

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: FEED

Page: 204
 Report Date:04/29/2009

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
Male							
Southern Research Institute	059902703	08/12/02	729	50 (3)	37(705)	452.8	Chromium picolinate monohydrate
Battelle Columbus Laboratory	050517405	08/05/02	729	50 (3)	33(703)	510.0	Cresols
Southern Research Institute	059900705	04/21/03	729	50 (3)	33(679)	460.9	Goldenseal root powder
Southern Research Institute	059201305	01/20/00	730	50 (3)	31(702)	448.0	4-Methylimidazole
Southern Research Institute	052000803	03/04/03	729	50 (3)	36(704)	452.1	Milk thistle extract
Female							
Southern Research Institute	059902703	08/12/02	733	50 (5)	36(702)	314.7	Chromium picolinate monohydrate
Battelle Columbus Laboratory	050517405	N/A	N/A	0 (0)	0(0)	N/A	Cresols
Southern Research Institute	059900705	04/21/03	731	50 (5)	30(699)	326.0	Goldenseal root powder
Southern Research Institute	059201305	01/20/00	735	50 (5)	40(702)	311.3	4-Methylimidazole
Southern Research Institute	052000803	03/04/03	732	50 (5)	38(693)	328.4	Milk thistle extract

NOTE: The text on page 2 ("Report Description") describes how the studies listed here are displayed on the data pages that follow.

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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 205
Report Date: 04/29/2009

		Male				Female			
#All Organs:									
Benign Tumors									
		49/50 (98%)	50/50 (100%)	47/50 (94%)		45/50 (90%)		46/50 (92%)	
		50/50 (100%)	50/50 (100%)			48/50 (96%)		39/50 (78%)	
Overall Incidence	Total	246/250 (98.4%)	Mean 98.4%	SD 2.61%	Total	178/200 (89%)	Mean 89%	SD 7.75%	
.....									
#All Organs:									
Malignant Tumors									
		27/50 (54%)	23/50 (46%)	29/50 (58%)		15/50 (30%)		19/50 (38%)	
		22/50 (44%)	26/50 (52%)			19/50 (38%)		18/50 (36%)	
Overall Incidence	Total	127/250 (50.8%)	Mean 50.8%	SD 5.76%	Total	71/200 (35.5%)	Mean 35.5%	SD 3.79%	
.....									
#All Organs:									
Malignant and Benign Tumors									
		50/50 (100%)	50/50 (100%)	50/50 (100%)		47/50 (94%)		48/50 (96%)	
		50/50 (100%)	50/50 (100%)			48/50 (96%)		46/50 (92%)	
Overall Incidence	Total	250/250 (100%)	Mean 100%	SD 0%	Total	189/200 (94.5%)	Mean 94.5%	SD 1.91%	
.....									
#All Organs:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	1/50 (2%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Hemangiosarcoma									
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 206
 Report Date:04/29/2009

		Male				Female			
#All Organs:									
Hemangiosarcoma or Hemangioma									
		2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Histiocytic Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)		
		0/50 (0%)	3/50 (6%)		2/50 (4%)		0/50 (0%)		
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 2.68%	Total	4/200 (2%)	Mean 2%	SD 1.63%	
.....									
#All Organs:									
Leukemia: Erythrocytic									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)		0/50 (0%)		1/50 (2%)		
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#All Organs:									
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated									
		19/50 (38%)	15/50 (30%)	21/50 (42%)	9/50 (18%)	9/50 (18%)	6/50 (12%)	9/50 (18%)	
		15/50 (30%)	17/50 (34%)		9/50 (18%)		6/50 (12%)		
Overall Incidence	Total	87/250 (34.8%)	Mean 34.8%	SD 5.22%	Total	33/200 (16.5%)	Mean 16.5%	SD 3%	
.....									
#All Organs:									
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type									
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)		
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 207
 Report Date:04/29/2009

		Male				Female			
#All Organs:									
Mesothelioma: Benign									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean 0%	SD 0%	Total	0/200	(0%)	Mean 0%
									SD 0%
.....									
#All Organs:									
Mesothelioma: Benign, Malignant, NOS									
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/250	(0.4%)	Mean 0.4%	SD 0.89%	Total	0/200	(0%)	Mean 0%
									SD 0%
.....									
#All Organs:									
Mesothelioma: Malignant									
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/250	(0.4%)	Mean 0.4%	SD 0.89%	Total	0/200	(0%)	Mean 0%
									SD 0%
.....									
#All Organs:									
Osteoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/250	(0.4%)	Mean 0.4%	SD 0.89%	Total	0/200	(0%)	Mean 0%
									SD 0%
.....									
#All Organs:									
Osteosarcoma									
		0/50	(0%)	0/50	(0%)	2/50	(4%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	2/250	(0.8%)	Mean 0.8%	SD 1.79%	Total	1/200	(0.5%)	Mean 0.5%
									SD 1%

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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 208
 Report Date:04/29/2009

		Male				Female			
#All Organs:									
Osteosarcoma or Osteoma									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)		
		0/50 (0%)	1/50 (2%)			1/50 (2%)	0/50 (0%)		0/50 (0%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Adrenal Cortex:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/48 (0%)		1/50 (2%)
		1/50 (2%)	2/50 (4%)			1/49 (2%)			
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	Total	4/197 (2.03%)	Mean 2.01%	SD 1.63%	
.....									
*Adrenal Cortex:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)		0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/49 (0%)			
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Medulla:									
Ganglioneuroma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/48 (0%)		0/48 (0%)
		0/50 (0%)	0/50 (0%)			0/48 (0%)			
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/194 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Medulla:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/48 (0%)		0/48 (0%)
		0/50 (0%)	0/50 (0%)			0/48 (0%)			
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/194 (0%)	Mean 0%	SD 0%	

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 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 209
 Report Date:04/29/2009

		Male				Female								
*Adrenal Medulla:														
 Pheochromocytoma Benign														
		8/50	(16%)	8/50	(16%)	5/49	(10%)	1/50	(2%)	0/48	(0%)			
		8/50	(16%)	5/50	(10%)			2/48	(4%)	1/48	(2%)			
Overall Incidence	Total	34/249	(13.65%)	Mean	13.64%	SD	3.23%	Total	4/194	(2.06%)	Mean	2.06%	SD	1.7%
.....														
*Adrenal Medulla:														
 Pheochromocytoma Complex														
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/48	(0%)			
		2/50	(4%)	1/50	(2%)			0/48	(0%)	1/48	(2%)			
Overall Incidence	Total	3/249	(1.2%)	Mean	1.2%	SD	1.79%	Total	1/194	(0.52%)	Mean	0.52%	SD	1.04%
.....														
*Adrenal Medulla:														
 Pheochromocytoma Malignant														
		3/50	(6%)	0/50	(0%)	1/49	(2%)	2/50	(4%)	0/48	(0%)			
		0/50	(0%)	0/50	(0%)			1/48	(2%)	0/48	(0%)			
Overall Incidence	Total	4/249	(1.61%)	Mean	1.61%	SD	2.61%	Total	3/194	(1.55%)	Mean	1.52%	SD	1.92%
.....														
*Adrenal Medulla:														
 Pheochromocytoma: Benign, Complex, Malignant, NOS														
		11/50	(22%)	8/50	(16%)	6/49	(12%)	3/50	(6%)	0/48	(0%)			
		10/50	(20%)	6/50	(12%)			3/48	(6%)	2/48	(4%)			
Overall Incidence	Total	41/249	(16.47%)	Mean	16.45%	SD	4.5%	Total	8/194	(4.12%)	Mean	4.1%	SD	2.89%
.....														
#Bone:														
 Chondrosarcoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD	0%	Total	0/200	(0%)	Mean	0%	SD	0%

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 #: Denominator is number of animals necropsied

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 Contract/Lab: All Laboratories
 Species: RATS
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 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 210
 Report Date:04/29/2009

		Male				Female			
#Bone:									
Chondrosarcoma or Chondroma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Bone:									
Chordoma									
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Bone:									
Osteoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Bone:									
Osteosarcoma									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			1/50 (2%)		0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Bone:									
Osteosarcoma or Osteoma									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			1/50 (2%)		0/50 (0%)	
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

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Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 211
 Report Date:04/29/2009

		Male				Female			
*Brain:									
Astrocytoma Malignant									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Ependymoma Benign									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Ependymoma Malignant									
		0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.41%	SD 0.91%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Glioma Malignant									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Granular Cell Tumor Benign									
		2/50 (4%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.8%	SD 1.79%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 212
Report Date:04/29/2009

		Male				Female								
*Brain:														
Medulloblastoma Mal														
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	0/249	(0%)	Mean	0%	SD	0%	Total	0/200	(0%)	Mean	0%	SD	0%
.....														
*Brain:														
Meningioma Malignant														
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	0/249	(0%)	Mean	0%	SD	0%	Total	0/200	(0%)	Mean	0%	SD	0%
.....														
*Brain:														
Meningioma: Benign, Malignant, NOS														
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	0/249	(0%)	Mean	0%	SD	0%	Total	0/200	(0%)	Mean	0%	SD	0%
.....														
*Brain:														
Oligodendroglioma Benign														
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	0/249	(0%)	Mean	0%	SD	0%	Total	0/200	(0%)	Mean	0%	SD	0%
.....														
*Brain:														
Oligodendroglioma Malignant														
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)			0/50	(0%)	1/50	(2%)			
Overall Incidence	Total	0/249	(0%)	Mean	0%	SD	0%	Total	1/200	(0.5%)	Mean	0.5%	SD	1%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 213
 Report Date:04/29/2009

		Male				Female								
*Brain:														
Oligodendroglioma, Glioma, or Astrocytoma														
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)			0/50	(0%)	1/50	(2%)			
Overall Incidence	Total	0/249	(0%)	Mean	0%	SD	0%	Total	1/200	(0.5%)	Mean	0.5%	SD	1%
.....														
*Brain:														
Osteosarcoma														
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	0/249	(0%)	Mean	0%	SD	0%	Total	0/200	(0%)	Mean	0%	SD	0%
.....														
*Brain:														
Schwannoma Malignant														
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	0/249	(0%)	Mean	0%	SD	0%	Total	0/200	(0%)	Mean	0%	SD	0%
.....														
*Clitoral/Preputial Gland:														
Adenoma														
		1/50	(2%)	5/50	(10%)	0/50	(0%)	10/50	(20%)	5/50	(10%)			
		2/50	(4%)	1/50	(2%)			8/50	(16%)	11/50	(22%)			
Overall Incidence	Total	9/250	(3.6%)	Mean	3.6%	SD	3.85%	Total	34/200	(17%)	Mean	17%	SD	5.29%
.....														
*Clitoral/Preputial Gland:														
Carcinoma														
		0/50	(0%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	4/50	(8%)			
		0/50	(0%)	2/50	(4%)			2/50	(4%)	3/50	(6%)			
Overall Incidence	Total	4/250	(1.6%)	Mean	1.6%	SD	2.19%	Total	9/200	(4.5%)	Mean	4.5%	SD	3.42%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 214
 Report Date:04/29/2009

		Male				Female			
*Clitoral/Preputial Gland: Carcinoma or Adenoma									
		1/50 (2%)	5/50 (10%)	2/50 (4%)		10/50 (20%)	9/50 (18%)		
		2/50 (4%)	3/50 (6%)			10/50 (20%)			
Overall Incidence	Total	13/250 (5.2%)	Mean 5.2%	SD 3.03%	Total	43/200 (21.5%)	Mean 21.5%	SD 4.43%	
.....									
*Clitoral/Preputial Gland: Fibrosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Clitoral/Preputial Gland: Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Clitoral/Preputial Gland: Squamous Cell Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Ear: Neural Crest Tumor									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 215
Report Date:04/29/2009

		Male				Female			
#Esophagus:									
Fibrosarcoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean 0%	SD 0%	Total	0/200	(0%)	Mean 0%
									SD 0%
.....									
#Esophagus:									
Lipoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean 0%	SD 0%	Total	0/200	(0%)	Mean 0%
									SD 0%
.....									
#Eye:									
Amelanotic Melanoma, Benign									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean 0%	SD 0%	Total	0/200	(0%)	Mean 0%
									SD 0%
.....									
#Eye:									
Melanoma Malignant									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean 0%	SD 0%	Total	0/200	(0%)	Mean 0%
									SD 0%
.....									
#Eye:									
Schwannoma Malignant									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/250	(0.4%)	Mean 0.4%	SD 0.89%	Total	0/200	(0%)	Mean 0%
									SD 0%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 216
Report Date:04/29/2009

		Male				Female			
#Harderian Gland: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Harderian Gland: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Heart: Schwannoma Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Heart: Schwannoma Malignant									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Intestine Large: Colon/Rectum: Adenoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 217
Report Date:04/29/2009

		Male				Female			
#Intestine Large: Colon/Rectum: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Large: Colon/Rectum: Carcinoma or Adenoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Large: Colon/Rectum: Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Duodenum: Carcinoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Duodenum: Leiomyoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 218
 Report Date:04/29/2009

		Male				Female			
#Intestine Small: Jejunum: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Jejunum: Granular Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Jejunum: Leiomyoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Jejunum: Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Site Unspecified: Carcinoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 219
 Report Date: 04/29/2009

		Male				Female			
#Intestine Small: Site Unspecified: Carcinoma or Adenoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Site Unspecified: Granular Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Site Unspecified: Leiomyoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Site Unspecified: Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Islets, Pancreatic: Adenoma									
		1/50 (2%)	1/49 (2%)	7/50 (14%)		2/49 (4%)	0/48 (0%)	0/49 (0%)	
		3/50 (6%)	3/50 (6%)			0/49 (0%)			
Overall Incidence	Total	15/249 (6.02%)	Mean 6.01%	SD 4.89%	Total	2/195 (1.03%)	Mean 1.02%	SD 2.04%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 220
Report Date:04/29/2009

		Male				Female			
*Islets, Pancreatic: Carcinoma									
		1/50 (2%)	1/49 (2%)	0/50 (0%)		0/49 (0%)		0/49 (0%)	
		0/50 (0%)	1/50 (2%)			0/49 (0%)		0/48 (0%)	
Overall Incidence	Total	3/249 (1.2%)	Mean 1.21%	SD 1.1%	Total	0/195 (0%)	Mean 0%	SD 0%	
.....									
*Islets, Pancreatic: Carcinoma or Adenoma									
		2/50 (4%)	2/49 (4%)	7/50 (14%)		2/49 (4%)		0/49 (0%)	
		3/50 (6%)	4/50 (8%)			0/49 (0%)		0/48 (0%)	
Overall Incidence	Total	18/249 (7.23%)	Mean 7.22%	SD 4.13%	Total	2/195 (1.03%)	Mean 1.02%	SD 2.04%	
.....									
*Kidney: Pelvis and Transitional Epithelium: Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/47 (0%)		0/49 (0%)	
		0/48 (0%)	0/50 (0%)			0/48 (0%)		0/48 (0%)	
Overall Incidence	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/192 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/47 (0%)		0/49 (0%)	
		0/48 (0%)	0/50 (0%)			0/48 (0%)		0/48 (0%)	
Overall Incidence	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/192 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Pelvis and Transitional Epithelium: Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)		0/49 (0%)	
		0/48 (0%)	0/50 (0%)			1/48 (2%)		0/48 (0%)	
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	1/192 (0.52%)	Mean 0.52%	SD 1.04%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 221
 Report Date:04/29/2009

		Male				Female			
*Kidney: Renal Tubule: Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)		0/49 (0%)	
		0/48 (0%)	0/50 (0%)			0/48 (0%)		0/48 (0%)	
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/192 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)		0/49 (0%)	
		0/48 (0%)	0/50 (0%)			0/48 (0%)		0/48 (0%)	
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/192 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)		0/49 (0%)	
		0/48 (0%)	0/50 (0%)			0/48 (0%)		0/48 (0%)	
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/192 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)		0/49 (0%)	
		0/48 (0%)	0/50 (0%)			0/48 (0%)		0/48 (0%)	
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/192 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Lipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)		0/49 (0%)	
		0/48 (0%)	0/50 (0%)			0/48 (0%)		0/48 (0%)	
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/192 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 222
 Report Date:04/29/2009

		Male				Female			
*Kidney: Renal Tubule: Mesenchymal Tumor Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)		0/49 (0%)	
		0/48 (0%)	0/50 (0%)			0/48 (0%)		0/48 (0%)	
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/192 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Nephroblastoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)		0/49 (0%)	
		0/48 (0%)	0/50 (0%)			0/48 (0%)		0/48 (0%)	
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/192 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)		1/49 (2%)	
		1/48 (2%)	0/50 (0%)			0/48 (0%)		0/48 (0%)	
Overall Incidence	Total	1/248 (0.4%)	Mean 0.42%	SD 0.93%	Total	1/192 (0.52%)	Mean 0.51%	SD 1.02%	
.....									
*Liver: Cholangioma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	1/50 (2%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Liver: Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 223
 Report Date:04/29/2009

		Male				Female			
*Liver:									
Hepatocellular Adenoma									
		1/50 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)		
		0/50 (0%)	3/50 (6%)		0/50 (0%)		2/50 (4%)		
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2.45%	Total	4/200 (2%)	Mean 2%	SD 2.31%	
.....									
*Liver:									
Hepatocellular Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		
		0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)		
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
Hepatocellular Carcinoma or Hepatoblastoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		
		0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)		
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
Hepatocellular Carcinoma or Hepatocellular Adenoma									
		1/50 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)		
		0/50 (0%)	3/50 (6%)		0/50 (0%)		2/50 (4%)		
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2.45%	Total	4/200 (2%)	Mean 2%	SD 2.31%	
.....									
*Liver:									
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma									
		1/50 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)		
		0/50 (0%)	3/50 (6%)		0/50 (0%)		2/50 (4%)		
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2.45%	Total	4/200 (2%)	Mean 2%	SD 2.31%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 224
 Report Date: 04/29/2009

		Male				Female			
*Lung:									
Alveolar/Bronchiolar Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	2/200 (1%)	Mean 1%	SD 1.15%	
.....									
*Lung:									
Alveolar/Bronchiolar Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Lung:									
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma									
		0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	
.....									
*Lung:									
Fibrosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Lung:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 225
 Report Date:04/29/2009

		Male				Female			
*Lung:									
Sarcoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean 0%	SD 0%	Total	0/200	(0%)	Mean 0%
									SD 0%
.....									
*Lung:									
Squamous Cell Carcinoma									
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/250	(0.4%)	Mean 0.4%	SD 0.89%	Total	0/200	(0%)	Mean 0%
									SD 0%
.....									
#Lymph Node:									
Hemangiosarcoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean 0%	SD 0%	Total	0/200	(0%)	Mean 0%
									SD 0%
.....									
#Mammary Gland:									
Adenolipoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean 0%	SD 0%	Total	0/200	(0%)	Mean 0%
									SD 0%
.....									
#Mammary Gland:									
Adenoma									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/250	(0.4%)	Mean 0.4%	SD 0.89%	Total	3/200	(1.5%)	Mean 1.5%
									SD 1.91%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 226
 Report Date: 04/29/2009

		Male				Female			
#Mammary Gland: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		4/50 (8%)	
		0/50 (0%)	0/50 (0%)			2/50 (4%)		4/50 (8%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	10/200 (5%)	Mean 5%	SD 3.83%	
.....									
#Mammary Gland: Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)		6/50 (12%)	
		0/50 (0%)	0/50 (0%)			2/50 (4%)		4/50 (8%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	13/200 (6.5%)	Mean 6.5%	SD 4.43%	
.....									
#Mammary Gland: Fibroadenoma									
		2/50 (4%)	0/50 (0%)	1/50 (2%)		29/50 (58%)		30/50 (60%)	
		3/50 (6%)	0/50 (0%)			24/50 (48%)		28/50 (56%)	
Overall Incidence	Total	6/250 (2.4%)	Mean 2.4%	SD 2.61%	Total	111/200 (55.5%)	Mean 55.5%	SD 5.26%	
.....									
#Mammary Gland: Fibroma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma									
		2/50 (4%)	1/50 (2%)	1/50 (2%)		30/50 (60%)		30/50 (60%)	
		3/50 (6%)	0/50 (0%)			24/50 (48%)		28/50 (56%)	
Overall Incidence	Total	7/250 (2.8%)	Mean 2.8%	SD 2.28%	Total	112/200 (56%)	Mean 56%	SD 5.66%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 227
Report Date:04/29/2009

		Male				Female			
#Mammary Gland:									
Fibroma, Fibroadenoma, Carcinoma, or Adenoma									
		2/50 (4%)	1/50 (2%)	1/50 (2%)		30/50 (60%)		31/50 (62%)	
		3/50 (6%)	0/50 (0%)			25/50 (50%)		28/50 (56%)	
Overall Incidence	Total	7/250 (2.8%)	Mean 2.8%	SD 2.28%	Total	114/200 (57%)	Mean 57%	SD 5.29%	
.....									
#Mesentery:									
Fibrosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			1/50 (2%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Mesentery:									
Hemangiosarcoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Mesentery:									
Lipoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Mesentery:									
Rhabdomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 228
 Report Date:04/29/2009

		Male				Female			
*Nose:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Nose:									
Chondroma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Nose:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Papilloma Squamous or Papilloma									
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 229
 Report Date:04/29/2009

		Male				Female			
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma									
		1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%)		1/50 (2%)	
		0/50 (0%)	1/50 (2%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 1.67%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Oral Mucosa: Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Oral Mucosa: Squamous Cell Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Ovary: Cystadenoma									
						0/50 (0%)		0/50 (0%)	
						0/50 (0%)		0/50 (0%)	
Overall Incidence	Total				Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Ovary: Granulosa Cell Tumor Benign									
						0/50 (0%)		0/50 (0%)	
						0/50 (0%)		0/50 (0%)	
Overall Incidence	Total				Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 230
Report Date:04/29/2009

	Male	Female
*Ovary:		
Granulosa Cell Tumor Malignant		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	2/50 (4%)
Overall Incidence	Total 2/200 (1%)	Mean 1% SD 2%
.....		
*Ovary:		
Granulosa Cell Tumor: Benign, Malignant, NOS		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	2/50 (4%)
Overall Incidence	Total 2/200 (1%)	Mean 1% SD 2%
.....		
*Ovary:		
Granulosa-Theca Tumor Benign		
	1/50 (2%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)
Overall Incidence	Total 1/200 (0.5%)	Mean 0.5% SD 1%
.....		
*Ovary:		
Granulosa-Theca Tumor Malignant		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)
Overall Incidence	Total 0/200 (0%)	Mean 0% SD 0%
.....		
*Ovary:		
Tubulostromal Adenoma		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)
Overall Incidence	Total 0/200 (0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 231
Report Date:04/29/2009

		Male				Female			
*Pancreas:									
Adenoma									
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/48 (0%)	0/49 (0%)
		1/50 (2%)	2/50 (4%)			0/49 (0%)			
Overall Incidence	Total	3/248 (1.21%)	Mean 1.2%	SD 1.79%	Total	0/195 (0%)	Mean 0%	SD 0%	
.....									
*Pancreas:									
Carcinoma									
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/48 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)			0/49 (0%)			
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%	
.....									
*Pancreas:									
Carcinoma or Adenoma									
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/48 (0%)	0/49 (0%)
		1/50 (2%)	2/50 (4%)			0/49 (0%)			
Overall Incidence	Total	3/248 (1.21%)	Mean 1.2%	SD 1.79%	Total	0/195 (0%)	Mean 0%	SD 0%	
.....									
*Pancreas:									
Mixed Tumor Benign									
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/48 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)			0/49 (0%)			
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%	
.....									
*Pancreas:									
Mixed Tumor Malignant									
		0/49 (0%)	0/49 (0%)	1/50 (2%)		0/49 (0%)	0/49 (0%)	0/48 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)			0/49 (0%)			
Overall Incidence	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/195 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 232
 Report Date:04/29/2009

		Male				Female			
*Parathyroid Gland:									
Adenoma									
		1/45 (2%)	1/46 (2%)	0/49 (0%)		0/48 (0%)		0/49 (0%)	
		1/48 (2%)	0/50 (0%)			0/50 (0%)		0/49 (0%)	
Overall Incidence	Total	3/238 (1.26%)	Mean 1.3%	SD 1.18%	Total	0/196 (0%)	Mean 0%	SD 0%	
.....									
#Peripheral Nerve:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Peripheral Nerve:									
Schwannoma: Benign, Malignant, NOS									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Adenoma									
		10/50 (20%)	20/50 (40%)	8/50 (16%)		24/49 (49%)		25/50 (50%)	
		16/49 (33%)	13/50 (26%)			29/48 (60%)		20/50 (40%)	
Overall Incidence	Total	67/249 (26.91%)	Mean 26.93%	SD 9.64%	Total	98/197 (49.75%)	Mean 49.85%	SD 8.36%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/49 (2%)		0/50 (0%)	
		0/49 (0%)	0/50 (0%)			0/48 (0%)		1/50 (2%)	
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	2/197 (1.02%)	Mean 1.01%	SD 1.17%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 233
 Report Date: 04/29/2009

		Male				Female			
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma									
		10/50 (20%)	20/50 (40%)	8/50 (16%)		25/49 (51%)	21/50 (42%)	25/50 (50%)	
		16/49 (33%)	13/50 (26%)			29/48 (60%)			
Overall Incidence	Total	67/249 (26.91%)	Mean 26.93%	SD 9.64%	Total	100/197 (50.76%)	Mean 50.86%	SD 7.54%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site: Ganglioneuroma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)			0/48 (0%)			
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%	
.....									
*Pituitary Gland: Pars Intermedia: Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)			0/48 (0%)			
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/197 (0%)	Mean 0%	SD 0%	
.....									
*Pituitary Gland: Pars Intermedia: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)			0/48 (0%)			
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%	
.....									
*Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)			0/48 (0%)			
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/197 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 234
 Report Date:04/29/2009

		Male				Female			
*Prostate:									
Adenoma									
		0/50	(0%)	0/50	(0%)	1/50	(2%)		
		0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%		
.....									
*Prostate:									
Carcinoma or Adenoma									
		0/50	(0%)	0/50	(0%)	1/50	(2%)		
		0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%		
.....									
*Salivary Glands:									
Sarcoma									
		0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/48	(0%)			0/50	(0%)
Overall Incidence	Total	0/247	(0%)	Mean	0%	SD	0%	Total	0/200 (0%)
								Mean	0%
								SD	0%
.....									
#Seminal Vesicle:									
Adenoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD	0%		
.....									
#Skeletal Muscle:									
Fibrous Histiocytoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)			0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD	0%	Total	0/200 (0%)
								Mean	0%
								SD	0%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 235
Report Date:04/29/2009

		Male				Female			
#Skeletal Muscle: Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skeletal Muscle: Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skeletal Muscle: Lipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skeletal Muscle: Rhabdomyosarcoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skeletal Muscle: Rhabdomyosarcoma or Rhabdomyoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 236
 Report Date:04/29/2009

		Male				Female			
#Skeletal Muscle:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Adenoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Adenoma or Basosquamous Tumor Benign									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		1/50 (2%)	
		1/50 (2%)	0/50 (0%)			1/50 (2%)		0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	2/200 (1%)	Mean 1%	SD 1.15%	
.....									
#Skin:									
Basal Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 237
 Report Date:04/29/2009

		Male				Female			
#Skin:									
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		1/50 (2%)	
		1/50 (2%)	1/50 (2%)			1/50 (2%)		0/50 (0%)	
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	2/200 (1%)	Mean 1%	SD 1.15%	
.....									
#Skin:									
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma									
		4/50 (8%)	1/50 (2%)	2/50 (4%)		0/50 (0%)		1/50 (2%)	
		3/50 (6%)	6/50 (12%)			2/50 (4%)		1/50 (2%)	
Overall Incidence	Total	16/250 (6.4%)	Mean 6.4%	SD 3.85%	Total	4/200 (2%)	Mean 2%	SD 1.63%	
.....									
#Skin:									
Fibroma									
		4/50 (8%)	1/50 (2%)	5/50 (10%)		0/50 (0%)		1/50 (2%)	
		8/50 (16%)	3/50 (6%)			1/50 (2%)		1/50 (2%)	
Overall Incidence	Total	21/250 (8.4%)	Mean 8.4%	SD 5.18%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	
.....									
#Skin:									
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma									
		4/50 (8%)	4/50 (8%)	5/50 (10%)		0/50 (0%)		3/50 (6%)	
		8/50 (16%)	4/50 (8%)			1/50 (2%)		1/50 (2%)	
Overall Incidence	Total	25/250 (10%)	Mean 10%	SD 3.46%	Total	5/200 (2.5%)	Mean 2.5%	SD 2.52%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 238
 Report Date:04/29/2009

		Male				Female			
#Skin:									
Fibrosarcoma									
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma									
		0/50 (0%)	3/50 (6%)	0/50 (0%)		0/50 (0%)		2/50 (4%)	
		0/50 (0%)	1/50 (2%)			0/50 (0%)		1/50 (2%)	0/50 (0%)
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 2.61%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	
.....									
#Skin:									
Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 239
Report Date:04/29/2009

		Male				Female			
#Skin:									
Keratoacanthoma									
		3/50 (6%)	1/50 (2%)	2/50 (4%)		0/50 (0%)		0/50 (0%)	
		1/50 (2%)	4/50 (8%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	11/250 (4.4%)	Mean 4.4%	SD 2.61%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Lipoma									
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	1/50 (2%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Liposarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Neural Crest Tumor									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		1/50 (2%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Neural Crest Tumor, Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	1/50 (2%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 240
 Report Date:04/29/2009

		Male				Female			
#Skin:									
Neurofibroma or Schwannoma benign									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD	0%	Total	0/200 (0%)
				Mean	0%	SD	0%		0/200 (0%)
.....									
#Skin:									
Neurofibrosarcoma or Schwannoma (malignant or NOS)									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD	0%	Total	0/200 (0%)
				Mean	0%	SD	0%		0/200 (0%)
.....									
#Skin:									
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD	0%	Total	0/200 (0%)
				Mean	0%	SD	0%		0/200 (0%)
.....									
#Skin:									
Sarcoma									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	2/250	(0.8%)	Mean	0.8%	SD	1.1%	Total	2/200 (1%)
				Mean	0.8%	SD	1.1%		2/200 (1%)
.....									
#Skin:									
Schwannoma Benign									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD	0%	Total	0/200 (0%)
				Mean	0%	SD	0%		0/200 (0%)

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 241
 Report Date:04/29/2009

		Male				Female			
#Skin:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)			0/50 (0%)			
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	2/50 (4%)			0/50 (0%)			
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Squamous Cell Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			1/50 (2%)			
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Squamous Cell Papilloma or Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			1/50 (2%)			
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 242
 Report Date:04/29/2009

		Male				Female			
#Skin:									
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma									
		3/50 (6%)	1/50 (2%)	2/50 (4%)		0/50 (0%)		0/50 (0%)	
		2/50 (4%)	6/50 (12%)			1/50 (2%)		1/50 (2%)	
Overall Incidence	Total	14/250 (5.6%)	Mean 5.6%	SD 3.85%	Total	2/200 (1%)	Mean 1%	SD 1.15%	
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma									
		3/50 (6%)	1/50 (2%)	2/50 (4%)		0/50 (0%)		0/50 (0%)	
		1/50 (2%)	5/50 (10%)			1/50 (2%)		0/50 (0%)	
Overall Incidence	Total	12/250 (4.8%)	Mean 4.8%	SD 3.35%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Trichoepithelioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		1/50 (2%)	
		0/50 (0%)	0/50 (0%)			1/50 (2%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%	
.....									
#Skin: Sebaceous Gland:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin: Sebaceous Gland:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 243
 Report Date: 04/29/2009

		Male				Female			
#Skin: Sebaceous Gland:									
 Carcinoma or Adenoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD	0%	Total	0/200 (0%)
				Mean	0%	SD	0%		0/200 (0%)
.....									
#Spinal Cord:									
 Astrocytoma Benign									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD	0%	Total	0/200 (0%)
				Mean	0%	SD	0%		0/200 (0%)
.....									
#Spinal Cord:									
 Astrocytoma Malignant									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD	0%	Total	0/200 (0%)
				Mean	0%	SD	0%		0/200 (0%)
.....									
#Spinal Cord:									
 Glioma Malignant									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD	0%	Total	0/200 (0%)
				Mean	0%	SD	0%		0/200 (0%)
.....									
*Spleen:									
 Fibrosarcoma									
		0/50	(0%)	0/49	(0%)	0/49	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)
Overall Incidence	Total	0/248	(0%)	Mean	0%	SD	0%	Total	0/198 (0%)
				Mean	0%	SD	0%		0/198 (0%)

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 244
 Report Date:04/29/2009

		Male				Female			
*Spleen:									
Fibrous Histiocytoma									
		0/50 (0%)	0/49 (0%)	1/49 (2%)		0/50 (0%)		0/49 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/49 (0%)	
Overall Incidence	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%	Total	0/198 (0%)	Mean 0%	SD 0%	
.....									
*Spleen:									
Hemangioma									
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)		0/49 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/49 (0%)	
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%	
.....									
*Spleen:									
Hemangiosarcoma									
		1/50 (2%)	0/49 (0%)	0/49 (0%)		0/50 (0%)		0/49 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/49 (0%)	
Overall Incidence	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/198 (0%)	Mean 0%	SD 0%	
.....									
*Spleen:									
Leiomyosarcoma									
		1/50 (2%)	0/49 (0%)	0/49 (0%)		0/50 (0%)		0/49 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/49 (0%)	
Overall Incidence	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/198 (0%)	Mean 0%	SD 0%	
.....									
*Spleen:									
Sarcoma									
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)		0/49 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/49 (0%)	
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 245
Report Date:04/29/2009

		Male				Female			
#Stomach, Forestomach:									
Leiomyosarcoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma or Papilloma Squamous									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		1/50 (2%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Stomach, Forestomach:									
Squamous Cell Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		1/50 (2%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Stomach, Glandular:									
Lipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 246
 Report Date:04/29/2009

		Male			Female		
#Stomach, Glandular:							
Sarcoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0% SD 0%
.....							
*Testes:							
Adenoma							
		46/50 (92%)	49/50 (98%)	42/50 (84%)			
		46/50 (92%)	46/50 (92%)				
Overall Incidence	Total	229/250 (91.6%)	Mean 91.6%	SD 4.98%			
.....							
*Thymus:							
Sarcoma							
		0/48 (0%)	0/47 (0%)	0/48 (0%)	0/46 (0%)	0/49 (0%)	
		0/48 (0%)	0/41 (0%)		0/47 (0%)	0/50 (0%)	
Overall Incidence	Total	0/232 (0%)	Mean 0%	SD 0%	Total	0/192 (0%)	Mean 0% SD 0%
.....							
*Thymus:							
Thymoma Benign							
		0/48 (0%)	0/47 (0%)	1/48 (2%)	0/46 (0%)	0/49 (0%)	
		0/48 (0%)	0/41 (0%)		0/47 (0%)	0/50 (0%)	
Overall Incidence	Total	1/232 (0.43%)	Mean 0.42%	SD 0.93%	Total	0/192 (0%)	Mean 0% SD 0%
.....							
*Thymus:							
Thymoma Malignant							
		0/48 (0%)	0/47 (0%)	0/48 (0%)	0/46 (0%)	0/49 (0%)	
		0/48 (0%)	0/41 (0%)		0/47 (0%)	0/50 (0%)	
Overall Incidence	Total	0/232 (0%)	Mean 0%	SD 0%	Total	0/192 (0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 247
 Report Date:04/29/2009

		Male				Female			
*Thymus:									
Thymoma NOS									
		0/48 (0%)	0/47 (0%)	0/48 (0%)		0/46 (0%)		0/49 (0%)	
		0/48 (0%)	0/41 (0%)			0/47 (0%)		0/50 (0%)	
Overall Incidence	Total	0/232 (0%)	Mean 0%	SD 0%	Total	0/192 (0%)	Mean 0%	SD 0%	
.....									
*Thymus:									
Thymoma: Benign, Malignant, NOS									
		0/48 (0%)	0/47 (0%)	1/48 (2%)		0/46 (0%)		0/49 (0%)	
		0/48 (0%)	0/41 (0%)			0/47 (0%)		0/50 (0%)	
Overall Incidence	Total	1/232 (0.43%)	Mean 0.42%	SD 0.93%	Total	0/192 (0%)	Mean 0%	SD 0%	
.....									
*Thyroid Gland: C-Cell:									
Adenoma									
		5/50 (10%)	6/50 (12%)	7/50 (14%)		3/49 (6%)		4/50 (8%)	
		11/47 (23%)	5/48 (10%)			10/47 (21%)		2/47 (4%)	
Overall Incidence	Total	34/245 (13.88%)	Mean 13.96%	SD 5.51%	Total	19/193 (9.84%)	Mean 9.91%	SD 7.73%	
.....									
*Thyroid Gland: C-Cell:									
Carcinoma									
		4/50 (8%)	1/50 (2%)	1/50 (2%)		1/49 (2%)		1/50 (2%)	
		0/47 (0%)	1/48 (2%)			1/47 (2%)		0/47 (0%)	
Overall Incidence	Total	7/245 (2.86%)	Mean 2.82%	SD 3.03%	Total	3/193 (1.55%)	Mean 1.54%	SD 1.03%	
.....									
*Thyroid Gland: C-Cell:									
Carcinoma or Adenoma									
		9/50 (18%)	7/50 (14%)	8/50 (16%)		4/49 (8%)		5/50 (10%)	
		11/47 (23%)	6/48 (13%)			11/47 (23%)		2/47 (4%)	
Overall Incidence	Total	41/245 (16.73%)	Mean 16.78%	SD 4.24%	Total	22/193 (11.4%)	Mean 11.46%	SD 8.32%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 248
 Report Date:04/29/2009

		Male				Female			
*Thyroid Gland: Follicular Cell: Adenoma									
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/49 (0%)		0/50 (0%)	
		0/47 (0%)	0/48 (0%)			2/47 (4%)		0/47 (0%)	
Overall Incidence	Total	2/245 (0.82%)	Mean 0.8%	SD 1.79%	Total	2/193 (1.04%)	Mean 1.06%	SD 2.13%	
.....									
*Thyroid Gland: Follicular Cell: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)		0/50 (0%)	
		0/47 (0%)	0/48 (0%)			0/47 (0%)		1/47 (2%)	
Overall Incidence	Total	0/245 (0%)	Mean 0%	SD 0%	Total	1/193 (0.52%)	Mean 0.53%	SD 1.06%	
.....									
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma									
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/49 (0%)		0/50 (0%)	
		0/47 (0%)	0/48 (0%)			2/47 (4%)		1/47 (2%)	
Overall Incidence	Total	2/245 (0.82%)	Mean 0.8%	SD 1.79%	Total	3/193 (1.55%)	Mean 1.6%	SD 2.04%	
.....									
#Tissue NOS: Lipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Tissue NOS: Paraganglioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	1/50 (2%)			0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 249
 Report Date:04/29/2009

		Male				Female			
#Tissue NOS:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			1/50 (2%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Tongue:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Tongue:									
Squamous Cell Carcinoma or Papilloma Squamous									
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)		1/50 (2%)	
		0/50 (0%)	1/50 (2%)			0/50 (0%)		0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Tongue:									
Squamous Cell Papilloma									
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)		1/50 (2%)	
		0/50 (0%)	1/50 (2%)			0/50 (0%)		0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Tooth:									
Adamantinoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 250
 Report Date:04/29/2009

		Male				Female			
#Tooth:									
Odontoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean 0%	SD 0%	Total	0/200	(0%)	Mean 0%
									SD 0%
.....									
*Urinary Bladder:									
Carcinoma									
		0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)
Overall Incidence	Total	0/248	(0%)	Mean 0%	SD 0%	Total	0/199	(0%)	Mean 0%
									SD 0%
.....									
*Urinary Bladder:									
Carcinoma or Papilloma									
		0/50	(0%)	1/49	(2%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)
Overall Incidence	Total	1/248	(0.4%)	Mean 0.41%	SD 0.91%	Total	0/199	(0%)	Mean 0%
									SD 0%
.....									
*Urinary Bladder:									
Hemangiosarcoma									
		0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)
Overall Incidence	Total	0/248	(0%)	Mean 0%	SD 0%	Total	0/199	(0%)	Mean 0%
									SD 0%
.....									
*Urinary Bladder:									
Leiomyosarcoma									
		0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)
Overall Incidence	Total	0/248	(0%)	Mean 0%	SD 0%	Total	0/199	(0%)	Mean 0%
									SD 0%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 251
Report Date:04/29/2009

		Male				Female			
*Urinary Bladder:									
Papilloma									
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/49 (0%)	0/50 (0%)			0/49 (0%)		0/50 (0%)	
Overall Incidence	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
#Uterus:									
Adenoma									
						0/50 (0%)		0/50 (0%)	
						0/50 (0%)		1/50 (2%)	
Overall Incidence	Total				Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Uterus:									
Carcinoma									
						0/50 (0%)		0/50 (0%)	
						0/50 (0%)		0/50 (0%)	
Overall Incidence	Total				Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Uterus:									
Deciduoma Benign									
						0/50 (0%)		0/50 (0%)	
						0/50 (0%)		0/50 (0%)	
Overall Incidence	Total				Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Uterus:									
Hemangioma									
						0/50 (0%)		0/50 (0%)	
						0/50 (0%)		0/50 (0%)	
Overall Incidence	Total				Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 252
Report Date:04/29/2009

	Male	Female
#Uterus:		
Hemangiosarcoma		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)
Overall Incidence	Total 0/200 (0%)	Mean 0% SD 0%
.....		
#Uterus:		
Leiomyoma		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)
Overall Incidence	Total 0/200 (0%)	Mean 0% SD 0%
.....		
#Uterus:		
Leiomyosarcoma		
	0/50 (0%)	1/50 (2%)
	0/50 (0%)	0/50 (0%)
Overall Incidence	Total 1/200 (0.5%)	Mean 0.5% SD 1%
.....		
#Uterus:		
Polyp Stromal		
	10/50 (20%)	14/50 (28%)
	16/50 (32%)	10/50 (20%)
Overall Incidence	Total 50/200 (25%)	Mean 25% SD 6%
.....		
#Uterus:		
Sarcoma Stromal		
	0/50 (0%)	0/50 (0%)
	1/50 (2%)	0/50 (0%)
Overall Incidence	Total 1/200 (0.5%)	Mean 0.5% SD 1%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F344
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 253
Report Date:04/29/2009

		Male			Female		
#Uterus:							
Sarcoma Stromal or Polyp Stromal							
			10/50 (20%)			14/50 (28%)	
			17/50 (34%)		10/50 (20%)		
Overall Incidence		Total	51/200 (25.5%)		Mean 25.5%		SD 6.81%
.....							
#Uterus:							
Schwannoma Malignant							
			0/50 (0%)			0/50 (0%)	
			0/50 (0%)		0/50 (0%)		
Overall Incidence		Total	0/200 (0%)		Mean 0%		SD 0%
.....							
#Vagina:							
Polyp							
			0/50 (0%)			0/50 (0%)	
			0/50 (0%)		0/50 (0%)		
Overall Incidence		Total	0/200 (0%)		Mean 0%		SD 0%
.....							
#Vagina:							
Sarcoma							
			0/50 (0%)			0/50 (0%)	
			0/50 (0%)		0/50 (0%)		
Overall Incidence		Total	0/200 (0%)		Mean 0%		SD 0%
.....							
#Zymbal's Gland:							
Adenoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)		0/50 (0%)		
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2009
 Contract/Lab: All Laboratories
 Species: RATS
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 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 254
 Report Date:04/29/2009

		Male				Female			
#Zymbal's Gland:									
Carcinoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		3/50 (6%)	0/50 (0%)			0/50 (0%)			
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 2.61%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Zymbal's Gland:									
Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		3/50 (6%)	0/50 (0%)			0/50 (0%)			
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 2.61%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied