

**TDMs No.** 20009 - 03

**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS  
ABRIDGED) (a)**

**Date Report Requested:** 05/27/2011

**Test Type:** CHRONIC

beta-Picoline

**Time Report Requested:** 10:09:56

**Route:** DOSED WATER

**CAS Number:** 108-99-6

**First Dose M/F:** 11/18/04 / 11/19/04

**Species/Strain:** RATS/F 344/N

**Lab:** BAT

F2\_R2

**C Number:** C20009  
**Lock Date:** 06/05/2008  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.4.1.0\_004  
**PWG Approval Date:** 06/29/2010

Test Type: CHRONIC

beta-Picoline

Time Report Requested: 10:09:56

Route: DOSED WATER

CAS Number: 108-99-6

First Dose M/F: 11/18/04 / 11/19/04

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 mg/l	156.25 mg/l	312.5 mg/l	625 mg/l
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## Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	9	12	15	23
Natural Death	8	7	3	3
Survivors				
Terminal Sacrifice	33	31	32	24
Animals Examined Microscopically	50	50	50	50

## ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(45)	(47)	(48)	(48)
Intestine Large, Colon	(47)	(49)	(49)	(49)
Adenoma	1 (2%)			
Intestine Large, Rectum	(47)	(49)	(49)	(50)
Fibrous Histiocytoma, Metastatic, Skeletal Muscle				1 (2%)
Intestine Small, Duodenum	(48)	(49)	(49)	(50)
Intestine Small, Ileum	(46)	(47)	(48)	(49)
Intestine Small, Jejunum	(45)	(47)	(48)	(49)
Leiomyoma				1 (2%)
Liver	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Uncertain Primary Site			1 (2%)	
Fibrous Histiocytoma, Metastatic, Skeletal Muscle				1 (2%)
Hepatocellular Adenoma	2 (4%)	1 (2%)		2 (4%)
Hepatocellular Adenoma, Multiple	1 (2%)			
Hepatocellular Carcinoma			1 (2%)	
Osteosarcoma, Metastatic, Uncertain Primary Site		1 (2%)		
Mesentery	(4)	(8)	(4)	(6)
Fibrous Histiocytoma, Metastatic, Skeletal Muscle				1 (17%)
Osteosarcoma, Metastatic, Uncertain Primary Site		1 (13%)		

a - Number of animals examined microscopically at site and number of animals with lesion

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Lab: BAT

FISCHER 344 RATS MALE	0 mg/l	156.25 mg/l	312.5 mg/l	625 mg/l
Pancreas	(49)	(50)	(50)	(48)
Adenoma, Mixed Cell	1 (2%)	1 (2%)		
Fibrous Histiocytoma, Metastatic, Skeletal Muscle				1 (2%)
Osteosarcoma, Metastatic, Uncertain Primary Site		1 (2%)		
Acinus, Adenoma				1 (2%)
Salivary Glands	(50)	(50)	(50)	(50)
Carcinoma				1 (2%)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Papilloma		1 (2%)	1 (2%)	1 (2%)
Stomach, Glandular	(50)	(50)	(50)	(50)
Tongue	(0)	(0)	(2)	(1)
Squamous Cell Carcinoma			1 (50%)	1 (100%)
Squamous Cell Papilloma			1 (50%)	

## CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung				1 (2%)
Carcinoma, Metastatic, Salivary Glands				1 (2%)
Fibrous Histiocytoma, Metastatic, Skeletal Muscle				1 (2%)

## ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma	1 (2%)		1 (2%)	1 (2%)
Osteosarcoma, Metastatic, Uncertain Primary Site		1 (2%)		
Adrenal Medulla	(50)	(49)	(49)	(50)
Osteosarcoma, Metastatic, Uncertain Primary Site		1 (2%)		
Pheochromocytoma Benign	4 (8%)	5 (10%)	6 (12%)	5 (10%)

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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 mg/l	156.25 mg/l	312.5 mg/l	625 mg/l
Pheochromocytoma Complex	1 (2%)			
Pheochromocytoma Malignant			2 (4%)	
Bilateral, Pheochromocytoma Benign	1 (2%)			
Bilateral, Pheochromocytoma Malignant			1 (2%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	4 (8%)	1 (2%)	3 (6%)	2 (4%)
Parathyroid Gland	(50)	(47)	(48)	(48)
Pituitary Gland	(50)	(49)	(50)	(49)
Pars Distalis, Adenoma	28 (56%)	35 (71%)	28 (56%)	36 (73%)
Pars Intermedia, Adenoma			1 (2%)	
Thyroid Gland	(50)	(50)	(50)	(50)
C-cell, Adenoma	12 (24%)	10 (20%)	4 (8%)	8 (16%)
C-cell, Carcinoma	1 (2%)	3 (6%)	1 (2%)	
Follicular Cell, Adenoma			1 (2%)	
Follicular Cell, Carcinoma	1 (2%)	1 (2%)		

## GENERAL BODY SYSTEM

Peritoneum	(2)	(1)	(1)	(2)
Osteosarcoma, Metastatic, Uncertain Primary Site		1 (100%)		

## GENITAL SYSTEM

Epididymis	(50)	(50)	(50)	(50)
Osteosarcoma, Metastatic, Uncertain Primary Site		1 (2%)		
Preputial Gland	(50)	(50)	(50)	(50)
Adenoma		1 (2%)	2 (4%)	
Carcinoma	2 (4%)	1 (2%)	2 (4%)	
Prostate	(49)	(50)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Skeletal Muscle				1 (2%)
Osteosarcoma, Metastatic, Uncertain Primary Site		1 (2%)		
Seminal Vesicle	(50)	(50)	(50)	(50)

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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 mg/l	156.25 mg/l	312.5 mg/l	625 mg/l
Testes	(50)	(50)	(50)	(50)
Bilateral, Interstitial Cell, Adenoma	22 (44%)	20 (40%)	26 (52%)	24 (48%)
Interstitial Cell, Adenoma	13 (26%)	18 (36%)	16 (32%)	18 (36%)
Tunic, Leiomyosarcoma			1 (2%)	

## HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(9)	(11)	(11)	(8)
Deep Cervical, Carcinoma, Metastatic, Harderian Gland	1 (11%)			
Iliac, Chordoma, Metastatic, Uncertain Primary Site				1 (13%)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Uncertain Primary Site			1 (2%)	
Fibrous Histiocytoma, Metastatic, Skeletal Muscle				1 (2%)
Spleen	(50)	(50)	(50)	(50)
Osteosarcoma, Metastatic, Uncertain Primary Site		1 (2%)		
Thymus	(49)	(49)	(45)	(50)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung				1 (2%)
Carcinoma, Metastatic, Harderian Gland	1 (2%)			
Fibrous Histiocytoma, Metastatic, Skeletal Muscle				1 (2%)

## INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(49)	(50)	(50)
Adenoma			1 (2%)	
Carcinoma		1 (2%)		
Fibroadenoma	1 (2%)	1 (2%)	2 (4%)	
Skin	(50)	(50)	(50)	(50)
Basal Cell Adenoma	1 (2%)	2 (4%)	2 (4%)	
Carcinoma, Metastatic, Harderian Gland	1 (2%)			

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Lab: BAT

FISCHER 344 RATS MALE	0 mg/l	156.25 mg/l	312.5 mg/l	625 mg/l
Keratoacanthoma	5 (10%)	5 (10%)	7 (14%)	5 (10%)
Squamous Cell Carcinoma		1 (2%)		
Squamous Cell Papilloma			1 (2%)	
Subcutaneous Tissue, Fibroma	3 (6%)	4 (8%)	2 (4%)	5 (10%)
Subcutaneous Tissue, Fibrosarcoma	1 (2%)			
Subcutaneous Tissue, Hemangioma		1 (2%)		
Subcutaneous Tissue, Lipoma			2 (4%)	
Subcutaneous Tissue, Sarcoma			1 (2%)	

## MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Harderian Gland	1 (2%)			
Sarcoma			1 (2%)	
Skeletal Muscle	(0)	(0)	(0)	(1)
Fibrous Histiocytoma				1 (100%)

## NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
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## RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	3 (6%)	5 (10%)	1 (2%)	2 (4%)
Alveolar/Bronchiolar Carcinoma			3 (6%)	2 (4%)
Alveolar/Bronchiolar Carcinoma, Multiple			1 (2%)	
Carcinoma, Metastatic, Harderian Gland	1 (2%)			
Carcinoma, Metastatic, Preputial Gland	1 (2%)			
Carcinoma, Metastatic, Thyroid Gland		1 (2%)	1 (2%)	
Carcinoma, Metastatic, Zymbal'S Gland			1 (2%)	
Fibrous Histiocytoma, Metastatic, Skeletal Muscle				1 (2%)
Osteosarcoma, Metastatic, Uncertain Primary Site		1 (2%)		

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Lab: BAT

FISCHER 344 RATS MALE	0 mg/l	156.25 mg/l	312.5 mg/l	625 mg/l
Pheochromocytoma Malignant, Metastatic, Adrenal Medulla			1 (2%)	
Rhabdomyosarcoma, Metastatic, Uncertain Primary Site	1 (2%)			
Nose	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Harderian Gland	1 (2%)			
Respiratory Epithelium, Adenoma		1 (2%)		
Trachea	(49)	(50)	(50)	(50)

## SPECIAL SENSES SYSTEM

Ear	(2)	(0)	(0)	(0)
Neural Crest Tumor	1 (50%)			
Eye	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Harderian Gland	1 (2%)			
Harderian Gland	(50)	(50)	(50)	(50)
Carcinoma	1 (2%)			
Zymbal's Gland	(1)	(0)	(1)	(1)
Adenoma				1 (100%)
Carcinoma	1 (100%)		1 (100%)	

## URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Skeletal Muscle				1 (2%)
Hemangiosarcoma		1 (2%)		
Capsule, Osteosarcoma, Metastatic, Uncertain Primary Site		1 (2%)		
Renal Tubule, Adenoma		1 (2%)		1 (2%)
Renal Tubule, Adenoma, Multiple			1 (2%)	
Urinary Bladder	(50)	(50)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Skeletal Muscle				1 (2%)
Leiomyoma			1 (2%)	

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FISCHER 344 RATS MALE

0 mg/l

156.25 mg/l

312.5 mg/l

625 mg/l

SYSTEMIC LESIONS

	0 mg/l	156.25 mg/l	312.5 mg/l	625 mg/l
Multiple Organ	*(50)	*(50)	*(50)	*(50)
Leukemia Mononuclear	14 (28%)	19 (38%)	16 (32%)	14 (28%)
Lymphoma Malignant			1 (2%)	
Mesothelioma Malignant	4 (8%)	2 (4%)	1 (2%)	

a - Number of animals examined microscopically at site and number of animals with lesion

\* Number of animals with any tissue examined microscopically



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FISCHER 344 RATS MALE	0 mg/l	156.25 mg/l	312.5 mg/l	625 mg/l
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**Tumor Summary for Males**

Total Animals with Primary Neoplasms (b)	48	50	50	50
Total Primary Neoplasms	130	142	144	132
Total Animals with Benign Neoplasms	45	48	49	50
Total Benign Neoplasms	103	113	110	113
Total Animals with Malignant Neoplasms	22	25	30	19
Total Malignant Neoplasms	26	29	34	19
Total Animals with Metastatic Neoplasms	3	2	5	4
Total Metastatic Neoplasms	9	12	5	15
Total Animals with Malignant Neoplasms Uncertain Primary Site	1	1	2	1
Total Animals with Neoplasms Uncertain- Benign or Malignant	1			
Total Uncertain Neoplasms	1			

\*\*\* END OF MALE \*\*\*

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b - Primary tumors: all tumors except metastatic tumors

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Lab: BAT

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<b>FISCHER 344 RATS FEMALE</b>	<b>0 mg/l</b>	<b>156.25 mg/l</b>	<b>312.5 mg/l</b>	<b>625 mg/l</b>
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**Disposition Summary**

<b>Animals Initially In Study</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>
<b>Early Deaths</b>				
<b>Moribund Sacrifice</b>	<b>15</b>	<b>13</b>	<b>14</b>	<b>15</b>
<b>Natural Death</b>	<b>5</b>	<b>5</b>	<b>3</b>	<b>5</b>
<b>Survivors</b>				
<b>Natural Death</b>	<b>1</b>			
<b>Terminal Sacrifice</b>	<b>29</b>	<b>32</b>	<b>33</b>	<b>30</b>
<b>Animals Examined Microscopically</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>

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ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(46)	(45)	(47)	(45)
Intestine Large, Colon	(47)	(48)	(50)	(49)
Intestine Large, Rectum	(47)	(48)	(50)	(49)
Leiomyosarcoma, Metastatic, Uterus	1 (2%)			
Sarcoma, Metastatic, Uncertain Primary Site			1 (2%)	
Intestine Small, Duodenum	(50)	(47)	(50)	(50)
Intestine Small, Ileum	(47)	(46)	(49)	(50)
Intestine Small, Jejunum	(48)	(46)	(47)	(48)
Liver	(50)	(50)	(50)	(50)
Hepatocellular Adenoma	2 (4%)			
Mesentery	(4)	(7)	(7)	(8)
Sarcoma, Metastatic, Uncertain Primary Site			1 (14%)	
Oral Mucosa	(0)	(0)	(1)	(2)
Squamous Cell Papilloma			1 (100%)	1 (50%)
Pancreas	(50)	(50)	(49)	(50)
Sarcoma, Metastatic, Uncertain Primary Site			1 (2%)	
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(49)	(50)
Tongue	(0)	(0)	(0)	(1)
Squamous Cell Papilloma				1 (100%)

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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	0 mg/l	156.25 mg/l	312.5 mg/l	625 mg/l
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## CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)

## ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma	2 (4%)	4 (8%)	2 (4%)	3 (6%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	2 (4%)		3 (6%)	
Pheochromocytoma Malignant				1 (2%)
Islets, Pancreatic	(50)	(49)	(50)	(50)
Adenoma		1 (2%)		1 (2%)
Parathyroid Gland	(47)	(49)	(48)	(48)
Pituitary Gland	(50)	(49)	(49)	(50)
Pars Distalis, Adenoma	30 (60%)	27 (55%)	29 (59%)	26 (52%)
Pars Nervosa, Craniopharyngioma				1 (2%)
Thyroid Gland	(50)	(48)	(50)	(50)
Carcinoma			1 (2%)	1 (2%)
Bilateral, C-cell, Adenoma	1 (2%)		2 (4%)	
C-cell, Adenoma	9 (18%)	3 (6%)	1 (2%)	6 (12%)
C-cell, Carcinoma	1 (2%)	1 (2%)	2 (4%)	1 (2%)
Follicular Cell, Adenoma				1 (2%)

## GENERAL BODY SYSTEM

Peritoneum	(0)	(1)	(0)	(0)
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## GENITAL SYSTEM

Clitoral Gland	(50)	(50)	(50)	(50)
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Adenoma	7 (14%)	7 (14%)	12 (24%)	8 (16%)
Carcinoma		1 (2%)	1 (2%)	2 (4%)
Sarcoma	1 (2%)		1 (2%)	
Bilateral, Adenoma		2 (4%)		
Ovary	(50)	(50)	(50)	(50)
Granulosa Cell Tumor Benign			1 (2%)	
Granulosa Cell Tumor Malignant		2 (4%)		
Granulosa-Theca Tumor Malignant				1 (2%)
Schwannoma Malignant	1 (2%)			
Uterus	(50)	(50)	(50)	(50)
Leiomyosarcoma	1 (2%)		1 (2%)	
Polyp Stromal	8 (16%)	13 (26%)	13 (26%)	6 (12%)
Cervix, Sarcoma, Metastatic, Uncertain Primary Site			1 (2%)	
Endometrium, Adenoma			1 (2%)	
Endometrium, Carcinoma	1 (2%)			
Vagina	(1)	(1)	(0)	(2)
Polyp	1 (100%)	1 (100%)		2 (100%)

## HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(5)	(7)	(5)	(2)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Spleen	(50)	(50)	(50)	(50)
Thymus	(49)	(50)	(50)	(47)

## INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(50)	(50)	(50)
Adenoma			2 (4%)	1 (2%)
Carcinoma	2 (4%)		1 (2%)	
Fibroadenoma	22 (44%)	15 (30%)	17 (34%)	17 (34%)
Fibroadenoma, Multiple	12 (24%)	16 (32%)	11 (22%)	6 (12%)
Skin	(50)	(50)	(50)	(50)

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FISCHER 344 RATS FEMALE	0 mg/l	156.25 mg/l	312.5 mg/l	625 mg/l
Basal Cell Adenoma	1 (2%)			
Keratoacanthoma				1 (2%)
Subcutaneous Tissue, Fibroma	2 (4%)	2 (4%)	1 (2%)	
Subcutaneous Tissue, Fibrosarcoma		1 (2%)	1 (2%)	
Subcutaneous Tissue, Hemangiosarcoma			1 (2%)	
Subcutaneous Tissue, Lipoma				1 (2%)
Subcutaneous Tissue, Sarcoma				1 (2%)

## MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Osteosarcoma				1 (2%)
Skeletal Muscle	(0)	(1)	(0)	(0)

## NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
Glioma Benign	1 (2%)			

## RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma		3 (6%)	2 (4%)	5 (10%)
Alveolar/Bronchiolar Carcinoma		1 (2%)		
Carcinoma, Metastatic, Thyroid Gland	1 (2%)		1 (2%)	1 (2%)
Hemangiosarcoma, Metastatic, Skin			1 (2%)	
Nose	(50)	(50)	(50)	(50)
Respiratory Epithelium, Adenoma			1 (2%)	
Trachea	(50)	(50)	(50)	(50)

## SPECIAL SENSES SYSTEM

Eye	(50)	(48)	(48)	(50)
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Harderian Gland	(50)	(50)	(50)	(50)
Zymbal's Gland	(0)	(0)	(2)	(1)
Carcinoma			2 (100%)	

## URINARY SYSTEM

Kidney	(49)	(50)	(50)	(50)
Renal Tubule, Adenoma		1 (2%)	1 (2%)	
Urinary Bladder	(50)	(50)	(50)	(50)
Leiomyosarcoma, Metastatic, Uterus	1 (2%)			

## SYSTEMIC LESIONS

Multiple Organ	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma			1 (2%)	1 (2%)
Leukemia Mononuclear	12 (24%)	15 (30%)	18 (36%)	10 (20%)
Lymphoma Malignant				1 (2%)
Mesothelioma Malignant		1 (2%)		

a - Number of animals examined microscopically at site and number of animals with lesion

\* Number of animals with any tissue examined microscopically

Test Type: CHRONIC

beta-Picoline

Time Report Requested: 10:09:56

Route: DOSED WATER

CAS Number: 108-99-6

First Dose M/F: 11/18/04 / 11/19/04

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	0 mg/l	156.25 mg/l	312.5 mg/l	625 mg/l
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**Tumor Summary for Females**

Total Animals with Primary Neoplasms (b)	49	49	48	45
Total Primary Neoplasms	119	117	130	107
Total Animals with Benign Neoplasms	47	45	44	43
Total Benign Neoplasms	100	95	100	87
Total Animals with Malignant Neoplasms	17	18	26	18
Total Malignant Neoplasms	19	22	30	20
Total Animals with Metastatic Neoplasms	2		3	2
Total Metastatic Neoplasms	3		6	2
Total Animals with Malignant Neoplasms Uncertain Primary Site			1	1
Total Animals with Neoplasms Uncertain- Benign or Malignant				
Total Uncertain Neoplasms				

\*\*\* END OF REPORT \*\*\*

a - Number of animals examined microscopically at site and number of animals with lesion

b - Primary tumors: all tumors except metastatic tumors