, Forestomach		Leukemia Mononuclear	
* Testes	Bilateral, Interstit Cell	Adenoma	
[Adenoma TGLs = 3 - 11]			
* Thymus		Leukemia Mononuclear	
* Thyroid Gland	C Cell	Hyperplasia	Minimal
* Urinary Bladder		Inflammation	Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 19

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601499

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Pheochromocytoma Benign	
* Eye	Lens	Cataract	Minimal
	Retina	Degeneration	Minimal
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
		Leukemia Mononuclear	
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Prostate	Epithelium	Hyperplasia	Minimal
		Inflammation	Minimal
* Spleen		Leukemia Mononuclear	
		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Mild
Tooth		Malformation	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 20

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601500

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric | * Mammary Gland |
| * Parathyroid Gland | * Pituitary Gland | * Preputial Gland | * Prostate |
| * Salivary Glands | * Seminal Vesicle | * Skin | * Stomach, Forestomach |
| * Stomach, Glandular | * Thyroid Gland | * Trachea | * Urinary Bladder |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------|---------------------------|------------------|-------------------------|
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Nephropathy | Minimal |
| * Liver | | Clear Cell Focus | |
| | | Inflammation | Chronic Active, Minimal |
| * Nose | | Inflammation | Mild |
| * Pancreas | | Atrophy | Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 21

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601501

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Pancreas	* Parathyroid Gland	* Preputial Gland
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Esophagus	Epithelium	Hyperplasia	Minimal
* Heart		Cardiomyopathy	Moderate
* Intestine Large, Colon		Parasite Metazoan	
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Fatty Change	Diffuse, Mild
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
		Mixed Cell Focus	
	[Mixed Cell Focus TGLs = 1 - 14]		
* Lung		Alveolar/Bronchiolar Adenoma	Multiple
		Alveolar/Bronchiolar Carcinoma	
Lymph Node	Mediastinal	Hyperplasia	Lymphoid, Mild
	[Hyperplasia TGLs = 2 - 15]		
* Nose		Inflammation	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 3 - 8]		
* Prostate		Inflammation	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Interstit Cell	Hyperplasia	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 21

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601501

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus	Arteriole	Necrosis Atrophy	Minimal Moderate
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TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 22

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601502

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Parathyroid Gland | * Preputial Gland | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|--------------------|-------------------------|
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | Bile Duct | Hyperplasia | Mild |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| | [Eosinophilic Focus TGLs = 2 - 6+7+14] | | |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| * Pancreas | | Atrophy | Minimal |
| | Acinus | Hyperplasia | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| * Prostate | | Inflammation | Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 22

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601502

ORGAN AND ACCOUNTABLE SITE STATUS

* Thyroid Gland

C Cell

Adenoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 23

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601503

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Preputial Gland	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Eye	Retina	Degeneration	Minimal
* Heart		Cardiomyopathy	Mild
* Islets, Pancreatic		Adenoma	
* Kidney		Nephropathy	Mild
* Liver		Basophilic Focus	
		Fatty Change	Diffuse, Mild
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 1 - 8]		
* Prostate		Inflammation	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Interstit Cell	Adenoma	
	Interstit Cell	Hyperplasia	Mild
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Minimal
Tooth		Malformation	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 24

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601504

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Preputial Gland
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Adrenal Medulla		Hyperplasia	Moderate
* Eye	Lens	Cataract	Mild
	Retina	Degeneration	Moderate
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
	[Eosinophilic Focus TGLs = 1 - 14]		
* Lung	Alveolar Epith	Hyperplasia	Mild
Lymph Node	Mediastinal	Hyperplasia	Lymphoid, Mild
	[Hyperplasia TGLs = 2 - 15]		
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 3 - 8]		
* Prostate		Inflammation	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Interstit Cell	Hyperplasia	Mild

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 24

TMT: 1

SEX: Male

DAY ON TEST: 728

DOSE: 0.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601504

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Atrophy

Marked

* Thyroid Gland

C Cell

Hyperplasia

Minimal

Tooth

Malformation

Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 25

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 545
HISTO: 0601505

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	Peripheral Nerve	* Pituitary Gland	* Preputial Gland
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Trachea		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Minimal
Coagulating Gland		Inflammation	Mild
Note: Lesion was recorded because it was present in the routine section with seminal vesicles (B13).			
* Heart		Cardiomyopathy	Mild
* Kidney	Pelvis	Inflammation	Moderate
	Papilla	Necrosis	Marked
		Nephropathy	Mild
* Liver		Basophilic Focus	
		Fatty Change	Diffuse, Minimal
		Mixed Cell Focus	
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Prostate		Inflammation	Marked
Spinal Cord		Glioma Malignant	
Note: This is a poorly-differentiated glioma of a nerve root.			
Note: This glioma may have caused the moribund condition by causing bladder paralysis with resultant cystitis and pyelitis, and urethral obstruction by leukocytes.			
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Adenoma	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 25

TMT: 1

SEX: Male

DAY ON TEST: 545

DOSE: 0.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601505

ORGAN AND ACCOUNTABLE SITE STATUS

Ureter	Inflammation	Marked
Note: Hemorrhagic inflammation affects both ureters, which are dilated. [Inflammation TGLs = 1 - 18]		
Urethra	Inflammation	Marked
Note: Hemorrhagic urethritis is present with rupture at the level of the prostate gland - urethral obstruction led to rupture and uremia, acting as contributory COD.		
* Urinary Bladder	Inflammation	Marked
Note: Cystitis was hemorrhagic. [Inflammation TGLs = 2 - 5]		

PRIMARY CAUSE OF DEATH - Spinal Cord Glioma Malignant

CONTRIBUTORY CAUSE OF DEATH - Urethra Inflammation

Animal Note: Sciatic nerve and spinal cord were examined in this rat, per protocol, because it had clinical neurologic signs.

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 26

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601506

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Basophilic Focus	
		Clear Cell Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
Mesentery	Fat	Necrosis	Moderate
	[Necrosis TGLs = 2,3 - 14+15]		
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 1 - 8]		
* Prostate		Inflammation	Mild
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Testes	Interstit Cell	Hyperplasia	Mild
* Thymus		Atrophy	Marked

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 27

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601507

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric | * Mammary Gland |
| * Pancreas | * Parathyroid Gland | * Preputial Gland | * Salivary Glands |
| * Seminal Vesicle | * Spleen | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--|---------------------------|--------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Nephropathy | Mild |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | Bile Duct | Hyperplasia | Mild |
| | | Inflammation | Chronic Active, Minimal |
| Lymph Node | Mediastinal | Hyperplasia | Lymphoid, Mild |
| [Hyperplasia TGLs = 2 - 14] | | | |
| * Nose | | Inflammation | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Moderate |
| * Prostate | | Inflammation | Mild |
| * Skin | Subcut Tiss | Fibrosis | Marked |
| Note: Fibrosis was in mammary section. | | | |
| * Stomach, Forestomach | | Inflammation | Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| [Adenoma TGLs = 1 - 11] | | | |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Adenoma | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 28

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 709
HISTO: 0601508

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Brain
* Epididymis	* Eye	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Pheochromocytoma Benign	
* Bone Marrow		Hyperplasia	Moderate
* Esophagus	Muscularis	Degeneration	Mild
	Epithelium	Necrosis	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Nephropathy	Mild
* Liver		Fatty Change	Diffuse, Mild
	Bile Duct	Hyperplasia	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Skin	Subcut Tiss	Fibroma	
	Subcut Tiss	Liposarcoma	
	[Fibroma TGLs = 1 - 14]		
	[Liposarcoma TGLs = 2 - 15]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Moderate
		Inflammation	Moderate
		Ulcer	Mild
	[Hyperplasia TGLs = 4 - 14]		
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 3 - 11]		

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 28

TMT: 1

SEX: Male

DAY ON TEST: 709

DOSE: 0.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601508

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Atrophy

Marked

PRIMARY CAUSE OF DEATH

- Skin Subcut Tiss Liposarcoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 29

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Natural Death

DAY ON TEST: 613
HISTO: 0601509

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|----------------------------|--------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Mammary Gland | * Nose | * Pancreas | * Parathyroid Gland |
| * Pituitary Gland | * Preputial Gland | * Prostate | * Salivary Glands |
| * Seminal Vesicle | * Skin | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|---|--------------------------------------|--------------------|----------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Intestine Small, Ileum | | Lymphoma Malignant | |
| | | Necrosis | Minimal |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Fatty Change | Diffuse, Minimal |
| | Bile Duct | Hyperplasia | Minimal |
| * Lung | | Thrombosis | Minimal |
| Note: There are a few small emboli present in pulmonary vessels, however, there is no evidence of necrosis to suggest these were not terminal events. | | | |
| * Lymph Node, Mesenteric | | Lymphoma Malignant | |
| | [Lymphoma Malignant TGLs = 2 - 14] | | |
| * Spleen | Lymph Follic | Atrophy | Marked |
| | | Pigmentation | Hemosiderin, Minimal |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Minimal |
| | | Inflammation | Mild |
| | | Ulcer | Moderate |
| | [Ulcer TGLs = 3 - 15] | | |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 29

TMT: 1

SEX: Male

DAY ON TEST: 613

DOSE: 0.0 G/KG

DISP: Natural Death

HISTO: 0601509

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Atrophy

Marked

PRIMARY CAUSE OF DEATH

- Intestine Small, Ileum Lymphoma Malignant

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 30

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601510

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Parathyroid Gland | * Preputial Gland | * Salivary Glands | * Seminal Vesicle |
| * Spleen | * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--------------------------------------|--------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | [Eosinophilic Focus TGLs = 3 - 15] | | |
| * Lung | Alveolar Epith | Hyperplasia | Mild |
| * Pancreas | | Atrophy | Minimal |
| | Acinus | Hyperplasia | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Minimal |
| * Prostate | | Inflammation | Minimal |
| * Skin | Subcut Tiss | Lipoma | |
| | [Lipoma TGLs = 1 - 14] | | |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 2 - 11] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 31

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601511

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Parathyroid Gland |
| * Pituitary Gland | * Preputial Gland | * Salivary Glands | * Seminal Vesicle |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|---------------|---------------------------|------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Minimal |
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Mild |
| * Liver | | Clear Cell Focus | |
| | | Fatty Change | Diffuse, Mild |
| | Bile Duct | Hyperplasia | Mild |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| * Pancreas | | Atrophy | Minimal |
| * Prostate | Epithelium | Hyperplasia | Minimal |
| * Skin | Subcut Tiss | Fibroma | |
| | [Fibroma TGLs = 1 - 14] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 2 - 11] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 32

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 694
HISTO: 0601512

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Pancreas |
| * Parathyroid Gland | * Preputial Gland | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|---|--------------------------|-----------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Intestine Large, Colon | | Parasite Metazoan | |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Mild |
| * Liver | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| * Nose | | | |
| Note: Nasolacrimal duct has a foreign body (with inflammatory cells). | | | |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 1 - 8] | | |
| * Prostate | Epithelium | Hyperplasia | Minimal |
| | | Inflammation | Mild |
| * Spleen | | Pigmentation | Hemosiderin, Mild |
| * Testes | Interstit Cell | Hyperplasia | Minimal |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Hyperplasia | Minimal |

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 33

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 511
HISTO: 0601513

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Pancreas |
| * Parathyroid Gland | * Preputial Gland | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--------------------------|----------------|----------------------------------|----------------------|
| * Bone Marrow | | Hyperplasia | Moderate |
| * Heart | | Cardiomyopathy | Mild |
| * Islets, Pancreatic | | Hyperplasia | Minimal |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Moderate |
| * Liver | | Fatty Change | Diffuse, Marked |
| | | Hematopoietic Cell Proliferation | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| [Adenoma TGLs = 1 - 8] | | | |
| * Prostate | | Inflammation | Mild |
| * Spleen | | Hematopoietic Cell Proliferation | Moderate |
| | | Pigmentation | Hemosiderin, Minimal |
| * Stomach, Forestomach | | Inflammation | Mild |
| * Testes | Interstit Cell | Hyperplasia | Minimal |
| * Thymus | | Atrophy | Moderate |

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 34

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601514

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Pancreas | * Parathyroid Gland |
| * Preputial Gland | * Salivary Glands | * Seminal Vesicle | * Spleen |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---------------------------|-----------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Mild |
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Nose | | Inflammation | Mild |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Minimal |
| * Prostate | | Inflammation | Mild |
| * Skin | Subcut Tiss | Fibroma | |
| | [Fibroma TGLs = 1 - 14] | | |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 2 - 11] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 35

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Natural Death

DAY ON TEST: 689
HISTO: 0601515

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Epididymis	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Parathyroid Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Leukemia Mononuclear	
* Adrenal Medulla		Leukemia Mononuclear	
* Bone Marrow		Hyperplasia	Moderate
* Brain		Leukemia Mononuclear	
		Necrosis	Moderate
Note: Brain has hemorrhagic infarcts (likely secondary to leukemia). [Necrosis TGLs = 2 - 15]			
* Heart		Cardiomyopathy	Mild
		Leukemia Mononuclear	
* Kidney		Leukemia Mononuclear	
		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Leukemia Mononuclear	
[Leukemia Mononuclear TGLs = 3 - 6+7]			
* Lung		Leukemia Mononuclear	
		Necrosis	Minimal
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
		Leukemia Mononuclear	
* Spleen		Leukemia Mononuclear	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 35

TMT: 1

SEX: Male

DAY ON TEST: 689

DOSE: 0.0 G/KG

DISP: Natural Death

HISTO: 0601515

ORGAN AND ACCOUNTABLE SITE STATUS

[Leukemia Mononuclear TGLs = 1 - 14]

* Testes

Bilateral, Interstit Cell

Adenoma

[Adenoma TGLs = 4 - 11]

* Thymus

Atrophy

Marked

PRIMARY CAUSE OF DEATH

- Spleen Leukemia Mononuclear

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 37

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601517

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Pancreas		Atrophy	Minimal
* Testes	Interstit Cell	Adenoma	
	Interstit Cell	Hyperplasia	Moderate
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate
Tooth		Malformation	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 38

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601518

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| Blood Vessel | * Bone | * Brain | * Epididymis |
| * Esophagus | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Parathyroid Gland |
| * Preputial Gland | * Prostate | * Salivary Glands | * Seminal Vesicle |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|----------------------|--------------------------------------|----------------------------------|-------------------------|
| * Adrenal Cortex | Zona Fascult | Hyperplasia | Minimal |
| * Adrenal Medulla | Bilateral | Pheochromocytoma Benign | |
| * Bone Marrow | | Hyperplasia | Marked |
| * Eye | Retina | Degeneration | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| | Atrium | Thrombosis | Mild |
| * Islets, Pancreatic | | Hyperplasia | Marked |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Fatty Change | Diffuse, Minimal |
| | | Hematopoietic Cell Proliferation | Minimal |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Nose | | Inflammation | Mild |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Minimal |
| * Skin | Epidermis | Basal Cell Adenoma | |
| | [Basal Cell Adenoma TGLs = 1 - 14] | | |
| * Spleen | | Hematopoietic Cell Proliferation | Mild |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 38

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601518

ORGAN AND ACCOUNTABLE SITE STATUS

* Testes	Interstit Cell	Hyperplasia	Moderate
* Thymus		Atrophy	Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 39

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601519

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Rectum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Marked
* Epididymis		Inflammation	Minimal
		Mesothelioma Malignant	
* Heart		Cardiomyopathy	Moderate
* Intestine Large, Colon		Parasite Metazoan	
* Intestine Small, Duodenum		Ectopic Tissue	Mild
Note: There is ectopic pancreas in the duodenal lamina propria.			
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
Oral Mucosa		Squamous Cell Papilloma	
Note: Lesion noted in routine section B01.			
* Prostate	Epithelium	Hyperplasia	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
		Mesothelioma Malignant	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 39

TMT: 1

SEX: Male

DAY ON TEST: 727

DOSE: 0.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601519

ORGAN AND ACCOUNTABLE SITE STATUS

[Adenoma TGLs = 1 - 11]

* Thymus

Atrophy

Marked

* Thyroid Gland

C Cell

Hyperplasia

Marked

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 40

TMT: 1

SEX: Male

DAY ON TEST: 728

DOSE: 0.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601520

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Mild
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Hepatodiaphragmatic Nodule	
		Inflammation	Chronic Active, Minimal
Note: Both clear cell foci and eosinophilic foci were responsible for TGL-4.			
	[Eosinophilic Focus TGLs = 4 - 16]		
	[Hepatodiaphragmatic Nodule TGLs = 3 - 15]		
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Prostate	Epithelium	Hyperplasia	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1,2 - 11+14]		
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Adenoma	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 40

TMT: 1

SEX: Male

DAY ON TEST: 728

DOSE: 0.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601520

ORGAN AND ACCOUNTABLE SITE STATUS

Tooth

Malformation

Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 41

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601521

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Parathyroid Gland	* Preputial Gland
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
* Mammary Gland		Hyperplasia	Mild
* Nose		Inflammation	Mild
	Olfactory Epi	Metaplasia	Mild
* Pancreas		Atrophy	Mild
	Acinus	Hyperplasia	Moderate
Note: Pancreatic acinar hyperplasia was in section adjacent to the duodenum.			
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Prostate	Epithelium	Hyperplasia	Minimal
		Inflammation	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 41

TMT: 1

SEX: Male

DAY ON TEST: 728

DOSE: 0.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601521

ORGAN AND ACCOUNTABLE SITE STATUS

[Adenoma TGLs = 1 - 11]

* Thymus

Atrophy

Moderate

Animal Note: TGL 2 = NCL (No Corresponding Lesion)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 42

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Natural Death

DAY ON TEST: 504
HISTO: 0601522

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Pancreas	* Parathyroid Gland	* Preputial Gland
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular	* Mammary Gland
--------------------------	-----------------

OBSERVATIONS

* Brain		Hemorrhage	Minimal
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
* Liver	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Moderate
Mesentery	Fat	Necrosis	Mild
[Necrosis TGLs = 2 - 14]			
* Nose		Foreign Body	
		Inflammation	Moderate
* Pituitary Gland	Pars Distalis	Adenoma	
[Adenoma TGLs = 1 - 8]			
* Prostate		Inflammation	Mild
* Spleen	Lymph Follic	Atrophy	Moderate
		Hematopoietic Cell Proliferation	Mild
		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Moderate
		Inflammation	Moderate
* Testes	Germinal Epith	Degeneration	Mild
	Interstit Cell	Hyperplasia	Mild

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 42

TMT: 1

SEX: Male

DAY ON TEST: 504

DOSE: 0.0 G/KG

DISP: Natural Death

HISTO: 0601522

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Atrophy

Marked

PRIMARY CAUSE OF DEATH

- Pituitary Gland Pars Distalis Adenoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 43

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601523

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Pancreas	* Parathyroid Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
	[Eosinophilic Focus TGLs = 3 - 15]		
* Lung	Alveolar Epith	Hyperplasia	Mild
* Nose		Inflammation	Moderate
	Olfactory Epi	Metaplasia	Mild
* Pituitary Gland	Pars Distalis	Adenoma	
* Skin	Epidermis	Basal Cell Adenoma	
	[Basal Cell Adenoma TGLs = 1 - 14]		
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 2 - 11]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 43

TMT: 1

SEX: Male

DAY ON TEST: 728

DOSE: 0.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601523

ORGAN AND ACCOUNTABLE SITE STATUS

* Thyroid Gland
Tooth

C Cell

Adenoma
Malformation

Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 44

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601524

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
Mesentery	Fat	Necrosis	Marked
[Necrosis TGLs = 1,2 - 14+15]			
* Pituitary Gland	Pars Distalis	Adenoma	
[Adenoma TGLs = 3 - 8]			
* Prostate		Inflammation	Mild
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Testes	Interstit Cell	Hyperplasia	Mild
* Thymus		Atrophy	Marked
* Thyroid Gland	C Cell	Hyperplasia	Minimal
Tooth		Malformation	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 45

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Natural Death

DAY ON TEST: 594
HISTO: 0601525

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric | * Mammary Gland |
| * Pancreas | * Parathyroid Gland | * Preputial Gland | * Salivary Glands |
| * Seminal Vesicle | * Skin | * Stomach, Forestomach | * Stomach, Glandular |
| * Thyroid Gland | * Trachea | * Urinary Bladder | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--------------------------|----------------|----------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | Bile Duct | Hyperplasia | Mild |
| * Nose | | Inflammation | Mild |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 1 - 8] | | |
| * Prostate | | Inflammation | Mild |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Interstit Cell | Hyperplasia | Mild |
| * Thymus | | Atrophy | Marked |

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 46

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601526

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Parathyroid Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Pheochromocytoma Benign	
	[Pheochromocytoma Benign TGLs = 2 - 8]		
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Pancreas	Acinus	Hyperplasia	Mild
* Pituitary Gland	Pars Distalis	Adenoma	
* Stomach, Glandular	Epithelium	Necrosis	Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 47

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Natural Death

DAY ON TEST: 675
HISTO: 0601527

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lung |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Parathyroid Gland |
| * Pituitary Gland | * Preputial Gland | * Prostate | * Salivary Glands |
| * Seminal Vesicle | * Skin | * Stomach, Forestomach | * Stomach, Glandular |
| * Thyroid Gland | * Trachea | * Urinary Bladder | |

MISSING

- | | |
|--------------------------|----------|
| * Lymph Node, Mandibular | * Thymus |
|--------------------------|----------|

OBSERVATIONS

- | | | | |
|---------------|--|----------------------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Moderate |
| * Epididymis | | Mesothelioma Malignant | |
| | [Mesothelioma Malignant TGLs = 1 - 14] | | |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | | Necrosis | Mild |
| | [Necrosis TGLs = 3 - 6+7] | | |
| Mesentery | | Mesothelioma Malignant | |
| | Note: Mesothelioma implanted on many serosal surfaces including pancreas, prostate, seminal vesicles, testes, and urinary bladder. | | |
| | [Mesothelioma Malignant TGLs = 2 - 15] | | |
| * Pancreas | | Atrophy | Minimal |
| * Spleen | | Hematopoietic Cell Proliferation | Mild |
| | | Inflammation | Mild |
| | Note: Inflammation coded in spleen for accumulation of fibrin. | | |
| * Testes | Interstit Cell | Adenoma | |
| | | Mesothelioma Malignant | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 47

TMT: 1

SEX: Male

DAY ON TEST: 675

DOSE: 0.0 G/KG

DISP: Natural Death

HISTO: 0601527

ORGAN AND ACCOUNTABLE SITE STATUS

[Adenoma TGLs = 5 - 11]

PRIMARY CAUSE OF DEATH - Mesentery Mesothelioma Malignant

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 48

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 686
HISTO: 0601528

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Mammary Gland
* Nose	* Parathyroid Gland	* Preputial Gland	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Minimal
* Bone		Osteosarcoma	
	[Osteosarcoma TGLs = 2 - 14]		
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Mild
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
	Centrilobular	Fatty Change	Mild
		Hematopoietic Cell Proliferation	Minimal
* Lung	Mediastinum	Osteosarcoma	Metastatic (Bone)
	Note: Mediastinum in the aortic, lung, and thymus sections has extension of osteosarcoma from the primary in rib or vertebra.		
* Lymph Node, Mesenteric		Atrophy	Moderate
* Pancreas	Acinus	Hyperplasia	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Prostate		Inflammation	Mild
* Spleen		Hematopoietic Cell Proliferation	Mild
* Stomach, Forestomach	Epithelium	Dysplasia	Minimal
		Inflammation	Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 48

TMT: 1

SEX: Male

DAY ON TEST: 686

DOSE: 0.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601528

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Atrophy

Marked

PRIMARY CAUSE OF DEATH

- Bone Osteosarcoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 49

TMT: 1
 DOSE: 0.0 G/KG

SEX: Male
 DISP: Terminal Sacrifice

DAY ON TEST: 727
 HISTO: 0601529

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric | * Mammary Gland |
| * Nose | * Parathyroid Gland | * Prostate | * Salivary Glands |
| * Seminal Vesicle | * Skin | * Stomach, Forestomach | * Stomach, Glandular |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--|--|----------------------|-------------------------|
| Coagulating Gland | | Fibrosis | Moderate |
| Note: The lesion in coagulating gland was observed in the routine section taken with seminal vesicles (B13). | | | |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| | | Leukemia Mononuclear | |
| * Pancreas | Acinus | Hyperplasia | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Moderate |
| * Preputial Gland | | Carcinoma | |
| * Spleen | | Leukemia Mononuclear | |
| | [Leukemia Mononuclear TGLs = 1 - 14] | | |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 2 - 11] | | |
| * Thymus | | Atrophy | Marked |
| * Thyroid Gland | C Cell | Hyperplasia | Marked |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 50

TMT: 1
DOSE: 0.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601530

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Carcinoma	
* Adrenal Medulla		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Moderate
* Kidney		Nephropathy	Mild
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Nose		Inflammation	Mild
* Pancreas		Atrophy	Mild
* Parathyroid Gland		Adenoma	
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 1 - 8]		
* Prostate		Inflammation	Moderate
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 2 - 11]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 51

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601531

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| Blood Vessel | * Bone Marrow | * Brain | * Epididymis |
| * Esophagus | * Eye | * Harderian Gland | * Intestine Large, Cecum |
| * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric |
| * Mammary Gland | * Nose | * Pancreas | * Parathyroid Gland |
| * Preputial Gland | * Salivary Glands | * Seminal Vesicle | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--|---------------------------|-------------------------|-------------------------|
| * Adrenal Cortex | | Hypertrophy | Mild |
| * Adrenal Medulla | | Pheochromocytoma Benign | |
| * Bone | | Osteosarcoma | |
| Note: Osteosarcoma fills the marrow cavity in the tibia (joint) section. | | | |
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Mild |
| * Liver | | Basophilic Focus | |
| | Centrilobular | Fatty Change | Mild |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| [Adenoma TGLs = 2 - 8] | | | |
| * Prostate | | Inflammation | Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| [Adenoma TGLs = 1 - 11] | | | |
| * Thymus | | Atrophy | Marked |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 52

TMT: 3

SEX: Male

DAY ON TEST: 727

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601532

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Pheochromocytoma Benign	
* Bone Marrow		Hyperplasia	Mild
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Moderate
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
	Centrilobular	Fatty Change	Minimal
		Hepatodiaphragmatic Nodule	
	Bile Duct	Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
	[Hepatodiaphragmatic Nodule	TGLs = 1 - 14]	
* Nose		Foreign Body	
		Inflammation	Moderate
* Pancreas		Atrophy	Minimal
* Spleen		Leukemia Mononuclear	
		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 52

TMT: 3

SEX: Male

DAY ON TEST: 727

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601532

ORGAN AND ACCOUNTABLE SITE STATUS

[Adenoma TGLs = 2 - 11]

* Thymus

Atrophy

Moderate

* Thyroid Gland

C Cell

Adenoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 53

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601533

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric | * Mammary Gland |
| * Parathyroid Gland | * Preputial Gland | * Prostate | * Salivary Glands |
| * Seminal Vesicle | * Skin | * Stomach, Forestomach | * Stomach, Glandular |
| * Thyroid Gland | * Trachea | * Urinary Bladder | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---------------------------|--------------------|-------------------------|
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Angiectasis | Minimal |
| | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Nose | Respirat Epith | Hyperplasia | Minimal |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 54

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601534

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Parathyroid Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Degeneration	Cystic, Minimal
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
		Mixed Cell Focus	
	[Eosinophilic Focus TGLs = 2 - 14]		
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Pancreas		Atrophy	Minimal
	Acinus	Hyperplasia	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 1 - 8]		
* Prostate		Inflammation	Mild
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 54

TMT: 3

SEX: Male

DAY ON TEST: 727

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601534

ORGAN AND ACCOUNTABLE SITE STATUS

* Testes

Interstit Cell

Hyperplasia

Moderate

* Thymus

Atrophy

Marked

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 55

TMT: 3
 DOSE: 0.1 G/KG

SEX: Male
 DISP: Moribund Sacrifice

DAY ON TEST: 714
 HISTO: 0601535

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Mammary Gland	* Parathyroid Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Minimal
* Bone Marrow		Mast Cell Tumor Malignant	
* Heart		Cardiomyopathy	Mild
* Intestine Large, Cecum		Inflammation	Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Fatty Change	Diffuse, Mild
	Bile Duct	Hyperplasia	Moderate
	Oval Cell	Hyperplasia	Mild
		Mixed Cell Focus	
	[Fatty Change TGLs = 5 - 6+7]		
* Lung		Inflammation	Chronic Active, Minimal
Lymph Node	Pancreatic	Mast Cell Tumor Malignant	
	[Mast Cell Tumor Malignant TGLs = 3 - 15]		
* Lymph Node, Mesenteric		Mast Cell Tumor Malignant	
	Note: Tissue submitted as mesenteric lymph node has little if any remaining architecture to identify it as such microscopically.		
* Nose		Inflammation	Mild
* Pancreas		Mast Cell Tumor Malignant	
	[Mast Cell Tumor Malignant TGLs = 2 - 14]		
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Amyloid Deposition	Mild

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 55

TMT: 3

SEX: Male

DAY ON TEST: 714

DOSE: 0.1 G/KG

DISP: Moribund Sacrifice

HISTO: 0601535

ORGAN AND ACCOUNTABLE SITE STATUS

	Lymph Follic	Atrophy	Moderate
		Mast Cell Tumor Malignant	
		Pigmentation	Hemosiderin, Minimal
[Mast Cell Tumor Malignant	TGLs = 4 - 16]		
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Mild
* Stomach, Glandular		Inflammation	Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
[Adenoma	TGLs = 1 - 11]		
* Thymus		Atrophy	Marked
* Thyroid Gland	C Cell	Hyperplasia	Moderate
		Infiltration Cellular	Lymphocyte, Mild

PRIMARY CAUSE OF DEATH - Lymph Node Pancreatic Mast Cell Tumor Malignant

Animal Note: Within tumor masses (e.g. in pancreas and lymph node) cells are pleomorphic; some contain granules. Amyloid is also present.

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 56

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601536

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Preputial Gland	* Salivary Glands	* Seminal Vesicle	* Stomach, Forestomach
* Stomach, Glandular	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Pheochromocytoma Benign	
* Heart		Cardiomyopathy	Moderate
* Intestine Large, Colon		Parasite Metazoan	
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
	Centrilobular	Fatty Change	Mild
		Hepatodiaphragmatic Nodule	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
		Mixed Cell Focus	
	[Hepatodiaphragmatic Nodule TGLs = 2 - 14]		
	[Mixed Cell Focus TGLs = 3 - 6+7+14+15]		
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Prostate	Epithelium	Hyperplasia	Mild
		Inflammation	Mild
* Skin		Inflammation	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 56

TMT: 3

SEX: Male

DAY ON TEST: 727

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601536

ORGAN AND ACCOUNTABLE SITE STATUS

* Testes	Bilateral, Interstit Cell	Adenoma	
[Adenoma TGLs = 1 - 11]			
* Thymus		Atrophy	Mild
* Thyroid Gland	C Cell	Adenoma	

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 57

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601537

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Parathyroid Gland | * Preputial Gland | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---------------------------|--------------------|-------------------------|
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| * Prostate | | Inflammation | Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Marked |
| * Thyroid Gland | C Cell | Hyperplasia | Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 58

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 709
HISTO: 0601538

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Salivary Glands
* Seminal Vesicle	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Hematopoietic Cell Proliferation	Mild
* Bone Marrow		Hyperplasia	Moderate
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Basophilic Focus	
		Hematopoietic Cell Proliferation	Minimal
	Bile Duct	Hyperplasia	Minimal
* Lung		Osteosarcoma	Metastatic (Skin)
* Mammary Gland		Fibroadenoma	
	[Fibroadenoma TGLs = 1 - 14]		
* Nose	Respirat Epith	Hyperplasia	Mild
* Pancreas		Atrophy	Minimal
* Prostate		Inflammation	Mild
* Skin	Subcut Tiss	Osteosarcoma	
	[Osteosarcoma TGLs = 3 - 15]		
* Spleen		Hematopoietic Cell Proliferation	Moderate
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 2 - 11]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 58

TMT: 3

SEX: Male

DAY ON TEST: 709

DOSE: 0.1 G/KG

DISP: Moribund Sacrifice

HISTO: 0601538

ORGAN AND ACCOUNTABLE SITE STATUS

PRIMARY CAUSE OF DEATH

- Skin Subcut Tiss Osteosarcoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 59

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601539

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Moderate
* Heart		Cardiomyopathy	Moderate
* Intestine Large, Colon		Parasite Metazoan	
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
	Centrilobular	Fatty Change	Minimal
	Bile Duct	Hepatodiaphragmatic Nodule	
		Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
[Hepatodiaphragmatic Nodule	TGLs = 3 - 15]		
Mesentery	Fat	Necrosis	Minimal
[Necrosis TGLs = 2 - 14]			
* Nose		Inflammation	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Interstit Cell	Adenoma	
	Interstit Cell	Hyperplasia	Mild
[Adenoma TGLs = 1 - 11]			
* Thymus		Atrophy	Marked

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 59

TMT: 3

SEX: Male

DAY ON TEST: 728

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601539

ORGAN AND ACCOUNTABLE SITE STATUS

* Thyroid Gland

C Cell

Hyperplasia

Mild

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 60

TMT: 3

SEX: Male

DAY ON TEST: 679

DOSE: 0.1 G/KG

DISP: Moribund Sacrifice

HISTO: 0601540

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Pancreas	* Parathyroid Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Minimal
* Brain		Meningioma Malignant	
Note: Meningeal sarcoma.			
Note: There is demyelination secondary to the tumor.			
[Meningioma Malignant TGLs = 2 - 14]			
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Fatty Change	Diffuse, Minimal
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Moderate
	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Nose	Respirat Epith	Hyperplasia	Marked
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Leukemia Mononuclear	
		Pigmentation	Hemosiderin, Minimal
* Testes	Interstit Cell	Adenoma	
	Interstit Cell	Hyperplasia	Marked

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 60

TMT: 3

SEX: Male

DAY ON TEST: 679

DOSE: 0.1 G/KG

DISP: Moribund Sacrifice

HISTO: 0601540

ORGAN AND ACCOUNTABLE SITE STATUS

[Adenoma TGLs = 1 - 11]

* Thymus

Atrophy

Moderate

PRIMARY CAUSE OF DEATH - Brain Meningioma Malignant

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 61

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601541

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mesenteric
* Mammary Gland	* Pancreas	* Parathyroid Gland	* Preputial Gland
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Glandular
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Pheochromocytoma Benign	
	[Pheochromocytoma Benign TGLs = 2 - 8]		
* Heart		Cardiomyopathy	Mild
* Islets, Pancreatic		Adenoma	
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Basophilic Focus	
		Clear Cell Focus	
	Bile Duct	Hyperplasia	Minimal
	Hepatocyte	Hypertrophy	Minimal
		Inflammation	Chronic Active, Minimal
		Mixed Cell Focus	
	[Mixed Cell Focus TGLs = 4 - 14]		
* Lung	Alveolar Epith	Hyperplasia	Mild
	[Hyperplasia TGLs = 5 - 15]		
Mesentery	Fat	Necrosis	Mild
	[Necrosis TGLs = 1 - 14]		
* Nose		Inflammation	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Prostate		Inflammation	Mild

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 61

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601541

ORGAN AND ACCOUNTABLE SITE STATUS

* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
		Mineralization	Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 3 - 11]		
* Thymus		Atrophy	Mild
* Thyroid Gland	C Cell	Hyperplasia	Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 62

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601542

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Pancreas | * Parathyroid Gland | * Preputial Gland | * Salivary Glands |
| * Seminal Vesicle | * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--|--------------------------------|---------------------------|-------------------------|
| Coagulating Gland | | Inflammation | Moderate |
| Note: Inflammation observed in the routine section taken for seminal vesicles. | | | |
| * Heart | | Cardiomyopathy | Moderate |
| * Islets, Pancreatic | | Adenoma | |
| Note: Adenoma is in portion with duodenum. | | | |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Clear Cell Focus | |
| | Centrilobular | Fatty Change | Minimal |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | | Necrosis | Mild |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| | [Hyperplasia TGLs = 1 - 8] | | |
| * Prostate | | Inflammation | Moderate |
| | [Inflammation TGLs = 3 - 14] | | |
| * Skin | | Cyst Epithelial Inclusion | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 62

TMT: 3

SEX: Male

DAY ON TEST: 728

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601542

ORGAN AND ACCOUNTABLE SITE STATUS

[Adenoma TGLs = 2 - 11]

* Thymus

Atrophy

Moderate

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 63

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Natural Death

DAY ON TEST: 168
HISTO: 0601543

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Liver | * Lung | * Lymph Node, Mesenteric | * Mammary Gland |
| * Nose | * Pancreas | * Parathyroid Gland | * Pituitary Gland |
| * Preputial Gland | * Prostate | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Testes |
| * Thyroid Gland | * Trachea | * Urinary Bladder | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|---------------|----------------------------------|----------------------------------|---------|
| * Bone Marrow | | Hyperplasia | Marked |
| * Heart | | Cardiomyopathy | Minimal |
| * Kidney | | Nephroblastoma | |
| | [Nephroblastoma TGLs = 1 - 14] | | |
| * Spleen | | Hematopoietic Cell Proliferation | Mild |
| * Thymus | | Atrophy | Mild |

PRIMARY CAUSE OF DEATH - Kidney Nephroblastoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 64

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Natural Death

DAY ON TEST: 571
HISTO: 0601544

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Salivary Glands	* Seminal Vesicle	* Stomach, Forestomach
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Moderate
* Epididymis		Fibrous Histiocytoma	Metastatic (Skin)
* Heart		Cardiomyopathy	Minimal
		Fibrous Histiocytoma	Metastatic (Skin)
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Fibrous Histiocytoma	Metastatic (Skin)
	[Fibrous Histiocytoma TGLs = 3 - 6+7+15]		
* Lung		Fibrous Histiocytoma	Metastatic (Skin)
* Pancreas		Atrophy	Minimal
* Prostate		Inflammation	Mild
* Skin	Subcut Tiss	Fibrous Histiocytoma	
	[Fibrous Histiocytoma TGLs = 1 - 14]		
* Spleen	Lymph Follic	Atrophy	Mild
	[Hematopoietic Cell Proliferation TGLs = 2 - 5]	Hematopoietic Cell Proliferation	Moderate
* Stomach, Glandular	Epithelium	Necrosis	Mild
* Testes	Bilateral, Interstit Cell	Adenoma	
* Thymus		Atrophy	Marked

PRIMARY CAUSE OF DEATH - Skin Subcut Tiss Fibrous Histiocytoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 65

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601545

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Parathyroid Gland |
| * Preputial Gland | * Salivary Glands | * Seminal Vesicle | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|----------------------------|-------------------------|
| * Eye | Retina | Degeneration | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Mild |
| * Liver | Bile Duct | Hepatodiaphragmatic Nodule | |
| | | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | [Hepatodiaphragmatic Nodule | | |
| * Lung | TGLs = 4 - 15] | | |
| | Alveolar Epith | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | Note: There is cartilage lodged within a pulmonary artery -based upon the slight overlap with the artery, it is a floater. | | |
| Mesentery | Fat | Necrosis | Minimal |
| | [Necrosis TGLs = 3 - 14] | | |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 5 - 8] | | |
| * Prostate | | Inflammation | Mild |
| | [Inflammation TGLs = 2 - 13] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 65

TMT: 3

SEX: Male

DAY ON TEST: 728

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601545

ORGAN AND ACCOUNTABLE SITE STATUS

* Testes	Interstit Cell	Hyperplasia	Moderate
[Hyperplasia TGLs = 1 - 11]			
* Thymus		Atrophy	Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 66

TMT: 3

SEX: Male

DAY ON TEST: 728

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601546

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | Blood Vessel | * Bone | * Bone Marrow |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Pancreas | * Parathyroid Gland |
| * Pituitary Gland | * Preputial Gland | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---------------------------|-------------------------|-------------------------|
| * Adrenal Medulla | | Pheochromocytoma Benign | |
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolar Epith | Metaplasia | Squamous, Mild |
| * Nose | | Inflammation | Mild |
| * Prostate | | Inflammation | Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 67

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 689
HISTO: 0601547

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | Blood Vessel | * Bone | * Brain |
| * Epididymis | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lymph Node, Mesenteric |
| * Mammary Gland | * Nose | * Pancreas | * Parathyroid Gland |
| * Preputial Gland | * Salivary Glands | * Seminal Vesicle | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---|----------------------|----------|
| * Adrenal Medulla | | Hyperplasia | Moderate |
| * Bone Marrow | | Hyperplasia | Moderate |
| * Heart | | Cardiomyopathy | Minimal |
| | Atrium | Thrombosis | Minimal |
| * Kidney | | Leukemia Mononuclear | |
| | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Leukemia Mononuclear | |
| | [Leukemia Mononuclear TGLs = 3 - 6+7] | | |
| * Lung | | Leukemia Mononuclear | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Moderate |
| * Prostate | Epithelium | Hyperplasia | Mild |
| * Spleen | | Leukemia Mononuclear | |
| | [Leukemia Mononuclear TGLs = 2 - 14] | | |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Marked |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 67

TMT: 3

SEX: Male

DAY ON TEST: 689

DOSE: 0.1 G/KG

DISP: Moribund Sacrifice

HISTO: 0601547

ORGAN AND ACCOUNTABLE SITE STATUS

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 68

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601548

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Parathyroid Gland	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Pheochromocytoma Benign	
* Bone Marrow		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Marked
* Kidney		Mineralization	Minimal
		Nephropathy	Moderate
* Liver		Basophilic Focus	
		Clear Cell Focus	
	Bile Duct	Cyst	Minimal
	Bile Duct	Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
	[Clear Cell Focus TGLs = 3 - 14]		
* Nose		Foreign Body	
		Inflammation	Mild
* Pancreas		Atrophy	Minimal
	Acinus	Hyperplasia	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
* Preputial Gland		Schwannoma Malignant	
	[Schwannoma Malignant TGLs = 1 - 12]		
* Prostate		Inflammation	Mild
* Spleen		Hematopoietic Cell Proliferation	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 68

TMT: 3

SEX: Male

DAY ON TEST: 727

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601548

ORGAN AND ACCOUNTABLE SITE STATUS

* Testes	Bilateral, Interstit Cell	Pigmentation	Hemosiderin, Minimal
[Adenoma TGLs = 2 - 11]		Adenoma	
* Thymus		Atrophy	Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 69

TMT: 3
 DOSE: 0.1 G/KG

SEX: Male
 DISP: Terminal Sacrifice

DAY ON TEST: 728
 HISTO: 0601549

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric | * Mammary Gland |
| * Nose | * Parathyroid Gland | * Preputial Gland | * Prostate |
| * Salivary Glands | * Seminal Vesicle | * Skin | * Spleen |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---------------------------|------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Mild |
| * Liver | | Basophilic Focus | |
| | Centrilobular | Fatty Change | Minimal |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Pancreas | | Atrophy | Minimal |
| | Acinus | Hyperplasia | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 70

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601550

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland
* Pancreas	* Parathyroid Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Pheochromocytoma Malignant	
	[Pheochromocytoma Malignant TGLs = 3 - 15]		
* Epididymis		Inflammation	Minimal
* Eye	Retina	Degeneration	Minimal
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
	[Eosinophilic Focus TGLs = 2 - 14]		
* Lung	Alveolar Epith	Hyperplasia	Mild
* Nose		Inflammation	Mild
	Note: There is an adhesion of one maxillary turbinate to the nasal septum.		
* Pituitary Gland	Pars Distalis	Adenoma	
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 71

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 673
HISTO: 0601551

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Esophagus	* Eye	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Mammary Gland
* Pancreas	* Parathyroid Gland	* Preputial Gland	* Prostate
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Hypertrophy	Minimal
* Bone Marrow		Hyperplasia	Marked
* Epididymis		Mesothelioma Malignant	
Note: Mesothelioma is implanted on many serosal surfaces including colon, kidneys, pancreas, peritoneum, prostate, seminal vesicles, and urinary bladder.			
[Mesothelioma Malignant TGLs = 2 - 14]			
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver	Bile Duct	Hyperplasia	Minimal
* Lymph Node, Mesenteric		Atrophy	Minimal
Mesentery		Mesothelioma Malignant	
	Fat	Necrosis	Mild
[Necrosis TGLs = 4 - 15]			
* Nose		Inflammation	Mild
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Salivary Glands		Atrophy	Mild
* Spleen		Hematopoietic Cell Proliferation	Mild
* Testes	Bilateral, Interstit Cell	Adenoma	
		Mesothelioma Malignant	
[Adenoma TGLs = 3 - 11]			

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 71

TMT: 3

SEX: Male

DAY ON TEST: 673

DOSE: 0.1 G/KG

DISP: Moribund Sacrifice

HISTO: 0601551

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Atrophy

Marked

* Thyroid Gland

C Cell

Adenoma

PRIMARY CAUSE OF DEATH

- Mesentery Mesothelioma Malignant

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 72

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601552

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Parathyroid Gland
* Preputial Gland	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Hypertrophy	Minimal
* Adrenal Medulla		Hyperplasia	Mild
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Degeneration	Cystic, Minimal
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
* Pancreas		Basophilic Focus	
	Acinus	Hyperplasia	Mild
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
	[Hyperplasia TGLs = 2 - 8]		
* Prostate		Inflammation	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Marked
* Thyroid Gland	C Cell	Hyperplasia	Marked

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 72

TMT: 3

SEX: Male

DAY ON TEST: 729

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601552

ORGAN AND ACCOUNTABLE SITE STATUS

Tooth

Malformation

Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 73

TMT: 3
 DOSE: 0.1 G/KG

SEX: Male
 DISP: Natural Death

DAY ON TEST: 666
 HISTO: 0601553

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Pheochromocytoma Malignant	
	[Pheochromocytoma Malignant TGLs = 1 - 14]		
* Heart		Cardiomyopathy	Marked
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Fatty Change	Diffuse, Minimal
		Inflammation	Chronic Active, Minimal
		Mixed Cell Focus	
	[Eosinophilic Focus TGLs = 4 - 15]		
	[Mixed Cell Focus TGLs = 2 - 15]		
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Interstit Cell	Adenoma	
	Interstit Cell	Hyperplasia	Mild
	[Adenoma TGLs = 3 - 11]		
* Thymus		Atrophy	Moderate

PRIMARY CAUSE OF DEATH - Adrenal Medulla Pheochromocytoma Malignant

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 74

TMT: 3
 DOSE: 0.1 G/KG

SEX: Male
 DISP: Terminal Sacrifice

DAY ON TEST: 727
 HISTO: 0601554

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Brain	* Epididymis
* Esophagus	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Mammary Gland	* Nose	* Parathyroid Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Leukemia Mononuclear	
		Necrosis	Minimal
* Adrenal Medulla		Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Moderate
* Eye	Lens	Cataract	Minimal
	Retina	Degeneration	Minimal
* Heart		Cardiomyopathy	Moderate
* Kidney	Pelvis, Transit Epithe	Hyperplasia	Minimal
		Nephropathy	Minimal
* Liver	Bile Duct	Eosinophilic Focus	
		Hyperplasia	Mild
		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 3 - 6+7]		
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
		Leukemia Mononuclear	
* Lymph Node, Mesenteric		Leukemia Mononuclear	
* Pancreas	Acinus	Hyperplasia	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 1 - 8]		
* Spleen		Leukemia Mononuclear	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 74

TMT: 3

SEX: Male

DAY ON TEST: 727

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601554

ORGAN AND ACCOUNTABLE SITE STATUS

	[Leukemia Mononuclear TGLs = 4 - 14]		
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 2 - 11]		
* Thymus		Atrophy	Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 75

TMT: 3
 DOSE: 0.1 G/KG

SEX: Male
 DISP: Moribund Sacrifice

DAY ON TEST: 714
 HISTO: 0601555

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Preputial Gland
* Prostate	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Mild
* Eye	Retina	Degeneration	Minimal
* Heart			
Note: There are large tumor emboli (from the salivary gland) in the right ventricle and pulmonary artery (heart section).			
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Moderate
* Liver		Hematopoietic Cell Proliferation	Minimal
		Hepatodiaphragmatic Nodule	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
	[Hepatodiaphragmatic Nodule TGLs = 3 - 15]		
* Lung		Carcinoma	Metastatic (Salivary Glands)
		Inflammation	Chronic Active, Minimal
Oral Mucosa		Hyperplasia	Squamous, Moderate
Note: Hyperplasia was noted on the routinely taken nasal section (B01).			
* Pituitary Gland	Pars Distalis	Adenoma	
* Salivary Glands		Carcinoma	
Note: This tumor was diagnosed as a carcinoma based upon presence of distant metastases (unlike schwannoma, which is invasive only).			

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 75

TMT: 3

SEX: Male

DAY ON TEST: 714

DOSE: 0.1 G/KG

DISP: Moribund Sacrifice

HISTO: 0601555

ORGAN AND ACCOUNTABLE SITE STATUS

Note: That tumor is a carcinoma is also supported by cells in metastases lining up and also becoming individualized, as in carcinomas.

[Carcinoma TGLs = 2 - 14]

* Spleen		Hematopoietic Cell Proliferation	Mild
* Testes	Interstit Cell	Adenoma	
	Interstit Cell	Hyperplasia	Mild
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Marked
* Thyroid Gland	C Cell	Adenoma	
Tooth		Malformation	Minimal

PRIMARY CAUSE OF DEATH - Salivary Glands Carcinoma

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 76

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Dosing Accident

DAY ON TEST: 30
HISTO: 0601556

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Liver	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart	Cardiomyopathy	Minimal
* Lung	Congestion	Mild

[Congestion TGLs = 1 - 3+4]

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 77

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601557

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Parathyroid Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Moderate
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Fatty Change	Diffuse, Minimal
	Bile Duct	Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
* Nose		Inflammation	Mild
* Pancreas	Acinus	Hyperplasia	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate
* Thyroid Gland	Bilateral, C Cell	Adenoma	

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 78

TMT: 3
 DOSE: 0.1 G/KG

SEX: Male
 DISP: Terminal Sacrifice

DAY ON TEST: 728
 HISTO: 0601558

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Parathyroid Gland | * Pituitary Gland | * Prostate | * Salivary Glands |
| * Seminal Vesicle | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---|-----------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Moderate |
| | | Necrosis | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| * Liver | | Basophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| | | Leukemia Mononuclear | |
| Lymph Node | Mediastinal | Infiltration Cellular | Plasma Cell, Mild |
| | [Infiltration Cellular TGLs = 4 - 16] | | |
| * Pancreas | | Atrophy | Minimal |
| * Preputial Gland | | Carcinoma | |
| | [Carcinoma TGLs = 1 - 15] | | |
| * Skin | Subcut Tiss | Fibroma | |
| | [Fibroma TGLs = 2 - 14] | | |
| * Spleen | | Leukemia Mononuclear | |
| * Testes | Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 3 - 11] | | |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | Follicular Cel | Hyperplasia | Mild |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 79

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601559

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Preputial Gland	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Mild
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Lung		Mesothelioma Malignant	
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Prostate		Adenoma	
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate
		Mesothelioma Malignant	
* Thyroid Gland	C Cell	Adenoma	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 80

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601560

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Glandular
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Marked
* Pituitary Gland	Pars Distalis	Adenoma	
* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach		Inflammation	Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Mild
Tooth		Malformation	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 81

TMT: 3

SEX: Male

DAY ON TEST: 729

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601561

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Mammary Gland	* Nose	* Pancreas	* Preputial Gland
* Salivary Glands	* Seminal Vesicle	* Stomach, Forestomach	* Stomach, Glandular
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Hypertrophy	Minimal
* Adrenal Medulla		Hyperplasia	Mild
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Lymph Node, Mesenteric		Atrophy	Minimal
* Parathyroid Gland		Adenoma	
* Pituitary Gland	Pars Distalis	Adenoma	
* Prostate		Inflammation	Moderate
* Skin	Subcut Tiss	Fibroma	
	[Fibroma TGLs = 1 - 14]		
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Interstit Cell	Adenoma	
	Interstit Cell	Hyperplasia	Mild
	[Adenoma TGLs = 2 - 11]		
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Adenoma	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 81

TMT: 3

SEX: Male

DAY ON TEST: 729

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601561

ORGAN AND ACCOUNTABLE SITE STATUS

Tooth

Malformation

Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 82

TMT: 3

SEX: Male

DAY ON TEST: 728

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601562

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Pancreas |
| * Parathyroid Gland | * Preputial Gland | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--------------------------------------|--------------------|-------------------------|
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Fatty Change | Diffuse, Minimal |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | [Eosinophilic Focus TGLs = 2 - 14] | | |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| * Nose | | Foreign Body | |
| | | Inflammation | Mild |
| | Olfactory Epi | Metaplasia | Mild |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Moderate |
| * Prostate | Epithelium | Hyperplasia | Mild |
| | | Inflammation | Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 82

TMT: 3

SEX: Male

DAY ON TEST: 728

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601562

ORGAN AND ACCOUNTABLE SITE STATUS

[Adenoma TGLs = 1 - 11]

* Thymus

Atrophy

Moderate

* Thyroid Gland

C Cell

Adenoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 83

TMT: 3

SEX: Male

DAY ON TEST: 729

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601563

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Stomach, Forestomach	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Marked
* Heart		Cardiomyopathy	Mild
* Kidney		Leukemia Mononuclear	
		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Degeneration	Cystic, Minimal
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 4 - 6+7]		
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
		Leukemia Mononuclear	
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Prostate		Inflammation	Mild
* Skin	Subcut Tiss	Fibroma	
	[Fibroma TGLs = 1 - 14]		
* Spleen		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 2 - 15]		
* Stomach, Glandular		Inflammation	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 83

TMT: 3

SEX: Male

DAY ON TEST: 729

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601563

ORGAN AND ACCOUNTABLE SITE STATUS

* Testes	Interstit Cell	Adenoma	
	Interstit Cell	Hyperplasia	Mild
[Adenoma TGLs = 3 - 11]			
* Thymus		Atrophy	Moderate
Tooth		Malformation	Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 84

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601564

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Parathyroid Gland | * Pituitary Gland | * Preputial Gland | * Prostate |
| * Salivary Glands | * Seminal Vesicle | * Skin | * Spleen |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------|---------------------------|------------------|-------------------------|
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolar Epith | Hyperplasia | Moderate |
| * Pancreas | Acinus | Hyperplasia | Minimal |
| * Testes | Interstit Cell | Adenoma | |
| | Interstit Cell | Hyperplasia | Minimal |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 85

TMT: 3

SEX: Male

DAY ON TEST: 525

DOSE: 0.1 G/KG

DISP: Moribund Sacrifice

HISTO: 0601565

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Pancreas | * Parathyroid Gland | * Preputial Gland | * Salivary Glands |
| * Seminal Vesicle | * Skin | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|---|----------------|----------------------------------|------------------|
| * Bone Marrow | | Hyperplasia | Moderate |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | Pelvis | Dilatation | Mild |
| | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Fatty Change | Diffuse, Minimal |
| Lymph Node | | | |
| Note: There was no evidence in the section provided that the sarcoma (TGL-1) originated in a lymph node; the site of origin is not obvious microscopically. | | | |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | | | |
| * Prostate | | Inflammation | Mild |
| * Spleen | | Hematopoietic Cell Proliferation | Moderate |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Minimal |
| | | Inflammation | Minimal |
| * Testes | Interstit Cell | Hyperplasia | Minimal |
| * Thymus | | Atrophy | Moderate |
| Tissue NOS | | Rhabdomyosarcoma | |
| | | | |

[Rhabdomyosarcoma TGLs = 1 - 14]

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 85

TMT: 3

SEX: Male

DAY ON TEST: 525

DOSE: 0.1 G/KG

DISP: Moribund Sacrifice

HISTO: 0601565

ORGAN AND ACCOUNTABLE SITE STATUS

Tooth

Malformation

Minimal

PRIMARY CAUSE OF DEATH

- Tissue NOS Rhabdomyosarcoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 86

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601566

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Eye	Retina	Degeneration	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Degeneration	Cystic, Minimal
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
[Adenoma TGLs = 2 - 8]			
* Prostate		Inflammation	Moderate
* Skin	Subcut Tiss	Fibroma	
[Fibroma TGLs = 1 - 14]			
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Interstit Cell	Adenoma	
	Interstit Cell	Hyperplasia	Mild
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 87

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601567

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric | * Mammary Gland |
| * Nose | * Pancreas | * Parathyroid Gland | * Preputial Gland |
| * Salivary Glands | * Seminal Vesicle | * Skin | * Stomach, Forestomach |
| * Stomach, Glandular | * Thyroid Gland | * Trachea | * Urinary Bladder |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|------------------------|-------------------------|
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Eosinophilic Focus | |
| | | Hepatocellular Adenoma | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | [Hepatocellular Adenoma TGLs = 2 - 14] | | |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 3 - 8] | | |
| * Prostate | Epithelium | Hyperplasia | Moderate |
| | | Inflammation | Mild |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 88

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 646
HISTO: 0601568

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Pancreas	* Parathyroid Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
Ear		Neural Crest Tumor	
	[Neural Crest Tumor TGLs = 1 - 14]		
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
	[Clear Cell Focus TGLs = 2 - 15]		
* Lung		Neural Crest Tumor	Metastatic (Ear)
* Nose		Inflammation	Mild
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Stomach, Forestomach		Mineralization	Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 3 - 11]		
* Thymus		Atrophy	Moderate

PRIMARY CAUSE OF DEATH - Ear Neural Crest Tumor

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 89

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601569

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | Blood Vessel | * Bone | * Bone Marrow |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Pancreas |
| * Parathyroid Gland | * Preputial Gland | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---|-------------------------|-------------------------|
| * Adrenal Medulla | | Pheochromocytoma Benign | |
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | Bile Duct | Hyperplasia | Mild |
| | | Inflammation | Chronic Active, Minimal |
| | [Eosinophilic Focus TGLs = 2,3 - 14+15] | | |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| * Prostate | | Inflammation | Mild |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Hyperplasia | Mild |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 90

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601570

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric | * Mammary Gland |
| * Parathyroid Gland | * Preputial Gland | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|----------------------------|-------------------------|
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | Centrilobular | Fatty Change | Minimal |
| | Bile Duct | Hepatodiaphragmatic Nodule | |
| | | Hyperplasia | Mild |
| | | Inflammation | Chronic Active, Minimal |
| | | Necrosis | Minimal |
| | [Eosinophilic Focus TGLs = 4 - 6+7+15+16] | | |
| | [Hepatodiaphragmatic Nodule TGLs = 3 - 15] | | |
| * Nose | | Foreign Body | |
| | | Inflammation | Mild |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 1 - 14] | | |
| * Prostate | | Inflammation | Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 90

TMT: 3

SEX: Male

DAY ON TEST: 729

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601570

ORGAN AND ACCOUNTABLE SITE STATUS

* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 2 - 11]		
* Thymus		Atrophy	Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 91

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601571

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Bone Marrow		Hemorrhage	Marked
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
	Hepatocyte	Hypertrophy	Minimal
		Inflammation	Chronic Active, Minimal
		Leukemia Mononuclear	
	[Hypertrophy TGLs = 2 - 14]		
* Pituitary Gland	Pars Distalis	Hyperplasia	Moderate
* Spleen		Leukemia Mononuclear	
		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 92

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 700
HISTO: 0601572

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lung |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Pancreas |
| * Parathyroid Gland | * Preputial Gland | * Salivary Glands | * Seminal Vesicle |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|------------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Moderate |
| * Epididymis | | Mesothelioma Malignant | |
| | [Mesothelioma Malignant TGLs = 3 - 15] | | |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| Mesentery | | Mesothelioma Malignant | |
| | Fat | Necrosis | Minimal |
| | Note: Mesothelioma implantations are also on serosa of prostate. | | |
| | [Mesothelioma Malignant TGLs = 4 - 16] | | |
| | [Necrosis TGLs = 6 - 17] | | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| * Prostate | | Inflammation | Mild |
| * Skin | Subcut Tiss | Fibroma | |
| | Note: Fibroma is myxomatous and has thromboses. | | |
| | [Fibroma TGLs = 1 - 14] | | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 92

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 700
HISTO: 0601572

ORGAN AND ACCOUNTABLE SITE STATUS

* Spleen		Hematopoietic Cell Proliferation	Moderate
* Testes	Interstit Cell	Adenoma	
	Interstit Cell	Hyperplasia	Minimal
		Mesothelioma Malignant	
	[Adenoma TGLs = 5 - 11]		
	[Mesothelioma Malignant TGLs = 2 - 11]		
* Thymus		Atrophy	Moderate

PRIMARY CAUSE OF DEATH - Skin Subcut Tiss Fibroma
CONTRIBUTORY CAUSE OF DEATH - Mesentery Mesothelioma Malignant

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 93

TMT: 3

SEX: Male

DAY ON TEST: 727

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601573

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Parathyroid Gland
* Preputial Gland	* Salivary Glands	* Seminal Vesicle	* Stomach, Forestomach
* Stomach, Glandular	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Epididymis		Inflammation	Mild
* Heart		Cardiomyopathy	Mild
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Lung		Alveolar/Bronchiolar Carcinoma	
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
* Prostate		Inflammation	Minimal
* Skin		Inflammation	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 94

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601574

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Parathyroid Gland
* Preputial Gland	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Mild
		Hypertrophy	Mild
Coagulating Gland		Inflammation	Moderate
Note: Inflammation in coagulating glands was noted on the routine section of seminal vesicles (B13).			
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
	Bile Duct	Hyperplasia	Minimal
	Centrilobular	Necrosis	Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Pancreas	Acinus	Hyperplasia	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Marked
* Prostate	Epithelium	Hyperplasia	Minimal
		Inflammation	Moderate
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Interstit Cell	Hyperplasia	Minimal
* Thymus		Atrophy	Marked
* Thyroid Gland	C Cell	Hyperplasia	Minimal
Ureter		Polyp	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 94

TMT: 3

SEX: Male

DAY ON TEST: 727

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601574

ORGAN AND ACCOUNTABLE SITE STATUS

Note: Tissue is probably a ureteral polyp (possibly inflammatory) and resembles best uterine polyps of females, except this has a higher mitotic index.

Note: Lesion noted on routine section of prostate (B13).

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 95

TMT: 3

SEX: Male

DAY ON TEST: 571

DOSE: 0.1 G/KG

DISP: Natural Death

HISTO: 0601575

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lung |
| * Lymph Node, Mesenteric | * Mammary Gland | * Pancreas | * Parathyroid Gland |
| * Preputial Gland | * Salivary Glands | * Seminal Vesicle | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---|----------------------------------|----------------------|
| * Bone Marrow | | Hyperplasia | Moderate |
| * Epididymis | | Mesothelioma Malignant | |
| | [Mesothelioma Malignant TGLs = 3 - 14+15] | | |
| * Heart | | Cardiomyopathy | Mild |
| | Atrium | Thrombosis | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Hematopoietic Cell Proliferation | Minimal |
| | | Inflammation | Chronic Active, Mild |
| | Centrilobular | Necrosis | Moderate |
| Mesentery | | Mesothelioma Malignant | |
| | Note: Mesothelioma implants are also present on the peritoneal surface of the body wall and serosae of the pancreas and prostate. | | |
| * Nose | | Inflammation | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Minimal |
| * Prostate | Epithelium | Hyperplasia | Minimal |
| * Spleen | | Hematopoietic Cell Proliferation | Mild |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | | Mesothelioma Malignant | |
| | [Adenoma TGLs = 2 - 11] | | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 95

TMT: 3

SEX: Male

DAY ON TEST: 571

DOSE: 0.1 G/KG

DISP: Natural Death

HISTO: 0601575

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Atrophy

Marked

[Atrophy TGLs = 5 - 3]

PRIMARY CAUSE OF DEATH

- Epididymis Mesothelioma Malignant

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 96

TMT: 3

SEX: Male

DAY ON TEST: 728

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601576

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Mild
* Bone Marrow		Hyperplasia	Mild
* Brain		Hydrocephalus	Minimal
* Epididymis		Inflammation	Minimal
* Heart		Cardiomyopathy	Mild
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Cholangioma	
		Clear Cell Focus	
		Eosinophilic Focus	
		Hepatodiaphragmatic Nodule	
		Inflammation	Chronic Active, Minimal
	[Cholangioma TGLs = 1 - 14]		
	[Hepatodiaphragmatic Nodule TGLs = 2 - 15]		
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 3 - 11]		
* Thymus		Atrophy	Marked

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 96

TMT: 3

SEX: Male

DAY ON TEST: 728

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601576

ORGAN AND ACCOUNTABLE SITE STATUS

* Thyroid Gland

C Cell

Hyperplasia

Mild

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 97

TMT: 3
 DOSE: 0.1 G/KG

SEX: Male
 DISP: Moribund Sacrifice

DAY ON TEST: 615
 HISTO: 0601577

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Epididymis
* Esophagus	* Eye	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Mammary Gland	* Nose
* Parathyroid Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Thyroid Gland	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Marked
* Bone Marrow		Hyperplasia	Marked
* Brain		Hemorrhage	Minimal
		Leukemia Mononuclear	
* Heart		Cardiomyopathy	Mild
		Leukemia Mononuclear	
* Kidney		Leukemia Mononuclear	
		Mineralization	Minimal
		Nephropathy	Minimal
* Liver	Bile Duct	Hyperplasia	Moderate
	Oval Cell	Hyperplasia	Mild
		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 1 - 6+7]		
* Lung		Leukemia Mononuclear	
Lymph Node	Pancreatic	Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 5 - 15]		
* Lymph Node, Mesenteric		Leukemia Mononuclear	
Mesentery	Fat	Necrosis	Minimal
	[Necrosis TGLs = 4 - 14]		
* Pancreas		Leukemia Mononuclear	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 97

TMT: 3

SEX: Male

DAY ON TEST: 615

DOSE: 0.1 G/KG

DISP: Moribund Sacrifice

HISTO: 0601577

ORGAN AND ACCOUNTABLE SITE STATUS

* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 2 - 14]		
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Mild
* Stomach, Glandular		Inflammation	Minimal
* Testes	Interstit Cell	Adenoma	
	Interstit Cell	Hyperplasia	Mild
	[Adenoma TGLs = 3 - 11]		
* Thymus		Atrophy	Marked

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 98

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601578

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Adrenal Medulla		Pheochromocytoma Benign	
Ear		Neural Crest Tumor	
	[Neural Crest Tumor TGLs = 1 - 14]		
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
	[Eosinophilic Focus TGLs = 3,4 - 15+16]		
* Prostate	Epithelium	Hyperplasia	Mild
		Inflammation	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 2 - 11]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 98

TMT: 3

SEX: Male

DAY ON TEST: 728

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601578

ORGAN AND ACCOUNTABLE SITE STATUS

* Thyroid Gland

C Cell

Hyperplasia

Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 99

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601579

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Esophagus | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lymph Node, Mesenteric |
| * Mammary Gland | * Parathyroid Gland | * Preputial Gland | * Salivary Glands |
| * Seminal Vesicle | * Skin | * Stomach, Forestomach | * Stomach, Glandular |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---------------------------|--------------------|-------------------------|
| * Epididymis | | Inflammation | Minimal |
| * Eye | Retina | Degeneration | Minimal |
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Fatty Change | Diffuse, Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| * Nose | | Inflammation | Minimal |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 2 - 8] | | |
| * Prostate | Epithelium | Hyperplasia | Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Adenoma | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 99

TMT: 3

SEX: Male

DAY ON TEST: 727

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601579

ORGAN AND ACCOUNTABLE SITE STATUS

C Cell

Hyperplasia

Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 100

TMT: 3
DOSE: 0.1 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601580

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | Blood Vessel | * Bone | * Bone Marrow |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Parathyroid Gland | * Preputial Gland | * Prostate | * Salivary Glands |
| * Seminal Vesicle | * Skin | * Stomach, Forestomach | * Stomach, Glandular |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--------------------------------------|--------------------|-------------------------|
| * Adrenal Medulla | | Hyperplasia | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Fatty Change | Diffuse, Minimal |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | [Eosinophilic Focus TGLs = 4 - 15] | | |
| | Mesentery | | |
| | [Necrosis TGLs = 2 - 14] | | |
| * Pancreas | Acinus | Hyperplasia | Mild |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 1 - 8] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Interstit Cell | Adenoma | |
| | Interstit Cell | Hyperplasia | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 100

TMT: 3

SEX: Male

DAY ON TEST: 727

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601580

ORGAN AND ACCOUNTABLE SITE STATUS

[Adenoma TGLs = 3 - 11]

* Thymus

Atrophy

Marked

* Thyroid Gland

Follicular Cel

Hyperplasia

Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 101

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601581

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fasciata	Hyperplasia	Minimal
* Heart		Cardiomyopathy	Moderate
* Kidney		Nephropathy	Mild
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Fatty Change	Diffuse, Minimal
	Bile Duct	Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Marked

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 102

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601582

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Eye	Retina	Degeneration	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Inflammation	Chronic Active, Minimal
		Pigmentation	Hemosiderin, Mild
		Fibroadenoma	
* Mammary Gland	[Fibroadenoma TGLs = 1 - 14]		
* Nose	Respirat Epith	Hyperplasia	Minimal
* Pancreas	Acinus	Hyperplasia	Mild
Skeletal Muscle	[Rhabdomyosarcoma TGLs = 2 - 15]	Rhabdomyosarcoma	
* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 3 - 11]		
* Thymus		Atrophy	Marked
* Thyroid Gland	C Cell	Adenoma	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 103

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 664
HISTO: 0601583

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lung |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Pancreas |
| * Parathyroid Gland | * Preputial Gland | * Prostate | * Salivary Glands |
| * Seminal Vesicle | * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---------------------------|----------------------------------|----------|
| * Bone Marrow | | Hyperplasia | Mild |
| * Epididymis | | Inflammation | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Minimal |
| * Skin | Subcut Tiss | Fibroma | |
| | [Fibroma TGLs = 1 - 14] | | |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 2 - 11] | | |
| * Thymus | | Atrophy | Moderate |

PRIMARY CAUSE OF DEATH - Skin Subcut Tiss Fibroma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 104

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Natural Death

DAY ON TEST: 630
HISTO: 0601584

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Mild
		Mineralization	Minimal
* Intestine Large, Colon		Parasite Metazoan	
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Mild
Note: TGL-3 = no corresponding microscopic finding.			
* Nose		Inflammation	Mild
* Pancreas		Atrophy	Minimal
	Acinus	Hyperplasia	Moderate
Peritoneum		Paraganglioma	
Note: TGL-1 is a retroperitoneal paraganglioma. [Paraganglioma TGLs = 1 - 14]			
* Spleen	Lymph Follic	Atrophy	Mild
		Pigmentation	Hemosiderin, Minimal
* Testes	Interstit Cell	Adenoma	
	Interstit Cell	Hyperplasia	Moderate
[Adenoma TGLs = 2 - 11]			

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 104

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Natural Death

DAY ON TEST: 630
HISTO: 0601584

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Atrophy

Moderate

PRIMARY CAUSE OF DEATH - Peritoneum Paraganglioma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 105

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601585

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Pheochromocytoma Benign	
* Epididymis		Inflammation	Mild
* Eye	Retina	Degeneration	Minimal
* Heart		Cardiomyopathy	Mild
* Intestine Large, Colon		Parasite Metazoan	
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
	Alveolus	Infiltration Cellular	Histiocyte, Minimal
		Inflammation	Chronic Active, Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Skin	Subcut Tiss	Fibroma	
	[Fibroma TGLs = 2 - 14]		
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 106

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601586

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Clear Cell Focus	
		Fatty Change	Diffuse, Minimal
	Bile Duct	Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Nose		Inflammation	Minimal
* Prostate		Inflammation	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 107

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601587

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Parathyroid Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Adrenal Medulla		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Pancreas		Atrophy	Minimal
	Acinus	Hyperplasia	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate
Tooth		Malformation	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 108

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601588

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Pancreas	* Parathyroid Gland
* Preputial Gland	* Salivary Glands	* Seminal Vesicle	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Eye	Retina	Degeneration	Moderate
* Heart		Cardiomyopathy	Mild
* Kidney		Accumulation, Hyaline Droplet	Minimal
		Mineralization	Minimal
		Nephropathy	Moderate
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Fatty Change	Diffuse, Minimal
	Bile Duct	Hyperplasia	Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
Mesentery	Fat	Necrosis	Mild
	[Necrosis TGLs = 2 - 14]		
* Nose		Inflammation	Mild
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 4 - 8]		
* Prostate		Inflammation	Mild
* Skin	Subcut Tiss	Fibroma	
	[Fibroma TGLs = 3 - 15]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Mild

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 108

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601588

ORGAN AND ACCOUNTABLE SITE STATUS

* Testes	Bilateral, Interstit Cell	Adenoma	
[Adenoma TGLs = 1 - 11]			
* Thymus		Atrophy	Marked

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 109

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601589

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Parathyroid Gland | * Preputial Gland | * Prostate | * Salivary Glands |
| * Seminal Vesicle | * Skin | * Stomach, Forestomach | * Stomach, Glandular |
| * Thyroid Gland | * Trachea | * Urinary Bladder | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---------------------------|--------------------|----------------------|
| * Bone Marrow | | Hyperplasia | Minimal |
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Nephropathy | Minimal |
| * Liver | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | Pars Distalis | Hyperplasia | Minimal |
| | [Adenoma TGLs = 2 - 8] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 110

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601590

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Bone Marrow |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Pancreas |
| * Parathyroid Gland | * Preputial Gland | * Prostate | * Salivary Glands |
| * Seminal Vesicle | * Skin | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|--------------------------------------|--------------------|-------------------------|
| * Adrenal Cortex | | Hypertrophy | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Mild |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | Centrilobular | Fatty Change | Minimal |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | [Eosinophilic Focus TGLs = 2 - 14] | | |
| * Nose | | Inflammation | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Mild |
| | | Inflammation | Mild |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Moderate |
| Tooth | | Malformation | Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 111

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601591

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Eye	* Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Parathyroid Gland	* Preputial Gland
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Liver	Bile Duct	Clear Cell Focus Hyperplasia Inflammation	Mild Chronic Active, Minimal
* Lung	Alveolar Epith Alveolus	Hyperplasia Infiltration Cellular	Minimal Histiocyte, Minimal
* Pancreas	Acinus	Hyperplasia	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
[Hyperplasia TGLs = 1 - 8]			
* Prostate		Inflammation	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Interstit Cell Interstit Cell	Adenoma Hyperplasia	Marked
[Adenoma TGLs = 2 - 11]			
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 112

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601592

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Epididymis
* Esophagus	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Hematopoietic Cell Proliferation	Minimal
* Bone Marrow		Hyperplasia	Mild
* Brain	Chor Plexus	Infiltration Cellular	Lymphocyte, Mild
* Eye	Retina	Degeneration	Mild
* Heart		Cardiomyopathy	Mild
* Kidney		Infarct	Minimal
		Mineralization	Minimal
* Liver		Nephropathy	Mild
		Basophilic Focus	
* Mammary Gland		Leukemia Mononuclear	
	[Fibroadenoma TGLs = 1 - 14]	Fibroadenoma	
* Prostate		Inflammation	Mild
* Spleen		Leukemia Mononuclear	
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 2 - 11]		
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Adenoma	
	C Cell	Hyperplasia	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 113

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Natural Death

DAY ON TEST: 728
HISTO: 0601593

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Brain	* Epididymis
* Esophagus	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Parathyroid Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Hypertrophy	Minimal
		Leukemia Mononuclear	
* Adrenal Medulla		Leukemia Mononuclear	
* Bone Marrow		Hyperplasia	Moderate
* Eye	Retina	Degeneration	Minimal
* Heart		Cardiomyopathy	Marked
	Atrium	Thrombosis	Minimal
* Kidney		Nephropathy	Moderate
* Liver		Fatty Change	Diffuse, Moderate
	Bile Duct	Hyperplasia	Mild
		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 3 - 15]		
* Lung		Leukemia Mononuclear	
* Pancreas	Acinus	Hyperplasia	Moderate
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 4 - 8]		
* Prostate		Inflammation	Mild
* Spleen		Leukemia Mononuclear	
		Pigmentation	Hemosiderin, Minimal
	[Leukemia Mononuclear TGLs = 2 - 14]		

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 113

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Natural Death

DAY ON TEST: 728
HISTO: 0601593

ORGAN AND ACCOUNTABLE SITE STATUS

* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation	Moderate Marked
* Testes [Adenoma TGLs = 1 - 11]	Bilateral, Interstit Cell	Ulcer Adenoma	Marked
* Thymus		Atrophy	Marked
Tooth		Malformation	Minimal

PRIMARY CAUSE OF DEATH - Heart Cardiomyopathy
CONTRIBUTORY CAUSE OF DEATH - Spleen Leukemia Mononuclear

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 114

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 701
HISTO: 0601594

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Skin	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Moderate
* Bone Marrow		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Moderate
	[Nephropathy TGLs = 1 - 5]		
* Liver		Basophilic Focus	
		Hepatodiaphragmatic Nodule	
	Bile Duct	Hyperplasia	Minimal
		Leukemia Mononuclear	
		Pigmentation	Hemosiderin, Minimal
	[Hepatodiaphragmatic Nodule TGLs = 2 - 14]		
* Lung	Alveolar Epith	Hyperplasia	Minimal
	Alveolar Epith	Hypertrophy	Minimal
	Alveolus	Infiltration Cellular	Histiocyte, Mild
		Inflammation	Chronic Active, Minimal
	Alveolar Epith	Metaplasia	Mild
	Note: There is bronchiolar metaplasia in several foci in the lungs.		
* Nose		Inflammation	Minimal
* Pancreas		Atrophy	Minimal
* Parathyroid Gland		Hyperplasia	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 114

TMT: 5
 DOSE: 0.3 G/KG

SEX: Male
 DISP: Moribund Sacrifice

DAY ON TEST: 701
 HISTO: 0601594

ORGAN AND ACCOUNTABLE SITE STATUS

* Pituitary Gland	Pars Distalis	Adenoma	
[Adenoma TGLs = 4 - 8]			
* Prostate		Inflammation	Mild
* Spleen	Lymph Follic	Atrophy	Marked
		Leukemia Mononuclear	
		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Moderate
		Inflammation	Marked
		Ulcer	Marked
[Ulcer TGLs = 6 - 15]			
* Stomach, Glandular		Carcinoid Tumor Malignant	
		Inflammation	Mild
[Carcinoid Tumor Malignant TGLs = 5 - 14]			
* Testes	Interstit Cell	Adenoma	
	Interstit Cell	Hyperplasia	Mild
[Adenoma TGLs = 3 - 11]			
* Thymus		Atrophy	Marked
* Thyroid Gland	Follicular Cel	Adenoma	

PRIMARY CAUSE OF DEATH - Stomach, Forestomach Ulcer
 CONTRIBUTORY CAUSE OF DEATH - Stomach, Glandular Carcinoid Tumor Malignant

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 115

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601595

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Mild
* Epididymis		Mesothelioma Malignant	
	[Mesothelioma Malignant TGLs = 5 - 17]		
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Mild
	Hepatocyte	Hypertrophy	Minimal
		Inflammation	Chronic Active, Minimal
	[Eosinophilic Focus TGLs = 2,3 - 15+16]		
* Lung	Alveolar Epith	Hyperplasia	Minimal
	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 6 - 8]		
* Skin	Subcut Tiss	Fibroma	
	[Fibroma TGLs = 1 - 14]		
* Spleen		Pigmentation	Hemosiderin, Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 115

TMT: 5

SEX: Male

DAY ON TEST: 728

DOSE: 0.3 G/KG

DISP: Terminal Sacrifice

HISTO: 0601595

ORGAN AND ACCOUNTABLE SITE STATUS

* Testes	Bilateral, Interstit Cell	Adenoma	
[Adenoma TGLs = 4 - 11]			
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 116

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601596

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Parathyroid Gland |
| * Prostate | * Salivary Glands | * Seminal Vesicle | * Spleen |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---|-------------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Moderate |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Mild |
| * Liver | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| * Lung | | Squamous Cell Carcinoma | Metastatic (Skin) |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| * Preputial Gland | | Inflammation | Mild |
| * Skin | Epidermis | Squamous Cell Carcinoma | |
| | [Squamous Cell Carcinoma TGLs = 2 - 14] | | |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 117

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 702
HISTO: 0601597

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Epididymis | * Esophagus | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mesenteric | * Mammary Gland |
| * Nose | * Parathyroid Gland | * Preputial Gland | * Salivary Glands |
| * Seminal Vesicle | * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--|---------------------------|----------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Marked |
| * Eye | Retina | Degeneration | Minimal |
| * Heart | | Cardiomyopathy | Moderate |
| | Coron Artery | Degeneration | Minimal |
| | Epicardium | Inflammation | Minimal |
| Note: Intimal proliferation and degeneration is present in a coronary artery. | | | |
| Note: Epicardial inflammation involves the heart base and is fibrinosuppurative. | | | |
| * Islets, Pancreatic | | Adenoma | Multiple |
| | [Adenoma TGLs = 5 - 16] | | |
| * Kidney | | Inflammation | Acute, Mild |
| | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | Hepatocyte | Hyperplasia | Mild |
| * Lung | | Inflammation | Chronic Active, Minimal |
| | | Osteosarcoma | Metastatic (Skin) |
| Note: A floater of mesothelioma (from another case) is present in B03. | | | |
| * Pancreas | | Atrophy | Mild |
| | | Inflammation | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 2 - 8] | | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 117

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 702
HISTO: 0601597

ORGAN AND ACCOUNTABLE SITE STATUS

* Prostate		Inflammation	Minimal
* Skin	Subcut Tiss	Osteosarcoma	
	[Osteosarcoma TGLs = 1 - 14]		
* Spleen		Hematopoietic Cell Proliferation	Moderate
	Lymph Follic	Hyperplasia	Moderate
	[Hyperplasia TGLs = 4 - 15]		
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 3 - 11]		
* Thymus		Atrophy	Marked

PRIMARY CAUSE OF DEATH - Skin Subcut Tiss Osteosarcoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 118

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 689
HISTO: 0601598

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Pancreas	* Parathyroid Gland	* Preputial Gland
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Eye	Retina	Degeneration	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Eosinophilic Focus	
		Hepatodiaphragmatic Nodule	
	Bile Duct	Hyperplasia	Minimal
	[Hepatodiaphragmatic Nodule TGLs = 2 - 14]		
* Lung	Alveolar Epith	Hyperplasia	Mild
* Nose		Inflammation	Mild
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 1 - 8]		
* Prostate	Epithelium	Hyperplasia	Minimal
		Inflammation	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 3 - 11]		
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 118

TMT: 5

SEX: Male

DAY ON TEST: 689

DOSE: 0.3 G/KG

DISP: Moribund Sacrifice

HISTO: 0601598

ORGAN AND ACCOUNTABLE SITE STATUS

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 119

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601599

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Epididymis	* Esophagus	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Minimal
* Eye	Retina	Degeneration	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Nephropathy	Mild
* Liver		Basophilic Focus	
		Fatty Change	Diffuse, Minimal
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Pancreas		Atrophy	Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 120

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601600

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Mammary Gland
* Nose	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular	* Parathyroid Gland
--------------------------	---------------------

OBSERVATIONS

* Adrenal Cortex		Leukemia Mononuclear	
* Bone Marrow		Hyperplasia	Mild
Ear		Neural Crest Tumor	
	[Neural Crest Tumor TGLs = 1 - 14]		
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
* Liver		Hyperplasia	Minimal
	Oval Cell	Hyperplasia	Minimal
	Bile Duct	Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 4 - 6+7]		
* Lung		Hyperplasia	Minimal
	Alveolar Epith	Leukemia Mononuclear	
		Neural Crest Tumor	Metastatic (Ear)
* Lymph Node, Mesenteric		Leukemia Mononuclear	
* Pancreas		Atrophy	Minimal
* Pituitary Gland		Hyperplasia	Minimal
* Spleen		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 3 - 15]		
* Testes		Adenoma	
	[Adenoma TGLs = 2 - 11]		
	Bilateral, Interstit Cell		

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 120

TMT: 5

SEX: Male

DAY ON TEST: 728

DOSE: 0.3 G/KG

DISP: Terminal Sacrifice

HISTO: 0601600

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Atrophy

Moderate

* Thyroid Gland

C Cell

Hyperplasia

Marked

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 121

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601601

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Mild
* Eye	Lens	Cataract	Mild
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Fatty Change	Diffuse, Mild
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
		Mixed Cell Focus	
	[Mixed Cell Focus TGLs = 2 - 14]		
* Pancreas		Atrophy	Minimal
* Prostate		Inflammation	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Marked
* Thyroid Gland	C Cell	Hyperplasia	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 122

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601602

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Parathyroid Gland | * Preputial Gland | * Prostate | * Salivary Glands |
| * Seminal Vesicle | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---|----------------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Nephropathy | Mild |
| * Liver | | Clear Cell Focus | |
| | | Hepatodiaphragmatic Nodule | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | [Hepatodiaphragmatic Nodule
TGLs = 4 - 16] | Hyperplasia | Moderate |
| | Alveolar Epith | Infiltration Cellular | Histiocyte, Minimal |
| | Alveolus | Inflammation | Chronic Active, Minimal |
| | | Necrosis | Minimal |
| | Mesentery | | |
| | [Necrosis TGLs = 3 - 15] | | |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Minimal |
| * Skin | Subcut Tiss | Fibroma | |
| | [Fibroma TGLs = 1 - 14] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Interstit Cell | Adenoma | |
| | Interstit Cell | Hyperplasia | Marked |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 122

TMT: 5

SEX: Male

DAY ON TEST: 727

DOSE: 0.3 G/KG

DISP: Terminal Sacrifice

HISTO: 0601602

ORGAN AND ACCOUNTABLE SITE STATUS

[Adenoma TGLs = 2 - 11]

* Thymus

Atrophy

Marked

* Thyroid Gland

Bilateral, C Cell

Adenoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 123

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601603

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Moderate
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
	Bile Duct	Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
		Inflammation	Chronic Active, Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Marked
* Thyroid Gland	C Cell	Adenoma	
	C Cell	Carcinoma	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 124

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601604

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Parathyroid Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
		Hypertrophy	Minimal
* Epididymis		Inflammation	Mild
* Heart		Cardiomyopathy	Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Angiectasis	Minimal
		Clear Cell Focus	
	Centrilobular	Fatty Change	Minimal
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Pancreas	Acinus	Hyperplasia	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Marked

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 125

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601605

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Eye	Retina	Degeneration	Moderate
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Moderate
* Liver		Angiectasis	Minimal
		Basophilic Focus	
		Clear Cell Focus	
	Centrilobular	Fatty Change	Mild
	Bile Duct	Hyperplasia	Minimal
	Hepatocyte	Hypertrophy	Minimal
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Mild
* Pancreas		Atrophy	Minimal
		Inflammation	Minimal
* Prostate		Inflammation	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Interstit Cell	Adenoma	
	Interstit Cell	Hyperplasia	Mild

[Adenoma TGLs = 1 - 11]

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 125

TMT: 5

SEX: Male

DAY ON TEST: 728

DOSE: 0.3 G/KG

DISP: Terminal Sacrifice

HISTO: 0601605

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus
Tooth

Atrophy
Malformation

Moderate
Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 126

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601606

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Bone Marrow |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Parathyroid Gland |
| * Preputial Gland | * Prostate | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|----------------------------|---------------------------|--------------------|-------------------------|
| * Adrenal Cortex | Zona Fascult | Hyperplasia | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Mild |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| Mesentery | Fat | Necrosis | Minimal |
| [Necrosis TGLs = 2 - 14] | | | |
| * Pancreas | Acinus | Adenoma | |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| [Adenoma TGLs = 3 - 8] | | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Stomach, Forestomach | Epithelium | Dysplasia | Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| [Adenoma TGLs = 1 - 11] | | | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 126

TMT: 5

SEX: Male

DAY ON TEST: 727

DOSE: 0.3 G/KG

DISP: Terminal Sacrifice

HISTO: 0601606

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Atrophy

Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 127

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601607

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Pancreas	* Parathyroid Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Pheochromocytoma Benign	
* Heart		Cardiomyopathy	Mild
* Intestine Large, Colon		Parasite Metazoan	
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Lung		Alveolar/Bronchiolar Adenoma	
	Alveolar Epith	Hyperplasia	Minimal
* Nose		Inflammation	Mild
	Olfactory Epi	Metaplasia	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 128

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601608

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Epididymis	* Esophagus	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Moderate
* Eye	Retina	Degeneration	Minimal
* Heart		Cardiomyopathy	Minimal
	Atrium	Thrombosis	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
	Centrilobular	Degeneration	Mild
		Hematopoietic Cell Proliferation	Mild
		Inflammation	Chronic Active, Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Moderate
* Skin		Basal Cell Adenoma	
	[Basal Cell Adenoma TGLs = 1 - 14]		
* Spleen		Hematopoietic Cell Proliferation	Mild
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 2 - 11]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 129

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601609

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Pancreas | * Parathyroid Gland | * Pituitary Gland | * Preputial Gland |
| * Salivary Glands | * Seminal Vesicle | * Stomach, Forestomach | * Stomach, Glandular |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-----------------|-----------------------------------|-----------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | Pelvis, Transit Epithe | Hyperplasia | Mild |
| | | Mineralization | Minimal |
| | | Nephropathy | Mild |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| * Prostate | | Inflammation | Mild |
| * Skin | Subcut Tiss | Hemangiosarcoma | |
| | [Hemangiosarcoma TGLs = 1 - 14] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 2 - 11] | | |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Hyperplasia | Marked |
| * Urin Bladder | | | |

Note: There is osseous metaplasia in the bladder wall.

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 130

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Dosing Accident

DAY ON TEST: 598
HISTO: 0601610

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Epididymis
* Esophagus	* Eye	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Mild
* Brain		Necrosis	Moderate
Note: Necrosis in the brain possibly caused by (thyroid) tumor emboli. [Necrosis TGLs = 6 - 9]			
* Heart		Cardiomyopathy	Moderate
* Kidney		Nephropathy	Minimal
* Liver		Fatty Change	Diffuse, Mild
	Bile Duct	Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
		Mixed Cell Focus	
[Fatty Change TGLs = 5 - 6+7+15]			
* Lung		Congestion	Moderate
[Congestion TGLs = 2 - 3+4]			
Mesentery	Fat	Necrosis	Mild
[Necrosis TGLs = 3 - 14]			
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
[Adenoma TGLs = 4 - 11]			

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 130

TMT: 5

SEX: Male

DAY ON TEST: 598

DOSE: 0.3 G/KG

DISP: Dosing Accident

HISTO: 0601610

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Atrophy

Moderate

* Thyroid Gland

Follicular Cel

Carcinoma

[Carcinoma TGLs = 1 - 8]

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 131

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 664
HISTO: 0601611

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Cortex | Blood Vessel | * Bone | * Brain |
| * Epididymis | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Parathyroid Gland | * Preputial Gland | * Prostate | * Salivary Glands |
| * Seminal Vesicle | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--------------------------|----------------|----------------------------------|-------------------------|
| * Adrenal Medulla | | Hyperplasia | Minimal |
| * Bone Marrow | | Hyperplasia | Moderate |
| * Heart | | Cardiomyopathy | Mild |
| * Intestine Large, Colon | | Parasite Metazoan | |
| * Islets, Pancreatic | | Hyperplasia | Minimal |
| * Kidney | | Nephropathy | Minimal |
| * Liver | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolar Epith | Hypertrophy | Mild |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| | | [Hyperplasia TGLs = 3 - 8] | |
| * Skin | Subcut Tiss | Fibroma | |
| | | [Fibroma TGLs = 1 - 14] | |
| * Spleen | | Hematopoietic Cell Proliferation | Mild |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Minimal |
| * Testes | Interstit Cell | Adenoma | |
| | Interstit Cell | Hyperplasia | Mild |
| | | [Adenoma TGLs = 2 - 11] | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 131

TMT: 5

SEX: Male

DAY ON TEST: 664

DOSE: 0.3 G/KG

DISP: Moribund Sacrifice

HISTO: 0601611

ORGAN AND ACCOUNTABLE SITE STATUS

Tooth

Malformation

Minimal

PRIMARY CAUSE OF DEATH

- Skin Subcut Tiss Fibroma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 132

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 709
HISTO: 0601612

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Pancreas | * Parathyroid Gland | * Preputial Gland | * Salivary Glands |
| * Seminal Vesicle | * Skin | * Stomach, Forestomach | * Stomach, Glandular |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|-----------------------------|--------------------|----------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Mild |
| * Liver | | Degeneration | Cystic, Minimal |
| | | Eosinophilic Focus | |
| | | Fatty Change | Diffuse, Minimal |
| | Bile Duct | Hyperplasia | Minimal |
| * Lung | | Carcinoma | Metastatic (Thyroid Gland) |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 3 - 8] | | |
| * Prostate | | Inflammation | Mild |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Marked |
| * Thyroid Gland | C Cell | Carcinoma | |
| | [Carcinoma TGLs = 2 - 14] | | |

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 133

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 694
HISTO: 0601613

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Pancreas | * Parathyroid Gland | * Preputial Gland | * Salivary Glands |
| * Seminal Vesicle | * Skin | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|-------------------------------|------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Islets, Pancreatic | | Adenoma | |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Mild |
| * Liver | | Clear Cell Focus | |
| | Bile Duct | Hyperplasia | Mild |
| | | Inflammation | Chronic Active, Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 1 - 8] | | |
| * Prostate | | Inflammation | Mild |
| * Spleen | | Pigmentation | Hemosiderin, Mild |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Mild |
| | | Inflammation | Moderate |
| | | Mineralization | Minimal |
| | | Ulcer | Mild |
| | [Hyperplasia TGLs = 2 - 14] | | |
| * Testes | Interstit Cell | Hyperplasia | Minimal |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | Bilateral, C Cell | Adenoma | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 133

TMT: 5

SEX: Male

DAY ON TEST: 694

DOSE: 0.3 G/KG

DISP: Moribund Sacrifice

HISTO: 0601613

ORGAN AND ACCOUNTABLE SITE STATUS

Tooth

Malformation

Minimal

PRIMARY CAUSE OF DEATH

- Pituitary Gland Pars Distalis Adenoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 134

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601614

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Parathyroid Gland | * Preputial Gland | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---------------------------|----------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Clear Cell Focus | |
| | Bile Duct | Hyperplasia | Mild |
| | | Leukemia Mononuclear | |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| * Prostate | | Inflammation | Mild |
| * Spleen | | Leukemia Mononuclear | |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Marked |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 135

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601615

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Parathyroid Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Skin	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Fibrosarcoma	Metastatic (Stomach, Glandular)
	Bile Duct	Hyperplasia	Moderate
		Inflammation	Chronic Active, Minimal
Mesentery	Fat	Necrosis	Mild
[Necrosis TGLs = 2 - 14]			
* Pancreas	Acinus	Hyperplasia	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
[Adenoma TGLs = 3 - 8]			
* Prostate		Inflammation	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Marked
		Inflammation	Minimal
* Stomach, Glandular	Muscularis	Fibrosarcoma	
[Fibrosarcoma TGLs = 4 - 15]			
* Testes	Bilateral, Interstit Cell	Adenoma	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 135

TMT: 5

SEX: Male

DAY ON TEST: 729

DOSE: 0.3 G/KG

DISP: Terminal Sacrifice

HISTO: 0601615

ORGAN AND ACCOUNTABLE SITE STATUS

[Adenoma TGLs = 1 - 11]

* Thymus

Atrophy

Moderate

* Thyroid Gland

C Cell

Adenoma

C Cell

Hyperplasia

Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 136

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601616

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Parathyroid Gland	* Preputial Gland	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Adrenal Medulla		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Clear Cell Focus	
		Fatty Change	Diffuse, Minimal
	Bile Duct	Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
* Nose		Inflammation	Minimal
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Prostate		Inflammation	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Adenoma	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 137

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601617

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Pancreas | * Parathyroid Gland |
| * Preputial Gland | * Prostate | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---------------------------|------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Minimal |
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Moderate |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | Bile Duct | Hyperplasia | Mild |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | | Inflammation | Chronic Active, Minimal |
| * Nose | | Inflammation | Mild |
| | Olfactory Epi | Metaplasia | Mild |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Adenoma | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 138

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 689
HISTO: 0601618

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Brain |
| * Epididymis | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lymph Node, Mesenteric |
| * Mammary Gland | * Nose | * Pancreas | * Parathyroid Gland |
| * Prostate | * Seminal Vesicle | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | | |

MISSING

- | | |
|--------------------------|-------------------|
| * Lymph Node, Mandibular | * Preputial Gland |
|--------------------------|-------------------|

OBSERVATIONS

- | | | | |
|------------------------|---|----------------------------------|------------------------------|
| * Adrenal Cortex | Zona Fascult | Hyperplasia | Minimal |
| * Bone Marrow | | Hyperplasia | Moderate |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| | | Schwannoma Malignant | Metastatic (Salivary Glands) |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Minimal |
| * Salivary Glands | | Schwannoma Malignant | |
| | [Schwannoma Malignant TGLs = 2 - 14+15] | | |
| * Skin | Subcut Tiss | Schwannoma Malignant | Metastatic (Salivary Glands) |
| | [Schwannoma Malignant TGLs = 1 - 16+17] | | |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |
| | | Pigmentation | Hemosiderin, Minimal |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Mild |
| | | Inflammation | Moderate |
| | | Ulcer | Moderate |
| | [Ulcer TGLs = 4 - 6] | | |
| * Testes | Bilateral, Interstit Cell | Adenoma | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 138

TMT: 5

SEX: Male

DAY ON TEST: 689

DOSE: 0.3 G/KG

DISP: Moribund Sacrifice

HISTO: 0601618

ORGAN AND ACCOUNTABLE SITE STATUS

[Adenoma TGLs = 3 - 11]

* Thymus

Atrophy

Moderate

PRIMARY CAUSE OF DEATH - Salivary Glands Schwannoma Malignant

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 139

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 608
HISTO: 0601619

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Epididymis	* Esophagus	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Parathyroid Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Stomach, Forestomach	* Stomach, Glandular
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Mild
* Eye	Cornea	Inflammation	Moderate
Note: The cornea is perforated in this rat. [Inflammation TGLs = 2 - 10]			
* Heart		Cardiomyopathy	Mild
* Intestine Large, Colon		Parasite Metazoan	
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Degeneration	Cystic, Minimal
	Bile Duct	Hyperplasia	Minimal
		Mixed Cell Focus	
* Lung		Alveolar/Bronchiolar Adenoma	
	Alveolar Epith	Hyperplasia	Mild
	Alveolar Epith	Metaplasia	Squamous, Mild
[Alveolar/Bronchiolar Adenoma TGLs = 6 - 3]			
Lymph Node	Mediastinal	Ectasia	Mild
[Ectasia TGLs = 5 - 14]			
* Pancreas		Atrophy	Mild
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Skin	Subcut Tiss	Fibroma	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 139

TMT: 5

SEX: Male

DAY ON TEST: 608

DOSE: 0.3 G/KG

DISP: Moribund Sacrifice

HISTO: 0601619

ORGAN AND ACCOUNTABLE SITE STATUS

[Fibroma TGLs = 1 - 15]

* Spleen

* Testes

Interstit Cell

Interstit Cell

Pigmentation

Adenoma

Hyperplasia

Hemosiderin, Minimal

Mild

[Adenoma TGLs = 4 - 11]

* Thymus

* Thyroid Gland

Zymbal's Gland

C Cell

Atrophy

Hyperplasia

Carcinoma

Marked

Minimal

[Carcinoma TGLs = 3 - 16]

PRIMARY CAUSE OF DEATH

- Zymbal's Gland Carcinoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 140

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601620

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Brain |
| * Epididymis | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lymph Node, Mesenteric |
| * Mammary Gland | * Nose | * Pancreas | * Parathyroid Gland |
| * Preputial Gland | * Salivary Glands | * Seminal Vesicle | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Trachea | * Urinary Bladder |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|----------------------------|----------|
| * Adrenal Cortex | | Leukemia Mononuclear | |
| * Bone Marrow | | Hyperplasia | Mild |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Mild |
| * Liver | | Clear Cell Focus | |
| | | Hepatodiaphragmatic Nodule | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Leukemia Mononuclear | |
| | [Hepatodiaphragmatic Nodule TGLs = 4 - 15] | | |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Minimal |
| | [Hyperplasia TGLs = 1 - 14] | | |
| * Prostate | | Inflammation | Mild |
| * Spleen | | Leukemia Mononuclear | |
| | [Leukemia Mononuclear TGLs = 3 - 5] | | |
| * Testes | Interstit Cell | Adenoma | |
| | Interstit Cell | Hyperplasia | Mild |
| | [Adenoma TGLs = 2 - 11] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 140

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601620

ORGAN AND ACCOUNTABLE SITE STATUS

* Thyroid Gland

C Cell

Hyperplasia

Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 141

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 616
HISTO: 0601621

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Pancreas |
| * Parathyroid Gland | * Pituitary Gland | * Preputial Gland | * Prostate |
| * Seminal Vesicle | * Skin | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|--|----------------------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Mild |
| * Heart | | Cardiomyopathy | Mild |
| * Islets, Pancreatic | | Hyperplasia | Minimal |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Degeneration | Cystic, Mild |
| | | Eosinophilic Focus | |
| | Centrilobular | Fatty Change | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Salivary Glands | | Schwannoma Malignant | |
| | [Schwannoma Malignant TGLs = 1 - 14] | | |
| * Spleen | | Hematopoietic Cell Proliferation | Mild |
| * Stomach, Forestomach | | Erosion | Mild |
| | Epithelium | Hyperplasia | Moderate |
| | | Inflammation | Moderate |
| * Testes | | Adenoma | |
| | Bilateral, Interstit Cell | | |
| | [Adenoma TGLs = 2 - 11] | | |
| * Thymus | | Atrophy | Marked |

PRIMARY CAUSE OF DEATH - Salivary Glands Schwannoma Malignant

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 142

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 673
HISTO: 0601622

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Brain |
| * Esophagus | * Eye | * Harderian Gland | * Intestine Large, Cecum |
| * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic | * Mammary Gland | * Nose |
| * Pituitary Gland | * Skin | * Spleen | * Thyroid Gland |
| * Trachea | | | |

MISSING

- | | |
|--------------------------|---------------------|
| * Lymph Node, Mandibular | * Parathyroid Gland |
|--------------------------|---------------------|

OBSERVATIONS

- | | | | |
|--------------------------|----------------|----------------------------|-------------------------|
| * Adrenal Cortex | | Necrosis | Minimal |
| * Bone Marrow | | Hyperplasia | Moderate |
| * Epididymis | | Lymphoma Malignant | |
| * Heart | | Lymphoma Malignant | |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Fatty Change | Diffuse, Marked |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolar Epith | Hyperplasia | Mild |
| | | Lymphoma Malignant | |
| * Lymph Node, Mesenteric | | Lymphoma Malignant | |
| Mesentery | | Lymphoma Malignant | |
| | Fat | Necrosis | Mild |
| | | [Necrosis TGLs = 3 - 15] | |
| * Pancreas | | Lymphoma Malignant | |
| * Preputial Gland | | Lymphoma Malignant | |
| * Prostate | | Lymphoma Malignant | |
| * Salivary Glands | | Atrophy | Mild |
| * Seminal Vesicle | | Lymphoma Malignant | |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 142

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 673
HISTO: 0601622

ORGAN AND ACCOUNTABLE SITE STATUS

Inflammation Mild
Lymphoma Malignant
Ulcer Moderate

[Lymphoma Malignant TGLs = 2 - 14]
* Stomach, Glandular

Epithelium

Lymphoma Malignant
Necrosis Mild

[Lymphoma Malignant TGLs = 4 - 15]
* Testes Bilateral, Interstit Cell

Adenoma

[Adenoma TGLs = 1- 11]

* Thymus

Lymphoma Malignant

* Urinary Bladder

Lymphoma Malignant

PRIMARY CAUSE OF DEATH - Stomach, Glandular Lymphoma Malignant

Animal Note: Lymphoma was also present in the intestinal walls.

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 143

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601623

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | Blood Vessel | * Bone | * Bone Marrow |
| * Epididymis | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lymph Node, Mesenteric |
| * Mammary Gland | * Nose | * Parathyroid Gland | * Pituitary Gland |
| * Preputial Gland | * Salivary Glands | * Seminal Vesicle | * Skin |
| * Spleen | * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|---|---------------------------|-----------------------|-------------------------|
| * Adrenal Medulla | | Hyperplasia | Marked |
| * Brain | | Necrosis | Moderate |
| Note: There are two areas of old infarction (now cavitated) in the cerebral cortex. | | | |
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Moderate |
| * Liver | | Clear Cell Focus | |
| | | Fatty Change | Diffuse, Minimal |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| * Pancreas | | Atrophy | Minimal |
| | Acinus | Hyperplasia | Minimal |
| * Prostate | | Adenoma | |
| | | Inflammation | Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 144

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601624

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Parathyroid Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Semivary Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 145

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 590
HISTO: 0601625

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Mild
* Bone Marrow		Hyperplasia	Moderate
* Heart		Cardiomyopathy	Minimal
	Atrium	Thrombosis	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver	Bile Duct	Hyperplasia	Mild
		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 3 - 6+7]		
* Lung		Leukemia Mononuclear	
		Thrombosis	Minimal
Mesentery		Leukemia Mononuclear	
		Thrombosis	Moderate
	[Thrombosis TGLs = 7 - 15]		
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 5 - 8]		
* Spleen		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 2 - 15]		
* Stomach, Forestomach	Epithelium	Dysplasia	Minimal
	Epithelium	Hyperplasia	Marked

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 145

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 590
HISTO: 0601625

ORGAN AND ACCOUNTABLE SITE STATUS

		Inflammation	Moderate
		Ulcer	Mild
[Hyperplasia TGLs = 6 - 14]			
* Stomach, Glandular		Inflammation	Mild
* Testes	Bilateral, Interstit Cell	Adenoma	
[Adenoma TGLs = 1 - 11]			
* Thymus		Atrophy	Marked
Tooth		Malformation	Minimal

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 146

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601626

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Pancreas	* Parathyroid Gland	* Preputial Gland
* Salivary Glands	* Seminal Vesicle	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Adrenal Medulla		Hyperplasia	Moderate
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Moderate
* Liver		Clear Cell Focus	
	Bile Duct	Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Nose		Foreign Body	
		Inflammation	Mild
	Olfactory Epi	Metaplasia	Minimal
Note: There is a hair shaft in the nasal cavity inciting inflammation.			
* Pituitary Gland	Pars Distalis	Angiectasis	Mild
* Prostate		Inflammation	Minimal
* Skin	Subcut Tiss	Lipoma	
	Epidermis	Trichoepithelioma	

Note: Trichoepithelioma is in B12 recut.
 [Lipoma TGLs = 2 - 14]

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 146

TMT: 5

SEX: Male

DAY ON TEST: 728

DOSE: 0.3 G/KG

DISP: Terminal Sacrifice

HISTO: 0601626

ORGAN AND ACCOUNTABLE SITE STATUS

* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 147

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601627

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Pancreas |
| * Parathyroid Gland | * Preputial Gland | * Prostate | * Salivary Glands |
| * Seminal Vesicle | * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---|-----------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Minimal |
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Mild |
| * Liver | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| | Lymph Node | Infiltration Cellular | Plasma Cell, Moderate |
| | [Infiltration Cellular TGLs = 3 - 15] | | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| * Skin | Epidermis | Keratoacanthoma | |
| | [Keratoacanthoma TGLs = 1 - 14] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 2 - 11] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 148

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Natural Death

DAY ON TEST: 454
HISTO: 0601628

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Liver	* Lung	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
* Thymus		Atrophy	Moderate

PRIMARY CAUSE OF DEATH - Heart Cardiomyopathy

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 149

TMT: 5
 DOSE: 0.3 G/KG

SEX: Male
 DISP: Moribund Sacrifice

DAY ON TEST: 664
 HISTO: 0601629

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla | * Bone | * Brain | * Epididymis |
| * Esophagus | * Eye | * Harderian Gland | * Intestine Large, Cecum |
| * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland |
| * Nose | * Parathyroid Gland | * Preputial Gland | * Salivary Glands |
| * Stomach, Forestomach | * Thyroid Gland | * Trachea | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|---|--------------------------------------|--------------------|----------------------|
| * Adrenal Cortex | Zona Fascult | Hyperplasia | Minimal |
| Blood Vessel | Pulmn Artery | Inflammation | Chronic Active, Mild |
| * Bone Marrow | | Hyperplasia | Minimal |
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Moderate |
| * Liver | | Fatty Change | Diffuse, Minimal |
| | Bile Duct | Hyperplasia | Minimal |
| * Lung | | Inflammation | Chronic Active, Mild |
| * Pancreas | Acinus | Hyperplasia | Minimal |
| * Pituitary Gland | | Hemorrhage | Mild |
| Note: The pituitary in this animal has apparent hyperplasia of tubular remnants of Rathkes cleft, though this may be partially function of cut. | | | |
| * Prostate | | Inflammation | Marked |
| | [Inflammation TGLs = 3 - 15] | | |
| * Seminal Vesicle | | Inflammation | Mild |
| * Skin | | Basal Cell Adenoma | |
| | [Basal Cell Adenoma TGLs = 1 - 14] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Stomach, Glandular | | Inflammation | Minimal |
| | Epithelium | Necrosis | Mild |
| * Testes | Interstit Cell | Adenoma | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 149

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 664
HISTO: 0601629

ORGAN AND ACCOUNTABLE SITE STATUS

[Adenoma TGLs = 2 - 11]

Interstit Cell

Hyperplasia

Mild

* Thymus

Atrophy

Marked

Tooth

Malformation

Minimal

* Urinary Bladder

Inflammation

Mild

PRIMARY CAUSE OF DEATH - Prostate Inflammation

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 150

TMT: 5
DOSE: 0.3 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601630

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Parathyroid Gland | * Preputial Gland | * Salivary Glands | * Seminal Vesicle |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|-------------------------------|------------------|-------------------------|
| * Eye | Lens | Cataract | Mild |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Mild |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Pancreas | | Atrophy | Marked |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| * Prostate | Epithelium | Hyperplasia | Minimal |
| | | Inflammation | Minimal |
| * Skin | Epidermis | Hyperplasia | Basal Cell, Moderate |
| | [Hyperplasia TGLs = 1 - 14] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 2 - 11] | | |
| * Thymus | | Atrophy | Moderate |
| Tooth | | Malformation | Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 151

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601631

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Hypertrophy	Minimal
* Bone Marrow		Hyperplasia	Mild
* Heart		Cardiomyopathy	Mild
* Intestine Large, Colon		Parasite Metazoan	
* Kidney		Mineralization	Minimal
		Nephropathy	Moderate
* Liver		Eosinophilic Focus	
		Fatty Change	Diffuse, Minimal
	Hepatocyte	Hypertrophy	Mild
		Inflammation	Chronic Active, Minimal
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Spleen		Leukemia Mononuclear	
* Testes	Bilateral, Interstit Cell	Adenoma	
		Cyst	Marked
	[Adenoma TGLs = 1 - 11]		
	[Cyst TGLs = 2 - 14]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 152

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601632

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Mild
* Epididymis		Mesothelioma Malignant	
	[Mesothelioma Malignant TGLs = 2 - 11+14]		
* Eye	Retina	Degeneration	Minimal
* Heart		Cardiomyopathy	Marked
* Kidney		Mineralization	Minimal
		Nephropathy	Moderate
* Liver		Clear Cell Focus	
	Centrilobular	Fatty Change	Minimal
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Prostate		Inflammation	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
		Mesothelioma Malignant	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 153

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 556
HISTO: 0601633

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung	* Lymph Node, Mesenteric
* Mammary Gland	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Eye	Antr Chamber	Inflammation	Mild
* Harderian Gland		Carcinoma	Metastatic (Oral Mucosa)
	[Carcinoma TGLs = 1 - 15]		
* Heart		Cardiomyopathy	Mild
* Islets, Pancreatic		Adenoma	
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Clear Cell Focus	
		Degeneration	Cystic, Minimal
		Eosinophilic Focus	
* Nose	Olfactory Epi	Inflammation	Chronic Active, Minimal
Oral Mucosa		Metaplasia	Minimal
		Squamous Cell Carcinoma	
	Note: Squamous cell carcinoma grossly diagnosed as arising in tooth was in oral mucosa.		
	[Squamous Cell Carcinoma TGLs = 3 - 14]		
* Skin		Cyst Epithelial Inclusion	Moderate
	[Cyst Epithelial Inclusion TGLs = 2 - 16]		
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 153

TMT: 7

SEX: Male

DAY ON TEST: 556

DOSE: 1.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601633

ORGAN AND ACCOUNTABLE SITE STATUS

[Adenoma TGLs = 4 - 11]

* Thymus

Atrophy

Moderate

PRIMARY CAUSE OF DEATH

- Oral Mucosa Squamous Cell Carcinoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 154

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 589
HISTO: 0601634

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Brain	* Epididymis
* Esophagus	* Eye	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric
* Mammary Gland	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Salivary Glands	* Seminal Vesicle	* Spleen
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Adrenal Medulla		Hyperplasia	Mild
* Bone Marrow		Hyperplasia	Moderate
* Heart		Cardiomyopathy	Minimal
* Kidney	Pelvis, Transit Epithe	Hyperplasia	Mild
		Mineralization	Minimal
		Nephropathy	Marked
	[Nephropathy TGLs = 3 - 5]		
* Liver	Bile Duct	Hyperplasia	Minimal
	Hepatocyte	Hypertrophy	Minimal
		Tension Lipidosis	Mild
	[Tension Lipidosis TGLs = 4 - 14]		
* Nose	Respirat Epith	Hyperplasia	Minimal
* Prostate		Inflammation	Minimal
* Skin		Basal Cell Adenoma	
	[Basal Cell Adenoma TGLs = 1 - 15]		
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Mild
		Ulcer	Mild
* Testes	Bilateral, Interstit Cell	Adenoma	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 154

TMT: 7

SEX: Male

DAY ON TEST: 589

DOSE: 1.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601634

ORGAN AND ACCOUNTABLE SITE STATUS

[Adenoma TGLs = 2 - 11]

* Thymus
Tooth

Atrophy
Malformation

Moderate
Minimal

PRIMARY CAUSE OF DEATH - Kidney Nephropathy

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 155

TMT: 7

SEX: Male

DAY ON TEST: 728

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601635

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Mammary Gland	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Moderate
* Kidney		Nephropathy	Marked
* Liver		Eosinophilic Focus	
	Centrilobular	Fatty Change	Mild
		Inflammation	Chronic Active, Minimal
* Lymph Node, Mesenteric		Atrophy	Mild
* Nose		Inflammation	Minimal
* Preputial Gland		Adenoma	
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Mild

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 156

TMT: 7
 DOSE: 1.0 G/KG

SEX: Male
 DISP: Terminal Sacrifice

DAY ON TEST: 729
 HISTO: 0601636

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Esophagus	* Eye	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Mammary Gland	* Parathyroid Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Minimal
* Epididymis		Mesothelioma Malignant	
	[Mesothelioma Malignant TGLs = 4 - 11+16]		
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Moderate
* Liver		Clear Cell Focus	
	Centrilobular	Fatty Change	Mild
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Lung		Foreign Body	
	Alveolus	Infiltration Cellular	Histiocyte, Mild
		Inflammation	Granulomatous, Moderate
	Note: Foreign bodies in lung are plant material and gray-blue amorphous material, consistent with aspiration.		
* Lymph Node, Mesenteric		Atrophy	Mild
Mesentery		Mesothelioma Malignant	
	Note: Nodules described grossly as in "skin" (TGL-3) are mesotheliomas implanted upon the peritoneal surface of the abdominal wall.		
	[Mesothelioma Malignant TGLs = 2,3 - 14+15]		
* Nose		Inflammation	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 156

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601636

ORGAN AND ACCOUNTABLE SITE STATUS

* Pancreas		Atrophy	Minimal
		Inflammation	Mild
* Pituitary Gland	Pars Distalis	Adenoma	
* Prostate			
Note: Mesothelioma present upon prostate also (not an available diagnosis for prostate in LDAS II).			
* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Mesothelioma Malignant	
* Testes	Bilateral, Interstit Cell	Adenoma	
		Mesothelioma Malignant	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 157

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 629
HISTO: 0601637

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Mammary Gland	* Pituitary Gland	* Preputial Gland
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Mild
* Heart		Cardiomyopathy	Moderate
* Kidney	Pelvis, Transit Epithe	Hyperplasia	Minimal
		Nephropathy	Marked
	[Nephropathy TGLs = 3 - 5]		
* Liver		Fatty Change	Diffuse, Mild
		Hepatodiaphragmatic Nodule	
	Bile Duct	Hyperplasia	Minimal
	Hepatocyte	Hypertrophy	Mild
		Inflammation	Chronic Active, Minimal
	[Hepatodiaphragmatic Nodule TGLs = 2 - 14]		
* Lymph Node, Mesenteric		Atrophy	Minimal
* Nose		Inflammation	Minimal
	Olfactory Epi	Metaplasia	Minimal
* Pancreas	Acinus	Hyperplasia	Mild
* Parathyroid Gland		Hyperplasia	Minimal
* Prostate		Inflammation	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Moderate
		Inflammation	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 157

TMT: 7

SEX: Male

DAY ON TEST: 629

DOSE: 1.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601637

ORGAN AND ACCOUNTABLE SITE STATUS

Ulcer Moderate

[Ulcer TGLs = 4 - 15]
* Testes Bilateral, Interstit Cell

Adenoma

[Adenoma TGLs = 1 - 11]

* Thymus
Tooth

Atrophy Moderate

Malformation Minimal

PRIMARY CAUSE OF DEATH - Kidney Nephropathy

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 158

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601638

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Brain	* Epididymis
* Esophagus	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Mammary Gland	* Nose	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Leukemia Mononuclear	
* Adrenal Medulla		Leukemia Mononuclear	
* Bone Marrow		Hyperplasia	Moderate
* Eye	Retina	Degeneration	Mild
* Heart		Cardiomyopathy	Mild
* Kidney	Pelvis, Transit Epithe	Hyperplasia	Minimal
		Leukemia Mononuclear	
		Mineralization	Minimal
		Nephropathy	Marked
* Liver	Bile Duct	Hyperplasia	Mild
		Leukemia Mononuclear	
* Lung	Alveolar Epith	Hyperplasia	Minimal
		Inflammation	Granulomatous, Minimal
		Leukemia Mononuclear	
Lymph Node	Pancreatic	Leukemia Mononuclear	
Note: Leukemia in pancreatic lymph node was observed in the routine section of pancreas (B06).			
* Lymph Node, Mesenteric		Leukemia Mononuclear	
* Pancreas		Atrophy	Minimal
* Spleen		Leukemia Mononuclear	
		Thrombosis	Mild

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 158

TMT: 7

SEX: Male

DAY ON TEST: 727

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601638

ORGAN AND ACCOUNTABLE SITE STATUS

Note: Thrombotic area is recanalized.

[Leukemia Mononuclear TGLs = 2 - 14]

* Testes

Bilateral, Interstit Cell

Adenoma

[Adenoma TGLs = 1 - 11]

* Thymus

Atrophy

Mild

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 159

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 709
HISTO: 0601639

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lung |
| * Mammary Gland | * Nose | * Salivary Glands | * Skin |
| * Stomach, Glandular | * Thyroid Gland | * Trachea | * Urinary Bladder |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--------------------------|-------------------------------|----------------------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Moderate |
| * Heart | | Cardiomyopathy | Mild |
| * Intestine Large, Colon | | Parasite Metazoan | |
| * Kidney | | Accumulation, Hyaline Droplet | Minimal |
| | Pelvis, Transit Epithe | Hyperplasia | Minimal |
| | | Nephropathy | Marked |
| | [Nephropathy TGLs = 2 - 5] | | |
| * Liver | | Basophilic Focus | |
| | | Degeneration | Cystic, Mild |
| | | Fatty Change | Diffuse, Minimal |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Lymph Node, Mesenteric | | Atrophy | Moderate |
| * Pancreas | | Atrophy | Minimal |
| * Parathyroid Gland | | Hyperplasia | Moderate |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| | [Hyperplasia TGLs = 3 - 14] | | |
| * Preputial Gland | Duct | Hyperplasia | Atypical, Minimal |
| * Prostate | | Inflammation | Moderate |
| * Seminal Vesicle | | Inflammation | Mild |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 159

TMT: 7

SEX: Male

DAY ON TEST: 709

DOSE: 1.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601639

ORGAN AND ACCOUNTABLE SITE STATUS

* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation Ulcer	Moderate Mild Mild
[Ulcer TGLs = 4 - 15]			
* Testes	Bilateral, Interstit Cell	Adenoma	
[Adenoma TGLs = 1 - 11]			
* Thymus		Atrophy	Marked

PRIMARY CAUSE OF DEATH - Kidney Nephropathy

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 160

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Natural Death

DAY ON TEST: 447
HISTO: 0601640

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Bone Marrow |
| * Epididymis | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lung |
| * Lymph Node, Mesenteric | * Mammary Gland | * Pancreas | * Parathyroid Gland |
| * Preputial Gland | * Salivary Glands | * Seminal Vesicle | * Skin |
| * Stomach, Glandular | * Trachea | * Urinary Bladder | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex | Zona Fascult | Hyperplasia | Minimal |
| * Brain | | Hemorrhage | Mild |
| | [Hemorrhage TGLs = 2 - 9] | | |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Nephropathy | Mild |
| * Liver | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Nose | | Inflammation | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | Note: Pituitary tumor had abundant hemorrhage. | | |
| | [Adenoma TGLs = 1 - 8] | | |
| * Prostate | | Inflammation | Minimal |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |
| | | Pigmentation | Hemosiderin, Minimal |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Mild |
| | [Hyperplasia TGLs = 3 - 6] | | |
| * Testes | Interstit Cell | Hyperplasia | Minimal |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | Follicular Cel | Hypertrophy | Minimal |

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 161

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 673
HISTO: 0601641

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Epididymis	* Esophagus
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Mammary Gland	* Pancreas	* Parathyroid Gland
* Preputial Gland	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Adrenal Medulla		Hyperplasia	Moderate
* Bone Marrow		Hyperplasia	Moderate
* Brain		Hydrocephalus	Minimal
		Necrosis	Mild
Note: Necrosis in the brain section is consistent with a hemorrhagic infarct. [Necrosis TGLs = 4 - 15]			
* Eye	Retina	Degeneration	Mild
	Iris	Inflammation	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney	Pelvis, Transit Epithe	Hyperplasia	Minimal
		Nephropathy	Marked
[Nephropathy TGLs = 2 - 5]			
* Liver		Degeneration	Cystic, Minimal
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Minimal
* Lymph Node, Mesenteric		Atrophy	Minimal
* Nose		Foreign Body	
		Inflammation	Mild
* Pituitary Gland	Pars Distalis	Hyperplasia	Moderate
* Prostate		Lymphoma Malignant	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 161

TMT: 7

SEX: Male

DAY ON TEST: 673

DOSE: 1.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601641

ORGAN AND ACCOUNTABLE SITE STATUS

* Spleen		Fibrosis	Minimal
		Lymphoma Malignant	
		Pigmentation	Hemosiderin, Minimal
	[Fibrosis TGLs = 3 - 14]		
* Stomach, Forestomach		Erosion	Minimal
	Epithelium	Hyperplasia	Moderate
		Inflammation	Moderate
* Testes		Bilateral, Interstit Cell	
	[Adenoma TGLs = 1 - 11]	Adenoma	
* Thymus		Lymphoma Malignant	
Tooth		Malformation	Minimal

PRIMARY CAUSE OF DEATH - Kidney Nephropathy

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 162

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601642

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Bone Marrow |
| * Brain | * Epididymis | * Esophagus | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lung |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Pancreas |
| * Preputial Gland | * Prostate | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|---------------|--------------------|-------------------------|
| * Adrenal Cortex | Zona Fascult | Hyperplasia | Minimal |
| * Eye | Retina | Degeneration | Mild |
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | Cortex | Cyst | Mild |
| | | Nephropathy | Marked |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | Centrilobular | Fatty Change | Mild |
| | Bile Duct | Hyperplasia | Minimal |
| | Hepatocyte | Hypertrophy | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Parathyroid Gland | | Hyperplasia | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Moderate |
| | | Inflammation | Mild |
| | | Mineralization | Mild |
| | | Ulcer | Mild |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 162

TMT: 7

SEX: Male

DAY ON TEST: 728

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601642

ORGAN AND ACCOUNTABLE SITE STATUS

[Ulcer TGLs = 2 - 14]			
* Testes	Bilateral, Interstit Cell	Adenoma	
[Adenoma TGLs = 1 - 11]			
* Thymus		Atrophy	Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 163

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 640
HISTO: 0601643

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Parathyroid Gland
* Preputial Gland	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Glandular	* Thyroid Gland	* Trachea	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Nephropathy	Moderate
* Liver		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Minimal
	Hepatocyte	Hypertrophy	Mild
		Inflammation	Chronic Active, Minimal
		Pigmentation	Hemosiderin, Minimal
* Nose		Inflammation	Minimal
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 1 - 14]		
* Prostate		Inflammation	Moderate
* Spleen		Pigmentation	Hemosiderin, Mild
* Stomach, Forestomach	Epithelium	Hyperplasia	Marked
		Inflammation	Moderate
		Ulcer	Minimal
	[Hyperplasia TGLs = 3 - 15]		
* Testes	Interstit Cell	Adenoma	
	Interstit Cell	Hyperplasia	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 163

TMT: 7

SEX: Male

DAY ON TEST: 640

DOSE: 1.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601643

ORGAN AND ACCOUNTABLE SITE STATUS

[Adenoma TGLs = 2 - 11]

* Thymus

Atrophy

Marked

* Urinary Bladder

Inflammation

Mild

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 164

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601644

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Eye	Retina	Degeneration	Mild
* Heart		Cardiomyopathy	Moderate
* Kidney	Pelvis, Transit Epithe	Hyperplasia	Minimal
		Mineralization	Minimal
		Nephropathy	Moderate
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Degeneration	Cystic, Minimal
	Centrilobular	Fatty Change	Minimal
	Bile Duct	Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
* Lung		Inflammation	Chronic Active, Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 165

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601645

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Parathyroid Gland |
| * Pituitary Gland | * Preputial Gland | * Prostate | * Salivary Glands |
| * Seminal Vesicle | * Skin | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|------------------------|--------------------|-------------------------|
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | Pelvis, Transit Epithe | Hyperplasia | Minimal |
| | | Mineralization | Minimal |
| | | Nephropathy | Marked |
| * Liver | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Fatty Change | Diffuse, Minimal |
| | Bile Duct | Hyperplasia | Minimal |
| | Hepatocyte | Hypertrophy | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| * Nose | Respirat Epith | Hyperplasia | Minimal |
| | | Inflammation | Mild |
| * Pancreas | | Atrophy | Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Moderate |
| | | Inflammation | Mild |
| | | Ulcer | Minimal |

[Hyperplasia TGLs = 3 - 14]

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 165

TMT: 7

SEX: Male

DAY ON TEST: 729

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601645

ORGAN AND ACCOUNTABLE SITE STATUS

* Testes [Adenoma TGLs = 1 - 11]	Bilateral, Interstit Cell	Adenoma	
* Thymus		Atrophy	Moderate
* Thyroid Gland [Adenoma TGLs = 2 - 8]	C Cell	Adenoma	
Tooth		Malformation	Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 166

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601646

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Pancreas |
| * Parathyroid Gland | * Preputial Gland | * Prostate | * Salivary Glands |
| * Seminal Vesicle | * Skin | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|----------------------------|---------------------------|--------------------|-------------------------|
| * Eye | Retina | Degeneration | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Mild |
| * Liver | | Eosinophilic Focus | |
| | Centrilobular | Fatty Change | Minimal |
| | Bile Duct | Hyperplasia | Minimal |
| | Hepatocyte | Hypertrophy | Mild |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | | Inflammation | Chronic Active, Minimal |
| Mesentery | Fat | Necrosis | Mild |
| [Necrosis TGLs = 2 - 14] | | | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| [Adenoma TGLs = 1 - 11] | | | |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Hyperplasia | Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 167

TMT: 7
 DOSE: 1.0 G/KG

SEX: Male
 DISP: Moribund Sacrifice

DAY ON TEST: 694
 HISTO: 0601647

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| Blood Vessel | * Bone | * Brain | * Epididymis |
| * Esophagus | * Eye | * Harderian Gland | * Intestine Large, Cecum |
| * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland |
| * Nose | * Pituitary Gland | * Preputial Gland | * Prostate |
| * Salivary Glands | * Seminal Vesicle | * Skin | * Thyroid Gland |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|---|----------------------|-------------------------|
| * Adrenal Cortex | | Leukemia Mononuclear | |
| * Adrenal Medulla | | Hyperplasia | Mild |
| * Bone Marrow | | Hyperplasia | Marked |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | Pelvis, Transit Epithe | Hyperplasia | Mild |
| | | Mineralization | Minimal |
| | | Nephropathy | Marked |
| | [Nephropathy TGLs = 4 - 5] | | |
| * Liver | Bile Duct | Degeneration | Cystic, Minimal |
| | | Hyperplasia | Moderate |
| | | Leukemia Mononuclear | |
| | [Leukemia Mononuclear TGLs = 3 - 6+7] | | |
| * Lung | Alveolar Epith | Hyperplasia | Mild |
| | | Inflammation | Chronic Active, Minimal |
| | | Leukemia Mononuclear | |
| * Pancreas | | Atrophy | Minimal |
| * Parathyroid Gland | | Hyperplasia | Mild |
| * Spleen | | Leukemia Mononuclear | |
| | [Leukemia Mononuclear TGLs = 2 - 14] | | |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Mild |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 167

TMT: 7

SEX: Male

DAY ON TEST: 694

DOSE: 1.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601647

ORGAN AND ACCOUNTABLE SITE STATUS

Inflammation Mild
Mineralization Minimal
Ulcer Minimal

[Hyperplasia TGLs = 5 - 14]
* Stomach, Glandular

Epithelium

Inflammation Mild
Necrosis Moderate

[Necrosis TGLs = 5 - 14]
* Testes

Bilateral, Interstit Cell

Adenoma

[Adenoma TGLs = 1 - 11]

* Thymus

Atrophy Marked

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 168

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 665
HISTO: 0601648

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Mammary Gland	* Nose	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Glandular	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Marked
* Heart		Cardiomyopathy	Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Moderate
* Liver	Bile Duct	Hyperplasia	Mild
	[Leukemia Mononuclear TGLs = 3 - 6+7]	Leukemia Mononuclear	
* Lung		Inflammation	Granulomatous, Minimal
		Leukemia Mononuclear	
* Lymph Node, Mesenteric		Leukemia Mononuclear	
* Pancreas		Atrophy	Marked
* Prostate		Inflammation	Mild
* Spleen		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 1 - 14]		
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 2 - 11]		
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Minimal

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 169

TMT: 7
 DOSE: 1.0 G/KG

SEX: Male
 DISP: Terminal Sacrifice

DAY ON TEST: 727
 HISTO: 0601649

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Epididymis	* Esophagus	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Moderate
* Eye	Retina	Degeneration	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney	Pelvis, Transit Epithe	Hyperplasia	Minimal
		Hyperplasia	Oncocytic, Minimal
		Mineralization	Minimal
		Nephropathy	Marked
* Liver		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Mild
	Oval Cell	Hyperplasia	Minimal
		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 4 - 6+7]		
* Lung		Hemorrhage	Minimal
	Arteriole	Hyperplasia	Minimal
	Alveolus	Infiltration Cellular	Histiocyte, Moderate
		Leukemia Mononuclear	
	[Hemorrhage TGLs = 5 - 15]		
* Nose		Inflammation	Minimal
* Pancreas		Atrophy	Minimal
	Acinus	Metaplasia	Hepatocyte, Mild

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 169

TMT: 7
 DOSE: 1.0 G/KG

SEX: Male
 DISP: Terminal Sacrifice

DAY ON TEST: 727
 HISTO: 0601649

ORGAN AND ACCOUNTABLE SITE STATUS

* Parathyroid Gland		Hyperplasia	Mild
* Spleen		Hematopoietic Cell Proliferation	Mild
		Hyperplasia	Histiocytic, Mild
		Leukemia Mononuclear	
		Thrombosis	Moderate
	[Hematopoietic Cell Proliferation TGLs = 2 - 14]		
	[Thrombosis TGLs = 3 - 14]		
* Stomach, Forestomach	Epithelium	Dysplasia	Marked
	Epithelium	Hyperplasia	Marked
		Inflammation	Moderate
		Ulcer	Minimal
	[Hyperplasia TGLs = 7 - 17]		
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Marked
* Thyroid GI			
	Note: One thyroid gland was missing at trim.		
Tooth		Malformation	Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 170

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601650

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | Blood Vessel | * Bone | * Bone Marrow |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Parathyroid Gland | * Pituitary Gland | * Preputial Gland | * Prostate |
| * Salivary Glands | * Seminal Vesicle | * Skin | * Spleen |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---------------------------|-------------------------|-------------------------|
| * Adrenal Medulla | | Pheochromocytoma Benign | |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Moderate |
| * Liver | | Basophilic Focus | |
| | Centrilobular | Fatty Change | Mild |
| | | Hepatocellular Adenoma | |
| | Bile Duct | Hyperplasia | Mild |
| | Hepatocyte | Hypertrophy | Mild |
| | | Inflammation | Chronic Active, Minimal |
| * Pancreas | | Atrophy | Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 171

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Natural Death

DAY ON TEST: 679
HISTO: 0601651

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Mammary Gland	* Nose	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Spleen	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Marked
		Necrosis	Mild
* Heart		Cardiomyopathy	Moderate
		Fibrous Histiocytoma	Metastatic (Skeletal Muscle)
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Fibrous Histiocytoma	Metastatic (Skeletal Muscle)
	[Fibrous Histiocytoma TGLs = 2 - 6+7]		
* Lung		Fibrous Histiocytoma	Metastatic (Skeletal Muscle)
	[Fibrous Histiocytoma TGLs = 7 - 3+4]		
	Lymph Node Deep Cervical	Fibrous Histiocytoma	Metastatic (Skeletal Muscle)
	[Fibrous Histiocytoma TGLs = 3 - 15]		
* Lymph Node, Mesenteric		Fibrous Histiocytoma	Metastatic (Skeletal Muscle)
* Pancreas	Acinus	Metaplasia	Hepatocyte, Minimal
Skeletal Muscle		Fibrous Histiocytoma	
	[Fibrous Histiocytoma TGLs = 6 - 17]		
* Skin	Dermis	Fibroma	
	Note: The fibroma is overlying the histiocytoma on the back.		
	[Fibroma TGLs = 5 - 16]		

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 171

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Natural Death

DAY ON TEST: 679
HISTO: 0601651

ORGAN AND ACCOUNTABLE SITE STATUS

* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation	Mild Mild
* Testes	Bilateral, Interstit Cell	Ulcer Adenoma	Minimal
[Adenoma TGLs = 1 - 11]			
* Thymus		Atrophy Fibrous Histiocytoma	Marked Metastatic (Skeletal Muscle)
[Fibrous Histiocytoma TGLs = 4 - 14]			

PRIMARY CAUSE OF DEATH - Skeletal Muscle Fibrous Histiocytoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 172

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601652

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Mild
* Eye	Retina	Degeneration	Mild
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Moderate
* Liver		Basophilic Focus	
	Centrilobular	Fatty Change	Mild
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Pancreas	Acinus	Metaplasia	Hepatocyte, Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 173

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Dosing Accident

DAY ON TEST: 30
HISTO: 0601653

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Eye	* Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Liver	Hepatocyte	Hypertrophy	Minimal
* Lung		Congestion	Mild

[Congestion TGLs = 1 - 3+4]

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 174

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601654

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Parathyroid Gland	* Preputial Gland
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Eye	Retina	Degeneration	Moderate
* Heart		Cardiomyopathy	Moderate
* Kidney	Pelvis, Transit Epithe	Hyperplasia	Mild
		Mineralization	Minimal
		Nephropathy	Marked
	[Nephropathy TGLs = 3 - 5]		
* Liver		Basophilic Focus	
		Inflammation	Chronic Active, Minimal
* Lung		Alveolar/Bronchiolar Adenoma	
	Alveolar Epith	Hypertrophy	Minimal
	Alveolus	Infiltration Cellular	Histiocyte, Minimal
Mesentery	Fat	Necrosis	Mild
	[Necrosis TGLs = 2 - 15]		
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
* Prostate		Inflammation	Moderate
* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Moderate
		Inflammation	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 174

TMT: 7

SEX: Male

DAY ON TEST: 727

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601654

ORGAN AND ACCOUNTABLE SITE STATUS

* Testes

Bilateral, Interstit Cell

Adenoma

[Adenoma TGLs = 1- 14]

* Thymus

Atrophy

Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 175

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601655

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Marked
* Liver		Basophilic Focus	
		Clear Cell Focus	
	Centrilobular	Fatty Change	Mild
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Mild
* Preputial Gland		Inflammation	Marked
	[Inflammation TGLs = 1 - 12]		
* Prostate	Epithelium	Hyperplasia	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 2 - 11]		
* Thymus		Atrophy	Marked

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 176

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601656

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Eosinophilic Focus	
		Fatty Change	Diffuse, Mild
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Lung		Alveolar/Bronchiolar Adenoma	
	Alveolar Epith	Hyperplasia	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
		Inflammation	Minimal
		Ulcer	Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 177

TMT: 7

SEX: Male

DAY ON TEST: 729

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601657

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland
* Pancreas	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Minimal
* Eye	Retina	Degeneration	Minimal
* Heart		Cardiomyopathy	Minimal
* Kidney	Pelvis, Transit Epithe	Hyperplasia	Minimal
		Mineralization	Minimal
		Nephropathy	Marked
* Liver		Basophilic Focus	
	Centrilobular	Fatty Change	Minimal
	Bile Duct	Hyperplasia	Minimal
	Hepatocyte	Hypertrophy	Minimal
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Nose		Inflammation	Mild
* Parathyroid Gland		Hyperplasia	Moderate
* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Moderate
		Inflammation	Mild
		Ulcer	Minimal

[Hyperplasia TGLs = 2 - 14]

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 177

TMT: 7

SEX: Male

DAY ON TEST: 729

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601657

ORGAN AND ACCOUNTABLE SITE STATUS

* Stomach, Glandular		Inflammation	Mild
	Epithelium	Necrosis	Mild
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 178

TMT: 7
 DOSE: 1.0 G/KG

SEX: Male
 DISP: Terminal Sacrifice

DAY ON TEST: 727
 HISTO: 0601658

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Parathyroid Gland
* Preputial Gland	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Eye	Retina	Degeneration	Mild
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Moderate
* Liver		Basophilic Focus	
	Centrilobular	Fatty Change	Mild
	Bile Duct	Hyperplasia	Minimal
	Hepatocyte	Hypertrophy	Minimal
		Inflammation	Chronic Active, Minimal
* Lung		Inflammation	Chronic Active, Minimal
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Prostate		Inflammation	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate
Tooth		Malformation	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 179

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601659

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
		Hypertrophy	Minimal
* Bone Marrow		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Basophilic Focus	
	Centrilobular	Fatty Change	Mild
	Bile Duct	Hyperplasia	Minimal
	Hepatocyte	Hypertrophy	Minimal
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
* Pancreas		Atrophy	Moderate
	Acinus	Hyperplasia	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 180

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 727
HISTO: 0601660

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Epididymis	* Esophagus	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Minimal
* Eye	Retina	Degeneration	Mild
* Heart		Cardiomyopathy	Mild
* Islets, Pancreatic		Hyperplasia	Marked
* Kidney		Mineralization	Minimal
		Nephropathy	Marked
* Liver		Angiectasis	Minimal
	Centrilobular	Fatty Change	Mild
	Bile Duct	Hyperplasia	Minimal
	Hepatocyte	Hypertrophy	Minimal
		Inflammation	Chronic Active, Minimal
* Parathyroid Gland		Hyperplasia	Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate
Tooth		Malformation	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 181

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601661

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | Blood Vessel | * Bone | * Brain |
| * Epididymis | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung | * Lymph Node, Mesenteric |
| * Mammary Gland | * Pancreas | * Parathyroid Gland | * Pituitary Gland |
| * Preputial Gland | * Prostate | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|----------------------|---------------------------|-------------------------|-------------------------|
| * Adrenal Medulla | | Pheochromocytoma Benign | |
| * Bone Marrow | | Hyperplasia | Mild |
| * Heart | | Cardiomyopathy | Mild |
| * Islets, Pancreatic | | Adenoma | |
| * Kidney | Pelvis, Transit Epithe | Hyperplasia | Minimal |
| | | Nephropathy | Marked |
| * Liver | | Basophilic Focus | |
| | Centrilobular | Fatty Change | Mild |
| | Hepatocyte | Hypertrophy | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Nose | Respirat Epith | Hyperplasia | Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 14] | | |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Hyperplasia | Marked |
| Tooth | | Malformation | Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 182

TMT: 7

SEX: Male

DAY ON TEST: 689

DOSE: 1.0 G/KG

DISP: Natural Death

HISTO: 0601662

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Salivary Glands	* Skin
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Moderate
* Heart		Cardiomyopathy	Moderate
	Atrium	Thrombosis	Mild
* Kidney		Nephropathy	Mild
* Liver	Bile Duct	Hyperplasia	Mild
		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 5-6+7+14]		
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Moderate
		Leukemia Mononuclear	
* Pancreas		Atrophy	Minimal
* Prostate		Atrophy	Mild
	[Atrophy TGLs = 3 - 13]		
* Seminal Vesicle		Atrophy	Mild
	[Atrophy TGLs = 2 - 13]		
* Spleen		Fibrosis	Mild
		Leukemia Mononuclear	
		Pigmentation	Hemosiderin, Minimal
	[Fibrosis TGLs = 6 - 5]		
	[Leukemia Mononuclear TGLs = 4 - 5]		
* Stomach, Forestomach		Inflammation	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 182

TMT: 7

SEX: Male

DAY ON TEST: 689

DOSE: 1.0 G/KG

DISP: Natural Death

HISTO: 0601662

ORGAN AND ACCOUNTABLE SITE STATUS

* Testes	Bilateral, Interstit Cell	Mineralization	Mild
[Adenoma TGLs = 1 - 11]		Ulcer	Mild
		Adenoma	
* Thymus		Atrophy	Marked

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

CONTRIBUTORY CAUSE OF DEATH - Heart Atrium Thrombosis

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 183

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Dosing Accident

DAY ON TEST: 528
HISTO: 0601663

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Pancreas	* Parathyroid Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Eye	Iris	Inflammation	Minimal
* Heart		Cardiomyopathy	Mild
		Inflammation	Suppurative, Mild
Note: Fibrinosuppurative inflammation at heart base, with bacterial colonies.			
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver	Centrilobular	Fatty Change	Minimal
	Hepatocyte	Hypertrophy	Minimal
* Lung	Serosa	Inflammation	Acute, Mild
* Nose		Inflammation	Minimal
	Olfactory Epi	Metaplasia	Mild
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen	Lymph Follic	Atrophy	Mild
		Pigmentation	Hemosiderin, Mild
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
* Testes	Interstit Cell	Adenoma	
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 184

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 673
HISTO: 0601664

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Epididymis | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Parathyroid Gland |
| * Preputial Gland | * Salivary Glands | * Seminal Vesicle | * Skin |
| * Stomach, Glandular | * Trachea | * Urinary Bladder | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|------------------------------|------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Marked |
| | [Nephropathy TGLs = 2 - 5] | | |
| * Liver | | Basophilic Focus | |
| | | Fatty Change | Diffuse, Mild |
| | Bile Duct | Hyperplasia | Minimal |
| | Hepatocyte | Hypertrophy | Mild |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | | Inflammation | Chronic Active, Minimal |
| * Nose | | Inflammation | Minimal |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | | Adenoma | |
| * Prostate | Pars Distalis | Inflammation | Moderate |
| * Spleen | | Pigmentation | Hemosiderin, Mild |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Moderate |
| | | Inflammation | Moderate |
| | | Ulcer | Moderate |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 184

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 673
HISTO: 0601664

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus		Atrophy	Marked
* Thyroid Gland	C Cell	Hyperplasia	Minimal
Tooth		Malformation	Minimal

PRIMARY CAUSE OF DEATH - Kidney Nephropathy

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 185

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Moribund Sacrifice

DAY ON TEST: 670
HISTO: 0601665

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Brain |
| * Epididymis | * Esophagus | * Harderian Gland | * Intestine Large, Cecum |
| * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland |
| * Pancreas | * Parathyroid Gland | * Preputial Gland | * Salivary Glands |
| * Skin | * Trachea | * Urinary Bladder | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|------------------------------|-----------------------|-------------------------|
| * Adrenal Cortex | Zona Fascult | Hyperplasia | Mild |
| * Bone Marrow | | Hyperplasia | Mild |
| * Eye | Retina | Degeneration | Mild |
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | Pelvis, Transit Epithe | Hyperplasia | Mild |
| | Pelvis | Inflammation | Minimal |
| | | Mineralization | Minimal |
| | | Nephropathy | Marked |
| | [Nephropathy TGLs = 3 - 5] | | |
| * Liver | | Fatty Change | Diffuse, Mild |
| | Bile Duct | Hyperplasia | Minimal |
| | Hepatocyte | Hypertrophy | Minimal |
| | Centrilobular | Necrosis | Moderate |
| | [Necrosis TGLs = 2 - 6+7] | | |
| * Lung | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Nose | | Inflammation | Mild |
| | Olfactory Epi | Metaplasia | Mild |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 4 - 8] | | |
| * Prostate | | Inflammation | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 185

TMT: 7

SEX: Male

DAY ON TEST: 670

DOSE: 1.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601665

ORGAN AND ACCOUNTABLE SITE STATUS

* Seminal Vesicle		Inflammation	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Marked
		Inflammation	Mild
	[Hyperplasia TGLs = 5 - 14]		
* Stomach, Glandular		Inflammation	Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Marked
* Thyroid Gland	C Cell	Hyperplasia	Minimal

PRIMARY CAUSE OF DEATH - Kidney Nephropathy

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 186

TMT: 7

SEX: Male

DAY ON TEST: 454

DOSE: 1.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601666

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Brain	* Epididymis
* Esophagus	* Eye	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland
* Pancreas	* Parathyroid Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
		Hypertrophy	Minimal
* Bone	Ligament	Mineralization	Mild
Note: Cruciate ligaments are mineralized.			
* Bone Marrow		Hyperplasia	Moderate
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Mild
* Nose		Inflammation	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Skin	Subcut Tiss	Fibroma	
	[Fibroma TGLs = 1 - 14]		
* Spleen		Hematopoietic Cell Proliferation	Mild
* Testes	Interstit Cell	Adenoma	
	Interstit Cell	Hyperplasia	Mild
* Thymus		Atrophy	Moderate

PRIMARY CAUSE OF DEATH - Skin Subcut Tiss Fibroma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 187

TMT: 7
 DOSE: 1.0 G/KG

SEX: Male
 DISP: Terminal Sacrifice

DAY ON TEST: 728
 HISTO: 0601667

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| Blood Vessel | * Bone | * Brain | * Esophagus |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Mammary Gland | * Nose | * Parathyroid Gland | * Pituitary Gland |
| * Preputial Gland | * Prostate | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---|----------------------|----------|
| * Adrenal Cortex | | Leukemia Mononuclear | |
| * Adrenal Medulla | | Hyperplasia | Minimal |
| | | Leukemia Mononuclear | |
| * Bone Marrow | | Hyperplasia | Moderate |
| * Epididymis | | Inflammation | Mild |
| * Eye | Retina | Degeneration | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| | | Leukemia Mononuclear | |
| * Kidney | Pelvis, Transit Epithe | Hyperplasia | Minimal |
| | | Leukemia Mononuclear | |
| | | Mineralization | Minimal |
| | | Nephropathy | Marked |
| * Liver | Bile Duct | Hyperplasia | Mild |
| | | Leukemia Mononuclear | |
| | [Leukemia Mononuclear TGLs = 5 - 6+7] | | |
| * Lung | | Leukemia Mononuclear | |
| Lymph Node | Pancreatic | Leukemia Mononuclear | |
| | Mediastinal | Leukemia Mononuclear | |
| | [Leukemia Mononuclear TGLs = 6 -15] | | |
| | [Leukemia Mononuclear TGLs = 4 - 14] | | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 187

TMT: 7

SEX: Male

DAY ON TEST: 728

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601667

ORGAN AND ACCOUNTABLE SITE STATUS

* Lymph Node, Mesenteric		Leukemia Mononuclear	
Mesentery	Fat	Necrosis	Minimal
	[Necrosis TGLs = 3 - 15]		
* Pancreas	Acinus	Metaplasia	Hepatocyte, Mild
* Spleen		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 2 - 14]		
* Stomach, Forestomach		Erosion	Minimal
	Epithelium	Hyperplasia	Moderate
		Inflammation	Mild
	[Hyperplasia TGLs = 7 - 16]		
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate
Tooth		Malformation	Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 188

TMT: 7

SEX: Male

DAY ON TEST: 451

DOSE: 1.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601668

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Mild
* Heart		Cardiomyopathy	Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Salivary Glands		Sarcoma	
	[Sarcoma TGLs = 1,2 - 14+15]		
* Spleen		Hematopoietic Cell Proliferation	Mild
		Pigmentation	Hemosiderin, Minimal
* Testes	Interstit Cell	Hyperplasia	Marked
* Thymus		Atrophy	Moderate
* Thyroid GI			

Note: Part of salivary gland tumor is present in thyroid section, but not invading thyroid glands.

PRIMARY CAUSE OF DEATH - Salivary Glands Sarcoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 189

TMT: 7

SEX: Male

DAY ON TEST: 727

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601669

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Marked
* Heart		Cardiomyopathy	Mild
* Kidney		Nephropathy	Moderate
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
	Centrilobular	Fatty Change	Mild
	Bile Duct	Hyperplasia	Minimal
	Hepatocyte	Hypertrophy	Minimal
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Pancreas		Atrophy	Minimal
* Prostate		Inflammation	Mild
* Spleen		Pigmentation	Hemosiderin, Mild
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 190

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601670

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Nose | * Pancreas |
| * Parathyroid Gland | * Preputial Gland | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--------------------------------|------------------|----------------------|
| * Bone Marrow | | Hyperplasia | Mild |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Clear Cell Focus | |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 14] | | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Minimal |
| * Prostate | Epithelium | Hyperplasia | Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 2 - 11] | | |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Hyperplasia | Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 191

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601671

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Brain |
| * Epididymis | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mesenteric | * Mammary Gland |
| * Nose | * Pancreas | * Parathyroid Gland | * Pituitary Gland |
| * Preputial Gland | * Prostate | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|-----------------------------|------------------------------|-------------------------|
| * Adrenal Cortex | Zona Fascult | Hyperplasia | Minimal |
| * Bone Marrow | | Hyperplasia | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Islets, Pancreatic | | Adenoma | |
| * Kidney | | Nephropathy | Moderate |
| * Liver | Centrilobular
Hepatocyte | Fatty Change | Minimal |
| | | Hypertrophy | Mild |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | | Alveolar/Bronchiolar Adenoma | |
| | Alveolar Epith | Hyperplasia | Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Minimal |
| | | Inflammation | Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 192

TMT: 7
 DOSE: 1.0 G/KG

SEX: Male
 DISP: Terminal Sacrifice

DAY ON TEST: 729
 HISTO: 0601672

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Brain	* Esophagus
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Glandular	* Thymus	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Leukemia Mononuclear	
* Adrenal Medulla		Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Moderate
* Epididymis		Mesothelioma Malignant	
	[Mesothelioma Malignant TGLs = 5 - 11+14]		
* Eye	Retina	Degeneration	Minimal
* Heart		Leukemia Mononuclear	
* Kidney	Pelvis, Transit Epithe	Hyperplasia	Minimal
		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Fibrosis	Mild
	Bile Duct	Hyperplasia	Moderate
		Inflammation	Chronic Active, Marked
		Leukemia Mononuclear	
		Necrosis	Moderate
		Pigmentation	Hemosiderin, Minimal

Note: Liver has a sequestrum with abundant inflammation (abscess formation).

[Inflammation TGLs = 4 - 15]

[Leukemia Mononuclear TGLs = 3 - 6+7+15]

* Lung		Inflammation	Chronic Active, Minimal
--------	--	--------------	-------------------------

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 192

TMT: 7

SEX: Male

DAY ON TEST: 729

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601672

ORGAN AND ACCOUNTABLE SITE STATUS

Leukemia Mononuclear

Lymph Node

Pancreatic

Leukemia Mononuclear

Note: Leukemia in the pancreatic lymph nodes was observed in the routine section of pancreas (B06).

* Nose

Inflammation

Minimal

* Prostate

Inflammation

Minimal

* Spleen

Leukemia Mononuclear

[Leukemia Mononuclear TGLs = 1 - 5]

* Stomach, Forestomach

Erosion

Minimal

Epithelium

Hyperplasia

Minimal

Inflammation

Minimal

[Inflammation TGLs = 6 - 16]

* Testes

Bilateral, Interstit Cell

Adenoma

[Adenoma TGLs = 2 - 11]

* Thyroid Gland

C Cell

Adenoma

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 193

TMT: 7

SEX: Male

DAY ON TEST: 3

DOSE: 1.0 G/KG

DISP: Dosing Accident

HISTO: 0601673

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
* Eye	* Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney	* Liver
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Lung

Note: TGL-2 had no corresponding microscopic finding.

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 194

TMT: 7

SEX: Male

DAY ON TEST: 728

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601674

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Epididymis	* Esophagus
* Eye	* Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Leukemia Mononuclear	
* Adrenal Medulla		Hemorrhage	Moderate
		Leukemia Mononuclear	
		Thrombosis	Mild
	[Hemorrhage TGLs = 5 - 8]		
* Bone Marrow		Hyperplasia	Moderate
* Brain		Hemorrhage	Mild
		Necrosis	Minimal
	[Hemorrhage TGLs = 6 - 9]		
* Kidney		Nephropathy	Marked
* Liver	Bile Duct	Hyperplasia	Minimal
		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 4 - 6+7]		
* Lung		Alveolar/Bronchiolar Adenoma	
		Leukemia Mononuclear	
* Nose		Inflammation	Mild
* Pancreas		Atrophy	Mild
* Prostate		Inflammation	Minimal
* Spleen		Accessory Spleen	
		Leukemia Mononuclear	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 194

TMT: 7

SEX: Male

DAY ON TEST: 728

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601674

ORGAN AND ACCOUNTABLE SITE STATUS

[Accessory Spleen TGLs = 2 - 15]	Pigmentation	Hemosiderin, Minimal
[Leukemia Mononuclear TGLs = 1 - 14]		
* Stomach, Forestomach Epithelium	Hyperplasia	Marked
	Inflammation	Mild
* Testes Bilateral, Interstit Cell	Adenoma	
[Adenoma TGLs = 3 - 11]		
* Thymus	Atrophy	Marked

Note: Ectopic parathyroid gland is present.

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 195

TMT: 7
 DOSE: 1.0 G/KG

SEX: Male
 DISP: Terminal Sacrifice

DAY ON TEST: 727
 HISTO: 0601675

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Epididymis | * Esophagus | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mesenteric | * Mammary Gland |
| * Parathyroid Gland | * Preputial Gland | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Spleen | * Stomach, Forestomach | * Stomach, Glandular |
| * Thyroid Gland | * Trachea | * Urinary Bladder | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|----------------------|--------------------------------|-----------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Mild |
| * Eye | Retina | Degeneration | Minimal |
| * Heart | | Cardiomyopathy | Moderate |
| * Islets, Pancreatic | | Hyperplasia | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Mild |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | Centrilobular | Fatty Change | Minimal |
| | Bile Duct | Hyperplasia | Minimal |
| | Hepatocyte | Hypertrophy | Mild |
| | | Inflammation | Chronic Active, Minimal |
| | [Hypertrophy TGLs = 1 - 6+7] | | |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| | Lymph Node | Hyperplasia | Lymphoid, Mild |
| | [Hyperplasia TGLs = 3 - 14] | | |
| * Nose | | Inflammation | Minimal |
| * Pancreas | Acinus | Metaplasia | Hepatocyte, Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 195

TMT: 7

SEX: Male

DAY ON TEST: 727

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601675

ORGAN AND ACCOUNTABLE SITE STATUS

* Pituitary Gland	Pars Distalis	Adenoma	
* Prostate	Epithelium	Hyperplasia	Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
[Adenoma TGLs = 2 - 11]			
* Thymus		Atrophy	Mild

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 196

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601676

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Epididymis | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung |
| * Lymph Node, Mesenteric | * Mammary Gland | * Parathyroid Gland | * Pituitary Gland |
| * Preputial Gland | * Prostate | * Salivary Glands | * Seminal Vesicle |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|----------------------|---------------------------|----------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Mild |
| * Heart | | Cardiomyopathy | Moderate |
| * Islets, Pancreatic | | Hyperplasia | Minimal |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Moderate |
| * Liver | Centrilobular | Fatty Change | Mild |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Nose | Respirat Epith | Hyperplasia | Minimal |
| * Pancreas | | Atrophy | Minimal |
| | Acinus | Metaplasia | Hepatocyte, Mild |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Testes | Bilateral, Interstit Cell | Adenoma | |
| | [Adenoma TGLs = 1 - 11] | | |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | Follicular Cel | Hyperplasia | Mild |
| Tooth | | Malformation | Mild |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 197

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601677

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Minimal
* Epididymis		Inflammation	Minimal
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Moderate
* Liver	Bile Duct	Hyperplasia	Minimal
	Hepatocyte	Hypertrophy	Minimal
		Inflammation	Chronic Active, Minimal
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Nose		Foreign Body	
		Inflammation	Mild
	Olfactory Epi	Metaplasia	Mild
Note: Respiratory hyperplasia in the nose was not added as a diagnosis since it was considered secondary to the inflammation.			
* Spleen		Leukemia Mononuclear	
* Stomach, Forestomach		Inflammation	Minimal
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 1 - 11]		
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 198

TMT: 7
DOSE: 1.0 G/KG

SEX: Male
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601678

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Pancreas	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Spleen	* Thyroid Gland	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Mild
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Moderate
* Liver	Centrilobular	Clear Cell Focus	
		Fatty Change	Mild
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Mammary Gland		Fibroadenoma	
	[Fibroadenoma TGLs = 1 - 14]		
* Nose		Inflammation	Minimal
* Parathyroid Gland		Hyperplasia	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Skin		Inflammation	Mild
	Note: Inflammation was submaxillary, in B02.		
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
* Stomach, Glandular		Hyperplasia	Mild
	Epithelium	Necrosis	Mild

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 198

TMT: 7

SEX: Male

DAY ON TEST: 729

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601678

ORGAN AND ACCOUNTABLE SITE STATUS

* Testes	[Necrosis TGLs = 3 - 15]	Bilateral, Interstit Cell	Adenoma	
* Thymus	[Adenoma TGLs = 2 - 11]		Atrophy	Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 199

TMT: 7
 DOSE: 1.0 G/KG

SEX: Male
 DISP: Moribund Sacrifice

DAY ON TEST: 559
 HISTO: 0601679

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Glandular
* Thyroid Gland	* Trachea		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Necrosis	Mild
* Heart		Cardiomyopathy	Mild
* Kidney		Nephropathy	Moderate
* Liver		Fatty Change	Diffuse, Minimal
	Centrilobular	Fatty Change	Mild
	Fat	Necrosis	Minimal
Mesentery			
[Necrosis TGLs = 2 - 15]			
* Pancreas		Atrophy	Minimal
* Parathyroid Gland		Hyperplasia	Mild
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Preputial Gland		Inflammation	Marked
[Inflammation TGLs = 1 - 14]			
* Prostate		Inflammation	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach		Erosion	Minimal
	Epithelium	Hyperplasia	Minimal
		Inflammation	Mild
[Inflammation TGLs = 3 - 6]			
* Testes	Bilateral, Interstit Cell	Adenoma	
* Thymus		Atrophy	Marked

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 199

TMT: 7

SEX: Male

DAY ON TEST: 559

DOSE: 1.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601679

ORGAN AND ACCOUNTABLE SITE STATUS

* Urinary Bladder

Inflammation

Moderate

PRIMARY CAUSE OF DEATH

- Preputial Gland Inflammation

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 200

TMT: 7

SEX: Male

DAY ON TEST: 729

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601680

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	* Brain	* Epididymis
* Esophagus	* Eye	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

Blood Vessel		Mineralization	Minimal
Note: Pulmonary artery affected in B07.			
* Bone		Osteopetrosis	Mild
* Bone Marrow		Hyperplasia	Moderate
* Heart		Cardiomyopathy	Mild
* Kidney		Accumulation, Hyaline Droplet	Minimal
		Nephropathy	Marked
* Liver		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Mild
	Hepatocyte	Hypertrophy	Mild
		Inflammation	Chronic Active, Minimal
		Leukemia Mononuclear	
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Mammary Gland		Fibroadenoma	
[Fibroadenoma TGLs = 1 - 14]			
Mesentery	Fat	Necrosis	Mild
[Necrosis TGLs = 3 - 15]			
* Parathyroid Gland		Hyperplasia	Mild
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Prostate		Inflammation	Mild

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 200

TMT: 7

SEX: Male

DAY ON TEST: 729

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601680

ORGAN AND ACCOUNTABLE SITE STATUS

* Spleen		Leukemia Mononuclear Pigmentation	Hemosiderin, Minimal
	[Leukemia Mononuclear TGLs = 4 - 16]		
* Testes	Bilateral, Interstit Cell	Adenoma	
	[Adenoma TGLs = 2 - 11]		
* Thymus		Atrophy	Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 201

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 705
HISTO: 0601681

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Pancreas	* Salivary Glands
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

MISSING

* Lymph Node, Mandibular	* Parathyroid Gland
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OBSERVATIONS

* Bone Marrow		Hyperplasia	Mild
* Heart		Cardiomyopathy	Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Inflammation	Chronic Active, Minimal
		Mixed Cell Focus	
	[Basophilic Focus TGLs = 3 - 6+7]		
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Nose		Inflammation	Minimal
* Ovary		Cyst	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 4 - 8]		
* Skin	Subcut Tiss	Fibroma	
	[Fibroma TGLs = 1 - 13]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Hyperplasia	Histiocytic, Moderate
		Pigmentation	Hemosiderin, Minimal
	[Hyperplasia TGLs = 2 - 14]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 201

TMT: 2

SEX: Female

DAY ON TEST: 705

DOSE: 0.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601681

ORGAN AND ACCOUNTABLE SITE STATUS

PRIMARY CAUSE OF DEATH

- Skin Subcut Tiss Fibroma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 202

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601682

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Nose	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular	* Parathyroid Gland
--------------------------	---------------------

OBSERVATIONS

* Heart	Cardiomyopathy	Mild
* Kidney	Mineralization	Minimal
* Liver	Basophilic Focus	
	Inflammation	Chronic Active, Minimal
	Mixed Cell Focus	
[Basophilic Focus TGLs = 3 - 6+7+14+15]		
* Lung	Alveolar Epith	Hyperplasia
* Mammary Gland		Fibroadenoma
[Fibroadenoma TGLs = 1 - 13]		
* Ovary	Cyst	Minimal
* Pancreas	Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Adenoma
[Adenoma TGLs = 2 - 8]		
* Spleen	Hematopoietic Cell Proliferation	Minimal
	Pigmentation	Hemosiderin, Minimal
* Thymus	Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 203

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601683

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
		Mixed Cell Focus	
	[Basophilic Focus TGLs = 2 - 6+7+14]		
* Lymph Node, Mesenteric		Inflammation	Moderate
Mesentery	Fat	Necrosis	Minimal
	[Necrosis TGLs = 1 - 13]		
* Pituitary Gland	Pars Distalis	Adenoma	
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 204

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601684

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Eye	Lens	Cataract	Marked
	Retina	Degeneration	Marked
	[Cataract TGLs = 1 - 10]		
* Heart		Cardiomyopathy	Minimal
* Kidney		Mineralization	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
		Mixed Cell Focus	
	[Basophilic Focus TGLs = 4 - 6+7+14]		
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Mammary Gland		Fibroadenoma	
	[Fibroadenoma TGLs = 2 - 13]		
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 3 - 8]		
* Thymus		Atrophy	Moderate
Tooth		Malformation	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 205

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601685

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Bone Marrow |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Nose | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | * Uterus | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---|--|---------------------------------|
| * Adrenal Cortex | Zona Fascult | Hyperplasia
Necrosis | Minimal
Mild |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization
Nephropathy | Minimal
Minimal |
| * Liver | | Basophilic Focus
Eosinophilic Focus
Inflammation |

Chronic Active, Minimal |
| | [Basophilic Focus TGLs = 2 - 6+7] | | |
| | [Eosinophilic Focus TGLs = 3 - 14] | | |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 13] | | |
| * Ovary | | Cystadenoma | |
| | Note: Very tiny cystadenoma is present. | | |
| * Pancreas | | Atrophy
Basophilic Focus | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 4 - 8] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 205

TMT: 2

SEX: Female

DAY ON TEST: 729

DOSE: 0.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601685

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus
Tooth

Atrophy
Malformation

Moderate
Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 206

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601686

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Degeneration	Cystic, Mild
* Bone Marrow		Hyperplasia	Mild
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
* Lymph Node, Mesenteric		Inflammation	Mild
* Mammary Gland		Fibroadenoma	Multiple
	[Fibroadenoma TGLs = 1,2,3 - 13+14+15]		
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 4 - 8]		
* Spleen		Pigmentation	Hemosiderin, Mild
* Thymus		Atrophy	Mild
* Thyroid Gland	C Cell	Hyperplasia	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 207

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601687

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Ovary | * Pancreas | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | * Uterus | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|------------------------------------|----------------------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Minimal |
| * Heart | | Cardiomyopathy | Minimal |
| * Kidney | Cortex | Cyst | Mild |
| | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Fatty Change | Diffuse, Mild |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| | [Mixed Cell Focus TGLs = 2 - 13] | | |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 1 - 8] | | |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |
| | | Pigmentation | Hemosiderin, Mild |
| * Thymus | | Atrophy | Mild |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 208

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601688

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric | * Mammary Gland |
| * Nose | * Ovary | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|-------------------------------------|------------------|-------------------------|
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Inflammation | Chronic Active, Minimal |
| | [Basophilic Focus TGLs = 1 - 6+7] | | |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| | [Hyperplasia TGLs = 2 - 8] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Mild |
| * Thyroid Gland | C Cell | Adenoma | |
| | Follicular Cel | Adenoma | |
| | C Cell | Hyperplasia | Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 209

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 506
HISTO: 0601689

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Mammary Gland	* Nose	* Ovary	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Marked
		Myelofibrosis	Minimal
* Eye	Cornea	Fibrosis	Mild
	[Fibrosis TGLs = 2 - 10]		
* Kidney		Mineralization	Minimal
* Liver	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
	[Leukemia Mononuclear TGLs = 3 - 6+7]	Leukemia Mononuclear	
* Lung		Leukemia Mononuclear	
* Lymph Node, Mesenteric		Leukemia Mononuclear	
Mesentery	Fat	Necrosis	Mild
	[Necrosis TGLs = 4 - 14]		
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 1 - 13]		
* Thymus		Atrophy	Moderate

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 210

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601690

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric | * Nose |
| * Ovary | * Pancreas | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | * Uterus | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|-------------------------------------|--------------------|-------------------------|
| * Heart | | Cardiomyopathy | Minimal |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| * Mammary Gland | | Fibroadenoma | Multiple |
| | [Fibroadenoma TGLs = 1,2 - 13+14] | | |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 211

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601691

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Ovary | * Pancreas | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|-----------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| | [Eosinophilic Focus TGLs = 2 - 6+7] | | |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| | Note: Angiectasis secondary to hyperplasia accounts for most of the gross appearance of the lesion in pituitary (TGL-3). | | |
| | [Hyperplasia TGLs = 3 - 8] | | |
| * Spleen | | Pigmentation | Hemosiderin, Mild |
| * Thymus | | Atrophy | Moderate |
| * Uterus | | Polyp Stromal | |
| | [Polyp Stromal TGLs = 1 - 13] | | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 212

TMT: 2

SEX: Female

DAY ON TEST: 730

DOSE: 0.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601692

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Ovary	* Parathyroid Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Trachea
* Urinary Bladder	* Uterus		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Angiectasis	Mild
		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
		Mixed Cell Focus	
		Necrosis	Mild
		Pigmentation	Hemosiderin, Mild
Note: TGL-2 appears to be an area of relatively normal liver demarcated by angiectasis and hemorrhage.			
		[Angiectasis TGLs = 1 - 13]	
		[Eosinophilic Focus TGLs = 2 - 14]	
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Mammary Gland		Fibroadenoma	
		[Fibroadenoma TGLs = 3 - 15]	
* Nose		Foreign Body	
		Inflammation	Minimal
	Olfactory Epi	Metaplasia	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 212

TMT: 2

SEX: Female

DAY ON TEST: 730

DOSE: 0.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601692

ORGAN AND ACCOUNTABLE SITE STATUS

* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
[Adenoma TGLs = 4 - 8]			
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Adenoma	

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 213

TMT: 2
 DOSE: 0.0 G/KG

SEX: Female
 DISP: Terminal Sacrifice

DAY ON TEST: 728
 HISTO: 0601693

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Esophagus	* Eye	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Degeneration	Cystic, Minimal
* Bone Marrow		Hyperplasia	Mild
* Clitoral Gland		Inflammation	Moderate
	[Inflammation TGLs = 1 - 13]		
* Heart		Cardiomyopathy	Mild
* Islets, Pancreatic		Adenoma	
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Inflammation	Chronic Active, Minimal
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Ovary		Cyst	Multiple, Marked
	[Cyst TGLs = 3,5 - 11+15]		
* Thymus		Atrophy	Moderate
Tooth		Malformation	Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal
		Polyp Stromal	
		Sarcoma Stromal	

Note: Stromal sarcoma appears to originate in a large uterine polyp.

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 213

TMT: 2

SEX: Female

DAY ON TEST: 728

DOSE: 0.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601693

ORGAN AND ACCOUNTABLE SITE STATUS

Note: There is a uterine polyp in each horn. In the right horn the polyp diagnosis was superceded by presence of the sarcoma, so only one polyp was diagnosed.

[Polyp Stromal TGLs = 4 - 11]

[Sarcoma Stromal TGLs = 2 - 14]

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 214

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 621
HISTO: 0601694

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric | * Mammary Gland |
| * Ovary | * Pancreas | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|------------------------------------|------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | Cortex | Cyst | Minimal |
| | | Mineralization | Minimal |
| * Liver | | Basophilic Focus | |
| | | Fatty Change | Diffuse, Mild |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| | [Mixed Cell Focus TGLs = 1 - 13] | | |
| Mesentery | Fat | Necrosis | Mild |
| | [Necrosis TGLs = 2 - 14] | | |
| * Nose | | Inflammation | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 3 - 8] | | |
| * Spleen | | Pigmentation | Hemosiderin, Mild |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Minimal |
| | | Inflammation | Minimal |
| * Thymus | | Atrophy | Moderate |

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 215

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601695

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Hypertrophy	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Infarct	Minimal
		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
	[Basophilic Focus TGLs = 1 - 6+7]		
* Lung	Alveolar Epith	Metaplasia	Squamous, Mild
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 2 - 8]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 216

TMT: 2
 DOSE: 0.0 G/KG

SEX: Female
 DISP: Terminal Sacrifice

DAY ON TEST: 729
 HISTO: 0601696

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Minimal
* Eye	Retina	Degeneration	Moderate
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
	[Basophilic Focus TGLs = 4 - 6+7]		
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Mammary Gland		Adenoma	
		Fibroadenoma	Multiple
	[Adenoma TGLs = 3 - 15]		
	[Fibroadenoma TGLs = 1,2 - 13+14]		
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 5 - 8]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 217

TMT: 2

SEX: Female

DAY ON TEST: 705

DOSE: 0.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601697

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Brain	* Clitoral Gland
* Esophagus	* Eye	* Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Nose	* Ovary	* Parathyroid Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Leukemia Mononuclear	
* Bone		Osteopetrosis	Moderate
* Bone Marrow		Hyperplasia	Mild
		Myelofibrosis	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver	Bile Duct	Hyperplasia	Minimal
		Leukemia Mononuclear	
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Mammary Gland		Fibroadenoma	Multiple
	[Fibroadenoma TGLs = 2,3 - 13+14]		
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 1 - 8]		
* Spleen		Leukemia Mononuclear	
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 218

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601698

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland	* Ovary
* Pancreas	* Parathyroid Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Nose		Inflammation	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 1- 8]		
* Spleen		Pigmentation	Hemosiderin, Mild
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Moderate
* Uterus		Polyp Stromal	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 219

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601699

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Kidney | * Lymph Node, Mesenteric | * Pancreas | * Parathyroid Gland |
| * Salivary Glands | * Skin | * Stomach, Forestomach | * Stomach, Glandular |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|----------------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Mild |
| * Heart | | Cardiomyopathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Hepatodiaphragmatic Nodule | |
| | Hepatocyte | Hypertrophy | Mild |
| | | Inflammation | Chronic Active, Minimal |
| | [Hepatodiaphragmatic Nodule TGLs = 4 - 15] | | |
| * Lung | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 13] | | |
| * Nose | | Inflammation | Minimal |
| * Ovary | | Cyst | Mild |
| | [Cyst TGLs = 2 - 11] | | |
| * Pituitary Gland | Pars Distalis | Carcinoma | |
| | [Carcinoma TGLs = 5 - 8] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Adenoma | |
| | Follicular Cel | Hyperplasia | Moderate |
| * Uterus | Endometrium | Hyperplasia | Cystic, Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 219

TMT: 2

SEX: Female

DAY ON TEST: 728

DOSE: 0.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601699

ORGAN AND ACCOUNTABLE SITE STATUS

Polyp Stromal

[Polyp Stromal TGLs = 3 - 14]

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 220

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601700

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
		Mixed Cell Focus	
	[Basophilic Focus TGLs = 2 - 6+7+14]		
* Lung	Alveolar Epith	Hyperplasia	Minimal
		Inflammation	Chronic Active, Mild
* Mammary Gland		Fibroadenoma	
	[Fibroadenoma TGLs = 1 - 13]		
Mesentery	Fat	Necrosis	Minimal
	[Necrosis TGLs = 4 - 14]		
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 3 - 15]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 220

TMT: 2

SEX: Female

DAY ON TEST: 729

DOSE: 0.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601700

ORGAN AND ACCOUNTABLE SITE STATUS

* Thyroid Gland

C Cell

Hyperplasia

Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 221

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 510
HISTO: 0601701

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Lymphoma Malignant	
* Heart		Lymphoma Malignant	
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Fatty Change	Focal, Minimal
		Lymphoma Malignant	
* Lung		Lymphoma Malignant	
Lymph Node	Mediastinal	Lymphoma Malignant	
	Pancreatic	Lymphoma Malignant	
Note: Leukemia in the pancreatic lymph node was observed in the routine section of pancreas (B06).			
	[Lymphoma Malignant TGLs = 5 - 16]		
* Lymph Node, Mesenteric		Lymphoma Malignant	
	[Lymphoma Malignant TGLs = 2 - 13]		
Mesentery	Fat	Necrosis	Mild
	[Necrosis TGLs = 4 - 15]		
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Lymphoma Malignant	
	[Lymphoma Malignant TGLs = 3 - 14]		
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation	Marked Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 221

TMT: 2

SEX: Female

DAY ON TEST: 510

DOSE: 0.0 G/KG

DISP: Natural Death

HISTO: 0601701

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Lymphoma Malignant

PRIMARY CAUSE OF DEATH

- Lymph Node, Mesenteric Lymphoma Malignant

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 222

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601702

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Mild
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Angiectasis	Mild
	[Angiectasis TGLs = 1 - 8]		
Skeletal Muscle		Inflammation	Moderate
	Note: Lesion noted in routine section of skin/mammary gland.		
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach		Inflammation	Minimal
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 223

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 9
HISTO: 0601703

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney	* Liver
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow

Note: Marrow hyperplasia not diagnosed because of animals age (9 days on test).

* Lung

Atelectasis

Marked

Note: The pulmonary atelectasis was associated with gross chylothorax.

PRIMARY CAUSE OF DEATH

- Lung Atelectasis

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 224

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601704

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
		Fatty Change	Diffuse, Minimal
		Inflammation	Chronic Active, Minimal
	[Basophilic Focus TGLs = 3 - 6+7]		
* Lung	Alveolar Epith	Hyperplasia	Minimal
	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Mammary Gland		Fibroadenoma	
	[Fibroadenoma TGLs = 2 - 13]		
Mesentery	Fat	Necrosis	Minimal
	[Necrosis TGLs = 4 - 14]		
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 1 - 8]		
* Spleen		Hematopoietic Cell Proliferation	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 224

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601704

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Pigmentation
Atrophy

Hemosiderin, Minimal
Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 225

TMT: 2

SEX: Female

DAY ON TEST: 728

DOSE: 0.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601705

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Ovary
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Pheochromocytoma Benign	
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
	[Basophilic Focus TGLs = 1 - 6+7+14]		
* Nose		Cyst	Minimal
		Inflammation	Minimal
	Note: Epidermal inclusion cyst is present beneath the olfactory mucosa of the dorsal meatus.		
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 2 - 13]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Moderate
Tooth		Malformation	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 226

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Dosing Accident

DAY ON TEST: 692
HISTO: 0601706

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Kidney	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Necrosis	Marked
* Bone Marrow		Hemorrhage	Moderate
		Necrosis	Moderate
* Heart		Cardiomyopathy	Mild
* Islets, Pancreatic		Hyperplasia	Minimal
* Liver		Necrosis	Marked
	[Necrosis TGLs = 1 - 6+7]		
* Lung		Congestion	Mild
	Note: Alveolar capillaries contain cells with fragmented (keryorrhctic) nuclei similar to those in the bone marrow and liver.		
	[Congestion TGLs = 4 - 3+4]		
Mesentery	Fat	Necrosis	Minimal
	[Necrosis TGLs = 2 - 13]		
* Spleen	Lymph Follic	Necrosis	Marked
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Marked
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 227

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 450
HISTO: 0601707

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Nose	* Ovary	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Mild
* Bone Marrow		Hyperplasia	Moderate
* Heart		Fibrosarcoma	Metastatic (Lung)
* Kidney	Medulla	Cyst	Minimal
		Mineralization	Minimal
* Liver		Basophilic Focus	
		Fatty Change	Diffuse, Minimal
		Inflammation	Chronic Active, Minimal
* Lung	Mediastinum	Fibrosarcoma	
	Mediastinum	Foreign Body	
	Mediastinum	Inflammation	Chronic Active, Marked
<p>Note: TGL-2 has a large area of necrosis with foreign material (plant matter) surrounded by leukocytes and very exuberant fibrous tissue from which the tumor arises. [Fibrosarcoma TGLs = 2 - 14+15]</p>			
* Mammary Gland		Fibroadenoma	
<p>[Fibroadenoma TGLs = 1 - 13]</p>			
* Pancreas		Atrophy	Minimal
* Spleen		Hematopoietic Cell Proliferation	Mild
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Mild
		Ulcer	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 227

TMT: 2

SEX: Female

DAY ON TEST: 450

DOSE: 0.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601707

ORGAN AND ACCOUNTABLE SITE STATUS

[Ulcer TGLs = 3 - 16]

* Thymus

Atrophy

Marked

Infiltration Cellular

Plasma Cell, Mild

* Uterus

Polyp Stromal

PRIMARY CAUSE OF DEATH

- Lung Mediastinum Fibrosarcoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 228

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 701
HISTO: 0601708

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Brain	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Degeneration	Cystic, Minimal
* Adrenal Medulla		Pheochromocytoma Benign	
* Bone Marrow		Hyperplasia	Marked
* Clitoral Gland		Carcinoma	Multiple
[Carcinoma TGLs = 1,2 - 13+14]			
* Heart		Cardiomyopathy	Minimal
* Kidney		Mineralization	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
	Hepatocyte	Hypertrophy	Minimal
		Inflammation	Chronic Active, Minimal
Note: Clear cell focus herein has granular rather than completely clear cells but it resembles clear cell foci in the other rats more than eosinophilic ones.			
* Mammary Gland		Adenolipoma	
[Adenolipoma TGLs = 3 - 15]			
* Nose		Inflammation	Mild
* Spleen		Hematopoietic Cell Proliferation	Mild
* Thymus		Atrophy	Moderate

PRIMARY CAUSE OF DEATH - Clitoral Gland Carcinoma
 CONTRIBUTORY CAUSE OF DEATH - Mammary Gland Adenolipoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 229

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601709

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Esophagus	* Eye	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Hypertrophy	Marked
* Bone Marrow	Hyperplasia	Minimal
* Clitoral Gland	Adenoma	
[Adenoma TGLs = 3 - 12]		
* Heart	Cardiomyopathy	Mild
* Kidney	Nephropathy	Minimal
* Liver	Basophilic Focus	
	Clear Cell Focus	
	Eosinophilic Focus	
	Inflammation	Chronic Active, Minimal
[Eosinophilic Focus TGLs = 5 - 16]		
* Mammary Gland	Fibroadenoma	Multiple
[Fibroadenoma TGLs = 1,2,4 - 13+14+15]		
* Pituitary Gland	Pars Distalis	Adenoma
[Adenoma TGLs = 6 - 8]		
* Spleen	Pigmentation	Hemosiderin, Minimal
* Thymus	Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 230

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601710

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Ovary | * Pancreas | * Parathyroid Gland | * Pituitary Gland |
| * Salivary Glands | * Skin | * Stomach, Forestomach | * Stomach, Glandular |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--------------------------|---|----------------------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Intestine Large, Colon | | Parasite Metazoan | |
| * Kidney | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| | [Basophilic Focus TGLs = 2 - 6+7+14+15] | | |
| | [Eosinophilic Focus TGLs = 3 - 15] | | |
| * Spleen | Lymph Follic | Atrophy | Mild |
| | | Hematopoietic Cell Proliferation | Minimal |
| | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Hyperplasia | Marked |
| * Uterus | Endometrium | Hyperplasia | Cystic, Minimal |
| | | Polyp Stromal | |
| | [Polyp Stromal TGLs = 1 - 13] | | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 231

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601711

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Nose | * Ovary | * Pancreas |
| * Parathyroid Gland | * Salivary Glands | * Skin | * Stomach, Forestomach |
| * Stomach, Glandular | * Thyroid Gland | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|----------------------------|-------------------------|
| * Eye | Retina | Degeneration | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | | Hepatodiaphragmatic Nodule | |
| | Hepatocyte | Hypertrophy | Mild |
| | | Inflammation | Chronic Active, Minimal |
| | [Hepatodiaphragmatic Nodule TGLs = 2 - 14] | | |
| * Lung | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| * Mammary Gland | | Fibroadenoma | Multiple |
| | [Fibroadenoma TGLs = 1,3 - 13+15] | | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 232

TMT: 2
 DOSE: 0.0 G/KG

SEX: Female
 DISP: Terminal Sacrifice

DAY ON TEST: 729
 HISTO: 0601712

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lung |
| * Lymph Node, Mesenteric | * Nose | * Ovary | * Parathyroid Gland |
| * Salivary Glands | * Skin | * Stomach, Forestomach | * Stomach, Glandular |
| * Thyroid Gland | * Trachea | * Urinary Bladder | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|----------------------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Minimal |
| * Eye | Retina | Degeneration | Minimal |
| | Cornea | Inflammation | Mild |
| | [Inflammation TGLs = 1 - 10] | | |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| | [Basophilic Focus TGLs = 5 - 6+7+16] | | |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 2 - 13] | | |
| Mesentery | Fat | Necrosis | Mild |
| | [Necrosis TGLs = 4 - 15] | | |
| * Pancreas | Acinus | Hyperplasia | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| | [Hyperplasia TGLs = 6 - 8] | | |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 232

TMT: 2

SEX: Female

DAY ON TEST: 729

DOSE: 0.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601712

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

* Uterus

[Hyperplasia TGLs = 3 - 14]

Endometrium

Pigmentation

Atrophy

Hyperplasia

Hemosiderin, Minimal

Moderate

Cystic, Marked

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 233

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601713

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Ovary | * Pancreas | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|----------------------------------|-------------------------|
| * Heart | | Cardiomyopathy | Minimal |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Hepatodiaphragmatic Nodule | |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| | [Hepatodiaphragmatic Nodule TGLs = 1 - 13] | | |
| * Lung | | Inflammation | Chronic Active, Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| | [Hyperplasia TGLs = 2 - 8] | | |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Hyperplasia | Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 234

TMT: 2
 DOSE: 0.0 G/KG

SEX: Female
 DISP: Moribund Sacrifice

DAY ON TEST: 519
 HISTO: 0601714

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Heart | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Ovary | * Pancreas | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Thyroid Gland | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|---|----------------------|----------|
| * Bone Marrow | | Hyperplasia | Moderate |
| * Kidney | | Mineralization | Minimal |
| * Liver | Bile Duct | Hyperplasia | Minimal |
| | [Leukemia Mononuclear TGLs = 1 - 6+7] | Leukemia Mononuclear | |
| * Lung | | Leukemia Mononuclear | |
| Mesentery | Fat | Necrosis | Mild |
| | [Necrosis TGLs = 2 - 13] | | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Minimal |
| * Spleen | | Leukemia Mononuclear | |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Moderate |
| | | Inflammation | Moderate |
| * Stomach, Glandular | Epithelium | Necrosis | Minimal |
| * Thymus | | Atrophy | Moderate |

PRIMARY CAUSE OF DEATH - Liver Leukemia Mononuclear

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 235

TMT: 2
 DOSE: 0.0 G/KG

SEX: Female
 DISP: Moribund Sacrifice

DAY ON TEST: 669
 HISTO: 0601715

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | Blood Vessel | * Bone | * Bone Marrow |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Ovary |
| * Pancreas | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--------------------------|-----------------------|-------------------------|
| * Adrenal Medulla | | Hyperplasia | Minimal |
| * Heart | | Cardiomyopathy | Minimal |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Fatty Change | Diffuse, Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| * Lung | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 1 - 8] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 236

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 615
HISTO: 0601716

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric |
| * Mammary Gland | * Nose | * Ovary | * Pancreas |
| * Parathyroid Gland | * Salivary Glands | * Skin | * Stomach, Forestomach |
| * Stomach, Glandular | * Thyroid Gland | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|---|---------------|----------------------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Marked |
| * Clitoral Gland | | Carcinoma | |
| Note: Both clitoral gland sections submitted as "normal" appear to be involved in the carcinoma.
[Carcinoma TGLs = 1 - 13] | | | |
| * Heart | | Cardiomyopathy | Mild |
| * Intestine Large, Colon | | Parasite Metazoan | |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Hematopoietic Cell Proliferation | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| [Adenoma TGLs = 3 - 8] | | | |
| * Spleen | | Hematopoietic Cell Proliferation | Marked |
| [Hematopoietic Cell Proliferation TGLs = 2 - 5] | | | |
| * Thymus | | Atrophy | Moderate |

PRIMARY CAUSE OF DEATH - Clitoral Gland Carcinoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 237

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601717

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Mild
* Eye	Retina	Gliosis	Mild
* Heart		Cardiomyopathy	Mild
* Intestine Large, Colon		Parasite Metazoan	
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
		Mixed Cell Focus	
	[Basophilic Focus TGLs = 4 - 6+7+16]		
	[Mixed Cell Focus TGLs = 3 -15]		
* Mammary Gland		Fibroadenoma	Multiple
	[Fibroadenoma TGLs = 1,2 - 13+14]		
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 5 - 8]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 238

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601718

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

Blood Vessel	Inflammation	Moderate
Note: Branches off aorta in aortic section (B07) are affected.		
* Bone Marrow	Hyperplasia	Mild
* Heart	Cardiomyopathy	Minimal
* Kidney	Nephropathy	Minimal
* Liver	Basophilic Focus	
	Eosinophilic Focus	
	Inflammation	Chronic Active, Minimal
[Basophilic Focus TGLs = 1 - 6+7]		
* Mammary Gland	Fibroadenoma	
[Fibroadenoma TGLs = 2 - 13]		
* Pituitary Gland	Pars Distalis	Adenoma
[Adenoma TGLs = 4 - 8]		
* Spleen	Pigmentation	Hemosiderin, Minimal
* Thymus	Atrophy	Moderate
* Thyroid Gland	C Cell	
	C Cell	Hyperplasia
		Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 239

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601719

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Infarct	Minimal
	Pelvis	Inflammation	Mild
		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
		Hepatodiaphragmatic Nodule	
		Inflammation	Chronic Active, Minimal
	[Hepatodiaphragmatic Nodule TGLs = 2 - 14]		
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Mammary Gland		Fibroadenoma	
	[Fibroadenoma TGLs = 1 - 13]		
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 240

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601720

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Nose	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

MISSING

* Lymph Node, Mandibular	* Parathyroid Gland
--------------------------	---------------------

OBSERVATIONS

* Bone Marrow		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Inflammation	Chronic Active, Minimal
	[Basophilic Focus TGLs = 3 - 6+7]		
* Lung	Alveolar Epith	Hyperplasia	Mild
* Mammary Gland		Adenoma	
	[Adenoma TGLs = 2 - 14]		
* Ovary		Cyst	Marked
	[Cyst TGLs = 1 - 13]		
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 4 - 8]		
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 241

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 693
HISTO: 0601721

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Nose | * Ovary |
| * Pancreas | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Glandular | * Trachea | * Urinary Bladder | * Uterus |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|--------------------------------|------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Moderate |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Fatty Change | Diffuse, Mild |
| | Hepatocyte | Hypertrophy | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 2 - 13] | | |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 1 - 8] | | |
| * Spleen | | Pigmentation | Hemosiderin, Mild |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Minimal |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Hyperplasia | Mild |

PRIMARY CAUSE OF DEATH - Mammary Gland Fibroadenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 242

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601722

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | Blood Vessel | * Bone | * Brain |
| * Clitoral Gland | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lymph Node, Mesenteric |
| * Mammary Gland | * Nose | * Ovary | * Pancreas |
| * Parathyroid Gland | * Salivary Glands | * Skin | * Spleen |
| * Stomach, Forestomach | * Stomach, Glandular | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--|---------------------------|-------------------------|-------------------------|
| * Adrenal Medulla | | Pheochromocytoma Benign | |
| Note: Appearance of tumor cells in adjacent vein was interpreted to represent portions that were cut off at trim, based upon appearance of remainder of tumor. | | | |
| | [Pheochromocytoma Benign | TGLs = 2 - 14] | |
| * Bone Marrow | | Hyperplasia | Mild |
| Ear | | Neural Crest Tumor | |
| | [Neural Crest Tumor | TGLs = 1 - 13] | |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Moderate |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Adenoma | |
| | C Cell | Hyperplasia | Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 243

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601723

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Parathyroid Gland | * Pituitary Gland | * Salivary Glands | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------|----------------------------------|----------------------------------|----------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| | [Basophilic Focus TGLs = 2-13] | | |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| * Ovary | | Cyst | Marked |
| | [Cyst TGLs = 1 - 11] | | |
| * Pancreas | | Atrophy | Minimal |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |
| | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |
| * Uterus | Bilateral | Polyp Stromal | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 244

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 693
HISTO: 0601724

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Heart | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Nose | * Ovary | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | * Uterus | |

MISSING

- | | |
|--------------------------|---------------------|
| * Lymph Node, Mandibular | * Parathyroid Gland |
|--------------------------|---------------------|

OBSERVATIONS

- | | | | |
|--------------------------|--|----------------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Mild |
| * Kidney | | Leukemia Mononuclear | |
| | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Fatty Change | Diffuse, Minimal |
| | Serosa | Fibrosis | Moderate |
| | Bile Duct | Hepatodiaphragmatic Nodule | |
| | | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | | Leukemia Mononuclear | |
| | Artery | Necrosis | Mild |
| | [Hepatodiaphragmatic Nodule TGLs = 5 - 15] | | |
| | [Leukemia Mononuclear TGLs = 4 - 6+7] | | |
| * Lung | | Inflammation | Chronic Active, Marked |
| | | Leukemia Mononuclear | |
| | Alveolar Epith | Metaplasia | Mild |
| * Lymph Node, Mesenteric | | Atrophy | Moderate |
| * Mammary Gland | | Carcinoma | |
| | [Carcinoma TGLs = 1 - 13] | | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 244

TMT: 2

SEX: Female

DAY ON TEST: 693

DOSE: 0.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601724

ORGAN AND ACCOUNTABLE SITE STATUS

* Pancreas		Leukemia Mononuclear	
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 3 - 8]		
* Spleen		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 2 - 14]		
* Thymus		Atrophy	Moderate

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

CONTRIBUTORY CAUSE OF DEATH - Lung Inflammation

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 245

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 664
HISTO: 0601725

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Trachea
* Urinary Bladder	* Uterus		

MISSING

* Lymph Node, Mandibular	* Parathyroid Gland
--------------------------	---------------------

OBSERVATIONS

* Adrenal Medulla		Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Minimal
* Eye	Lens	Cataract	Moderate
	Retina	Degeneration	Marked
	[Cataract TGLs = 2 - 10]		
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Inflammation	Chronic Active, Minimal
	[Basophilic Focus TGLs = 4 - 6+7]		
* Ovary		Cyst	Marked
	[Cyst TGLs = 3 - 13]		
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 1 - 8]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Mild
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Moderate

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 246

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601726

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Esophagus | * Eye | * Harderian Gland |
| * Heart | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Nose | * Ovary | * Pancreas |
| * Parathyroid Gland | * Salivary Glands | * Skin | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|--------------------------------|----------------------|---------------------------------|
| * Bone Marrow | | Hyperplasia | Moderate |
| * Clitoral Gland | | Adenoma | |
| | [Adenoma TGLs = 2 - 14] | | |
| * Kidney | | Mineralization | Minimal |
| * Liver | | Basophilic Focus | |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 13] | | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| * Spleen | | Leukemia Mononuclear | |
| * Stomach, Forestomach | | Hyperplasia | Atypical, Marked |
| | | Sarcoma | Metastatic (Stomach, Glandular) |
| | [Hyperplasia TGLs = 5 - 17] | | |
| | [Sarcoma TGLs = 3-15] | | |
| * Stomach, Glandular | | Sarcoma | |
| | [Sarcoma TGLs = 4 - 16] | | |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Hyperplasia | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 247

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 637
HISTO: 0601727

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
* Liver		Basophilic Focus	
		Inflammation	Chronic Active, Minimal
* Mammary Gland		Fibroadenoma	
	[Fibroadenoma TGLs = 1 - 13]		
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 2 - 8]		
* Spleen		Pigmentation	Hemosiderin, Mild
* Thymus		Atrophy	Moderate

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 248

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601728

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Ovary | * Pancreas |
| * Parathyroid Gland | * Pituitary Gland | * Salivary Glands | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-----------------|-------------------------------------|--------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| | Alveolar Epith | Hypertrophy | Minimal |
| * Mammary Gland | | Fibroadenoma | Multiple |
| | [Fibroadenoma TGLs = 1,2 - 13+14] | | |
| * Nose | | Foreign Body | |
| | | Inflammation | Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 249

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601729

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Nose | * Pancreas | * Parathyroid Gland |
| * Salivary Glands | * Skin | * Stomach, Forestomach | * Stomach, Glandular |
| * Thyroid Gland | * Trachea | * Urinary Bladder | * Uterus |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Mild |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Fatty Change | Diffuse, Minimal |
| | Hepatocyte | Hypertrophy | Mild |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| | [Mixed Cell Focus TGLs = 6 - 17] | | |
| * Lung | | Inflammation | Chronic Active, Minimal |
| * Mammary Gland | | Fibroadenoma | Multiple |
| | [Fibroadenoma TGLs = 1,2,3 - 13+14+15] | | |
| Mesentery | Fat | Necrosis | Minimal |
| | [Necrosis TGLs = 5 - 16] | | |
| * Ovary | | Cyst | Mild |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 4 - 8] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 249

TMT: 2

SEX: Female

DAY ON TEST: 728

DOSE: 0.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601729

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Atrophy

Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 250

TMT: 2
DOSE: 0.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601730

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric	* Nose
* Ovary	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular	* Parathyroid Gland
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OBSERVATIONS

* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Fatty Change	Diffuse, Minimal
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Mammary Gland		Fibroadenoma	Multiple
	[Fibroadenoma TGLs = 1,2,3 - 13+14+15]		
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 4 - 8]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Minimal
Tooth		Malformation	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 251

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 727
HISTO: 0601731

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Salivary Glands
* Skin	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Leukemia Mononuclear	
* Adrenal Medulla		Leukemia Mononuclear	
* Bone Marrow		Hyperplasia	Marked
* Brain		Necrosis	Minimal
* Heart	Valve	Leukemia Mononuclear	
		Thrombosis	Mild
Note: Valvular thrombosis is septic.			
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Fatty Change	Diffuse, Mild
	Oval Cell	Hyperplasia	Mild
	Bile Duct	Hyperplasia	Moderate
		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 3 - 6+7]		
* Lung		Inflammation	Chronic Active, Mild
		Leukemia Mononuclear	
* Pituitary Gland	Pars Distalis	Angiectasis	Minimal
	[Angiectasis TGLs = 1 - 13]		
* Spleen		Fibrosis	Mild
		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 2 - 5]		

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 251

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 727
HISTO: 0601731

ORGAN AND ACCOUNTABLE SITE STATUS

* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Mild
		Ulcer	Marked
* Stomach, Glandular		Inflammation	Mild
* Thymus		Atrophy	Moderate
		Leukemia Mononuclear	
* Thyroid Gland	C Cell	Hyperplasia	Mild

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 252

TMT: 4

SEX: Female

DAY ON TEST: 639

DOSE: 0.1 G/KG

DISP: Moribund Sacrifice

HISTO: 0601732

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Nose | * Ovary | * Parathyroid Gland |
| * Salivary Glands | * Skin | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---|----------------------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Mild |
| * Heart | | Cardiomyopathy | Minimal |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Fatty Change | Diffuse, Minimal |
| | | Hepatodiaphragmatic Nodule | |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| | [Hepatodiaphragmatic Nodule TGLs = 4 - 7] | | |
| | [Mixed Cell Focus TGLs = 3 - 6+14] | | |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 13] | | |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Minimal |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |
| | | Pigmentation | Hemosiderin, Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 252

TMT: 4

SEX: Female

DAY ON TEST: 639

DOSE: 0.1 G/KG

DISP: Moribund Sacrifice

HISTO: 0601732

ORGAN AND ACCOUNTABLE SITE STATUS

* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Minimal
* Thymus		Atrophy	Moderate
* Uterus		Polyp Stromal	
[Polyp Stromal TGLs = 2 - 15]			

PRIMARY CAUSE OF DEATH - Mammary Gland Fibroadenoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 253

TMT: 4
 DOSE: 0.1 G/KG

SEX: Female
 DISP: Moribund Sacrifice

DAY ON TEST: 678
 HISTO: 0601733

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Bone Marrow |
| * Clitoral Gland | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lung |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Ovary |
| * Pancreas | * Parathyroid Gland | * Salivary Glands | * Stomach, Forestomach |
| * Stomach, Glandular | * Trachea | * Urinary Bladder | * Uterus |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------------------------|----------------|--------------------|-------------------------|
| * Adrenal Cortex | | Hypertrophy | Minimal |
| * Brain | | Hemorrhage | Moderate |
| * Heart | | Cardiomyopathy | Minimal |
| * Kidney | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| [Eosinophilic Focus TGLs = 2 - 7] | | | |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| [Adenoma TGLs = 1 - 8] | | | |
| * Skin | Epidermis | Hyperplasia | Basal Cell, Mild |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | Follicular Cel | Hyperplasia | Minimal |
| Tooth | | Malformation | Minimal |

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma
 CONTRIBUTORY CAUSE OF DEATH - Brain Hemorrhage

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 254

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601734

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Degeneration	Cystic, Minimal
* Clitoral Gland		Adenoma	
		Hyperplasia	Moderate
	[Adenoma TGLs = 1 - 12]		
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
	[Eosinophilic Focus TGLs = 2,3 - 13+14]		
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Pancreas	Acinus	Hyperplasia	Mild
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 4 - 8]		
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Mild

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 255

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601735

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular	* Parathyroid Gland
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OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Moderate
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Leukemia Mononuclear	
[Leukemia Mononuclear TGLs = 2 - 6+7]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Marked
[Hyperplasia TGLs = 3 - 8]			
* Spleen		Leukemia Mononuclear	
[Leukemia Mononuclear TGLs = 1 - 13]			
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Minimal
* Uterus		Polyp Stromal	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 256

TMT: 4

SEX: Female

DAY ON TEST: 730

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601736

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Mild
* Clitoral Gland		Carcinoma	
[Carcinoma TGLs = 1 - 13]			
* Heart		Cardiomyopathy	Mild
* Intestine Large, Colon		Parasite Metazoan	
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
[Eosinophilic Focus TGLs = 4 - 6+7+16]			
* Lung		Inflammation	Chronic Active, Minimal
* Mammary Gland		Fibroadenoma	Multiple
[Fibroadenoma TGLs = 2,3 - 14+15]			
Mesentery	Fat	Necrosis	Minimal
[Necrosis TGLs = 5 - 17]			
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Mild

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 257

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601737

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Infarct	Mild
		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
	[Eosinophilic Focus TGLs = 1 - 6+7]		
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 258

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601738

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Nose | * Ovary |
| * Pancreas | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Minimal |
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| | [Basophilic Focus TGLs = 1 - 6+7+13] | | |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 2 - 14] | | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| | [Hyperplasia TGLs = 3 - 15] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Adenoma | |

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 259

TMT: 4

SEX: Female

DAY ON TEST: 728

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601739

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Esophagus	* Eye	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney	* Lymph Node, Mesenteric
* Nose	* Ovary	* Parathyroid Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Minimal
* Clitoral Gland		Inflammation	Mild
	[Inflammation TGLs = 3 - 12]		
* Heart		Cardiomyopathy	Mild
* Liver		Angiectasis	Mild
		Basophilic Focus	
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
	[Angiectasis TGLs = 5 - 16]		
	[Basophilic Focus TGLs = 5 - 6+7]		
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Mammary Gland		Fibroadenoma	Multiple
	[Fibroadenoma TGLs = 1,2 - 13+14]		
Mesentery	Fat	Necrosis	Mild
	[Necrosis TGLs = 4 - 15]		
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 6 - 8]		

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 259

TMT: 4

SEX: Female

DAY ON TEST: 728

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601739

ORGAN AND ACCOUNTABLE SITE STATUS

* Spleen

Pigmentation

Hemosiderin, Minimal

* Thymus

Atrophy

Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 260

TMT: 4

SEX: Female

DAY ON TEST: 730

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601740

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
		Fatty Change	Diffuse, Minimal
	Bile Duct	Hyperplasia	Minimal
	Hepatocyte	Hypertrophy	Minimal
		Mixed Cell Focus	
	[Basophilic Focus TGLs = 4 - 15+16]		
* Mammary Gland		Carcinoma	
		Fibroadenoma	
	[Carcinoma TGLs = 2 - 14]		
	[Fibroadenoma TGLs = 1 - 13]		
* Pituitary Gland	Pars Distalis	Adenoma	
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 260

TMT: 4

SEX: Female

DAY ON TEST: 730

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601740

ORGAN AND ACCOUNTABLE SITE STATUS

* Thyroid Gland

C Cell

Hyperplasia

Marked

* Uterus

Hemorrhage

Moderate

[Hemorrhage TGLs = 3 - 15]

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 261

TMT: 4

SEX: Female

DAY ON TEST: 730

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601741

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Nose | * Ovary |
| * Pancreas | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|---|---------------------------------------|----------------------------------|-------------------------|
| * Heart | | Cardiomyopathy | Minimal |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | Bile Duct | Hyperplasia | Mild |
| | | Inflammation | Chronic Active, Minimal |
| | [Basophilic Focus TGLs = 2 - 14+15] | | |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 13] | | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Minimal |
| Note: The focal hyperplasia is unlikely to have been responsible for TGL-3; the retained secretion present is probably responsible but not considered abnormal. | | | |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |
| | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Hyperplasia | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 262

TMT: 4

SEX: Female

DAY ON TEST: 705

DOSE: 0.1 G/KG

DISP: Moribund Sacrifice

HISTO: 0601742

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Nose	* Ovary	* Pancreas
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular	* Parathyroid Gland
--------------------------	---------------------

OBSERVATIONS

* Adrenal Cortex		Degeneration	Cystic, Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
* Liver	Bile Duct	Basophilic Focus	
		Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Mild
* Mammary Gland		Fibroadenoma	Multiple
Note: TGL-1 = largely cystic (galactocoele-like).			
[Fibroadenoma TGLs = 1,2,3,4 - 13+14+15+16]			
* Pituitary Gland	Pars Distalis	Adenoma	
[Adenoma TGLs = 5 - 8]			
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Thymoma Benign	
* Thyroid Gland	C Cell	Hyperplasia	Moderate

PRIMARY CAUSE OF DEATH - Mammary Gland Fibroadenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 263

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 670
HISTO: 0601743

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Clitoral Gland	* Esophagus
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Leukemia Mononuclear	
* Adrenal Medulla		Leukemia Mononuclear	
* Bone Marrow		Hyperplasia	Marked
* Brain		Leukemia Mononuclear	
		Necrosis	Minimal
* Eye	Lens	Cataract	Marked
	Retina	Degeneration	Marked
	[Cataract TGLs = 1 - 10]		
* Heart		Cardiomyopathy	Mild
* Kidney		Leukemia Mononuclear	
		Mineralization	Minimal
* Liver	Bile Duct	Hyperplasia	Mild
	[Leukemia Mononuclear TGLs = 3 - 14]	Leukemia Mononuclear	
* Lung	Alveolar Epith	Hyperplasia	Moderate
		Leukemia Mononuclear	
	Alveolar Epith	Metaplasia	Squamous, Minimal
Lymph Node	Mediastinal	Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 4 - 13]		
* Lymph Node, Mesenteric		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 5 - 15]		

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 263

TMT: 4

SEX: Female

DAY ON TEST: 670

DOSE: 0.1 G/KG

DISP: Natural Death

HISTO: 0601743

ORGAN AND ACCOUNTABLE SITE STATUS

* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 2 - 13]		
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
* Thymus		Leukemia Mononuclear	

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 264

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601744

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Bone Marrow |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Ovary | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Glandular | * Trachea | * Urinary Bladder | * Uterus |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|--|----------------------|-------------------------|
| * Adrenal Cortex | | Adenoma | |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Infarct | Minimal |
| | | Mineralization | Minimal |
| | | Nephropathy | Mild |
| | [Infarct TGLs = 2 - 13] | | |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | | Fatty Change | Diffuse, Mild |
| | | Inflammation | Chronic Active, Minimal |
| | | Leukemia Mononuclear | |
| | Note: Eosinophilic foci in this liver have more fat than usual in each cell hence could also be called mixed foci. | | |
| | [Leukemia Mononuclear TGLs = 1 - 6+7] | | |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 3 - 8] | | |
| * Spleen | | Leukemia Mononuclear | |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Minimal |
| | | Inflammation | Minimal |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 264

TMT: 4

SEX: Female

DAY ON TEST: 729

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601744

ORGAN AND ACCOUNTABLE SITE STATUS

* Thyroid Gland

C Cell

Hyperplasia

Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 265

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601745

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Nose | * Ovary | * Pancreas |
| * Parathyroid Gland | * Salivary Glands | * Skin | * Stomach, Glandular |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|--|----------------------------------|---------------------|
| * Bone Marrow | | Hyperplasia | Moderate |
| * Heart | | Cardiomyopathy | Minimal |
| * Kidney | | Mineralization | Minimal |
| * Liver | | Hematopoietic Cell Proliferation | Minimal |
| | | Leukemia Mononuclear | |
| | Centrilobular | Necrosis | Moderate |
| | [Leukemia Mononuclear TGLs = 4 - 16] | | |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| * Mammary Gland | | Fibroadenoma | Multiple |
| | [Fibroadenoma TGLs = 2,3 - 14+15] | | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| | [Hyperplasia TGLs = 5 - 8] | | |
| * Spleen | | Hematopoietic Cell Proliferation | Mild |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Marked |
| | | Inflammation | Moderate |
| * Thymus | | Atrophy | Marked |
| * Thyroid Gland | C Cell | Adenoma | |
| Tooth | | Malformation | Minimal |
| * Uterus | | Congestion | Marked |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 265

TMT: 4

SEX: Female

DAY ON TEST: 728

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601745

ORGAN AND ACCOUNTABLE SITE STATUS

Endometrium

Hyperplasia

Cystic, Mild

Leukemia Mononuclear

Necrosis

Moderate

Note: Mass (TGL-1) appears to be due to congestion, edema, and necrosis of endometrium, consistent with a venous thrombus (not in section) secondary to leukemia.

[Congestion TGLs = 1 - 13]

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 266

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601746

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Esophagus	* Eye	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Degeneration	Cystic, Minimal
* Bone Marrow		Hyperplasia	Mild
* Clitoral Gland		Adenoma	
	[Adenoma TGLs = 1 - 12]		
* Heart		Cardiomyopathy	Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Hematopoietic Cell Proliferation	Minimal
		Inflammation	Chronic Active, Minimal
		Mixed Cell Focus	
	[Eosinophilic Focus TGLs = 5 - 15+16]		
* Lung	Alveolar Epith	Hyperplasia	Minimal
	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Mammary Gland		Fibroadenoma	Multiple
	[Fibroadenoma TGLs = 2,3 - 13+14]		
* Ovary		Cyst	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 4 - 8]		
* Spleen		Hematopoietic Cell Proliferation	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 266

TMT: 4

SEX: Female

DAY ON TEST: 728

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601746

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal
		Polyp Stromal	

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 267

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601747

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Mammary Gland	* Nose	* Pancreas
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular	* Parathyroid Gland
--------------------------	---------------------

OBSERVATIONS

* Adrenal Cortex		Degeneration	Cystic, Mild
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Hematopoietic Cell Proliferation	Minimal
		Inflammation	Chronic Active, Minimal
	[Eosinophilic Focus TGLs = 1 - 13+14]		
* Lymph Node, Mesenteric		Atrophy	Moderate
* Ovary		Cyst	Marked
	[Cyst TGLs = 2 - 11]		
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 3 - 8]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Mild
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 268

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601748

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | Blood Vessel | * Bone | * Brain |
| * Esophagus | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lung | * Mammary Gland | * Nose |
| * Ovary | * Pancreas | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--------------------------|--------------------------------------|-------------------------|-------------------------|
| * Adrenal Medulla | | Pheochromocytoma Benign | |
| * Bone Marrow | | Hyperplasia | Minimal |
| * Clitoral Gland | | Adenoma | |
| | | Hyperplasia | Moderate |
| | [Adenoma TGLs = 1 - 12] | | |
| * Eye | Retina | Degeneration | Mild |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| * Liver | | Angiectasis | Minimal |
| | | Basophilic Focus | |
| | Bile Duct | Cyst | Minimal |
| | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| | | Leukemia Mononuclear | |
| | [Eosinophilic Focus TGLs = 2 - 13] | | |
| * Lymph Node, Mesenteric | | Leukemia Mononuclear | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Moderate |
| * Spleen | | Leukemia Mononuclear | |
| | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 268

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601748

ORGAN AND ACCOUNTABLE SITE STATUS

* Thyroid Gland

C Cell

Adenoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 269

TMT: 4

SEX: Female

DAY ON TEST: 730

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601749

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Degeneration	Cystic, Minimal
* Bone Marrow		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Inflammation	Chronic Active, Minimal
		Mixed Cell Focus	
	[Basophilic Focus TGLs = 3-6+7+15]		
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Mammary Gland		Fibroadenoma	
	[Fibroadenoma TGLs = 1 - 13]		
Mesentery	Fat	Necrosis	Mild
	[Necrosis TGLs = 2 - 14]		
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 4 - 8]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 269

TMT: 4

SEX: Female

DAY ON TEST: 730

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601749

ORGAN AND ACCOUNTABLE SITE STATUS

* Thyroid Gland

C Cell

Hyperplasia

Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 270

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 558
HISTO: 0601750

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Bone Marrow |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Ovary |
| * Pancreas | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|----------------------------|---------------|-----------------------|-------------------------|
| * Adrenal Cortex | | Amyloid Deposition | Mild |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| * Liver | | Basophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| Mesentery | Fat | Necrosis | Minimal |
| [Necrosis TGLs = 2 - 13] | | | |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| [Adenoma TGLs = 1 - 8] | | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 271

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 631
HISTO: 0601751

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Brain |
| * Clitoral Gland | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Mammary Gland |
| * Nose | * Ovary | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Thyroid Gland | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|---|------------------------|-------------------------------|------------------|
| * Adrenal Cortex | | Leukemia Mononuclear | |
| * Bone Marrow | | Hyperplasia | Marked |
| * Heart | | Leukemia Mononuclear | |
| * Kidney | | Accumulation, Hyaline Droplet | Moderate |
| | | Leukemia Mononuclear | |
| | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Fatty Change | Diffuse, Minimal |
| | Bile Duct | Hyperplasia | Minimal |
| | | Leukemia Mononuclear | |
| * Lung | | Leukemia Mononuclear | |
| Lymph Node | Pancreatic | Leukemia Mononuclear | |
| | Mediastinal | Leukemia Mononuclear | |
| Note: Mediastinal lymph node lesion was present in B16 with thymus. | | | |
| | [Leukemia Mononuclear | TGLs = 5 - 15] | |
| * Lymph Node, Mesenteric | | Leukemia Mononuclear | |
| | [Leukemia Mononuclear | TGLs = 4 - 6] | |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma | TGLs = 1 - 14] | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 271

TMT: 4

SEX: Female

DAY ON TEST: 631

DOSE: 0.1 G/KG

DISP: Moribund Sacrifice

HISTO: 0601751

ORGAN AND ACCOUNTABLE SITE STATUS

* Spleen		Fibrosis	Minimal
		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 2 - 5]		
* Stomach, Forestomach		Erosion	Minimal
	Epithelium	Hyperplasia	Marked
		Inflammation	Moderate
	[Hyperplasia TGLs = 3 - 13]		
* Stomach, Glandular		Inflammation	Mild
	Epithelium	Necrosis	Mild
* Thymus		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 6 - 16]		

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 272

TMT: 4
 DOSE: 0.1 G/KG

SEX: Female
 DISP: Terminal Sacrifice

DAY ON TEST: 729
 HISTO: 0601752

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Nose	* Ovary
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
	[Eosinophilic Focus TGLs = 4 - 6+7+16]		
* Lung	Alveolar Epith	Hyperplasia	Marked
	Alveolar Epith	Hypertrophy	Mild
	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Mammary Gland		Fibroadenoma	
	[Fibroadenoma TGLs = 2 - 14]		
* Pancreas	Acinus	Hyperplasia	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Moderate
	[Hyperplasia TGLs = 1 - 13]		
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Uterus		Hemorrhage	Mild
	[Hemorrhage TGLs = 3 - 15]		

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 273

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Dosing Accident

DAY ON TEST: 51
HISTO: 0601753

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Liver	Inflammation	Chronic Active, Minimal
---------	--------------	-------------------------

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 274

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601754

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Parathyroid Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Urinary Bladder
* Uterus			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Hepatodiaphragmatic Nodule	
		Inflammation	Chronic Active, Minimal
	[Hepatodiaphragmatic Nodule TGLs = 1 - 13]		
* Ovary		Cyst	Minimal
* Pancreas		Atrophy	Mild
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 2 - 8]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 275

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601755

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lung |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Ovary |
| * Pancreas | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--|---------------|-------------------------|-------------------------|
| * Clitoral Gland | | Adenoma | |
| [Adenoma TGLs = 1 - 12] | | | |
| * Esophagus | | Hyperplasia | Minimal |
| | | Inflammation | Mild |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| [Basophilic Focus TGLs = 2 - 13] | | | |
| Oral Mucosa | | Squamous Cell Papilloma | |
| Note: Papilloma was present in the routine nose/turbinate section (B01). | | | |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| [Adenoma TGLs = 4 - 8] | | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Adenoma | |
| [Adenoma TGLs = 3 - 8] | | | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 276

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601756

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Minimal
* Kidney		Mineralization	Minimal
* Liver		Basophilic Focus	
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Ovary		Cyst	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 277

TMT: 4

SEX: Female

DAY ON TEST: 729

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601757

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Nose | * Ovary |
| * Pancreas | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|----------------------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| | [Basophilic Focus TGLs = 2 - 6+7+15] | | |
| | [Eosinophilic Focus TGLs = 3 - 14] | | |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | Alveolar Epith | Metaplasia | Squamous, Moderate |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 13] | | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Marked |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |
| | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 278

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601758

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mesenteric |
| * Nose | * Ovary | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|----------------------|--|----------------------------|-------------------------|
| * Clitoral Gland | | Adenoma | |
| * Heart | | Cardiomyopathy | Minimal |
| * Islets, Pancreatic | | Adenoma | |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | | Hepatodiaphragmatic Nodule | |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| | [Hepatodiaphragmatic Nodule TGLs = 3 - 14] | | |
| * Lung | | Inflammation | Chronic Active, Minimal |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 13] | | |
| Mesentery | Fat | Necrosis | Mild |
| | [Necrosis TGLs = 2 - 14] | | |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 278

TMT: 4

SEX: Female

DAY ON TEST: 728

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601758

ORGAN AND ACCOUNTABLE SITE STATUS

* Thyroid Gland

C Cell

Adenoma

* Uterus

Polyp Stromal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 279

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601759

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Nose | * Ovary |
| * Parathyroid Gland | * Salivary Glands | * Skin | * Stomach, Forestomach |
| * Stomach, Glandular | * Thyroid Gland | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--------------------------------------|----------------------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Minimal |
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| | [Eosinophilic Focus TGLs = 3 - 15] | | |
| * Mammary Gland | | Fibroadenoma | Multiple |
| | [Fibroadenoma TGLs = 1,2 - 13+14] | | |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Moderate |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |
| | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 280

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601760

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow	Hyperplasia	Minimal
* Heart	Cardiomyopathy	Minimal
* Kidney	Nephropathy	Minimal
* Liver	Basophilic Focus	
	Clear Cell Focus	
	Eosinophilic Focus	
	Inflammation	Chronic Active, Minimal
* Mammary Gland	Fibroadenoma	
[Fibroadenoma TGLs = 1 - 13]		
* Ovary	Cyst	Minimal
* Spleen	Hematopoietic Cell Proliferation	Minimal
	Pigmentation	Hemosiderin, Minimal
* Thymus	Atrophy	Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 281

TMT: 4

SEX: Female

DAY ON TEST: 729

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601761

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Nose	* Ovary	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
	[Eosinophilic Focus TGLs = 2 - 14+15]		
* Mammary Gland		Fibroadenoma	
	[Fibroadenoma TGLs = 1 - 13]		
Mesentery	Fat	Necrosis	Mild
	[Necrosis TGLs = 3 - 15]		
* Pancreas		Atrophy	Mild
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 282

TMT: 4

SEX: Female

DAY ON TEST: 729

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601762

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Ovary |
| * Pancreas | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Trachea | * Urinary Bladder |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|----------------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | | Hepatodiaphragmatic Nodule | |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| | [Basophilic Focus TGLs = 3 - 6+7+15] | | |
| | [Hepatodiaphragmatic Nodule TGLs = 4 - 13] | | |
| * Lung | Alveolar Epith | Metaplasia | Squamous, Minimal |
| * Nose | | Inflammation | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 1 - 8] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Adenoma | |
| * Uterus | | Polyp Stromal | |

Note: TGL-2 is also present in B11.

[Polyp Stromal TGLs = 2 - 14]

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 283

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 701
HISTO: 0601763

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Esophagus	* Eye	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Moderate
		Myelofibrosis	Mild
* Clitoral Gland		Adenoma	
	[Adenoma TGLs = 1 - 12]		
* Heart		Cardiomyopathy	Minimal
	Atrium	Thrombosis	Mild
* Kidney		Mineralization	Minimal
* Liver		Basophilic Focus	
	Bile Duct	Fatty Change	Diffuse, Mild
		Hyperplasia	Mild
		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 3 - 6+7+13]		
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
		Leukemia Mononuclear	
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 2 - 13]		
* Thymus		Atrophy	Moderate

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 284

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 688
HISTO: 0601764

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Salivary Glands
* Skin	* Stomach, Glandular	* Trachea	* Urinary Bladder
* Uterus			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Ovary		Cyst	Marked
	[Cyst TGLs = 2 - 11]		
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 1 - 8]		
* Spleen	Lymph Follic	Atrophy	Mild
		Pigmentation	Hemosiderin, Mild
* Stomach, Forestomach		Inflammation	Minimal
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Moderate

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 285

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 615
HISTO: 0601765

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Esophagus	* Eye	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Clitoral Gland	* Lymph Node, Mandibular
------------------	--------------------------

OBSERVATIONS

* Adrenal Cortex		Hypertrophy	Minimal
* Bone Marrow		Hyperplasia	Moderate
* Heart		Cardiomyopathy	Mild
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Mammary Gland		Fibroadenoma	
	[Fibroadenoma TGLs = 1 - 13]		
* Spleen		Hematopoietic Cell Proliferation	Mild
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

PRIMARY CAUSE OF DEATH - Mammary Gland Fibroadenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 286

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601766

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Mild
* Clitoral Gland		Hyperplasia	Mild
* Eye	Lens	Cataract	Mild
	Retina	Degeneration	Moderate
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
	[Basophilic Focus TGLs = 1 - 6+7+13]		
* Pancreas	Acinus	Metaplasia	Hepatocyte, Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 287

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 605
HISTO: 0601767

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Clitoral Gland	* Esophagus
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Leukemia Mononuclear	
* Adrenal Medulla		Leukemia Mononuclear	
* Bone Marrow		Hyperplasia	Marked
* Brain		Hemorrhage	Moderate
		Leukemia Mononuclear	
		Necrosis	Moderate
* Eye	Retina	Degeneration	Mild
	Retina	Inflammation	Minimal
* Heart		Leukemia Mononuclear	
* Kidney		Leukemia Mononuclear	
		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Fatty Change	Diffuse, Mild
	Bile Duct	Hyperplasia	Mild
	Oval Cell	Hyperplasia	Mild
		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 2 - 6+7]		
* Lung		Inflammation	Chronic Active, Minimal
		Leukemia Mononuclear	
Lymph Node	Pancreatic	Leukemia Mononuclear	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 287

TMT: 4

SEX: Female

DAY ON TEST: 605

DOSE: 0.1 G/KG

DISP: Moribund Sacrifice

HISTO: 0601767

ORGAN AND ACCOUNTABLE SITE STATUS

	Mediastinal	Leukemia Mononuclear	
[Leukemia Mononuclear	TGLs = 5 - 16]		
[Leukemia Mononuclear	TGLs = 3 - 14]		
* Lymph Node, Mesenteric		Leukemia Mononuclear	
[Leukemia Mononuclear	TGLs = 4 - 15]		
* Spleen		Fibrosis	Mild
		Leukemia Mononuclear	
[Leukemia Mononuclear	TGLs = 1 - 13]		
* Thymus		Leukemia Mononuclear	

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

CONTRIBUTORY CAUSE OF DEATH - Brain Necrosis

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 288

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 5
HISTO: 0601768

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Heart | * Intestine Large, Cecum |
| * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic | * Kidney | * Liver |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Ovary |
| * Pancreas | * Parathyroid Gland | * Pituitary Gland | * Salivary Glands |
| * Skin | * Spleen | * Stomach, Forestomach | * Stomach, Glandular |
| * Thymus | * Thyroid Gland | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | |
|--------|-------------|--------|
| * Lung | Atelectasis | Marked |
|--------|-------------|--------|
- Note: The atelectasis was associated with gross chylothorax.

PRIMARY CAUSE OF DEATH - Lung Atelectasis

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 289

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601769

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Ovary | * Pancreas | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---------------------------------|-----------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Fatty Change | Diffuse, Minimal |
| | Hepatocyte | Hypertrophy | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | | Necrosis | Minimal |
| | [Hypertrophy TGLs = 2 - 6+7] | | |
| * Lung | | Hyperplasia | Minimal |
| | Alveolar Epith | Infiltration Cellular | Histiocyte, Minimal |
| | Alveolus | Hyperplasia | Mild |
| * Pituitary Gland | | | |
| | Pars Distalis | | |
| | [Hyperplasia TGLs = 3 - 8] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |
| * Uterus | | Polyp Stromal | |
| | [Polyp Stromal TGLs = 1 - 11] | | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 290

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 632
HISTO: 0601770

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lymph Node, Mesenteric |
| * Ovary | * Parathyroid Gland | * Pituitary Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | * Uterus | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------|--------------------------------------|----------------------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Moderate |
| * Clitoral Gland | | Inflammation | Mild |
| | [Inflammation TGLs = 2 - 12] | | |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | | Fatty Change | Diffuse, Minimal |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 13] | | |
| Mesentery | Fat | Necrosis | Moderate |
| | [Necrosis TGLs = 3,4,5 - 14+15+16] | | |
| * Nose | | Inflammation | Minimal |
| * Pancreas | | Atrophy | Minimal |
| * Spleen | | Hematopoietic Cell Proliferation | Moderate |
| * Thymus | | Atrophy | Moderate |

PRIMARY CAUSE OF DEATH - Mammary Gland Fibroadenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 291

TMT: 4

SEX: Female

DAY ON TEST: 730

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601771

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lung |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Ovary |
| * Pancreas | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---------------------------------|--------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Minimal |
| * Eye | Lens | Cataract | Moderate |
| | Retina | Degeneration | Marked |
| | [Cataract TGLs = 1 - 10] | | |
| * Heart | | Cardiomyopathy | Minimal |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| Mesentery | Fat | Necrosis | Mild |
| | [Necrosis TGLs = 3 - 13] | | |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 4 - 14] | | |
| * Spleen | | Pigmentation | Hemosiderin, Mild |
| * Thymus | | Atrophy | Moderate |
| * Uterus | | Polyp Stromal | |
| | [Polyp Stromal TGLs = 2 - 11] | | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 292

TMT: 4
 DOSE: 0.1 G/KG

SEX: Female
 DISP: Terminal Sacrifice

DAY ON TEST: 729
 HISTO: 0601772

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | Blood Vessel | * Bone | * Brain |
| * Clitoral Gland | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lymph Node, Mesenteric |
| * Nose | * Pancreas | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---|----------------------------|------------------------------|
| * Adrenal Medulla | | Pheochromocytoma Malignant | |
| | [Pheochromocytoma Malignant TGLs = 5 - 17] | | |
| * Bone Marrow | | Hyperplasia | Moderate |
| * Heart | | Cardiomyopathy | Moderate |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | Serosa | Fibrosis | Mild |
| | | Hepatodiaphragmatic Nodule | |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| | | Pheochromocytoma Malignant | Metastatic (Adrenal Medulla) |
| | [Eosinophilic Focus TGLs = 12, 15 - 7+21+22] | | |
| | [Fibrosis TGLs = 10 - 18] | | |
| | [Hepatodiaphragmatic Nodule TGLs = 11 - 16] | | |
| | [Pheochromocytoma Malignant TGLs = 8,9 - 18+19] | | |
| * Lung | | Carcinoma | Metastatic (Mammary Gland) |
| | | Pheochromocytoma Malignant | Metastatic (Adrenal Medulla) |

Note: One metastasis in B04 appears similar to areas of the mammary carcinoma.

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 292

TMT: 4

SEX: Female

DAY ON TEST: 729

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601772

ORGAN AND ACCOUNTABLE SITE STATUS

[Pheochromocytoma Malignant TGLs = 6,7 - 3+4+20]			
* Mammary Gland		Adenoma Carcinoma Fibroadenoma	
[Adenoma TGLs = 2 - 14]			
[Carcinoma TGLs = 3 - 15]			
[Fibroadenoma TGLs = 1 - 13]			
Mesentery	Fat	Necrosis	Mild
[Necrosis TGLs = 4 - 16]			
* Ovary		Cyst	Mild
* Pituitary Gland	Pars Distalis	Adenoma	
[Adenoma TGLs = 13 - 8]			
* Spleen		Hematopoietic Cell Proliferation Pigmentation	Mild Hemosiderin, Minimal
* Stomach, Forestomach		Inflammation	Minimal
* Thymus		Atrophy	Moderate
* Uterus	Endometrium	Hyperplasia Polyp Stromal	Cystic, Minimal
[Polyp Stromal TGLs = 16 - 11]			

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 293

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 705
HISTO: 0601773

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Nose | * Ovary | * Pancreas |
| * Parathyroid Gland | * Salivary Glands | * Skin | * Stomach, Forestomach |
| * Stomach, Glandular | * Thyroid Gland | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--------------------------------|----------------------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Moderate |
| * Heart | | Cardiomyopathy | Minimal |
| * Kidney | | Mineralization | Minimal |
| * Liver | | Basophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 13] | | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |
| | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Mild |

PRIMARY CAUSE OF DEATH - Mammary Gland Fibroadenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 294

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601774

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Nose	* Ovary	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Mild
* Heart		Cardiomyopathy	Marked
* Kidney		Mineralization	Minimal
* Liver	Bile Duct	Basophilic Focus	
		Hyperplasia	Mild
		Inflammation	Chronic Active, Minimal
		Leukemia Mononuclear	
* Lung	Alveolar Epith	Hyperplasia	Moderate
	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Mammary Gland		Fibroadenoma	Multiple
	[Fibroadenoma TGLs = 1,2 - 13+14]		
* Pancreas	Acinus	Hyperplasia	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 3 - 8]		
* Spleen		Leukemia Mononuclear	
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Minimal
Tooth		Malformation	Mild

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 295

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601775

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Bone Marrow |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Nose | * Pancreas |
| * Parathyroid Gland | * Salivary Glands | * Skin | * Stomach, Forestomach |
| * Stomach, Glandular | * Thyroid Gland | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--------------------------------|--------------------|-------------------------|
| * Adrenal Cortex | | Hypertrophy | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Infarct | Mild |
| | Pelvis | Inflammation | Minimal |
| | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| | [Infarct TGLs = 2,3 - 5+14] | | |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 13] | | |
| * Ovary | | Cyst | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 296

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601776

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Bone Marrow |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Nose | * Ovary |
| * Pancreas | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex | | Degeneration | Cystic, Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Hepatodiaphragmatic Nodule | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| | [Basophilic Focus TGLs = 3 - 15] | | |
| | [Hepatodiaphragmatic Nodule TGLs = 2 - 14] | | |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 13] | | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |
| | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 297

TMT: 4

SEX: Female

DAY ON TEST: 632

DOSE: 0.1 G/KG

DISP: Moribund Sacrifice

HISTO: 0601777

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | Blood Vessel | * Bone | * Brain |
| * Clitoral Gland | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lung |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Ovary |
| * Parathyroid Gland | * Salivary Glands | * Skin | * Stomach, Forestomach |
| * Stomach, Glandular | * Trachea | * Urinary Bladder | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---|-------------------------------|----------|
| * Adrenal Medulla | | Necrosis | Marked |
| * Bone Marrow | | Hyperplasia | Moderate |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Accumulation, Hyaline Droplet | Moderate |
| | | Glomerulosclerosis | Minimal |
| | | Leukemia Mononuclear | |
| | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Leukemia Mononuclear | |
| | [Leukemia Mononuclear TGLs = 4 - 6+7] | | |
| * Pancreas | | Atrophy | Moderate |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| | [Hyperplasia TGLs = 1 - 13] | | |
| * Spleen | | Leukemia Mononuclear | |
| | [Leukemia Mononuclear TGLs = 3 - 5] | | |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Hyperplasia | Moderate |
| * Uterus | | Polyp Stromal | |
| | [Polyp Stromal TGLs = 2 - 14] | | |

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 297

TMT: 4

SEX: Female

DAY ON TEST: 632

DOSE: 0.1 G/KG

DISP: Moribund Sacrifice

HISTO: 0601777

ORGAN AND ACCOUNTABLE SITE STATUS

CONTRIBUTORY CAUSE OF DEATH - Adrenal Medulla Necrosis

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 298

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601778

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Mild
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Mammary Gland		Carcinoma	
	[Carcinoma TGLs = 1 - 13]		
* Ovary		Cyst	Moderate
	[Cyst TGLs = 2 - 11]		
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 299

TMT: 4

SEX: Female

DAY ON TEST: 730

DOSE: 0.1 G/KG

DISP: Terminal Sacrifice

HISTO: 0601779

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Clitoral Gland		Adenoma	
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
	[Basophilic Focus TGLs = 1 - 6+7+13]		
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 300

TMT: 4
DOSE: 0.1 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601780

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Brain |
| * Clitoral Gland | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lymph Node, Mesenteric |
| * Nose | * Ovary | * Pancreas | * Parathyroid Gland |
| * Salivary Glands | * Skin | * Stomach, Forestomach | * Stomach, Glandular |
| * Thyroid Gland | * Trachea | * Urinary Bladder | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|-----------------------|-------------------------|
| * Adrenal Cortex | | Carcinoma | |
| | [Carcinoma TGLs = 2 - 14] | | |
| * Bone Marrow | | Hyperplasia | Mild |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Fatty Change | Diffuse, Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| | [Eosinophilic Focus TGLs = 3 - 6+7+15] | | |
| * Lung | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 13] | | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Marked |
| * Uterus | Endometrium | Hyperplasia | Cystic, Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 301

TMT: 6
 DOSE: 0.3 G/KG

SEX: Female
 DISP: Moribund Sacrifice

DAY ON TEST: 705
 HISTO: 0601781

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mesenteric | * Mammary Gland |
| * Nose | * Ovary | * Pancreas | * Pituitary Gland |
| * Salivary Glands | * Skin | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | | |

MISSING

- | | |
|--------------------------|---------------------|
| * Lymph Node, Mandibular | * Parathyroid Gland |
|--------------------------|---------------------|

OBSERVATIONS

- | | | | |
|---|---------------------------------------|-------------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Marked |
| * Eye | Retina | Degeneration | Moderate |
| | Cornea | Inflammation | Mild |
| | | Synechia | Marked |
| Note: Lens is absent from the affected eye. | | | |
| [Inflammation TGLs = 1 - 10] | | | |
| * Heart | | Cardiomyopathy | Mild |
| * Islets, Pancreatic | | Hyperplasia | Mild |
| * Kidney | | Mineralization | Minimal |
| * Liver | | Basophilic Focus | |
| | Bile Duct | Hyperplasia | Moderate |
| | Oval Cell | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | | Leukemia Mononuclear | |
| | [Leukemia Mononuclear TGLs = 4-14] | | |
| * Lung | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| | | Leukemia Mononuclear | |
| Lymph Node | Mediastinal | Leukemia Mononuclear | |
| | [Leukemia Mononuclear TGLs = 2 -13] | | |
| Oral Mucosa | | Squamous Cell Papilloma | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 301

TMT: 6

SEX: Female

DAY ON TEST: 705

DOSE: 0.3 G/KG

DISP: Moribund Sacrifice

HISTO: 0601781

ORGAN AND ACCOUNTABLE SITE STATUS

Note: Papilloma was present in the routine section of nose (B01).

* Spleen		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 3 - 5]		
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Mild
* Thymus		Atrophy	Moderate
Tooth		Malformation	Minimal
* Uterus		Polyp Stromal	

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 302

TMT: 6

SEX: Female

DAY ON TEST: 730

DOSE: 0.3 G/KG

DISP: Terminal Sacrifice

HISTO: 0601782

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Parathyroid Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Brain		Necrosis	Mild
Note: Cavitation in the cerebrum is evidence of a (healed) area of necrosis.			
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Inflammation	Chronic Active, Minimal
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
[Adenoma TGLs = 2 - 8]			
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Mild
* Uterus		Polyp Stromal	
[Polyp Stromal TGLs = 1 - 13]			

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 303

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Dosing Accident

DAY ON TEST: 98
HISTO: 0601783

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Intestine Large, Colon	Parasite Metazoan	
* Kidney	Mineralization	Minimal
* Liver	Inflammation	Chronic Active, Minimal
* Spleen	Pigmentation	Hemosiderin, Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 304

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 628
HISTO: 0601784

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Minimal
* Kidney		Mineralization	Minimal
* Liver		Basophilic Focus	
		Inflammation	Chronic Active, Minimal
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Mammary Gland		Fibroadenoma	
	[Fibroadenoma TGLs = 1 - 13]		
* Nose		Inflammation	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 2 - 8]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

CONTRIBUTORY CAUSE OF DEATH - Mammary Gland Fibroadenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 305

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 532
HISTO: 0601785

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Ovary | * Pancreas | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | * Uterus | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---|--------------------|-------------------------|
| * Eye | Cornea | Inflammation | Marked |
| | Note: Cornea is perforated.
[Inflammation TGLs = 4 - 10] | | |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | | Fatty Change | Diffuse, Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| | [Eosinophilic Focus TGLs = 1,3 - 13+15] | | |
| | [Mixed Cell Focus TGLs = 2 - 14] | | |
| Mesentery | Fat | Necrosis | Mild |
| | [Necrosis TGLs = 6 - 16] | | |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | Note: There was no corresponding finding for the white focus in the pituitary - perhaps it represented the neurohypophysis.
[Adenoma TGLs = 5 - 8] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 305

TMT: 6

SEX: Female

DAY ON TEST: 532

DOSE: 0.3 G/KG

DISP: Moribund Sacrifice

HISTO: 0601785

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Atrophy

Moderate

PRIMARY CAUSE OF DEATH

- Eye Cornea Inflammation

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 306

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 519
HISTO: 0601786

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Trachea
* Urinary Bladder	* Uterus		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Medulla		Pheochromocytoma Benign	
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Inflammation	Chronic Active, Minimal
* Pancreas		Atrophy	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Thyroid Gland	Follicular Cel	Adenoma	
	[Adenoma TGLs = 1 - 8]		

PRIMARY CAUSE OF DEATH - Thyroid Gland Follicular Cel Adenoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 307

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 615
HISTO: 0601787

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lung |
| * Lymph Node, Mesenteric | * Nose | * Ovary | * Pancreas |
| * Parathyroid Gland | * Pituitary Gland | * Salivary Glands | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | |
|--------------------------|------------------------------------|-------------------------|
| * Bone Marrow | Hyperplasia | Mild |
| * Heart | Cardiomyopathy | Mild |
| * Intestine Large, Colon | Parasite Metazoan | |
| * Kidney | Mineralization | Minimal |
| | Nephropathy | Minimal |
| * Liver | Basophilic Focus | |
| | Eosinophilic Focus | |
| | Fatty Change | Diffuse, Minimal |
| | Inflammation | Chronic Active, Minimal |
| | [Basophilic Focus TGLs = 2 - 14] | |
| * Mammary Gland | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 13] | |
| * Spleen | Hematopoietic Cell Proliferation | Minimal |
| | Pigmentation | Hemosiderin, Minimal |
| * Thymus | Atrophy | Moderate |

PRIMARY CAUSE OF DEATH - Mammary Gland Fibroadenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 308

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 618
HISTO: 0601788

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Nose	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Inflammation	Histiocytic, Mild
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Inflammation	Chronic Active, Mild
		Pigmentation	Hemosiderin, Minimal
* Mammary Gland		Fibroadenoma	
	[Fibroadenoma TGLs = 1 - 14]		
* Ovary		Cyst	Marked
	[Cyst TGLs = 2 - 11]		
* Pancreas		Atrophy	Marked
	[Atrophy TGLs = 5 - 13]		
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 3 - 8]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Hyperplasia	Histiocytic, Moderate
		Pigmentation	Hemosiderin, Minimal
	[Hyperplasia TGLs = 4 - 13]		
* Thymus		Atrophy	Marked

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 308

TMT: 6

SEX: Female

DAY ON TEST: 618

DOSE: 0.3 G/KG

DISP: Moribund Sacrifice

HISTO: 0601788

ORGAN AND ACCOUNTABLE SITE STATUS

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma
CONTRIBUTORY CAUSE OF DEATH - Pancreas Atrophy

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 309

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601789

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Ovary | * Parathyroid Gland | * Salivary Glands | * Stomach, Forestomach |
| * Stomach, Glandular | * Thyroid Gland | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|-------------------------------------|----------------------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| | [Basophilic Focus TGLs = 2 - 6+7] | | |
| * Lung | Alveolar Epith | Hyperplasia | Mild |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 3 - 8] | | |
| * Skin | Epidermis | Hyperkeratosis | Mild |
| | [Hyperkeratosis TGLs = 1 - 13] | | |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |
| | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 310

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 681
HISTO: 0601790

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Clitoral Gland		Hyperplasia	Mild
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Nose	Respirat Epith	Hyperplasia	Mild
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

PRIMARY CAUSE OF DEATH - Heart Cardiomyopathy

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 311

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601791

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Parathyroid Gland |
| * Salivary Glands | * Skin | * Stomach, Forestomach | * Stomach, Glandular |
| * Trachea | * Urinary Bladder | * Uterus | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|---|---------------------------------------|----------------------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Intestine Large, Colon | | Parasite Metazoan | |
| * Kidney | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| | [Eosinophilic Focus TGLs = 1 - 6+7] | | |
| * Lung | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| * Mammary GI | | | |
| Note: TGLs 1 and 2 = abundant fat within mammary gland and subcutis but no evidence for neoplasm (no corresponding microscopic lesion). | | | |
| * Ovary | | Cyst | Minimal |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |
| | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Adenoma | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 312

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601792

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Nose | * Ovary |
| * Pancreas | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- | | |
|--------------------------|----------|
| * Lymph Node, Mandibular | * Thymus |
|--------------------------|----------|

OBSERVATIONS

- | | | | |
|-------------------|------------------------------------|----------------------------------|----------------------|
| * Bone Marrow | | Hyperplasia | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | Pelvis, Transit Epithe | Hyperplasia | Minimal |
| | Pelvis | Inflammation | Minimal |
| | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Fatty Change | Diffuse, Minimal |
| | Bile Duct | Hyperplasia | Minimal |
| | | Mixed Cell Focus | |
| | [Mixed Cell Focus TGLs = 2 - 14] | | |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 13] | | |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 3 - 8] | | |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |
| | | Pigmentation | Hemosiderin, Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 313

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601793

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Pancreas |
| * Parathyroid Gland | * Salivary Glands | * Skin | * Stomach, Glandular |
| * Thyroid Gland | * Trachea | * Urinary Bladder | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|--|----------------------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| | [Mixed Cell Focus TGLs = 2 - 6+7+13] | | |
| * Lung | Alveolar Epith | Hyperplasia | Mild |
| | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| * Ovary | | Cyst | Marked |
| | [Cyst TGLs = 1 - 11] | | |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 3 - 14] | | |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |
| | | Pigmentation | Hemosiderin, Mild |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Minimal |
| * Thymus | | Atrophy | Moderate |
| * Uterus | | Polyp Stromal | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 314

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Dosing Accident

DAY ON TEST: 539
HISTO: 0601794

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Esophagus		Inflammation	Moderate
		Perforation	Marked
	[Perforation TGLs = 3 - 14]		
* Heart		Cardiomyopathy	Minimal
* Intestine Large, Colon		Parasite Metazoan	
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
	[Basophilic Focus TGLs = 1 - 6+7]	Inflammation	Chronic Active, Minimal
* Nose		Inflammation	Moderate
* Pituitary Gland		Cyst	Minimal
	Pars Distalis	Hyperplasia	Minimal
	[Cyst TGLs = 2 - 13]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
		Inflammation	Mild
	[Inflammation TGLs = 4 - 3]		
* Trachea	Peritrach Tiss	Inflammation	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 315

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 439
HISTO: 0601795

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Heart | * Intestine Large, Cecum |
| * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic | * Liver | * Lung |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Ovary |
| * Pancreas | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|----------------------------------|----------------|-------------------|
| * Kidney | | Mineralization | Minimal |
| | Renal Tubule | Necrosis | Moderate |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Moderate |
| | [Hyperplasia TGLs = 4 - 8] | | |
| * Spleen | Lymph Follic | Atrophy | Mild |
| | [Atrophy TGLs = 2 - 5] | Pigmentation | Hemosiderin, Mild |
| * Thymus | | Atrophy | Marked |
| | [Atrophy TGLs = 3 - 3] | | |
| * Uterus | Endometrium | Carcinosarcoma | |
| | [Carcinosarcoma TGLs = 1 - 13] | Hyperplasia | Cystic, Marked |
| | [Hyperplasia TGLs = 6 - 11] | | |

PRIMARY CAUSE OF DEATH - Uterus Carcinosarcoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 316

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 652
HISTO: 0601796

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Salivary Glands	* Skin
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular	* Parathyroid Gland
--------------------------	---------------------

OBSERVATIONS

* Eye	Lens	Cataract	Marked
	Retina	Degeneration	Marked
	[Cataract TGLs = 1 - 10]		
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
* Liver		Basophilic Focus	
		Inflammation	Chronic Active, Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach		Erosion	Minimal
* Stomach, Glandular		Amyloid Deposition	Mild
* Thymus		Atrophy	Moderate

PRIMARY CAUSE OF DEATH - Heart Cardiomyopathy

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 317

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 688
HISTO: 0601797

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Ovary |
| * Pancreas | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Glandular | * Thyroid Gland | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--|---------------|--------------------|-------------------------|
| * Clitoral Gland | | Adenoma | |
| [Adenoma TGLs = 1 - 12] | | | |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| [Eosinophilic Focus TGLs = 4,5,6 - 14+15+16] | | | |
| [Mixed Cell Focus TGLs = 3 - 13] | | | |
| * Lung | | Inflammation | Chronic Active, Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| [Adenoma TGLs = 2 - 8] | | | |
| * Spleen | Lymph Follic | Atrophy | Mild |
| | | Pigmentation | Hemosiderin, Mild |
| * Stomach, Forestomach | | Erosion | Minimal |
| | Epithelium | Hyperplasia | Mild |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 317

TMT: 6

SEX: Female

DAY ON TEST: 688

DOSE: 0.3 G/KG

DISP: Moribund Sacrifice

HISTO: 0601797

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Inflammation
Atrophy

Mild
Moderate

PRIMARY CAUSE OF DEATH

- Pituitary Gland Pars Distalis Adenoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 318

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601798

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Parathyroid Gland	* Salivary Glands	* Skin
* Spleen	* Stomach, Glandular	* Trachea	* Urinary Bladder
* Uterus			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Degeneration	Cystic, Mild
* Bone Marrow		Hyperplasia	Moderate
* Heart		Cardiomyopathy	Mild
* Kidney		Accumulation, Hyaline Droplet	Mild
		Mineralization	Minimal
* Liver		Fatty Change	Diffuse, Mild
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Nose	Glands	Dilatation	Moderate
		Inflammation	Moderate
	Olfactory Epi	Metaplasia	Moderate
* Ovary		Cyst	Moderate
	[Cyst TGLs = 1 - 11]		
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
Skeletal Muscle		Rhabdomyosarcoma	
	[Rhabdomyosarcoma TGLs = 2 - 13]		
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Moderate
		Ulcer	Mild

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 318

TMT: 6

SEX: Female

DAY ON TEST: 728

DOSE: 0.3 G/KG

DISP: Terminal Sacrifice

HISTO: 0601798

ORGAN AND ACCOUNTABLE SITE STATUS

[Ulcer TGLs = 3 - 14]

* Thymus

Atrophy

Marked

* Thyroid Gland

C Cell

Adenoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 319

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601799

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Clitoral Gland		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
	[Eosinophilic Focus TGLs = 3 - 6+7+14]		
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Mammary Gland		Fibroadenoma	
	[Fibroadenoma TGLs = 1 - 13]		
* Pituitary Gland	Pars Distalis	Adenoma	
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal
		Polyp Stromal	
	[Polyp Stromal TGLs = 2 - 11]		

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 320

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601800

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Nose	* Ovary
* Parathyroid Gland	* Salivary Glands	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
	[Eosinophilic Focus TGLs = 4 - 6+7+16]		
* Mammary Gland		Carcinoma	
		Hyperplasia	Moderate
	[Carcinoma TGLs = 2 - 14]		
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 3 - 15]		
* Skin	Subcut Tiss	Lipoma	
	Note: Lipoma is largely necrotic.		
	[Lipoma TGLs = 1 - 13]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 321

TMT: 6
 DOSE: 0.3 G/KG

SEX: Female
 DISP: Terminal Sacrifice

DAY ON TEST: 729
 HISTO: 0601801

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric |
| * Mammary Gland | * Ovary | * Pancreas | * Parathyroid Gland |
| * Salivary Glands | * Skin | * Spleen | * Stomach, Forestomach |
| * Stomach, Glandular | * Trachea | * Urinary Bladder | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--------------------------|-------------------------------------|--------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Moderate |
| * Clitoral Gland | | Adenoma | |
| | [Adenoma TGLs = 1 - 13] | | |
| * Heart | | Cardiomyopathy | Mild |
| * Intestine Large, Colon | | Parasite Metazoan | |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| | [Basophilic Focus TGLs = 3 - 6+7] | | |
| * Nose | | Inflammation | Minimal |
| * Pituitary Gland | Pars Distalis | Angiectasis | Mild |
| | [Angiectasis TGLs = 2 - 8] | | |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | Follicular Cel | Hyperplasia | Mild |
| * Uterus | Endometrium | Hyperplasia | Adenomatous, Mild |
| | Stroma | Hyperplasia | Moderate |

Note: "Reticulum cell hyperplasia" was diagnosed for a lesion that does not protrude but has the cellular morphology of a stromal polyp (inverted polyp?).

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 322

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601802

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney	* Lung
* Lymph Node, Mesenteric	* Nose	* Ovary	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Degeneration	Cystic, Minimal
* Bone		Osteosarcoma	
Note: Osteosarcoma in femur.			
* Eye	Retina	Degeneration	Mild
* Heart		Cardiomyopathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
[Basophilic Focus TGLs = 1 - 6+7+14]			
* Mammary Gland		Fibroadenoma	
[Fibroadenoma TGLs = 2 - 13]			
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 323

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 518
HISTO: 0601803

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular	* Parathyroid Gland
--------------------------	---------------------

OBSERVATIONS

* Bone Marrow		Hyperplasia	Moderate
* Heart		Cardiomyopathy	Mild
* Kidney		Infarct	Moderate
		Leukemia Mononuclear	
		Mineralization	Minimal
		Nephropathy	Minimal
	[Infarct TGLs = 4 - 15]		
* Liver		Leukemia Mononuclear	
* Lung		Leukemia Mononuclear	
Lymph Node	Pancreatic	Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 3 - 14]		
* Lymph Node, Mesenteric		Leukemia Mononuclear	
* Pituitary Gland	Pars Distalis	Adenoma	
* Spleen		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 2 - 13]		
* Thymus		Atrophy	Mild

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 324

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601804

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Nose | * Ovary | * Parathyroid Gland |
| * Salivary Glands | * Skin | * Stomach, Forestomach | * Stomach, Glandular |
| * Thyroid Gland | * Trachea | * Urinary Bladder | * Uterus |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--------------------------------|--------------------|-------------------|
| * Clitoral Gland | | Hyperplasia | Mild |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 13] | | |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 2 - 8] | | |
| * Spleen | | Pigmentation | Hemosiderin, Mild |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 325

TMT: 6

SEX: Female

DAY ON TEST: 730

DOSE: 0.3 G/KG

DISP: Terminal Sacrifice

HISTO: 0601805

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Degeneration	Cystic, Minimal
* Heart		Cardiomyopathy	Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
* Lung		Alveolar/Bronchiolar Adenoma	Multiple
	Alveolar Epith	Hyperplasia	Marked
	Alveolus	Infiltration Cellular	Histiocyte, Minimal
Note: TGL-1 is present in B04 and B13; B04 has a second adenoma. B03 has hyperplasia.			
	[Alveolar/Bronchiolar Adenoma	TGLs = 1 - 13]	
* Pituitary Gland	Pars Distalis	Adenoma	
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 326

TMT: 6
 DOSE: 0.3 G/KG

SEX: Female
 DISP: Terminal Sacrifice

DAY ON TEST: 730
 HISTO: 0601806

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Nose | * Ovary | * Parathyroid Gland |
| * Salivary Glands | * Skin | * Spleen | * Stomach, Forestomach |
| * Stomach, Glandular | * Thyroid Gland | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|-------------------------------------|-----------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Mild |
| * Heart | | Cardiomyopathy | Minimal |
| * Kidney | Renal Tubule | Dilatation | Mild |
| | Pelvis, Transit Epithe | Hyperplasia | Mild |
| | | Infarct | Mild |
| | Pelvis | Inflammation | Mild |
| | Pelvis, Transit Epithe | Metaplasia | Mild |
| | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| * Lung | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| * Mammary Gland | | Fibroadenoma | Multiple |
| | [Fibroadenoma TGLs = 1,2 - 13+14] | | |
| Mesentery | Fat | Necrosis | Mild |
| | [Necrosis TGLs = 3 - 15] | | |
| * Pancreas | | Atrophy | Mild |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 326

TMT: 6

SEX: Female

DAY ON TEST: 730

DOSE: 0.3 G/KG

DISP: Terminal Sacrifice

HISTO: 0601806

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Atrophy

Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 327

TMT: 6
 DOSE: 0.3 G/KG

SEX: Female
 DISP: Moribund Sacrifice

DAY ON TEST: 629
 HISTO: 0601807

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| Blood Vessel | * Bone | * Clitoral Gland | * Esophagus |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Mammary Gland | * Nose | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--------------------------|--|-----------------------------|---------|
| * Adrenal Cortex | | Leukemia Mononuclear | |
| * Adrenal Medulla | | Leukemia Mononuclear | |
| * Bone Marrow | | Hyperplasia | Marked |
| * Brain | | Hemorrhage | Minimal |
| | | Necrosis | Mild |
| * Eye | Retina | Dysplasia | Mild |
| * Heart | | Leukemia Mononuclear | |
| * Kidney | | Leukemia Mononuclear | |
| | | Nephropathy | Minimal |
| * Liver | | Leukemia Mononuclear | |
| * Lung | | Leukemia Mononuclear | |
| Lymph Node | Mediastinal | Leukemia Mononuclear | |
| | [Leukemia Mononuclear TGLs = 5 - 16] | | |
| * Lymph Node, Mesenteric | | Leukemia Mononuclear | |
| | [Leukemia Mononuclear TGLs = 6 - 19] | | |
| * Ovary | | Granulosa Cell Tumor Benign | |
| | [Granulosa Cell Tumor Benign TGLs = 4 - 18] | | |
| * Pancreas | | Leukemia Mononuclear | |
| Peripheral Nerve | Trigeminal | Leukemia Mononuclear | |
| | Note: Sciatic nerve appeared normal (sampled as per protocol, because animal was paralysed). Trigeminal nerve lesion was in routine nasal section. | | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 327

TMT: 6

SEX: Female

DAY ON TEST: 629

DOSE: 0.3 G/KG

DISP: Moribund Sacrifice

HISTO: 0601807

ORGAN AND ACCOUNTABLE SITE STATUS

[Hyperplasia TGLs = 3 - 17]

Spinal Cord

Hemorrhage

Moderate

Necrosis

Mild

Note: Spinal cord sampled as per protocol, because animal was paralysed.

* Spleen

Accessory Spleen

Leukemia Mononuclear

[Accessory Spleen TGLs = 2 - 16]

[Leukemia Mononuclear TGLs = 1 - 5+16]

* Thymus

Leukemia Mononuclear

* Thyroid Gland

C Cell

Hyperplasia

Moderate

Tooth

Malformation

Minimal

* Urinary Bladder

Leukemia Mononuclear

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 328

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601808

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric | * Mammary Gland |
| * Nose | * Ovary | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland |
| * Trachea | * Urinary Bladder | * Uterus | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | |
|--|--|-------------------------|
| * Heart | Cardiomyopathy | Minimal |
| * Kidney | Mineralization | Minimal |
| | Nephropathy | Minimal |
| * Liver | Basophilic Focus | |
| | Clear Cell Focus | |
| | Eosinophilic Focus | |
| | Fatty Change | Diffuse, Minimal |
| | Inflammation | Chronic Active, Minimal |
| | [Eosinophilic Focus TGLs = 1 - 6+7+13] | |
| * Pancreas | Adenoma | Mixed Cell |
| Note: 1 mm length mixed islet-acinar adenoma is present. | | |
| * Pituitary Gland | Pars Distalis | Mild |
| * Spleen | Hyperplasia | Hemosiderin, Minimal |
| * Thymus | Pigmentation | Moderate |
| | Atrophy | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 329

TMT: 6
 DOSE: 0.3 G/KG

SEX: Female
 DISP: Moribund Sacrifice

DAY ON TEST: 705
 HISTO: 0601809

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Harderian Gland |
| * Heart | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Ovary | * Pancreas | * Parathyroid Gland | * Pituitary Gland |
| * Salivary Glands | * Skin | * Stomach, Forestomach | * Stomach, Glandular |
| * Thyroid Gland | * Trachea | * Urinary Bladder | * Uterus |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|---------------|---------------------------------|----------------------|----------------------|
| * Bone Marrow | | Hyperplasia | Moderate |
| | | Myelofibrosis | Mild |
| * Eye | Retina | Degeneration | Minimal |
| * Kidney | | Mineralization | Minimal |
| * Liver | | Fatty Change | Diffuse, Moderate |
| | Bile Duct | Hyperplasia | Mild |
| | Oval Cell | Hyperplasia | Minimal |
| | | Leukemia Mononuclear | |
| | [Fatty Change TGLs = 1 - 6+7] | | |
| * Spleen | | Leukemia Mononuclear | |
| | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

CONTRIBUTORY CAUSE OF DEATH - Liver Fatty Change

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 330

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 672
HISTO: 0601810

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Brain |
| * Clitoral Gland | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Nose | * Ovary | * Parathyroid Gland |
| * Salivary Glands | * Skin | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | |
|---|-------------------------------|-------------------|
| * Adrenal Cortex
[Degeneration TGLs = 3 - 14] | Degeneration | Cystic, Marked |
| * Bone Marrow | Hyperplasia | Minimal |
| * Heart | Cardiomyopathy | Mild |
| * Intestine Large, Cecum

[Necrosis TGLs = 1 - 13] | Inflammation
Necrosis | Marked
Marked |
| * Islets, Pancreatic | Hyperplasia | Minimal |
| * Kidney | Mineralization
Nephropathy | Mild
Moderate |
| * Liver | Fatty Change | Diffuse, Moderate |
| * Lung
Alveolus
Note: Macrophages in the alveoli contain abundant hemosiderin consistent with prior episode(s) of hemorrhage. | Infiltration Cellular | Histiocyte, Mild |
| * Lymph Node, Mesenteric | Atrophy | Moderate |
| * Mammary Gland

[Fibroadenoma TGLs = 4 - 15]
[Galactocele TGLs = 5 - 16] | Fibroadenoma
Galactocele | Marked |
| * Pancreas | Atrophy | Minimal |
| * Pituitary Gland
Pars Distalis
[Adenoma TGLs = 6 - 8] | Adenoma | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 330

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 672
HISTO: 0601810

ORGAN AND ACCOUNTABLE SITE STATUS

* Spleen	Lymph Follic	Atrophy Pigmentation	Marked Hemosiderin, Minimal
[Atrophy TGLs = 2 - 5]			
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation Ulcer	Mild Mild Mild
* Thymus		Atrophy	Marked
* Thyroid Gland	Follicular Cel	Hyperplasia	Minimal
Tooth		Malformation	Minimal

PRIMARY CAUSE OF DEATH - Intestine Large, Cecum Necrosis
CONTRIBUTORY CAUSE OF DEATH - Adrenal Cortex Degeneration

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 331

TMT: 6

SEX: Female

DAY ON TEST: 729

DOSE: 0.3 G/KG

DISP: Terminal Sacrifice

HISTO: 0601811

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Trachea
* Urinary Bladder	* Uterus		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Esophagus	Periesoph Tiss	Lipoma	
	[Lipoma TGLs = 6 - 16]		
* Eye	Retina	Gliososis	Mild
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
	[Eosinophilic Focus TGLs = 4 - 15]		
* Mammary Gland		Fibroadenoma	Multiple
	[Fibroadenoma TGLs = 1,2 - 13+14]		
* Ovary		Cyst	Minimal
	[Cyst TGLs = 5 - 11]		
* Pituitary Gland	Pars Distalis	Hyperplasia	Moderate
	[Hyperplasia TGLs = 3 - 8]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 331

TMT: 6

SEX: Female

DAY ON TEST: 729

DOSE: 0.3 G/KG

DISP: Terminal Sacrifice

HISTO: 0601811

ORGAN AND ACCOUNTABLE SITE STATUS

* Thyroid Gland

C Cell

Hyperplasia

Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 332

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601812

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Ovary | * Pancreas | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|--------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | [Eosinophilic Focus TGLs = 1 - 6+7+13] | | |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Adenoma | |
| | C Cell | Hyperplasia | Mild |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 333

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601813

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mesenteric	* Mammary Gland
* Ovary	* Pancreas	* Parathyroid Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Inflammation	Chronic Active, Minimal
Note: Clear cell focus diagnosed since these foci more closely resemble that than other eosinophilic foci in this study.			
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
Mesentery	Fat	Necrosis	Mild
	[Necrosis TGLs = 1 - 13]		
* Nose		Inflammation	Mild
* Pituitary Gland	Pars Distalis	Adenoma	
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 334

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 579
HISTO: 0601814

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Ovary | * Pancreas | * Salivary Glands | * Skin |
| * Stomach, Glandular | * Thyroid Gland | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- | | |
|--------------------------|---------------------|
| * Lymph Node, Mandibular | * Parathyroid Gland |
|--------------------------|---------------------|

OBSERVATIONS

- | | | | |
|----------------------------|---------------|------------------|-------------------------|
| * Brain | | Hemorrhage | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| Mesentery | Fat | Necrosis | Mild |
| [Necrosis TGLs = 2 - 13] | | | |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| [Adenoma TGLs = 1 - 8] | | | |
| * Spleen | | Pigmentation | Hemosiderin, Mild |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Moderate |
| | | Inflammation | Moderate |
| | | Ulcer | Moderate |
| [Ulcer TGLs = 3 - 13] | | | |
| * Thymus | | Atrophy | Moderate |

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma
 CONTRIBUTORY CAUSE OF DEATH - Stomach, Forestomach Ulcer

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 335

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601815

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Bone Marrow |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Ovary | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--|--|--------------------|-------------------------|
| * Adrenal Cortex | | Hypertrophy | Mild |
| * Heart | | Cardiomyopathy | Minimal |
| * Kidney | | Mineralization | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| | [Eosinophilic Focus TGLs = 1 - 6+7+13] | | |
| Oral Mucosa | | Hyperplasia | Squamous, Marked |
| Note: Squamous hyperplasia was in routine section taken for nose/turbinates (B01). | | | |
| * Pancreas | Acinus | Adenoma | |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 336

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 653
HISTO: 0601816

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular	* Parathyroid Gland
--------------------------	---------------------

OBSERVATIONS

* Heart		Cardiomyopathy	Mild
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Fatty Change	Diffuse, Minimal
		Hepatodiaphragmatic Nodule	
	Bile Duct	Hyperplasia	Minimal
		Inflammation	Chronic Active, Minimal
		Mixed Cell Focus	
	[Eosinophilic Focus TGLs = 3 - 15]		
	[Hepatodiaphragmatic Nodule TGLs = 1,2 - 13+14]		
	[Mixed Cell Focus TGLs = 4 - 16]		
* Spleen	Lymph Follic	Atrophy	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

PRIMARY CAUSE OF DEATH - UNCERTAIN

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 337

TMT: 6

SEX: Female

DAY ON TEST: 730

DOSE: 0.3 G/KG

DISP: Terminal Sacrifice

HISTO: 0601817

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Urinary Bladder
* Uterus			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Mild
* Clitoral Gland		Hyperplasia	Mild
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
	[Eosinophilic Focus TGLs = 1 - 13]		
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Thyroid Gland	Follicular Cel	Hyperplasia	Marked

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 338

TMT: 6
 DOSE: 0.3 G/KG

SEX: Female
 DISP: Natural Death

DAY ON TEST: 664
 HISTO: 0601818

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Ovary | * Pancreas | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--|------------------------|----------------------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | Pelvis, Transit Epithe | Hyperplasia | Mild |
| | | Infarct | Minimal |
| | Pelvis | Inflammation | Mild |
| | | Mineralization | Minimal |
| | Papilla | Necrosis | Minimal |
| | | Nephropathy | Minimal |
| Note: There is granulation tissue associated with the inflammation in one renal pelvis. | | | |
| * Liver | | Basophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| Note: There is extensive hemorrhage secondary to this pituitary tumor.
[Adenoma TGLs = 1 - 8] | | | |
| * Spleen | | Hematopoietic Cell Proliferation | Mild |
| | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | C Cell | Adenoma | |

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 339

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 532
HISTO: 0601819

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Parathyroid Gland	* Salivary Glands	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone		Osteosarcoma	Metastatic (Skin)
Note: Multiple fairly well-differentiated small tumors are present in the femur and tibia in B02; these were interpreted as metastases from the large skin tumor.			
* Intestine Large, Colon		Parasite Metazoan	
* Kidney		Mineralization	Minimal
* Liver		Basophilic Focus	
* Lung		Osteosarcoma	Metastatic (Skin)
[Osteosarcoma TGLs = 4 - 3+4]			
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Marked
[Hyperplasia TGLs = 3 - 8]			
* Skin	Subcut Tiss	Osteosarcoma	
Note: The osteosarcoma in the skin is the largest of the bone tumors, consistent with it being a primary tumor.			
[Osteosarcoma TGLs = 1 - 13]			
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Uterus		Polyp Stromal	
[Polyp Stromal TGLs = 2 - 14]			

PRIMARY CAUSE OF DEATH - Skin Subcut Tiss Osteosarcoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 340

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 658
HISTO: 0601820

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric | * Ovary |
| * Pancreas | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--------------------------------|--------------------|----------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 13] | | |
| * Nose | | Inflammation | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 2 - 8] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 341

TMT: 6

SEX: Female

DAY ON TEST: 730

DOSE: 0.3 G/KG

DISP: Terminal Sacrifice

HISTO: 0601821

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Nose	* Ovary
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Mild
* Intestine Large, Colon		Parasite Metazoan	
* Kidney	Pelvis	Inflammation	Minimal
		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Fatty Change	Diffuse, Minimal
	Hepatocyte	Hypertrophy	Minimal
		Inflammation	Chronic Active, Minimal
	[Basophilic Focus TGLs = 1 - 6+7+14]		
* Mammary Gland		Fibroadenoma	
	[Fibroadenoma TGLs = 2 - 13]		
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Marked
	[Hyperplasia TGLs = 3 - 8]		
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Uterus		Polyp Stromal	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 342

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 632
HISTO: 0601822

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Brain	* Clitoral Gland
* Esophagus	* Eye	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Leukemia Mononuclear	
* Adrenal Medulla		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 4 - 8]		
* Bone Marrow		Hyperplasia	Marked
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver	Bile Duct	Hyperplasia	Minimal
	[Leukemia Mononuclear TGLs = 2,3 - 6+7]		
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
		Leukemia Mononuclear	
* Ovary		Cyst	Minimal
* Pancreas		Atrophy	Minimal
* Spleen		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 1 - 13]		
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
		Inflammation	Minimal
* Thymus		Atrophy	Marked
* Thyroid Gland	C Cell	Hyperplasia	Moderate
* Uterus		Polyp Stromal	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 342

TMT: 6

SEX: Female

DAY ON TEST: 632

DOSE: 0.3 G/KG

DISP: Moribund Sacrifice

HISTO: 0601822

ORGAN AND ACCOUNTABLE SITE STATUS

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 343

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601823

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Esophagus	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Clitoral Gland		Adenoma	
[Adenoma TGLs = 2 - 12]			
* Eye	Retina	Degeneration	Mild
	Retina	Gliosis	Mild
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Inflammation	Chronic Active, Minimal
* Mammary Gland		Fibroadenoma	
Note: Fibroadenoma was in section with clitoral gland.			
Mesentery	Fat	Necrosis	Mild
[Necrosis TGLs = 1 - 13]			
* Nose		Inflammation	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
[Adenoma TGLs = 3 - 8]			
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
Tooth		Malformation	Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 344

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601824

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Ovary |
| * Pancreas | * Parathyroid Gland | * Salivary Glands | * Spleen |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|--------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| | [Basophilic Focus TGLs = 3 - 6+7+15] | | |
| | [Eosinophilic Focus TGLs = 4 - 14] | | |
| * Nose | | Inflammation | Mild |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Moderate |
| | [Hyperplasia TGLs = 2 - 8] | | |
| * Skin | Subcut Tiss | Fibroma | |
| | [Fibroma TGLs = 1 - 13] | | |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 345

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 647
HISTO: 0601825

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Degeneration	Cystic, Minimal
* Bone Marrow		Hyperplasia	Mild
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic Active, Minimal
* Nose		Inflammation	Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Adenoma	
* Uterus	Endometrium	Hyperplasia	Cystic, Marked
		Sarcoma Stromal	

Note: TGL-2 grossly identified as ovary appears to be a large uterine polyp with a stromal sarcoma arising within it.

[Hyperplasia TGLs = 3 - 11]

[Sarcoma Stromal TGLs = 2 - 13]

PRIMARY CAUSE OF DEATH - Uterus Sarcoma Stromal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 346

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 729
HISTO: 0601826

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Cortex | Blood Vessel | * Bone | * Bone Marrow |
| * Esophagus | * Eye | * Harderian Gland | * Intestine Large, Cecum |
| * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland |
| * Nose | * Ovary | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Trachea | * Urinary Bladder |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--|--|-----------------------|-------------------------|
| * Adrenal Medulla | | Hyperplasia | Minimal |
| * Brain | | Infiltration Cellular | Mixed Cell, Minimal |
| * Clitoral Gland | | Hyperplasia | Moderate |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | Pelvis, Transit Epithe | Hyperplasia | Minimal |
| | Pelvis | Inflammation | Minimal |
| | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| Note: Foreign body (hair) present in renal pelvis. | | | |
| * Liver | | Basophilic Focus | |
| | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| | [Basophilic Focus TGLs = 1 - 6+7+13] | | |
| * Lung | | Inflammation | Chronic Active, Minimal |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 2 - 8] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 346

TMT: 6

SEX: Female

DAY ON TEST: 729

DOSE: 0.3 G/KG

DISP: Terminal Sacrifice

HISTO: 0601826

ORGAN AND ACCOUNTABLE SITE STATUS

* Stomach, Glandular [Hyperplasia TGLs = 3 - 14]	Epithelium	Hyperplasia	Moderate
* Thymus		Atrophy	Moderate
* Thyroid Gland	Follicular Cel	Hyperplasia	Moderate
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 347

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601827

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Mild
* Kidney		Infarct	Mild
		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
	Hepatocyte	Hypertrophy	Minimal
		Inflammation	Chronic Active, Minimal
	Fat	Necrosis	Minimal
	[Necrosis TGLs = 1 - 13]		
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Minimal
* Uterus		Polyp Stromal	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 348

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 639
HISTO: 0601828

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
		Necrosis	Minimal
* Bone Marrow		Hyperplasia	Mild
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Basophilic Focus	
		Fatty Change	Diffuse, Minimal
		Mixed Cell Focus	
* Mammary Gland		Hyperplasia	Moderate
[Hyperplasia TGLs = 1 - 13]			
Mesentery	Fat	Necrosis	Mild
[Necrosis TGLs = 2 - 14]			
* Pituitary Gland	Pars Distalis	Adenoma	
[Adenoma TGLs = 3 - 8]			
* Spleen		Pigmentation	Hemosiderin, Mild
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
		Inflammation	Mild
* Thymus		Atrophy	Mild

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 349

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 708
HISTO: 0601829

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric	* Nose
* Ovary	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

MISSING

* Lymph Node, Mandibular	* Parathyroid Gland
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OBSERVATIONS

* Adrenal Cortex		Degeneration	Cystic, Minimal
* Bone Marrow		Hyperplasia	Mild
* Eye	Retina	Gliosis	Mild
* Heart		Cardiomyopathy	Mild
* Intestine Large, Colon		Parasite Metazoan	
* Kidney		Mineralization	Minimal
* Liver	Hepatocyte	Basophilic Focus	
		Hypertrophy	Mild
		Inflammation	Chronic Active, Minimal
		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 2 - 6+7]		
* Mammary Gland		Fibroadenoma	
	[Fibroadenoma TGLs = 1 - 13]		
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 3 - 8]		
* Spleen		Hematopoietic Cell Proliferation	Mild
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

PRIMARY CAUSE OF DEATH - Mammary Gland Fibroadenoma

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 350

TMT: 6
DOSE: 0.3 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 702
HISTO: 0601830

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone Marrow | * Brain |
| * Clitoral Gland | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lung |
| * Lymph Node, Mesenteric | * Nose | * Ovary | * Pancreas |
| * Parathyroid Gland | * Salivary Glands | * Skin | * Stomach, Forestomach |
| * Stomach, Glandular | * Thyroid Gland | * Trachea | * Urinary Bladder |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---|----------------------------------|-------------------------|
| * Adrenal Cortex | | Degeneration | Cystic, Minimal |
| | | Metaplasia | Osseous, Mild |
| * Bone | | Osteoma | |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| | [Basophilic Focus TGLs = 5 - 6+7] | | |
| | [Eosinophilic Focus TGLs = 2-14,3-15] | | |
| | [Mixed Cell Focus TGLs = 4 - 16] | | |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 13] | | |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 6 - 8] | | |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |
| | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 350

TMT: 6

SEX: Female

DAY ON TEST: 702

DOSE: 0.3 G/KG

DISP: Natural Death

HISTO: 0601830

ORGAN AND ACCOUNTABLE SITE STATUS

* Uterus

Endometrium

Hyperplasia

Cystic, Minimal

PRIMARY CAUSE OF DEATH

- Pituitary Gland Pars Distalis Adenoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 351

TMT: 8

SEX: Female

DAY ON TEST: 730

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601831

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lymph Node, Mesenteric | * Mammary Gland | * Ovary |
| * Pancreas | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--------------------------|-----------------------|-------------------------|
| * Heart | | Cardiomyopathy | Minimal |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Moderate |
| * Liver | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Fatty Change | Diffuse, Mild |
| | Hepatocyte | Hypertrophy | Mild |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| * Nose | | Inflammation | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 1 - 8] | | |
| * Spleen | | Pigmentation | Hemosiderin, Mild |
| * Thymus | | Atrophy | Mild |
| * Thyroid Gland | C Cell | Hyperplasia | Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 352

TMT: 8

SEX: Female

DAY ON TEST: 728

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601832

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Ovary |
| * Pancreas | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Glandular | * Thyroid Gland | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|---------------------------------|-----------------------|-------------------------|
| * Eye | Lens | Cataract | Minimal |
| | Retina | Degeneration | Mild |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Angiectasis | Minimal |
| | | Eosinophilic Focus | |
| | | Fatty Change | Diffuse, Minimal |
| | Hepatocyte | Hypertrophy | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| * Lung | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| Mesentery | Fat | Necrosis | Moderate |
| | [Necrosis TGLs = 1,2 - 13+14] | | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Minimal |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 353

TMT: 8

SEX: Female

DAY ON TEST: 688

DOSE: 1.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601833

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Clitoral Gland | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lymph Node, Mesenteric |
| * Nose | * Ovary | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|---------------------------------|----------------------------|------------------|
| * Bone Marrow | | Hyperplasia | Moderate |
| * Brain | | Granular Cell Tumor Benign | |
| * Heart | | Cardiomyopathy | Minimal |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | Hepatocyte | Hypertrophy | Moderate |
| | | Leukemia Mononuclear | |
| * Lung | Alveolar Epith | Hyperplasia | Minimal |
| | | Leukemia Mononuclear | |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 13] | | |
| * Pancreas | Acinus | Metaplasia | Hepatocyte, Mild |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Marked |
| | [Hyperplasia TGLs = 3 - 14] | | |
| * Spleen | | Leukemia Mononuclear | |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | Follicular Cel | Hyperplasia | Minimal |
| * Uterus | | Polyp Stromal | |
| | [Polyp Stromal TGLs = 2 - 14] | | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 353

TMT: 8

SEX: Female

DAY ON TEST: 688

DOSE: 1.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601833

ORGAN AND ACCOUNTABLE SITE STATUS

PRIMARY CAUSE OF DEATH - Mammary Gland Fibroadenoma

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 354

TMT: 8
DOSE: 1.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601834

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Ovary	* Parathyroid Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Mild
Ear		Neural Crest Tumor	
	[Neural Crest Tumor TGLs = 1 - 13]		
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
	Hepatocyte	Hypertrophy	Mild
		Inflammation	Chronic Active, Minimal
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Nose		Inflammation	Mild
* Pancreas		Atrophy	Mild
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 355

TMT: 8

SEX: Female

DAY ON TEST: 730

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601835

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular	* Thymus
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OBSERVATIONS

* Heart		Cardiomyopathy	Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
	Hepatocyte	Hypertrophy	Moderate
		Inflammation	Chronic Active, Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 2 - 8]		
* Spleen		Pigmentation	Hemosiderin, Minimal
* Uterus		Hemorrhage	Moderate
	Endometrium	Hyperplasia	Cystic, Mild
	[Hemorrhage TGLs = 1 - 11]		

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 356

TMT: 8

SEX: Female

DAY ON TEST: 489

DOSE: 1.0 G/KG

DISP: Natural Death

HISTO: 0601836

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Ovary	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Minimal
* Intestine Large, Colon		Parasite Metazoan	
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Inflammation	Chronic Active, Minimal
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Nose		Inflammation	Minimal
* Pancreas		Atrophy	Moderate
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Mild

PRIMARY CAUSE OF DEATH - Pancreas Atrophy

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 357

TMT: 8

SEX: Female

DAY ON TEST: 730

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601837

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric | * Mammary Gland |
| * Nose | * Ovary | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|----------------|----------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | Hepatocyte | Hypertrophy | Mild |
| | | Inflammation | Chronic Active, Minimal |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Mild |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | Follicular Cel | Hyperplasia | Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 358

TMT: 8

SEX: Female

DAY ON TEST: 730

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601838

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Mammary Gland
* Ovary	* Parathyroid Gland	* Salivary Glands	* Skin
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Angiectasis	Minimal
		Clear Cell Focus	
	Hepatocyte	Hypertrophy	Mild
		Inflammation	Chronic Active, Minimal
		Leukemia Mononuclear	
* Lung	Alveolar Epith	Hyperplasia	Minimal
	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Lymph Node, Mesenteric		Leukemia Mononuclear	
* Nose		Inflammation	Minimal
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Leukemia Mononuclear	
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
* Thymus		Atrophy	Moderate
* Uterus		Polyp Stromal	

[Polyp Stromal TGLs = 1 - 11]

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 359

TMT: 8
DOSE: 1.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601839

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Mild
* Eye	Retina	Degeneration	Minimal
	Cornea	Inflammation	Mild
	[Inflammation TGLs = 1 - 10]		
* Heart		Cardiomyopathy	Mild
* Kidney		Accumulation, Hyaline Droplet	Moderate
		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
	Hepatocyte	Hypertrophy	Minimal
		Inflammation	Chronic Active, Minimal
* Lung		Alveolar/Bronchiolar Carcinoma	
	Alveolus	Infiltration Cellular	Histiocyte, Minimal
	[Alveolar/Bronchiolar Carcinoma TGLs = 5 - 15]		
Lymph Node	Mediastinal	Carcinoma	Metastatic (Lung)
	[Carcinoma TGLs = 6 - 16]		
* Ovary		Carcinoma	Metastatic (Lung)
	[Carcinoma TGLs = 3 - 11]		
* Parathyroid Gland		Adenoma	
* Pituitary Gland	Pars Distalis	Angiectasis	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 359

TMT: 8

SEX: Female

DAY ON TEST: 728

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601839

ORGAN AND ACCOUNTABLE SITE STATUS

[Angiectasis TGLs = 2 - 13]

Pleura	Mesothelium	Hyperplasia	Mild
Note: Pleural mesothelial hyperplasia was noted on routine lung sections and was probably secondary to presence of the carcinoma.			
* Spleen		Carcinoma	Metastatic (Lung)
		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Mild

[Carcinoma TGLs = 4 - 14]

* Thymus		Atrophy	Moderate
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TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 360

TMT: 8

SEX: Female

DAY ON TEST: 728

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601840

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Fatty Change	Diffuse, Minimal
	Hepatocyte	Hypertrophy	Mild
		Inflammation	Chronic Active, Minimal
* Lung		Inflammation	Chronic Active, Minimal
* Pancreas		Atrophy	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 361

TMT: 8
DOSE: 1.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601841

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Heart		Cardiomyopathy	Minimal
* Kidney	Pelvis, Transit Epithe	Hyperplasia	Minimal
		Infarct	Mild
	Pelvis	Inflammation	Mild
		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
	Hepatocyte	Hypertrophy	Mild
		Inflammation	Chronic Active, Minimal
	[Eosinophilic Focus TGLs = 1 - 13]		
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Ovary		Cyst	Mild
* Pancreas		Atrophy	Moderate
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Pigmentation	Hemosiderin, Mild
* Thymus		Atrophy	Mild

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 362

TMT: 8

SEX: Female

DAY ON TEST: 730

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601842

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Glandular	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Degeneration	Cystic, Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Fatty Change	Diffuse, Minimal
	Hepatocyte	Hypertrophy	Mild
		Inflammation	Chronic Active, Minimal
* Lung		Inflammation	Chronic Active, Minimal
* Pancreas		Inflammation	Minimal
* Spleen		Pigmentation	Hemosiderin, Mild
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
		Inflammation	Minimal
* Thymus		Atrophy	Marked
* Thyroid Gland	C Cell	Adenoma	
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 363

TMT: 8

SEX: Female

DAY ON TEST: 729

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601843

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Mild
* Heart		Cardiomyopathy	Mild
* Kidney	Pelvis, Transit Epithe	Hyperplasia	Minimal
	Pelvis	Inflammation	Mild
		Nephropathy	Minimal
* Liver	Hepatocyte	Hypertrophy	Mild
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Mammary Gland		Fibroadenoma	
	[Fibroadenoma TGLs = 1 - 13]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Adenoma	
* Uterus		Polyp Stromal	
	[Polyp Stromal TGLs = 2 - 11]		

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 364

TMT: 8
DOSE: 1.0 G/KG

SEX: Female
DISP: Dosing Accident

DAY ON TEST: 111
HISTO: 0601844

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Heart | * Intestine Large, Cecum |
| * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic | * Liver | * Lymph Node, Mesenteric |
| * Mammary Gland | * Nose | * Ovary | * Pancreas |
| * Parathyroid Gland | * Pituitary Gland | * Salivary Glands | * Skin |
| * Stomach, Glandular | * Thymus | * Thyroid Gland | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|-------------------------------|----------------|----------------------|
| * Kidney | | Mineralization | Minimal |
| * Lung | | Congestion | Mild |
| | [Congestion TGLs = 1 - 3+4] | | |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Mild |
| | | Inflammation | Minimal |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 365

TMT: 8

SEX: Female

DAY ON TEST: 730

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601845

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic | * Lymph Node, Mesenteric | * Ovary |
| * Parathyroid Gland | * Salivary Glands | * Skin | * Stomach, Forestomach |
| * Stomach, Glandular | * Thyroid Gland | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--------------------------|--|------------------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Minimal |
| * Eye | Retina | Degeneration | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Intestine Large, Colon | | Parasite Metazoan | |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Eosinophilic Focus | |
| | Hepatocyte | Hypertrophy | Mild |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | | Alveolar/Bronchiolar Adenoma | |
| | Alveolar Epith | Hyperplasia | Marked |
| | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | Note: This alveolar-bronchiolar adenoma is at the hilus of the lung and involves the pleura (appears exophytic). | | |
| * Mammary Gland | | Fibroadenoma | |
| | [Fibroadenoma TGLs = 1 - 13] | | |
| * Nose | | Inflammation | Minimal |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 365

TMT: 8

SEX: Female

DAY ON TEST: 730

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601845

ORGAN AND ACCOUNTABLE SITE STATUS

[Adenoma TGLs = 2 - 8]

* Spleen

Pigmentation

Hemosiderin, Minimal

* Thymus

Atrophy

Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 366

TMT: 8

SEX: Female

DAY ON TEST: 629

DOSE: 1.0 G/KG

DISP: Natural Death

HISTO: 0601846

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla | Blood Vessel | * Bone | * Brain |
| * Clitoral Gland | * Esophagus | * Eye | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lung |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Ovary |
| * Pancreas | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------------|---------------|----------------|-------------------------|
| * Adrenal Cortex | | Degeneration | Cystic, Mild |
| | | Hemorrhage | Marked |
| | | Necrosis | Mild |
| [Hemorrhage TGLs = 1 - 8] | | | |
| * Bone Marrow | | Hyperplasia | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Inflammation | Chronic Active, Minimal |
| Mesentery | Fat | Necrosis | Mild |
| [Necrosis TGLs = 3 - 13] | | | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Marked |
| [Hyperplasia TGLs = 2 - 8] | | | |
| * Spleen | | Pigmentation | Hemosiderin, Mild |
| * Thymus | | Atrophy | Moderate |

PRIMARY CAUSE OF DEATH - Adrenal Cortex Necrosis

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 367

TMT: 8
DOSE: 1.0 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 616
HISTO: 0601847

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric | * Mammary Gland |
| * Nose | * Ovary | * Pancreas | * Parathyroid Gland |
| * Pituitary Gland | * Salivary Glands | * Skin | * Stomach, Forestomach |
| * Stomach, Glandular | * Thyroid Gland | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-----------|----------------------------|----------------------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| * Liver | | Inflammation | Chronic Active, Minimal |
| Mesentery | Fat | Necrosis | Mild |
| | [Necrosis TGLs = 1 - 13] | | |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |
| | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |

PRIMARY CAUSE OF DEATH - Heart Cardiomyopathy

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 368

TMT: 8

SEX: Female

DAY ON TEST: 730

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601848

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
	Hepatocyte	Hypertrophy	Mild
	[Eosinophilic Focus TGLs = 1 - 6+7]		
* Pancreas	Acinus	Metaplasia	Hepatocyte, Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 369

TMT: 8
 DOSE: 1.0 G/KG

SEX: Female
 DISP: Moribund Sacrifice

DAY ON TEST: 688
 HISTO: 0601849

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Brain	* Esophagus
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Mammary Gland	* Nose	* Ovary
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Hypertrophy	Minimal
		Leukemia Mononuclear	
* Adrenal Medulla		Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Moderate
* Clitoral Gland		Adenoma	
	[Adenoma TGLs = 1 - 13]		
* Eye	Retina	Degeneration	Mild
* Heart		Cardiomyopathy	Minimal
	Atrium	Thrombosis	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Degeneration	Cystic, Minimal
		Fatty Change	Diffuse, Minimal
		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 2 - 6+7]		
* Lymph Node, Mesenteric		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 3 - 6]		
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
* Spleen		Leukemia Mononuclear	
		Pigmentation	Hemosiderin, Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 369

TMT: 8

SEX: Female

DAY ON TEST: 688

DOSE: 1.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601849

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

Atrophy

Moderate

* Uterus

Leukemia Mononuclear

Polyp Stromal

PRIMARY CAUSE OF DEATH

- Clitoral Gland Adenoma

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 370

TMT: 8
DOSE: 1.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601850

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Harderian Gland |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic | * Lymph Node, Mesenteric |
| * Mammary Gland | * Nose | * Ovary | * Pancreas |
| * Parathyroid Gland | * Salivary Glands | * Skin | * Stomach, Forestomach |
| * Stomach, Glandular | * Thyroid Gland | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|------------------------------|-----------------------|---------------------|
| * Bone Marrow | | Hyperplasia | Minimal |
| * Eye | Lens | Cataract | Marked |
| | Retina | Degeneration | Marked |
| | Postr Chamber | Inflammation | Minimal |
| | [Cataract TGLs = 1 - 10] | | |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | Hepatocyte | Hypertrophy | Mild |
| * Lung | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Marked |
| | [Hyperplasia TGLs = 2 - 8] | | |
| * Spleen | | Pigmentation | Hemosiderin, Mild |
| * Thymus | | Atrophy | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 371

TMT: 8

SEX: Female

DAY ON TEST: 729

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601851

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Nose	* Ovary	* Salivary Glands
* Skin	* Stomach, Glandular	* Trachea	* Urinary Bladder
* Uterus			

MISSING

* Lymph Node, Mandibular	* Parathyroid Gland
--------------------------	---------------------

OBSERVATIONS

* Bone Marrow		Hyperplasia	Minimal
* Eye	Retina	Degeneration	Mild
	Retina	Gliosis	Mild
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Moderate
* Liver		Fatty Change	Diffuse, Minimal
	Hepatocyte	Hypertrophy	Minimal
		Inflammation	Chronic Active, Minimal
* Mammary Gland		Fibroadenoma	
	[Fibroadenoma TGLs = 1 - 13]		
* Pancreas	Acinus	Metaplasia	Hepatocyte, Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 2 - 8]		
* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Moderate
		Inflammation	Mild
		Ulcer	Minimal
	[Hyperplasia TGLs = 4 - 15]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 371

TMT: 8

SEX: Female

DAY ON TEST: 729

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601851

ORGAN AND ACCOUNTABLE SITE STATUS

* Thyroid Gland

Bilateral, C Cell

Adenoma

[Adenoma TGLs = 3 - 14]

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 372

TMT: 8

SEX: Female

DAY ON TEST: 730

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601852

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Brain	* Clitoral Gland
* Esophagus	* Eye	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Mammary Gland	* Nose
* Ovary	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Leukemia Mononuclear	
* Adrenal Medulla		Leukemia Mononuclear	
* Bone Marrow		Hyperplasia	Mild
* Heart		Cardiomyopathy	Minimal
* Kidney		Leukemia Mononuclear	
		Nephropathy	Mild
* Liver		Angiectasis	Mild
	Bile Duct	Eosinophilic Focus	
		Hyperplasia	Minimal
* Lung		Leukemia Mononuclear	
* Lymph Node, Mesenteric		Leukemia Mononuclear	
* Pancreas		Leukemia Mononuclear	
* Spleen		Atrophy	Minimal
	[Leukemia Mononuclear TGLs = 1 - 5]	Leukemia Mononuclear	
* Stomach, Forestomach	Epithelium	Hyperplasia	Moderate
		Inflammation	Mild
		Ulcer	Mild
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 373

TMT: 8
DOSE: 1.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601853

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | Blood Vessel | * Bone | * Bone Marrow |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Ovary | * Pancreas | * Parathyroid Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|-------------------|--|-------------------------|-------------------------|
| * Adrenal Medulla | | Pheochromocytoma Benign | |
| | [Pheochromocytoma Benign TGLs = 3 - 8] | | |
| * Heart | | Cardiomyopathy | Minimal |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Eosinophilic Focus | |
| | Hepatocyte | Hypertrophy | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| Mesentery | Fat | Necrosis | Minimal |
| | [Necrosis TGLs = 2 - 13] | | |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| | [Hyperplasia TGLs = 1 - 8] | | |
| * Spleen | | Pigmentation | Hemosiderin, Mild |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | Follicular Cel | Hyperplasia | Mild |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 374

TMT: 8

SEX: Female

DAY ON TEST: 728

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601854

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Degeneration	Cystic, Minimal
* Heart		Cardiomyopathy	Minimal
* Intestine Large, Colon		Parasite Metazoan	
* Kidney	Pelvis, Transit Epithe	Hyperplasia	Minimal
	Pelvis	Inflammation	Minimal
		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
		Fatty Change	Diffuse, Minimal
	Hepatocyte	Hypertrophy	Minimal
		Inflammation	Chronic Active, Minimal
* Lung		Inflammation	Chronic Active, Minimal
* Pancreas		Atrophy	Moderate
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 1- 14]		
* Spleen		Pigmentation	Hemosiderin, Mild
		Note: The spleen has atrophic and fibrotic pancreatic tissue running through the section. Spleen itself is within normal limits for size (i.e. NCL for TGL-2).	
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 375

TMT: 8
DOSE: 1.0 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 687
HISTO: 0601855

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Parathyroid Gland | * Pituitary Gland | * Salivary Glands | * Skin |
| * Stomach, Glandular | * Thyroid Gland | * Trachea | * Urinary Bladder |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|-------------|------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | | Inflammation | Chronic Active, Minimal |
| * Ovary | | Cyst | Minimal |
| * Pancreas | Acinus | Metaplasia | Hepatocyte, Minimal |
| * Spleen | | Pigmentation | Hemosiderin, Mild |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Mild |
| * Thymus | | Atrophy | Mild |
| * Uterus | Endometrium | Hyperplasia | Cystic, Mild |

PRIMARY CAUSE OF DEATH - UNCERTAIN

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 376

TMT: 8
DOSE: 1.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 728
HISTO: 0601856

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Ovary |
| * Pancreas | * Parathyroid Gland | * Pituitary Gland | * Salivary Glands |
| * Skin | * Stomach, Forestomach | * Stomach, Glandular | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--------------------------|---------------------------------|----------------------------------|-------------------------|
| * Heart | | Cardiomyopathy | Minimal |
| * Intestine Large, Colon | | Parasite Metazoan | |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Clear Cell Focus | |
| | | Fatty Change | Diffuse, Minimal |
| | Hepatocyte | Hypertrophy | Mild |
| | | Inflammation | Chronic Active, Minimal |
| * Lung | Alveolus | Infiltration Cellular | Histiocyte, Minimal |
| Mesentery | Fat | Necrosis | Mild |
| | | | |
| | [Necrosis TGLs = 1 - 13] | | |
| * Spleen | | Hematopoietic Cell Proliferation | Minimal |
| | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Mild |
| * Thyroid Gland | C Cell | Hyperplasia | Mild |
| * Uterus | | Polyp Stromal | |
| | [Polyp Stromal TGLs = 2 - 14] | | |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 377

TMT: 8
DOSE: 1.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601857

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland	* Ovary
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Mild
* Kidney	Pelvis, Transit Epithe	Hyperplasia	Minimal
		Infarct	Mild
		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Hepatodiaphragmatic Nodule	
	Hepatocyte	Hypertrophy	Mild
		Inflammation	Chronic Active, Minimal
	[Hepatodiaphragmatic Nodule		
	TGLs = 1 - 13]		
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Nose		Inflammation	Mild
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Angiectasis	Mild
* Spleen		Pigmentation	Hemosiderin, Mild
* Thymus		Atrophy	Moderate
* Uterus	Endometrium	Adenoma	

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 378

TMT: 8
 DOSE: 1.0 G/KG

SEX: Female
 DISP: Terminal Sacrifice

DAY ON TEST: 729
 HISTO: 0601858

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Brain	* Clitoral Gland
* Esophagus	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Leukemia Mononuclear	
* Adrenal Medulla		Leukemia Mononuclear	
* Bone Marrow		Hyperplasia	Marked
* Eye	Retina	Degeneration	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver	Bile Duct	Hyperplasia	Minimal
		Leukemia Mononuclear	
* Lung		Leukemia Mononuclear	
Lymph Node	Mediastinal	Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 3 - 14]		
* Lymph Node, Mesenteric		Leukemia Mononuclear	
* Ovary		Leukemia Mononuclear	
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
	[Hyperplasia TGLs = 1 - 8]		
* Spleen		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 2 - 13]		
* Stomach, Forestomach		Inflammation	Minimal
* Thymus		Atrophy	Moderate
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 379

TMT: 8

SEX: Female

DAY ON TEST: 730

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601859

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
	Papilla	Necrosis	Minimal
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
	Hepatocyte	Hypertrophy	Mild
		Inflammation	Chronic Active, Minimal
	[Eosinophilic Focus TGLs = 2 - 14]		
Mesentery	Fat	Necrosis	Minimal
	[Necrosis TGLs = 1 - 13]		
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
	[Hyperplasia TGLs = 3 - 15]		
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 380

TMT: 8
DOSE: 1.0 G/KG

SEX: Female
DISP: Moribund Sacrifice

DAY ON TEST: 664
HISTO: 0601860

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Pancreas |
| * Parathyroid Gland | * Salivary Glands | * Skin | * Stomach, Glandular |
| * Thyroid Gland | * Trachea | * Urinary Bladder | * Uterus |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|--|----------------------|-------------------------|
| * Bone Marrow | | Hyperplasia | Moderate |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Basophilic Focus | |
| | Bile Duct | Hyperplasia | Minimal |
| | | Leukemia Mononuclear | |
| | | Pigmentation | Hemosiderin, Mild |
| | [Leukemia Mononuclear TGLs = 2 - 6+7+14] | | |
| * Lung | | Inflammation | Chronic Active, Minimal |
| * Ovary | | Cyst | Minimal |
| * Pituitary Gland | Pars Distalis | Adenoma | |
| | [Adenoma TGLs = 1 - 13] | | |
| * Spleen | | Fibrosis | Mild |
| | | Leukemia Mononuclear | |
| | | Pigmentation | Hemosiderin, Minimal |
| | [Fibrosis TGLs = 4 - 14] | | |
| | [Leukemia Mononuclear TGLs = 3 - 5] | | |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Moderate |
| | | Inflammation | Moderate |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 380

TMT: 8

SEX: Female

DAY ON TEST: 664

DOSE: 1.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601860

ORGAN AND ACCOUNTABLE SITE STATUS

Ulcer

Moderate

[Hyperplasia TGLs = 5 - 15]

[Ulcer TGLs = 6 - 15]

Atrophy

Moderate

* Thymus

PRIMARY CAUSE OF DEATH - Pituitary Gland Pars Distalis Adenoma

CONTRIBUTORY CAUSE OF DEATH - Spleen Leukemia Mononuclear

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 381

TMT: 8

SEX: Female

DAY ON TEST: 730

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601861

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Degeneration Hyperplasia Hypertrophy	Cystic, Minimal Minimal Minimal
* Bone Marrow		Hyperplasia	Mild
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization Nephropathy	Minimal Minimal
* Liver	Bile Duct	Basophilic Focus Hyperplasia Inflammation	Minimal Chronic Active, Minimal
* Lung		Leukemia Mononuclear Inflammation	Chronic Active, Minimal
* Lymph Node, Mesenteric		Leukemia Mononuclear	
* Pituitary Gland	Pars Distalis	Hyperplasia	Marked
	[Hyperplasia TGLs = 1 - 8]		
* Spleen		Leukemia Mononuclear	
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 382

TMT: 8

SEX: Female

DAY ON TEST: 729

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601862

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Ovary |
| * Pancreas | * Parathyroid Gland | * Pituitary Gland | * Salivary Glands |
| * Skin | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|-------------------------------|----------------------------|-------------------------|
| * Eye | Retina | Degeneration | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Clear Cell Focus | |
| | | Eosinophilic Focus | |
| | | Hepatodiaphragmatic Nodule | |
| | Bile Duct | Hyperplasia | Minimal |
| | Hepatocyte | Hypertrophy | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| | [Hepatodiaphragmatic Nodule | | |
| * Lung | TGLs = 1 - 13] | Infiltration Cellular | Histiocyte, Minimal |
| * Spleen | Alveolus | Pigmentation | Hemosiderin, Mild |
| * Stomach, Forestomach | Epithelium | Hyperplasia | Mild |
| | | Inflammation | Mild |
| | | Ulcer | Minimal |
| | [Hyperplasia TGLs = 3 - 14] | | |
| * Thymus | | Atrophy | Marked |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 382

TMT: 8

SEX: Female

DAY ON TEST: 729

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601862

ORGAN AND ACCOUNTABLE SITE STATUS

* Uterus

Polyp Stromal

[Polyp Stromal TGLs = 2 - 11]

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 383

TMT: 8
DOSE: 1.0 G/KG

SEX: Female
DISP: Dosing Accident

DAY ON TEST: 265
HISTO: 0601863

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Liver	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart	Cardiomyopathy	Minimal
* Kidney	Mineralization	Minimal
* Lung	Hemorrhage	Minimal
[Hemorrhage TGLs = 1 - 3]		
* Spleen	Pigmentation	Hemosiderin, Minimal

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 384

TMT: 8

SEX: Female

DAY ON TEST: 694

DOSE: 1.0 G/KG

DISP: Natural Death

HISTO: 0601864

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Mild
* Eye	Retina	Degeneration	Minimal
* Heart		Cardiomyopathy	Mild
		Schwannoma Malignant	Metastatic (Lung)
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
	Hepatocyte	Hypertrophy	Minimal
		Inflammation	Chronic Active, Minimal
	Centrilobular	Necrosis	Mild
	[Necrosis TGLs = 2 - 6+7]		
* Lung	Mediastinum	Schwannoma Malignant	
	[Schwannoma Malignant TGLs = 5 - 14]		
Mesentery	Fat	Necrosis	Minimal
	[Necrosis TGLs = 3 - 13]		
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
	[Hyperplasia TGLs = 4 - 8]		
* Spleen		Hematopoietic Cell Proliferation	Moderate
		Pigmentation	Hemosiderin, Minimal
* Thymus		Schwannoma Malignant	Metastatic (Lung)

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 384

TMT: 8

SEX: Female

DAY ON TEST: 694

DOSE: 1.0 G/KG

DISP: Natural Death

HISTO: 0601864

ORGAN AND ACCOUNTABLE SITE STATUS

* Thyroid Gland

Follicle

Cyst

Minimal

PRIMARY CAUSE OF DEATH

- Lung Mediastinum Schwannoma Malignant

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 385

TMT: 8

SEX: Female

DAY ON TEST: 729

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601865

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Ovary	* Pancreas
* Parathyroid Gland	* Skin	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
* Bone Marrow		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Fatty Change	Diffuse, Minimal
	Hepatocyte	Hypertrophy	Mild
		Inflammation	Chronic Active, Minimal
* Nose		Inflammation	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Moderate
	[Hyperplasia TGLs = 1 - 13]		
* Salivary Glands		Atrophy	Mild
* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Moderate
		Inflammation	Moderate
		Ulcer	Moderate
	[Ulcer TGLs = 2 - 14]		
* Thymus		Atrophy	Moderate

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 386

TMT: 8

SEX: Female

DAY ON TEST: 728

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601866

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Glandular
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Fatty Change	Diffuse, Minimal
	Hepatocyte	Hypertrophy	Mild
* Lung	Alveolar Epith	Hyperplasia	Mild
* Ovary		Cyst	Minimal
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Mild
		Ulcer	Mild
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Minimal
Tooth		Malformation	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 387

TMT: 8

SEX: Female

DAY ON TEST: 194

DOSE: 1.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601867

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic Active, Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Moderate
		Inflammation	Minimal
* Thymus		Atrophy	Mild

PRIMARY CAUSE OF DEATH

- UNCERTAIN

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 388

TMT: 8
DOSE: 1.0 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 140
HISTO: 0601868

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Heart | * Intestine Large, Cecum |
| * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic | * Liver | * Lung |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Ovary |
| * Pancreas | * Parathyroid Gland | * Pituitary Gland | * Salivary Glands |
| * Skin | * Stomach, Glandular | * Thyroid Gland | * Trachea |
| * Urinary Bladder | * Uterus | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|------------------------|--------------|----------------|----------------------|
| * Kidney | Renal Tubule | Mineralization | Mild |
| | | Necrosis | Mild |
| * Spleen | Lymph Follic | Atrophy | Mild |
| | | Pigmentation | Hemosiderin, Minimal |
| * Stomach, Forestomach | | Inflammation | Mild |
| | | Ulcer | Marked |
| * Thymus | | Atrophy | Minimal |

PRIMARY CAUSE OF DEATH - Stomach, Forestomach Ulcer

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 389

TMT: 8
DOSE: 1.0 G/KG

SEX: Female
DISP: Terminal Sacrifice

DAY ON TEST: 730
HISTO: 0601869

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
	Hepatocyte	Hypertrophy	Mild
		Inflammation	Chronic Active, Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Thymus		Atrophy	Moderate
Tooth	Peridont Tiss	Inflammation	Moderate
		Malformation	Moderate
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal
		Polyp Stromal	

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 390

TMT: 8

SEX: Female

DAY ON TEST: 730

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601870

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Spleen	* Stomach, Glandular	* Trachea	* Urinary Bladder
* Uterus			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Clitoral Gland		Hyperplasia	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney	Pelvis, Transit Epithe	Hyperplasia	Mild
		Infarct	Mild
	Pelvis	Inflammation	Mild
		Mineralization	Minimal
		Nephropathy	Minimal
	[Infarct TGLs = 2 - 5]		
* Liver	Hepatocyte	Eosinophilic Focus	
		Hypertrophy	Moderate
		Inflammation	Chronic Active, Minimal
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Ovary		Cyst	Moderate
	[Cyst TGLs = 1 - 13]		
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
* Thymus		Atrophy	Moderate
* Thyroid Gland	Follicular Cel	Hyperplasia	Marked

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 391

TMT: 8

SEX: Female

DAY ON TEST: 730

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601871

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Glandular	* Trachea	* Urinary Bladder	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Minimal
* Eye	Retina	Degeneration	Minimal
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
	Centrilobular	Fatty Change	Mild
	Hepatocyte	Hypertrophy	Mild
* Pancreas		Atrophy	Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
		Inflammation	Minimal
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Adenoma	
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate

[Hyperplasia TGLs = 1 - 11]

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 392

TMT: 8

SEX: Female

DAY ON TEST: 721

DOSE: 1.0 G/KG

DISP: Moribund Sacrifice

HISTO: 0601872

ORGAN AND ACCOUNTABLE SITE STATUS

Lymphoma Malignant

Lymphoma Malignant

* Uterus

[Lymphoma Malignant TGLs = 3,4,5 - 11+14+15]

PRIMARY CAUSE OF DEATH

- Uterus Lymphoma Malignant

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 393

TMT: 8
 DOSE: 1.0 G/KG

SEX: Female
 DISP: Terminal Sacrifice

DAY ON TEST: 728
 HISTO: 0601873

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lung | * Lymph Node, Mesenteric | * Mammary Gland | * Nose |
| * Ovary | * Parathyroid Gland | * Salivary Glands | * Skin |
| * Stomach, Forestomach | * Stomach, Glandular | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- * Lymph Node, Mandibular

OBSERVATIONS

- | | | | |
|--------------------------|----------------|--------------------|-------------------------|
| * Heart | | Cardiomyopathy | Mild |
| * Intestine Large, Colon | | Parasite Metazoan | |
| * Kidney | | Mineralization | Minimal |
| | | Nephropathy | Minimal |
| * Liver | | Eosinophilic Focus | |
| | | Fatty Change | Diffuse, Minimal |
| | Bile Duct | Hyperplasia | Minimal |
| | Hepatocyte | Hypertrophy | Minimal |
| | | Inflammation | Chronic Active, Minimal |
| | | Mixed Cell Focus | |
| * Pancreas | | Atrophy | Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| * Spleen | | Pigmentation | Hemosiderin, Minimal |
| * Thymus | | Atrophy | Moderate |
| * Thyroid Gland | Follicular Cel | Adenoma | |
| | Follicle | Cyst | Mild |

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 394

TMT: 8
DOSE: 1.0 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 380
HISTO: 0601874

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Brain	* Esophagus
* Eye	* Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

* Clitoral Gland	* Lymph Node, Mandibular	* Parathyroid Gland
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OBSERVATIONS

* Adrenal Cortex		Leukemia Mononuclear Necrosis	Mild
* Adrenal Medulla		Leukemia Mononuclear	
* Bone Marrow		Hyperplasia	Mild
* Kidney		Leukemia Mononuclear Mineralization	Minimal
* Liver	Bile Duct	Hyperplasia Leukemia Mononuclear	Minimal
	[Leukemia Mononuclear TGLs = 2 - 6+7]		
* Lung		Leukemia Mononuclear	
* Spleen		Leukemia Mononuclear	
	[Leukemia Mononuclear TGLs = 1 - 5]		
* Thymus		Atrophy	Moderate

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 395

TMT: 8

SEX: Female

DAY ON TEST: 729

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601875

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
* Eye	* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Salivary Glands
* Skin	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Heart		Cardiomyopathy	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
	Centrilobular	Fatty Change	Mild
	Bile Duct	Hyperplasia	Minimal
	Hepatocyte	Hypertrophy	Minimal
		Inflammation	Chronic Active, Minimal
	[Clear Cell Focus TGLs = 1 - 13]		
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Mild
	[Hyperplasia TGLs = 2 - 14]		
* Thymus		Atrophy	Moderate
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 396

TMT: 8

SEX: Female

DAY ON TEST: 729

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601876

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Glandular
* Trachea	* Urinary Bladder	* Uterus	

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Bone Marrow		Hyperplasia	Moderate
* Heart		Cardiomyopathy	Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
	Hepatocyte	Hypertrophy	Mild
		Inflammation	Chronic Active, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
	[Adenoma TGLs = 2 - 8]		
* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Hyperplasia	Minimal
Zymbal's Gland		Adenoma	
	[Adenoma TGLs = 1 - 13]		

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 397

TMT: 8

SEX: Female

DAY ON TEST: 730

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601877

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Parathyroid Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex	Zona Fascult	Hyperplasia	Minimal
		Hypertrophy	Minimal
* Bone Marrow		Hyperplasia	Minimal
* Eye	Lens	Cataract	Minimal
	Retina	Degeneration	Moderate
	Cornea	Fibrosis	Mild
	[Fibrosis TGLs = 1 - 10]		
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
	Hepatocyte	Hypertrophy	Mild
		Inflammation	Chronic Active, Minimal
* Lung		Inflammation	Chronic Active, Minimal
Mesentery	Fat	Necrosis	Minimal
	[Necrosis TGLs = 3 - 13]		
* Pancreas		Atrophy	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
Time Report Requested: 15:10:25
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

ANIMAL NUM: 397

TMT: 8

SEX: Female

DAY ON TEST: 730

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601877

ORGAN AND ACCOUNTABLE SITE STATUS

* Thymus

* Uterus

Note: The polyp is necrotic and hemorrhagic, consistent with it being strangulated.

[Polyp Stromal TGLs = 2 - 11]

Pigmentation

Atrophy

Polyp Stromal

Hemosiderin, Minimal

Moderate

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 398

TMT: 8

SEX: Female

DAY ON TEST: 730

DOSE: 1.0 G/KG

DISP: Terminal Sacrifice

HISTO: 0601878

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Glandular
* Trachea	* Urinary Bladder		

MISSING

* Lymph Node, Mandibular

OBSERVATIONS

* Adrenal Cortex		Degeneration	Cystic, Minimal
* Eye	Retina	Degeneration	Minimal
	Cornea	Inflammation	Mild
	[Inflammation TGLs = 2 - 10]		
* Heart		Cardiomyopathy	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
	Hepatocyte	Hypertrophy	Mild
		Inflammation	Chronic Active, Minimal
Mesentery	Fat	Necrosis	Mild
	[Necrosis TGLs = 1 - 13]		
* Nose		Inflammation	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Pigmentation	Hemosiderin, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
	[Hyperplasia TGLs = 3 - 14]		
* Thymus		Atrophy	Moderate
* Thyroid Gland	C Cell	Adenoma	
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 399

TMT: 8
DOSE: 1.0 G/KG

SEX: Female
DISP: Natural Death

DAY ON TEST: 399
HISTO: 0601879

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Bone Marrow | * Brain | * Clitoral Gland | * Esophagus |
| * Eye | * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic | * Lung | * Lymph Node, Mesenteric | * Mammary Gland |
| * Nose | * Ovary | * Pancreas | * Parathyroid Gland |
| * Salivary Glands | * Skin | * Stomach, Forestomach | * Stomach, Glandular |
| * Thyroid Gland | * Trachea | * Urinary Bladder | * Uterus |

MISSING

- | | |
|--------------------------|----------|
| * Lymph Node, Mandibular | * Thymus |
|--------------------------|----------|

OBSERVATIONS

- | | | | |
|-------------------|------------------------------|----------------|-------------------------|
| * Heart | | Cardiomyopathy | Minimal |
| * Kidney | | Mineralization | Mild |
| | Renal Tubule | Necrosis | Mild |
| * Liver | | Inflammation | Chronic Active, Minimal |
| * Pituitary Gland | Pars Distalis | Hyperplasia | Mild |
| | [Hyperplasia TGLs = 3 - 8] | | |
| * Spleen | Lymph Follic | Atrophy | Mild |
| | | Pigmentation | Hemosiderin, Mild |

PRIMARY CAUSE OF DEATH - Kidney Renal Tubule Necrosis

* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/17/2010
 Time Report Requested: 15:10:25
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

ANIMAL NUM: 400

TMT: 8
 DOSE: 1.0 G/KG

SEX: Female
 DISP: Moribund Sacrifice

DAY ON TEST: 559
 HISTO: 0601880

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- | | | | |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex | * Adrenal Medulla | Blood Vessel | * Bone |
| * Brain | * Clitoral Gland | * Esophagus | * Eye |
| * Harderian Gland | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic |
| * Lymph Node, Mesenteric | * Mammary Gland | * Nose | * Ovary |
| * Pituitary Gland | * Salivary Glands | * Skin | * Stomach, Forestomach |
| * Stomach, Glandular | * Thyroid Gland | * Trachea | * Urinary Bladder |
| * Uterus | | | |

MISSING

- | | |
|--------------------------|---------------------|
| * Lymph Node, Mandibular | * Parathyroid Gland |
|--------------------------|---------------------|

OBSERVATIONS

- | | | | |
|---------------|--|----------------------|----------------------|
| * Bone Marrow | | Hyperplasia | Moderate |
| | | Myelofibrosis | Minimal |
| * Heart | | Cardiomyopathy | Mild |
| * Kidney | | Nephropathy | Minimal |
| * Liver | Bile Duct | Hyperplasia | Mild |
| | | Leukemia Mononuclear | |
| | [Leukemia Mononuclear TGLs = 2 - 6+7+14] | | |
| * Lung | | Leukemia Mononuclear | |
| * Pancreas | | Atrophy | Minimal |
| * Spleen | | Leukemia Mononuclear | |
| | | Pigmentation | Hemosiderin, Minimal |
| | [Leukemia Mononuclear TGLs = 1 - 13] | | |
| * Thymus | | Atrophy | Marked |

PRIMARY CAUSE OF DEATH - Spleen Leukemia Mononuclear

*** END OF REPORT ***