

Experiment Number: 20212-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adenoviral vector (hGH)

CAS Number: HGH

Date Report Requested: 10/23/2014

Time Report Requested: 07:22:16

First Dose M/F: NA / NA

Lab: MBA

C Number: C20212

Lock Date: 06/16/2004

Cage Range: All

Date Range: All

Reasons For Removal: All

Removal Date Range: All

Treatment Groups: All

Study Gender: Male

PWG Approval Date NONE

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**F 344/N Rat Male
VEHICLE SALINE**

DAY ON TEST	0 0 0 0 0 0 0 0 0 0 0 0											
	0 0 0 0 0 0 0 0 0 0 0 0											
	0 0 0 0 2 2 2 2 2 2 2 2											
	3 3 3 3 9 9 9 9 9 9 9 9											
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	3	3	3	3
	0	0	0	0	0	1	1	1	0	0	0	0
	1	5	6	7	8	9	0	1	2	2	3	4

TOTALS*Alimentary System**

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	12
Liver	+	+	+	+	+	+	+	+	+	+	+	+	12
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	12
Atrophy, Focal													1 1.0
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	12
Left, Sublingual GI, Degeneration, Diffuse	1												1 1.0
Left, Sublingual GI, Inflammation, Diffuse	1												1 1.0
Parotid GI, Right, Degeneration, Focal	1	1	1										3 1.0
Right, Submandibular GI, Degeneration, Diffuse				1									1 1.0
Right, Submandibular GI, Inflammation, Diffuse				1									1 1.0
Right, Submandibular GI, Necrosis, Diffuse				1									1 1.0
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	12
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	12

Cardiovascular System

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

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1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

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VEHICLE SALINE**

	DAY ON TEST												
		0	0	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	3	3	3	3
	0	0	0	0	0	0	1	1	1	0	0	0	0
	1	5	6	7	8	9	0	1	2	2	3	4	
		*TOTALS											
Blood Vessel		+	+	+	+	+	+	+	+	+	+	+	12
Heart		+	+	+	+	+	+	+	+	+	+	+	12
Cardiomyopathy							1	1			2	1.0	
Endocrine System													
Adrenal Cortex		+	+	+	+	+	+	+	+	+	+	+	12
Adrenal Medulla		+	+	+	+	+	+	+	+	+	+	+	12
Islets, Pancreatic		+	+	+	+	+	+	+	+	+	+	+	12
Parathyroid Gland		+	+	+	+	+	M	+	+	+	+	+	11
Pituitary Gland		+	+	+	+	+	+	+	+	+	+	+	12
Thyroid Gland		+	+	+	+	+	+	+	+	+	+	+	12
General Body System													
NONE													
Genital System													
Epididymis		+	+	+	+	+	+	+	+	+	+	+	12
Preputial Gland		+	+	+	M	+	M	+	+	+	+	+	10
Prostate		+	+	+	+	+	+	+	+	+	+	+	12
Seminal Vesicle		+	+	+	+	+	+	+	+	+	+	+	12
Testes		+	+	+	+	+	+	+	+	+	+	+	12
Hematopoietic System													
Bone Marrow		+	+	+	+	+	+	+	+	+	+	+	12
Lymph Node, Mandibular		M	M	M	M	M	M	M	M	M	M	M	0

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VEHICLE SALINE**

DAY ON TEST												
	0	0	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	3	3	3
	0	0	0	0	0	0	1	1	0	0	0	0
	1	5	6	7	8	9	0	1	2	3	4	

***TOTALS**

Lymph Node, Mandibular	M	M	M	M	M	M	M	M	M	M	M	0
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	+	12
Spleen	+	+	+	+	+	+	+	+	+	+	+	12
Thymus	+	+	+	+	+	+	+	+	+	+	+	12
Depletion Lymphoid					1	1	2	1	1	2	1	1
Integumentary System												8 1.3
Mammary Gland	+	M	+	+	+	+	+	+	+	+	+	11
Skin	+	+	+	+	+	+	+	+	+	+	+	12
Musculoskeletal System												
Bone	+	+	+	+	+	+	+	+	+	+	+	12
Nervous System												
Brain	+	+	+	+	+	+	+	+	+	+	+	12
Respiratory System												
Lung	+	+	+	+	+	+	+	+	+	+	+	12
Nose	+	+	+	+	+	+	+	+	+	+	+	12
Trachea	+	+	+	+	+	+	+	+	+	+	+	12
Special Senses System												
Eye	+	I	+	+	+	+	+	+	+	+	+	11
Cornea, Degeneration									2	3		2 2.5
Sclera, Foreign Body				X							1	

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VEHICLE SALINE**

DAY ON TEST												
	0	0	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0
3	3	3	3	9	9	9	9	9	9	9	9	9
1	5	6	7	8	9	0	1	1	2	2	3	4

*TOTALS

Harderian Gland

+

+

+

+

+

+

+

+

+

+

+

+

12

Infiltration Cellular, Mononuclear Cl, Focal

2

1

2.0

Urinary System

Kidney

+

+

+

+

+

+

+

+

+

+

+

+

12

Urinary Bladder

+

+

+

+

+

+

+

+

+

+

+

+

12

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VEHICLE HCQ**

DAY ON TEST	0 0 0 0 0 0 0 0 0 0 0 0												
	0 0 0 0 0 0 0 0 0 0 0 0												
		0 0 2 2 0 0 2 2 2 2 2 2 2			3 3 9 9 3 3 9 9 9 9 9 9			0 0 0 0 0 0 0 0 0 0 0 0			0 0 0 0 0 0 0 0 0 0 0 0		
		0 0 0 0 0 0 0 0 0 0 0 0			0 0 0 0 0 0 0 0 0 0 0 0			0 0 0 0 0 0 0 0 0 0 0 0			0 0 0 0 0 0 0 0 0 0 0 0		
		0 0 0 0 0 0 0 0 0 0 0 0			0 0 0 0 0 0 0 0 0 0 0 0			0 0 0 0 0 0 0 0 0 0 0 0			0 0 0 0 0 0 0 0 0 0 0 0		
		1 1 1 1 1 1 2 2 2 2 2 1			3 4 6 7 8 9 0 1 2 3 4 5								

TOTALS*Alimentary System**

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	+	12
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	12
Liver	+	+	+	+	+	+	+	+	+	+	+	+	12
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	12
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	12
Parotid Gl, Right, Degeneration, Diffuse													3
Parotid Gl, Right, Degeneration, Focal													1 3.0
Right, Submandibul Gl, Degeneration, Diffuse	2	1		3	1								1 2.0
Right, Submandibul Gl, Degeneration, Multifocal													5 2.0
Right, Submandibul Gl, Inflammation, Diffuse	2	1		1	1								1 1.0
Right, Submandibul Gl, Inflammation, Multifocal													1 1.0
Right, Submandibul Gl, Necrosis, Diffuse	2	1		1	1								5 1.6
Right, Submandibul Gl, Necrosis, Multifocal													1 1.0

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VEHICLE HCQ**

DAY ON TEST	0 0 0 0 0 0 0 0 0 0 0 0												
	0 0 0 0 0 0 0 0 0 0 0 0												
	0 0 2 2 0 0 2 2 2 2 2 2												
	3 3 9 9 3 3 9 9 9 9 9 9												
ANIMAL ID	0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0	*TOTALS

Right, Submandibul GI, Regeneration,
Diffuse 2 1 2.0Right, Submandibul GI, Regeneration,
Multifocal 3 1 3.0

Stomach, Forestomach

+ + + + + + + + + + + + 12

Stomach, Glandular

+ + + + + + + + + + + + 12

Cardiovascular System

Blood Vessel

+ + + + + + + + + + + + 12

Heart

+ + + + + + + + + + + + 12

Cardiomyopathy

1 1 1 3 1.0

Endocrine System

Adrenal Cortex

+ + + + + + + + + + + + 12

Adrenal Medulla

+ + + + + + + + + + + + 12

Islets, Pancreatic

+ + + + + + + + + + + + 12

Parathyroid Gland

+ + + + + + M M + M M M 7

Pituitary Gland

+ + + + + + + + + + + + 11

Thyroid Gland

+ + + + + + + + + + + + 12

General Body System

NONE

Genital System

Epididymis

+ + + + + + + + + + + + 12

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**F 344/N Rat Male
VEHICLE HCQ**

| DAY ON TEST | | | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 2 | 2 | 0 | 0 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 3 | 3 | 9 | 9 | 3 | 3 | 9 | 9 | 9 | 9 | 9 | 9 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 |
| | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 1 |
| | 3 | 4 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

*TOTALS

Granuloma Sperm, Focal 3 1 3.0

Preputial Gland + + + M + M + + + + + + 10

Prostate + + + + + + + + + + + + 12

Seminal Vesicle + + + + + + + + + + + + 12

Testes + + + + + + + + + + + + 12

Hematopoietic System

Bone Marrow + + + + + + + + + + + + 12

Lymph Node, Mandibular M M M M M M M M M M M M 0

Lymph Node, Mesenteric + + + + + + + + + + + + 12

Spleen + + + + + + + + + + + + 12

Thymus + + + + + + + + + + + + 12

Depletion Lymphoid 1 1 2 1 2 2 1 1 8 1.4

Integumentary System

Mammary Gland + + + + + + M + + + + + 10

Skin + + + + + + + + + + + + 12

Musculoskeletal System

Bone + + + + + + + + + + + + 12

Nervous System

Brain + + + + + + + + + + + + 12

Respiratory System

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VEHICLE HCQ**

| DAY ON TEST | | | | | | | | | | | | |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 2 | 2 | 0 | 0 | 2 | 2 | 2 | 2 | 2 | 2 |
| ANIMAL ID | 3 | 3 | 9 | 9 | 3 | 3 | 9 | 9 | 9 | 9 | 9 | 9 |
| Lung | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Nose | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Trachea | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 |
| Special Senses System | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 1 |
| Eye | 3 | 4 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |
| Harderian Gland | | | | | | | | | | | | |
| Urinary System | | | | | | | | | | | | |
| Kidney | | | | | | | | | | | | |
| Urinary Bladder | | | | | | | | | | | | |

*TOTALS

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Alimentary System

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Left, Parotid GI, Degeneration, Focal | 1 | | 2 | 1 | | | | | | | | | 3 1.3 |
| Left, Submandibul GI, Degeneration, Multifocal | | | | | | | | | | | | | 1 1.0 |
| Left, Submandibul GI, Inflammation, Multifocal | | | | | | | | | | | | | 1 2.0 |
| Left, Submandibul GI, Necrosis, Multifocal | | | | | | | | | | | | | 1 1.0 |
| Left, Submandibul GI, Regeneration, Multifocal | | | | | | | | | | | | | 1 3.0 |
| Parotid GI, Right, Degeneration, Diffuse | | | | | 2 | 3 | | | | | | | 2 2.5 |
| Right, Submandibul GI, Degeneration, Diffuse | 4 | 3 | 3 | 3 | | | | | | | | | 4 3.3 |
| Right, Submandibul GI, Degeneration, Multifocal | | | | | | | 1 | 1 | 1 | 1 | 1 | 1 | 6 1.0 |

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6.0 E9 SALINE**

| DAY ON TEST | 0 0 0 0 0 0 0 0 0 0 0 0 | | | | | | | | | | | |
|-------------|-------------------------|--|--|--|--|--|--|--|--|--|--|--|
| | 0 0 0 0 0 0 0 0 0 0 0 0 | | | | | | | | | | | |
| ANIMAL ID | 0 0 0 0 2 2 2 2 2 2 2 2 | | | | | | | | | | | |
| | 3 3 3 3 9 9 9 9 9 9 9 9 | | | | | | | | | | | |

***TOTALS**

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Right, Submandibul GI, Inflammation, Diffuse | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2.3 |
| Right, Submandibul GI, Inflammation, Multifocal | | | | | | 2 | 2 | 2 | 2 | 2 | 3 | 6 2.2 |
| Right, Submandibul GI, Necrosis, Diffuse | 4 | 3 | 3 | 3 | | | | | | | 4 | 3.3 |
| Right, Submandibul GI, Necrosis, Multifocal | | | | | | 1 | 1 | 1 | 1 | 1 | 6 | 1.0 |
| Right, Submandibul GI, Regeneration, Multifocal | | | | | | 3 | 3 | 3 | 3 | 3 | 6 | 2.7 |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | 12 |

Cardiovascular System

| | | | | | | | | | | | | |
|----------------|---|---|---|---|---|---|---|---|---|---|---|-----|
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Heart | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Cardiomyopathy | | | | | | 1 | 2 | 1 | | | 3 | 1.3 |

Endocrine System

| | | | | | | | | | | | | |
|--------------------|---|---|---|---|---|---|---|---|---|---|---|----|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Parathyroid Gland | + | + | + | + | + | + | M | M | + | + | M | 8 |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | I | + | 11 |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | 12 |

General Body System

NONE

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20212-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adenoviral vector (hGH)

CAS Number: HGH

Date Report Requested: 10/23/2014

Time Report Requested: 07:22:17

First Dose M/F: NA / NA

Lab: MBA

**F 344/N Rat Male
6.0 E9 SALINE**

| DAY ON TEST | | | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 3 | 3 | 3 | 3 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 3 | 3 |
| | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 |
| | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 5 | 6 | 7 |

TOTALS*Genital System**

| | | | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Epididymis | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Preputial Gland | + | M | + | + | + | + | + | + | + | + | + | + | 11 |
| Prostate | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Seminal Vesicle | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Testes | + | + | + | + | + | + | + | + | + | + | + | + | 12 |

Hematopoietic System

| | | | | | | | | | | | | | |
|------------------------|---|---|---|---|---|---|---|---|---|---|----|-----|----|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Lymph Node, Mandibular | M | M | M | M | M | M | M | M | M | M | M | M | 0 |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Spleen | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Thymus | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Depletion Lymphoid | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 2 | 10 | 1.2 | |

Integumentary System

| | | | | | | | | | | | | | |
|---------------|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Mammary Gland | + | + | + | + | I | + | + | + | + | + | + | + | 11 |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | 12 |

Musculoskeletal System

| | | | | | | | | | | | | | |
|------|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
|------|---|---|---|---|---|---|---|---|---|---|---|---|----|

Nervous System

| | | | | | | | | | | | | | |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|----|

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20212-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adenoviral vector (hGH)

CAS Number: HGH

Date Report Requested: 10/23/2014

Time Report Requested: 07:22:17

First Dose M/F: NA / NA

Lab: MBA

**F 344/N Rat Male
6.0 E9 SALINE**

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 3 | 3 | 3 | 3 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 3 | 3 |
| | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 |
| | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 5 | 6 | 7 |

*TOTALS

Respiratory System

| | | | | | | | | | | | | |
|---------|---|---|---|---|---|---|---|---|---|---|---|----|
| Lung | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Nose | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | 12 |

Special Senses System

| | | | | | | | | | | | | |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|----|
| Eye | + | I | + | + | + | + | + | + | + | + | + | 11 |
| Cornea, Ulcer | | | | | | | | | | | | 2 |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Artery, Polyarteritis | | | | | | | | | | | | 1 |

1 2.0

1 1.0

Urinary System

| | | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|----|
| Kidney | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | 12 |

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20212-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adenoviral vector (hGH)

CAS Number: HGH

Date Report Requested: 10/23/2014

Time Report Requested: 07:22:17

First Dose M/F: NA / NA

Lab: MBA

**F 344/N Rat Male
1.5 E11 HCQ**

| DAY ON TEST | | | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 2 | 2 | 2 | 0 | 0 | 2 | 2 | 2 | 2 | 2 |
| | 3 | 3 | 9 | 9 | 9 | 3 | 3 | 9 | 9 | 9 | 9 | 9 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

TOTALS*Alimentary System**

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Duct, Concretion | | | | | | | X | | | | | | 1 |
| Infiltration Cellular, Mononuclear Cl, Focal | | | | | | | | 1 | | | | | 1 1.0 |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Parotid GI, Right, Degeneration, Diffuse | 3 | 2 | | | | 2 | | | | | | | 3 2.3 |
| Right, Submandibul GI, Degeneration, Diffuse | 4 | 4 | | | | 4 | 2 | | | | | | 4 3.5 |
| Right, Submandibul GI, Degeneration, Multifocal | | | 1 | 1 | 2 | | | 1 | 1 | | | | 5 1.2 |
| Right, Submandibul GI, Inflammation, Diffuse | 4 | 4 | | | | 4 | 2 | | | | | | 4 3.5 |
| Right, Submandibul GI, Inflammation, Multifocal | | | 1 | 2 | 3 | | | 2 | 2 | | | | 5 2.0 |
| Right, Submandibul GI, Necrosis, Diffuse | 4 | 4 | | | | 4 | 2 | | | | | | 4 3.5 |
| Right, Submandibul GI, Necrosis, Multifocal | | | 1 | 1 | 2 | | | 1 | 1 | | | | 5 1.2 |

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

- 1) Minimal 3) Moderate
- 2) Mild 4) Marked

Experiment Number: 20212-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adenoviral vector (hGH)

CAS Number: HGH

Date Report Requested: 10/23/2014

Time Report Requested: 07:22:18

First Dose M/F: NA / NA

Lab: MBA

**F 344/N Rat Male
1.5 E11 HCQ**

| DAY ON TEST | | | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3 | 3 | 9 | 9 | 9 | 3 | 3 | 9 | 9 | 9 | 9 | 9 |
| | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

***TOTALS**Right, Submandibul Gl, Regeneration,
Multifocal 2 3 4 2 3 5 2.8

Stomach, Forestomach + + + + + + + + + + + + 12

Stomach, Glandular + + + + + + + + + + + + 12

Cardiovascular System

Blood Vessel + + + + + + + + + + + + 12

Heart + + + + + + + + + + + + 12

Cardiomyopathy 1 2 1 1 4 1.3

Endocrine System

Adrenal Cortex + + + + + + + + + + + + 12

Adrenal Medulla + + + + + + + + + + + + 12

Islets, Pancreatic + + + + + + + + + + + + 12

Parathyroid Gland + + + + + + M + + + + + + 11

Pituitary Gland + + + + + + + + I + + + + + 11

Thyroid Gland + + + + + + + + + + + + 12

General Body System

NONE

Genital System

Epididymis + + + + + + + + + + + + 12

Granuloma Sperm, Focal 2 1 2.0

Preputial Gland + + M + M M + + + + + + 9

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

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2) Mild 4) Marked

Experiment Number: 20212-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adenoviral vector (hGH)

CAS Number: HGH

Date Report Requested: 10/23/2014

Time Report Requested: 07:22:18

First Dose M/F: NA / NA

Lab: MBA

**F 344/N Rat Male
1.5 E11 HCQ**

| DAY ON TEST | | | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 2 | 2 | 2 | 0 | 0 | 2 | 2 | 2 | 2 | 2 |
| | 3 | 3 | 9 | 9 | 9 | 3 | 3 | 9 | 9 | 9 | 9 | 9 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

***TOTALS**

| | | | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Prostate | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Seminal Vesicle | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Testes | + | + | + | + | + | + | + | + | + | + | + | + | 12 |

Hematopoietic System

| | | | | | | | | | | | | | |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Lymph Node, Mandibular | M | M | M | M | M | M | M | M | M | M | M | M | 0 |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Spleen | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Thymus | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Depletion Lymphoid | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | | 11 1.3 |

Integumentary System

| | | | | | | | | | | | | | |
|---------------|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Mammary Gland | + | + | M | + | + | + | + | + | + | + | + | + | 11 |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | 12 |

Musculoskeletal System

| | | | | | | | | | | | | | |
|------|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
|------|---|---|---|---|---|---|---|---|---|---|---|---|----|

Nervous System

| | | | | | | | | | | | | | |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|----|

Respiratory System

| | | | | | | | | | | | | | |
|------|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | 12 |

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20212-01

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Species/Strain: Rat/F 344/N

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Test Compound: Adenoviral vector (hGH)

CAS Number: HGH

Date Report Requested: 10/23/2014

Time Report Requested: 07:22:18

First Dose M/F: NA / NA

Lab: MBA

F 344/N Rat Male
1.5 E11 HCQ

| DAY ON TEST | | | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3 | 3 | 9 | 9 | 9 | 3 | 3 | 9 | 9 | 9 | 9 | 9 |
| | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

*TOTALS

Trachea

+ + + + + + + + + + + + 12

Special Senses System

Eye

I + + + + + + + + + + + 11

Cornea, Degeneration

2 1

2 1.5

Sclera, Edema

1 2

2 1.5

Harderian Gland

+ + + + + + + + + + + 12

Infiltration Cellular, Mononuclear Cl, Focal

3 1 3.0

Urinary System

Kidney

+ + + + + + + + + + + 12

Urinary Bladder

+ + + + + + + + + + + 12

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

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Time Report Requested: 07:22:18

First Dose M/F: NA / NA

Lab: MBA

**F 344/N Rat Male
6.0 E9 HCQ**

| DAY ON TEST | | | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 2 | 2 | 2 | 0 | 0 | 2 | 2 | 2 | 2 | 2 |
| | 3 | 3 | 9 | 9 | 9 | 3 | 3 | 9 | 9 | 9 | 9 | 9 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 4 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 |
| | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

TOTALS*Alimentary System**

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Liver | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Left, Parotid GI, Degeneration, Diffuse | 2 | | | | | | | | | | | 1 2.0 |
| Left, Parotid GI, Degeneration, Focal | | 1 | | | | | | | | | | 1 1.0 |
| Left, Submandibul GI, Degeneration, Diffuse | 3 | | | | | | | | | | | 1 3.0 |
| Left, Submandibul GI, Inflammation, Diffuse | 3 | | | | | | | | | | | 1 3.0 |
| Left, Submandibul GI, Necrosis, Diffuse | 3 | | | | | | | | | | | 1 3.0 |
| Parotid GI, Right, Degeneration, Diffuse | 3 | 3 | | | | | | | | | | 2 3.0 |
| Parotid GI, Right, Degeneration, Focal | | | 3 | 1 | | | | | | | | 2 2.0 |
| Right, Sublingul GI, Degeneration, Diffuse | | | | 3 | | | | | | | | 1 3.0 |
| Right, Sublingul GI, Inflammation, Diffuse | | | | 3 | | | | | | | | 1 3.0 |
| Right, Sublingul GI, Necrosis, Diffuse | | | | 1 | | | | | | | | 1 1.0 |

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

- 1) Minimal 3) Moderate
- 2) Mild 4) Marked

Experiment Number: 20212-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adenoviral vector (hGH)

CAS Number: HGH

Date Report Requested: 10/23/2014

Time Report Requested: 07:22:18

First Dose M/F: NA / NA

Lab: MBA

**F 344/N Rat Male
6.0 E9 HCQ**

| DAY ON TEST | | | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 2 | 2 | 2 | 0 | 0 | 2 | 2 | 2 | 2 | 2 |
| | 3 | 3 | 9 | 9 | 9 | 3 | 3 | 9 | 9 | 9 | 9 | 9 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 4 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 |
| | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

***TOTALS**

| | | | | |
|--|---|---|---|-----|
| Right, Submandibul GI, Degeneration, Diffuse | 3 | 3 | 2 | 3.0 |
|--|---|---|---|-----|

| | | | | | | |
|---|---|---|---|---|---|-----|
| Right, Submandibul GI, Degeneration, Multifocal | 1 | 1 | 1 | 1 | 7 | 1.0 |
|---|---|---|---|---|---|-----|

| | | | | |
|--|---|---|---|-----|
| Right, Submandibul GI, Inflammation, Diffuse | 2 | 3 | 2 | 2.5 |
|--|---|---|---|-----|

| | | | | | | |
|---|---|---|---|---|---|-----|
| Right, Submandibul GI, Inflammation, Multifocal | 2 | 2 | 1 | 1 | 6 | 1.5 |
|---|---|---|---|---|---|-----|

| | | | | |
|--|---|---|---|-----|
| Right, Submandibul GI, Necrosis, Diffuse | 2 | 3 | 2 | 2.5 |
|--|---|---|---|-----|

| | | | | | | |
|---|---|---|---|---|---|-----|
| Right, Submandibul GI, Necrosis, Multifocal | 1 | 1 | 1 | 1 | 7 | 1.0 |
|---|---|---|---|---|---|-----|

| | | | | | | |
|---|---|---|---|---|---|-----|
| Right, Submandibul GI, Regeneration, Multifocal | 3 | 4 | 1 | 1 | 5 | 2.4 |
|---|---|---|---|---|---|-----|

| | | | | | | | | | | | | |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|----|
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | 12 |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|----|

| | | | | | | | | | | | | |
|--------------------|---|---|---|---|---|---|---|---|---|---|---|----|
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | 12 |
|--------------------|---|---|---|---|---|---|---|---|---|---|---|----|

Cardiovascular System

| | | | | | | | | | | | | |
|--------------|---|---|---|---|---|---|---|---|---|---|---|----|
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | + | 12 |
|--------------|---|---|---|---|---|---|---|---|---|---|---|----|

| | | | | | | | | | | | | |
|-------|---|---|---|---|---|---|---|---|---|---|---|----|
| Heart | + | + | + | + | + | + | + | + | + | + | + | 12 |
|-------|---|---|---|---|---|---|---|---|---|---|---|----|

| | | | | | | | | | | | |
|----------------|--|--|--|--|---|--|--|--|--|---|-----|
| Cardiomyopathy | | | | | 1 | | | | | 1 | 1.0 |
|----------------|--|--|--|--|---|--|--|--|--|---|-----|

Endocrine System

| | | | | | | | | | | | | |
|----------------|---|---|---|---|---|---|---|---|---|---|---|----|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | 12 |
|----------------|---|---|---|---|---|---|---|---|---|---|---|----|

| | | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|----|
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | 12 |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|----|

| | | | | | | | | | | | | |
|--------------------|---|---|---|---|---|---|---|---|---|---|---|----|
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | 12 |
|--------------------|---|---|---|---|---|---|---|---|---|---|---|----|

| | | | | | | | | | | | | |
|-------------------|---|---|---|---|---|---|---|---|---|---|---|----|
| Parathyroid Gland | + | I | M | + | + | + | + | + | + | + | + | 10 |
|-------------------|---|---|---|---|---|---|---|---|---|---|---|----|

| | | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|----|
| Pituitary Gland | I | + | + | + | + | + | + | + | + | + | + | 11 |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|----|

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

- 1) Minimal 3) Moderate
- 2) Mild 4) Marked

Experiment Number: 20212-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adenoviral vector (hGH)

CAS Number: HGH

Date Report Requested: 10/23/2014

Time Report Requested: 07:22:18

First Dose M/F: NA / NA

Lab: MBA

**F 344/N Rat Male
6.0 E9 HCQ**

| DAY ON TEST | | | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 4 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 |
| | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

***TOTALS**

Thyroid Gland

+ + + + + + + + + + + + 12

General Body System

NONE

Genital System

Epididymis

+ + + + + + + + + + + + 12

Preputial Gland

+ M + M + M + + + + + + 9

Prostate

+ + + + + + + + + + + + 12

Seminal Vesicle

+ + + + + + + + + + + + 12

Testes

+ + + + + + + + + + + + 12

Hematopoietic System

Bone Marrow

+ + + + + + + + + + + + 12

Lymph Node, Mandibular

M M M M M M M M M M M M 0

Lymph Node, Mesenteric

+ + + + + + + + + + + + 12

Spleen

+ + + + + + + + + + + + 12

Thymus

+ + + + + + + + + + + + 12

Depletion Lymphoid

1 1 1 2 1 2 2 2 8 1.5

Integumentary System

Mammary Gland

+ + + + + + + + + + + + 12

Skin

+ + + + + + + + + + + + 12

Musculoskeletal System

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

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**F 344/N Rat Male
6.0 E9 HCQ**

| DAY ON TEST | | | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 4 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 |
| | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

***TOTALS**

| | | | | | | | | | | | | | |
|------------------------------|---|---|---|---|---|---|---|---|---|---|-----|---|-----|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Nervous System | | | | | | | | | | | | | |
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Respiratory System | | | | | | | | | | | | | |
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Special Senses System | | | | | | | | | | | | | |
| Eye | I | I | + | + | + | + | + | + | I | + | + | + | 9 |
| Cornea, Degeneration | | | | | | | | | | 2 | 2 | | 2.0 |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Necrosis | 1 | | | | | | | | 2 | | 2 | | 1.5 |
| Urinary System | | | | | | | | | | | | | |
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Mineralization, Focal | 1 | | | | | | | | | 1 | 1.0 | | |
| Renal Tubule, Dilatation | | 1 | | | | | | | | 1 | 1.0 | | |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | 12 |

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

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Experiment Number: 20212-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adenoviral vector (hGH)

CAS Number: HGH

Date Report Requested: 10/23/2014

Time Report Requested: 07:22:18

First Dose M/F: NA / NA

Lab: MBA

**F 344/N Rat Male
2.4 E8 HCQ**

| DAY ON TEST | | | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 3 | 3 | 2 | 3 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 3 | 3 |
| | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 6 | 6 | 6 |
| | 1 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 2 | 3 | 4 |

TOTALS*Alimentary System**

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|-----|----|-----|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | 12 | |
| Intestine Large, Cecum | + | + | + | + | + | + | + | A | + | + | + | 11 | |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | 12 | |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | 12 | |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | 12 | |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | 12 | |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | 12 | |
| Liver | + | + | + | + | + | + | + | + | + | + | + | 12 | |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | 12 | |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | 12 | |
| Left, Parotid GI, Degeneration, Focal | 1 | 1 | | | | | | | | 2 | 1.0 | | |
| Parotid GI, Right, Degeneration, Diffuse | 3 | | 2 | | | | | | | 2 | 2.5 | | |
| Parotid GI, Right, Degeneration, Focal | 3 | | 1 | | | | | | | 2 | 2.0 | | |
| Right, Submandibul GI, Degeneration, Diffuse | 3 | 3 | 3 | 3 | | | | | | 4 | 3.0 | | |
| Right, Submandibul GI, Degeneration, Multifocal | | | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 8 | 1.0 |
| Right, Submandibul GI, Inflammation, Diffuse | 3 | 2 | 2 | 2 | | | | | | 4 | 2.3 | | |
| Right, Submandibul GI, Inflammation, Multifocal | | | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 8 | 1.0 |
| Right, Submandibul GI, Necrosis, Diffuse | 3 | 3 | 3 | 3 | | | | | | 4 | 3.0 | | |
| Right, Submandibul GI, Necrosis, Multifocal | | | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 8 | 1.0 |

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

- 1) Minimal 3) Moderate
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Experiment Number: 20212-01

Test Type: 18-33 DAYS

Route: INTRADUCTAL CANNULATION

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Adenoviral vector (hGH)

CAS Number: HGH

Date Report Requested: 10/23/2014

Time Report Requested: 07:22:18

First Dose M/F: NA / NA

Lab: MBA

**F 344/N Rat Male
2.4 E8 HCQ**

| DAY ON TEST | | | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 3 | 3 |
| | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 6 | 6 | 6 | 6 |
| | 1 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 2 | 3 | 4 |

***TOTALS**

| | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|-----|
| Right, Submandibul Gl, Regeneration,
Multifocal | 3 | 1 | 1 | 2 | 2 | 2 | 1 | 1 | 1 | 8 | 1.5 |
|--|---|---|---|---|---|---|---|---|---|---|-----|

Stomach, Forestomach

+ + + + + + + + + + + + 12

Stomach, Glandular

+ + + + + + + + + + + + 12

Cardiovascular System

Blood Vessel

+ + + + + + + + + + + + 12

Heart

+ + + + + + + + + + + + 12

Cardiomyopathy

1 1 1 3 1.0

Endocrine System

Adrenal Cortex

+ + + + + + + + + + + + 12

Adrenal Medulla

+ + + + + + + + + + + + 12

Islets, Pancreatic

+ + + + + + + + + + + + 12

Parathyroid Gland

+ + M + + + M + M M M M 6

Pituitary Gland

+ + + + + + + + + + + + 12

Thyroid Gland

+ + + + + + + + + + + + 12

General Body System

NONE

Genital System

Epididymis

+ + + + + + + + + + + + 12

Preputial Gland

+ M + + + + + + + + + + 11

Prostate

+ + + + + + + + + + + + 12

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

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**F 344/N Rat Male
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| DAY ON TEST | | | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 3 | 3 | 2 | 3 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 3 | 3 |
| | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 6 | 6 | 6 |
| | 1 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 2 | 3 | 4 |

***TOTALS**

| | | | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Seminal Vesicle | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Testes | + | + | + | + | + | + | + | + | + | + | + | + | 12 |

Hematopoietic System

| | | | | | | | | | | | | | |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Lymph Node, Mandibular | M | M | M | M | M | M | M | M | M | M | M | M | 0 |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Spleen | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Thymus | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Depletion Lymphoid | 1 | | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 8 1.0 |

Integumentary System

| | | | | | | | | | | | | | |
|---------------|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Mammary Gland | + | + | + | + | + | + | + | + | M | + | + | + | 11 |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | 12 |

Musculoskeletal System

| | | | | | | | | | | | | | |
|------|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
|------|---|---|---|---|---|---|---|---|---|---|---|---|----|

Nervous System

| | | | | | | | | | | | | | |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|----|

Respiratory System

| | | | | | | | | | | | | | |
|---------|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | 12 |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | 12 |

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

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Species/Strain: Rat/F 344/N

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Test Compound: Adenoviral vector (hGH)

CAS Number: HGH

Date Report Requested: 10/23/2014

Time Report Requested: 07:22:19

First Dose M/F: NA / NA

Lab: MBA

F 344/N Rat Male
2.4 E8 HCQ

| DAY ON TEST | | | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 3 | 3 | 2 | 3 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 3 | 3 |
| | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 6 | 6 | 6 |
| | 1 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 2 | 3 | 4 |

*TOTALS

Special Senses System

| | | |
|-----------------|-------------------------|----|
| Ear | + | 1 |
| Eye | + + + + + + + + | 8 |
| Harderian Gland | + + + + + + + + + + + + | 12 |

Urinary System

| | | |
|-----------------|-------------------------|----|
| Kidney | + + + + + + + + + + + + | 12 |
| Urinary Bladder | + + + + + + + + + + + + | 12 |

END OF MALE DATA

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

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Time Report Requested: 07:22:19

First Dose M/F: NA / NA

Lab: MBA

** END OF REPORT **

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

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2) Mild 4) Marked