



National Toxicology Program
Department of Health and Human Services

NTP Historical Controls Report

All Routes and Vehicles

F 344/N RATS

June 2013

REPORT DESCRIPTION

This report shows the tumor rates of control group animals from selected studies. The studies used are shown on the Study Summary page.

The report combines all the data from all of the historical control studies into one section. To see this data broken up by route and vehicle you must run the "By Route And Vehicle" report.

The individual tumor rates shown on the data pages of the report relate to the Study Summary page as follows: the tumor rates are shown in the same order as the Study Summary page, except that they are grouped horizontally in sets of three, with the males in the first set of three and the females in the second set. For example if the study summary showed the studies like this:

Male

M1

M2

M3

M4

M5

Female

F1

F2

F3

F4

F5

the data would be shown as:

Male			Female		
M1	M2	M3	F1	F2	F3
M4	M5		F4	F5	

Directly beneath the individual tumor rates on the data pages are the overall totals for that tumor/site combination. This includes the total tumors/animals, the overall mean (in parentheses), the mean of the study means, and the standard deviation of the study means.

Studies with no control animals of a particular gender are listed on the summary page with the Number of Animals shown as zero and the Start Date and Length of Study shown as "N/A". On the data pages there are blank spaces where tumor rates for these studies would normally be found, so that the male and female rates for the remaining studies can be easily compared.

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	059903705	06/09/03	729	50(3)	27(662)	523.0	alpha/beta Thujone mixture
Battelle Northwest	052001105	07/14/03	729	50(5)	23(678)	526.9	1-Bromopropane
Battelle Northwest	059901705	08/25/03	729	50(5)	28(686)	525.6	Diethylamine
Battelle Columbus Laboratory	059903103	03/23/05	727	50(3)	38(706)	512.7	Ginkgo biloba extract
Battelle Columbus Laboratory	052000505	01/21/04	727	50(3)	30(679)	498.5	Ginseng
Battelle Columbus Laboratory	052000705	08/18/04	727	49(3)	34(692)	515.2	Kava kava extract
Southern Research Institute	059500305	04/05/04	729	50(1)	27(683)	508.5	Methyl trans-styryl ketone
Battelle Columbus Laboratory	052010703	10/20/04	727	50(3)	37(702)	503.5	N,N-Dimethyl-p-toluidine
Battelle Columbus Laboratory	052000903	11/18/04	726	50(3)	33(668)	516.1	beta-Picoline
Battelle Columbus Laboratory	059903203	09/15/04	727	50(1)	23(651)	510.1	Pyrogallol
Battelle Columbus Laboratory	059901305	05/12/05	726	50(3)	36(685)	522.7	Styrene-acrylonitrile trimer
Battelle Northwest	059302507	06/16/03	729	50(5)	20(668)	536.2	Tetralin
Southern Research Institute	058813307	01/18/05	729	50(1)	23(681)	516.1	Trimethylolpropane triacrylate
Battelle Northwest	052030305	06/06/05	729	50(5)	25(680)	532.1	Vinylidene chloride
Female							
Southern Research Institute	059903705	06/09/03	730	50(5)	35(689)	335.4	alpha/beta Thujone mixture
Battelle Northwest	052001105	07/14/03	730	50(5)	34(702)	386.5	1-Bromopropane
Battelle Northwest	059901705	08/25/03	730	50(5)	31(687)	378.3	Diethylamine
Battelle Columbus Laboratory	059903103	03/24/05	728	50(5)	37(700)	350.7	Ginkgo biloba extract
Battelle Columbus Laboratory	052000505	01/22/04	728	50(5)	36(700)	355.0	Ginseng
Battelle Columbus Laboratory	052000705	08/19/04	728	50(5)	34(683)	354.3	Kava kava extract
Southern Research Institute	059500305	04/05/04	732	50(1)	30(685)	356.2	Methyl trans-styryl ketone
Battelle Columbus Laboratory	052010703	10/21/04	728	50(5)	33(704)	354.1	N,N-Dimethyl-p-toluidine
Battelle Columbus Laboratory	052000903	11/19/04	727	50(5)	30(688)	352.7	beta-Picoline
Battelle Columbus Laboratory	059903203	09/16/04	728	50(1)	29(670)	351.0	Pyrogallol
Battelle Columbus Laboratory	059901305	05/13/05	727	50(5)	41(699)	371.2	Styrene-acrylonitrile trimer
Battelle Northwest	059302507	06/16/03	730	50(5)	31(682)	370.8	Tetralin
Southern Research Institute	058813307	01/18/05	731	50(1)	27(688)	352.8	Trimethylolpropane triacrylate
Battelle Northwest	052030305	06/06/05	731	50(5)	30(705)	375.6	Vinylidene chloride

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 4
 Report Date: 05/24/2013

		Male				Female			
#All Organs:									
Benign Tumors									
		44/50 (88%)	48/50 (96%)	44/50 (88%)	46/50 (92%)	45/50 (90%)	43/50 (86%)		
		50/50 (100%)	49/50 (98%)	49/49 (100%)	47/50 (94%)	42/50 (84%)	43/50 (86%)		
		46/50 (92%)	48/50 (96%)	45/50 (90%)	47/50 (94%)	46/50 (92%)	47/50 (94%)		
		47/50 (94%)	46/50 (92%)	48/50 (96%)	43/50 (86%)	42/50 (84%)	40/50 (80%)		
		48/50 (96%)	47/50 (94%)		43/50 (86%)	47/50 (94%)			
Overall Incidence	Total	659/699 (94.28%)	Mean 94.29%	SD 3.91%	Total	621/700 (88.71%)	Mean 88.71%	SD 4.68%	
.....									
#All Organs:									
Malignant Tumors									
		31/50 (62%)	38/50 (76%)	31/50 (62%)	20/50 (40%)	26/50 (52%)	24/50 (48%)		
		13/50 (26%)	26/50 (52%)	17/49 (35%)	12/50 (24%)	10/50 (20%)	11/50 (22%)		
		33/50 (66%)	20/50 (40%)	23/50 (46%)	22/50 (44%)	23/50 (46%)	17/50 (34%)		
		22/50 (44%)	22/50 (44%)	33/50 (66%)	12/50 (24%)	19/50 (38%)	25/50 (50%)		
		30/50 (60%)	27/50 (54%)		21/50 (42%)	24/50 (48%)			
Overall Incidence	Total	366/699 (52.36%)	Mean 52.34%	SD 13.92%	Total	266/700 (38%)	Mean 38%	SD 11.26%	
.....									
#All Organs:									
Malignant and Benign Tumors									
		48/50 (96%)	50/50 (100%)	49/50 (98%)	49/50 (98%)	49/50 (98%)	48/50 (96%)		
		50/50 (100%)	49/50 (98%)	49/49 (100%)	49/50 (98%)	45/50 (90%)	46/50 (92%)		
		48/50 (96%)	49/50 (98%)	48/50 (96%)	49/50 (98%)	49/50 (98%)	49/50 (98%)		
		49/50 (98%)	49/50 (98%)	50/50 (100%)	45/50 (90%)	44/50 (88%)	46/50 (92%)		
		50/50 (100%)	50/50 (100%)		47/50 (94%)	49/50 (98%)			
Overall Incidence	Total	688/699 (98.43%)	Mean 98.43%	SD 1.6%	Total	664/700 (94.86%)	Mean 94.86%	SD 3.74%	
.....									
#All Organs:									
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%)	0/49 (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%)	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%)			
Overall Incidence	Total	2/699 (0.29%)	Mean 0.29%	SD 0.73%	Total	0/700 (0%)	Mean 0%	SD 0%	

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 5
 Report Date: 05/24/2013

		Male				Female			
#All Organs:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (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%)	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	2/699 (0.29%)		Mean 0.29%	SD 0.73%	Total	0/700 (0%)		Mean 0%

#All Organs:									
Hemangiosarcoma or Hemangioma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (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%)	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%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/699 (0.57%)		Mean 0.57%	SD 0.94%	Total	0/700 (0%)		Mean 0%

#All Organs:									
Histiocytic Sarcoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (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%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	2/699 (0.29%)		Mean 0.29%	SD 0.73%	Total	2/700 (0.29%)		Mean 0.29%

#All Organs:									
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated									
		22/50 (44%)	29/50 (58%)	25/50 (50%)		10/50 (20%)	16/50 (32%)	15/50 (30%)	
		9/50 (18%)	18/50 (36%)	7/49 (14%)		8/50 (16%)	6/50 (12%)	5/50 (10%)	
		26/50 (52%)	14/50 (28%)	14/50 (28%)		18/50 (36%)	15/50 (30%)	12/50 (24%)	
		11/50 (22%)	15/50 (30%)	25/50 (50%)		8/50 (16%)	13/50 (26%)	17/50 (34%)	
		26/50 (52%)	17/50 (34%)			12/50 (24%)	10/50 (20%)		
Overall Incidence	Total	258/699 (36.91%)		Mean 36.88%	SD 14.14%	Total	165/700 (23.57%)		Mean 23.57%

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 6
 Report Date: 05/24/2013

		Male				Female								
#All Organs:														
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	1/49	(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%)	
		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%)	0/50	(0%)	
Overall Incidence	Total	1/699 (0.14%)		Mean 0.15%		SD 0.55%		Total	3/700 (0.43%)		Mean 0.43%		SD 0.85%	
#All Organs:														
Mesothelioma: Benign, Malignant, NOS														
		2/50	(4%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		3/50	(6%)	2/50	(4%)	3/49	(6%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		4/50	(8%)	1/50	(2%)	4/50	(8%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		2/50	(4%)	4/50	(8%)	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%)	0/50	(0%)	
Overall Incidence	Total	26/699 (3.72%)		Mean 3.72%		SD 3.13%		Total	0/700 (0%)		Mean 0%		SD 0%	
#All Organs:														
Mesothelioma: Malignant														
		2/50	(4%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		3/50	(6%)	2/50	(4%)	3/49	(6%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		4/50	(8%)	1/50	(2%)	4/50	(8%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		2/50	(4%)	4/50	(8%)	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%)	0/50	(0%)	
Overall Incidence	Total	26/699 (3.72%)		Mean 3.72%		SD 3.13%		Total	0/700 (0%)		Mean 0%		SD 0%	
#All Organs:														
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%)	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%)	0/50	(0%)	0/50	(0%)	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	1/699 (0.14%)		Mean 0.14%		SD 0.53%		Total	1/700 (0.14%)		Mean 0.14%		SD 0.53%	

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 7
 Report Date: 05/24/2013

		Male				Female			
#All Organs:									
Osteosarcoma									
		1/50 (2%)	2/50 (4%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	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%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	13/699 (1.86%)		Mean 1.86%	SD 1.83%	Total 2/700 (0.29%)		Mean 0.29%	SD 0.73%

#All Organs:									
Osteosarcoma or Osteoma									
		1/50 (2%)	2/50 (4%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	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%)	3/50 (6%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	2/50 (4%)			0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	14/699 (2%)		Mean 2%	SD 1.92%	Total 3/700 (0.43%)		Mean 0.43%	SD 0.85%

*Adrenal Cortex:									
Adenoma									
		1/50 (2%)	1/50 (2%)	1/50 (2%)		1/47 (2%)	3/50 (6%)	4/50 (8%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	1/50 (2%)		4/50 (8%)	3/50 (6%)	2/50 (4%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	8/50 (16%)	
		1/50 (2%)	4/49 (8%)			0/50 (0%)	2/50 (4%)		
Overall Incidence	Total	10/698 (1.43%)		Mean 1.44%	SD 2.18%	Total 29/697 (4.16%)		Mean 4.15%	SD 4.47%

*Adrenal Cortex:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/49 (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%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)			0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	2/698 (0.29%)		Mean 0.29%	SD 0.73%	Total 1/697 (0.14%)		Mean 0.14%	SD 0.53%

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

		Male				Female			
*Adrenal Medulla:									
Pheochromocytoma Benign									
		6/50 (12%)	10/50 (20%)	7/50 (14%)		2/48 (4%)	2/50 (4%)	0/50 (0%)	
		11/50 (22%)	4/50 (8%)	5/49 (10%)		2/50 (4%)	1/50 (2%)	3/50 (6%)	
		11/49 (22%)	6/50 (12%)	5/50 (10%)		1/49 (2%)	2/50 (4%)	2/50 (4%)	
		4/50 (8%)	4/50 (8%)	9/50 (18%)		1/50 (2%)	0/50 (0%)	2/50 (4%)	
		11/49 (22%)	5/49 (10%)			0/48 (0%)	0/50 (0%)		
Overall Incidence	Total	98/696 (14.08%)	Mean 14.09%	SD 5.68%	Total	18/695 (2.59%)	Mean 2.59%	SD 2%	

*Adrenal Medulla:									
Pheochromocytoma Complex									
		0/50 (0%)	1/50 (2%)	2/50 (4%)		1/48 (2%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/49 (0%)	1/50 (2%)	1/50 (2%)		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%)	
		0/49 (0%)	0/49 (0%)			0/48 (0%)	0/50 (0%)		
Overall Incidence	Total	5/696 (0.72%)	Mean 0.71%	SD 1.27%	Total	2/695 (0.29%)	Mean 0.29%	SD 0.74%	

*Adrenal Medulla:									
Pheochromocytoma Malignant									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/48 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/49 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	4/50 (8%)		0/50 (0%)	1/50 (2%)	1/50 (2%)	
		1/49 (2%)	2/49 (4%)			0/48 (0%)	1/50 (2%)		
Overall Incidence	Total	12/696 (1.72%)	Mean 1.72%	SD 2.34%	Total	3/695 (0.43%)	Mean 0.43%	SD 0.85%	

*Adrenal Medulla:									
Pheochromocytoma: Benign, Complex, Malignant, NOS									
		6/50 (12%)	11/50 (22%)	10/50 (20%)		3/48 (6%)	3/50 (6%)	0/50 (0%)	
		12/50 (24%)	4/50 (8%)	5/49 (10%)		2/50 (4%)	1/50 (2%)	3/50 (6%)	
		11/49 (22%)	8/50 (16%)	6/50 (12%)		1/49 (2%)	2/50 (4%)	2/50 (4%)	
		5/50 (10%)	4/50 (8%)	12/50 (24%)		1/50 (2%)	1/50 (2%)	3/50 (6%)	
		12/49 (24%)	6/49 (12%)			0/48 (0%)	1/50 (2%)		
Overall Incidence	Total	112/696 (16.09%)	Mean 16.1%	SD 6.43%	Total	23/695 (3.31%)	Mean 3.31%	SD 2.19%	

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 9
 Report Date: 05/24/2013

		Male				Female			
#Blood Vessel:									
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%)	0/49 (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%)	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%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/699 (0%)	Mean 0%	SD 0%	Total	1/700 (0.14%)	Mean 0.14%	SD 0.53%	

#Bone:									
Chordoma									
		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%)	0/49 (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%)	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%)	0/50 (0%)
Overall Incidence	Total	1/699 (0.14%)	Mean 0.14%	SD 0.53%	Total	0/700 (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%)	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%)	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%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/699 (0.14%)	Mean 0.14%	SD 0.53%	Total	1/700 (0.14%)	Mean 0.14%	SD 0.53%	

#Bone:									
Osteosarcoma									
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	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%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	12/699 (1.72%)	Mean 1.72%	SD 1.73%	Total	2/700 (0.29%)	Mean 0.29%	SD 0.73%	

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 10
 Report Date: 05/24/2013

		Male					Female				
#Bone:											
Osteosarcoma or Osteoma											
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	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%)	3/50 (6%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		2/50 (4%)	2/50 (4%)			0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	13/699 (1.86%)			Mean 1.86%	SD 1.83%	Total 3/700 (0.43%)			Mean 0.43%	SD 0.85%

*Brain:											
Glioma											
		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%)	0/49 (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%)	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%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/699 (0%)			Mean 0%	SD 0%	Total 1/700 (0.14%)			Mean 0.14%	SD 0.53%

*Brain:											
Glioma 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%)	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%)	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	0/699 (0%)			Mean 0%	SD 0%	Total 1/700 (0.14%)			Mean 0.14%	SD 0.53%

*Brain:											
Glioma Malignant											
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)		
		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%)	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	0/699 (0%)			Mean 0%	SD 0%	Total 2/700 (0.29%)			Mean 0.29%	SD 0.73%

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 11
 Report Date: 05/24/2013

		Male				Female			
*Brain:									
Oligodendroglioma, Glioma, or Astrocytoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)	
		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%)	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%)	0/50 (0%)	
Overall Incidence	Total	0/699 (0%)	Mean 0%	SD 0%	Total	3/700 (0.43%)	Mean 0.43%	SD 0.85%	

*Brain:									
Osteosarcoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (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%)	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	1/699 (0.14%)	Mean 0.14%	SD 0.53%	Total	0/700 (0%)	Mean 0%	SD 0%	

*Clitoral/Preputial Gland:									
Adenoma									
		2/49 (4%)	4/50 (8%)	0/50 (0%)		12/50 (24%)	3/49 (6%)	1/50 (2%)	
		4/50 (8%)	0/50 (0%)	0/49 (0%)		5/50 (10%)	1/50 (2%)	2/50 (4%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		6/50 (12%)	5/50 (10%)	7/50 (14%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		3/50 (6%)	3/50 (6%)	0/50 (0%)	
		3/50 (6%)	2/50 (4%)			4/50 (8%)	4/47 (9%)		
Overall Incidence	Total	17/698 (2.44%)	Mean 2.43%	SD 3.06%	Total	56/696 (8.05%)	Mean 8.05%	SD 6.07%	

*Clitoral/Preputial Gland:									
Carcinoma									
		1/49 (2%)	2/50 (4%)	1/50 (2%)		2/50 (4%)	1/49 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	1/50 (2%)	2/50 (4%)	
		3/50 (6%)	0/50 (0%)	2/50 (4%)		3/50 (6%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	4/50 (8%)	
		0/50 (0%)	2/50 (4%)			7/50 (14%)	1/47 (2%)		
Overall Incidence	Total	13/698 (1.86%)	Mean 1.86%	SD 2%	Total	22/696 (3.16%)	Mean 3.15%	SD 3.97%	

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

		Male					Female				
*Clitoral/Preputial Gland:											
Carcinoma or Adenoma											
		3/49 (6%)	6/50 (12%)	1/50 (2%)		14/50 (28%)	4/49 (8%)	1/50 (2%)			
		4/50 (8%)	0/50 (0%)	1/49 (2%)		5/50 (10%)	2/50 (4%)	4/50 (8%)			
		4/50 (8%)	0/50 (0%)	2/50 (4%)		9/50 (18%)	5/50 (10%)	7/50 (14%)			
		0/50 (0%)	2/50 (4%)	0/50 (0%)		4/50 (8%)	3/50 (6%)	4/50 (8%)			
		3/50 (6%)	4/50 (8%)			10/50 (20%)	5/47 (11%)				
Overall Incidence	Total	30/698 (4.3%)			Mean 4.3%	SD 3.83%	Total 77/696 (11.06%)			Mean 11.06%	SD 6.91%
*Clitoral/Preputial Gland:											
Sarcoma											
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)			
		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%)	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%)	0/47 (0%)				
Overall Incidence	Total	0/698 (0%)			Mean 0%	SD 0%	Total 1/696 (0.14%)			Mean 0.14%	SD 0.53%
#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%)	0/49 (0%)		0/50 (0%)	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%)	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	1/699 (0.14%)			Mean 0.14%	SD 0.53%	Total 2/700 (0.29%)			Mean 0.29%	SD 0.73%
#Eye:											
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%)	0/49 (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%)	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	0/699 (0%)			Mean 0%	SD 0%	Total 1/700 (0.14%)			Mean 0.14%	SD 0.53%

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

		Male				Female			
#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%)	0/50 (0%)	0/49 (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%)	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	0/699 (0%)	Mean 0%	SD 0%	Total	1/700 (0.14%)	Mean 0.14%	SD 0.53%	

#Harderian 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%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	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%)		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	0/699 (0%)	Mean 0%	SD 0%	Total	2/700 (0.29%)	Mean 0.29%	SD 1.07%	

#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%)	1/50 (2%)	0/49 (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%)	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%)	0/50 (0%)
Overall Incidence	Total	2/699 (0.29%)	Mean 0.29%	SD 0.73%	Total	0/700 (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%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		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%)	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	2/699 (0.29%)	Mean 0.29%	SD 0.73%	Total	2/700 (0.29%)	Mean 0.29%	SD 1.07%	

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 14
 Report Date: 05/24/2013

		Male				Female			
*Heart:									
Schwannoma Benign									
		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%)	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%)	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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/699 (0.29%)	Mean 0.29%	SD 1.07%	Total	0/700 (0%)	Mean 0%	SD 0%	
*Heart:									
Schwannoma 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%)
		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%)	0/50 (0%)	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%)	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	3/699 (0.43%)	Mean 0.43%	SD 1.16%	Total	0/700 (0%)	Mean 0%	SD 0%	
#Intestine Large: Colon/Rectum:									
Adenoma									
		0/50 (0%)	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%)	0/49 (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%)	0/50 (0%)	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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/699 (0.43%)	Mean 0.43%	SD 0.85%	Total	1/700 (0.14%)	Mean 0.14%	SD 0.53%	
#Intestine Large: Colon/Rectum:									
Carcinoma or Adenoma									
		0/50 (0%)	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%)	0/49 (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%)	0/50 (0%)	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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/699 (0.43%)	Mean 0.43%	SD 0.85%	Total	1/700 (0.14%)	Mean 0.14%	SD 0.53%	

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

		Male					Female									
#Intestine Small: Duodenum:																
Leiomyoma																
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)	0/49	(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%)	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	1/699 (0.14%)			Mean 0.14%		SD 0.53%		Total	1/700 (0.14%)			Mean 0.14%		SD 0.53%	
#Intestine Small: Duodenum:																
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%)	0/49	(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%)	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	0/699 (0%)			Mean 0%		SD 0%		Total	1/700 (0.14%)			Mean 0.14%		SD 0.53%	
#Intestine Small: Ileum:																
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%)	0/49	(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%)	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	0/699 (0%)			Mean 0%		SD 0%		Total	1/700 (0.14%)			Mean 0.14%		SD 0.53%	
#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%)	1/50	(2%)	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%)	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	1/699 (0.14%)			Mean 0.14%		SD 0.53%		Total	0/700 (0%)			Mean 0%		SD 0%	

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

		Male					Female								
#Intestine Small: Jejunum:															
Leiomyoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)				
		1/50	(2%)	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%)	0/50	(0%)	0/50	(0%)				
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	1/699 (0.14%)			Mean 0.14%		SD 0.53%		Total 0/700 (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%)	0/49	(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%)	0/50	(0%)	0/50	(0%)				
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	0/699 (0%)			Mean 0%		SD 0%		Total 1/700 (0.14%)			Mean 0.14%		SD 0.53%	
#Intestine Small: Site Unspecified:															
Adenoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)				
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(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%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	0/699 (0%)			Mean 0%		SD 0%		Total 1/700 (0.14%)			Mean 0.14%		SD 0.53%	
#Intestine Small: Site Unspecified:															
Carcinoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)				
		0/50	(0%)	1/50	(2%)	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%)	0/50	(0%)	0/50	(0%)				
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	1/699 (0.14%)			Mean 0.14%		SD 0.53%		Total 0/700 (0%)			Mean 0%		SD 0%	

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 17
 Report Date: 05/24/2013

		Male				Female					
#Intestine Small: Site Unspecified:											
Carcinoma or Adenoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	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%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/699 (0.14%)		Mean 0.14%		SD 0.53%		Total		1/700 (0.14%)	
								Mean		0.14%	
								SD		0.53%	

#Intestine Small: Site Unspecified:											
Leiomyoma											
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)	0/49	(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%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	2/699 (0.29%)		Mean 0.29%		SD 0.73%		Total		1/700 (0.14%)	
								Mean		0.14%	
								SD		0.53%	

#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%)	0/49	(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%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/699 (0%)		Mean 0%		SD 0%		Total		1/700 (0.14%)	
								Mean		0.14%	
								SD		0.53%	

#Intestine Small: Site Unspecified:											
Schwannoma Malignant											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/49	(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%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/699 (0%)		Mean 0%		SD 0%		Total		1/700 (0.14%)	
								Mean		0.14%	
								SD		0.53%	

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

		Male				Female			
*Islets, Pancreatic:									
Adenoma									
		1/50 (2%)	0/50 (0%)	6/50 (12%)		1/49 (2%)	0/50 (0%)	2/50 (4%)	
		4/50 (8%)	0/50 (0%)	4/49 (8%)		1/50 (2%)	1/50 (2%)	1/50 (2%)	
		5/49 (10%)	2/50 (4%)	4/50 (8%)		3/49 (6%)	0/50 (0%)	0/50 (0%)	
		3/50 (6%)	0/50 (0%)	3/50 (6%)		2/50 (4%)	1/50 (2%)	0/50 (0%)	
		18/50 (36%)	2/50 (4%)			3/50 (6%)	0/50 (0%)		
Overall Incidence	Total	52/698 (7.45%)	Mean 7.45%	SD 9.07%	Total	15/698 (2.15%)	Mean 2.15%	SD 2.16%	

*Islets, Pancreatic:									
Carcinoma									
		2/50 (4%)	3/50 (6%)	1/50 (2%)		0/49 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		3/49 (6%)	1/50 (2%)	0/50 (0%)		0/49 (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%)	
		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	13/698 (1.86%)	Mean 1.87%	SD 2.3%	Total	1/698 (0.14%)	Mean 0.14%	SD 0.53%	

*Islets, Pancreatic:									
Carcinoma or Adenoma									
		3/50 (6%)	3/50 (6%)	7/50 (14%)		1/49 (2%)	1/50 (2%)	2/50 (4%)	
		4/50 (8%)	0/50 (0%)	4/49 (8%)		1/50 (2%)	1/50 (2%)	1/50 (2%)	
		8/49 (16%)	3/50 (6%)	4/50 (8%)		3/49 (6%)	0/50 (0%)	0/50 (0%)	
		3/50 (6%)	0/50 (0%)	4/50 (8%)		2/50 (4%)	1/50 (2%)	0/50 (0%)	
		18/50 (36%)	4/50 (8%)			3/50 (6%)	0/50 (0%)		
Overall Incidence	Total	65/698 (9.31%)	Mean 9.32%	SD 8.81%	Total	16/698 (2.29%)	Mean 2.3%	SD 2.07%	

*Kidney: Pelvis and Transitional Epithelium:									
Papilloma									
		0/48 (0%)	1/50 (2%)	0/50 (0%)		0/44 (0%)	0/49 (0%)	0/50 (0%)	
		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%)	0/49 (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	1/697 (0.14%)	Mean 0.14%	SD 0.53%	Total	0/692 (0%)	Mean 0%	SD 0%	

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 19
 Report Date: 05/24/2013

		Male				Female			
*Kidney: Renal Tubule: Adenoma									
		0/48 (0%)	1/50 (2%)	0/50 (0%)		0/44 (0%)	0/49 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/49 (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%)	0/49 (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%)	
Overall Incidence	Total	4/697 (0.57%)	Mean 0.57%	SD 0.94%	Total	0/692 (0%)	Mean 0%	SD 0%	

*Kidney: Renal Tubule: Carcinoma									
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/44 (0%)	1/49 (2%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	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%)	0/49 (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%)	0/50 (0%)	
Overall Incidence	Total	1/697 (0.14%)	Mean 0.14%	SD 0.53%	Total	1/692 (0.14%)	Mean 0.15%	SD 0.55%	

*Kidney: Renal Tubule: Carcinoma or Adenoma									
		0/48 (0%)	1/50 (2%)	0/50 (0%)		0/44 (0%)	1/49 (2%)	0/50 (0%)	
		0/50 (0%)	2/50 (4%)	0/49 (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%)	0/49 (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%)	
Overall Incidence	Total	5/697 (0.72%)	Mean 0.71%	SD 1.27%	Total	1/692 (0.14%)	Mean 0.15%	SD 0.55%	

*Kidney: Renal Tubule: Lipoma									
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/44 (0%)	0/49 (0%)	0/50 (0%)	
		1/50 (2%)	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%)	0/49 (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%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/697 (0.14%)	Mean 0.14%	SD 0.53%	Total	1/692 (0.14%)	Mean 0.14%	SD 0.53%	

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

		Male					Female								
*Kidney: Renal Tubule:															
Mesenchymal Tumor Malignant															
		0/48	(0%)	0/50	(0%)	0/50	(0%)	1/44	(2%)	0/49	(0%)	0/50	(0%)		
		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%)	0/49	(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	1/697 (0.14%)			Mean 0.14%		SD 0.53%		Total 1/692 (0.14%)			Mean 0.16%		SD 0.61%	
*Kidney: Renal Tubule:															
Sarcoma															
		0/48	(0%)	0/50	(0%)	0/50	(0%)	0/44	(0%)	0/49	(0%)	0/50	(0%)		
		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%)	0/49	(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%)			1/50	(2%)	0/50	(0%)				
Overall Incidence	Total	0/697 (0%)			Mean 0%		SD 0%		Total 1/692 (0.14%)			Mean 0.14%		SD 0.53%	
*Liver:															
Hepatocellular Adenoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)		
		0/50	(0%)	0/50	(0%)	1/49	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		2/50	(4%)	0/50	(0%)	3/50	(6%)	0/50	(0%)	0/50	(0%)	2/50	(4%)		
		1/50	(2%)	0/50	(0%)	1/50	(2%)	2/50	(4%)	0/50	(0%)	0/50	(0%)		
		1/50	(2%)	1/50	(2%)			0/50	(0%)	1/50	(2%)				
Overall Incidence	Total	10/699 (1.43%)			Mean 1.43%		SD 1.83%		Total 6/700 (0.86%)			Mean 0.86%		SD 1.51%	
*Liver:															
Hepatocellular Carcinoma															
		0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)		
		0/50	(0%)	1/50	(2%)	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%)	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	4/699 (0.57%)			Mean 0.57%		SD 1.22%		Total 1/700 (0.14%)			Mean 0.14%		SD 0.53%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 21
 Report Date: 05/24/2013

		Male				Female			
*Liver:									
Hepatocellular Carcinoma or Hepatoblastoma									
		0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	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%)	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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/699 (0.57%)	Mean 0.57%	SD 1.22%	Total	1/700 (0.14%)	Mean 0.14%	SD 0.53%	

*Liver:									
Hepatocellular Carcinoma or Hepatocellular Adenoma									
		0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	2/50 (4%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	14/699 (2%)	Mean 2%	SD 1.92%	Total	7/700 (1%)	Mean 1%	SD 1.52%	

*Liver:									
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma									
		0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	2/50 (4%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	14/699 (2%)	Mean 2%	SD 1.92%	Total	7/700 (1%)	Mean 1%	SD 1.52%	

*Liver:									
Ito Cell Tumor Benign									
		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%)	0/49 (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%)	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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/699 (0.14%)	Mean 0.14%	SD 0.53%	Total	0/700 (0%)	Mean 0%	SD 0%	

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 22
 Report Date: 05/24/2013

		Male				Female			
*Lung:									
Alveolar/Bronchiolar Adenoma									
		1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)		
		1/50 (2%)	0/50 (0%)	2/49 (4%)	4/50 (8%)	1/50 (2%)	0/50 (0%)		
		2/50 (4%)	0/50 (0%)	3/50 (6%)	1/50 (2%)	1/50 (2%)	0/50 (0%)		
		1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		1/50 (2%)	3/50 (6%)		0/50 (0%)	1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	17/699 (2.43%)	Mean 2.43%	SD 2.11%	Total	9/700 (1.29%)	Mean 1.29%	SD 2.16%	

*Lung:									
Alveolar/Bronchiolar Carcinoma									
		1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)		
		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%)		
		3/50 (6%)	0/50 (0%)	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	9/699 (1.29%)	Mean 1.29%	SD 1.69%	Total	1/700 (0.14%)	Mean 0.14%	SD 0.53%	

*Lung:									
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma									
		2/50 (4%)	3/50 (6%)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)		
		1/50 (2%)	0/50 (0%)	2/49 (4%)	4/50 (8%)	1/50 (2%)	0/50 (0%)		
		2/50 (4%)	0/50 (0%)	3/50 (6%)	1/50 (2%)	1/50 (2%)	0/50 (0%)		
		4/50 (8%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		2/50 (4%)	3/50 (6%)		0/50 (0%)	1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	25/699 (3.58%)	Mean 3.58%	SD 2.38%	Total	10/700 (1.43%)	Mean 1.43%	SD 2.28%	

*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%)	0/49 (0%)	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%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/699 (0%)	Mean 0%	SD 0%	Total	1/700 (0.14%)	Mean 0.14%	SD 0.53%	

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 23
 Report Date: 05/24/2013

		Male					Female									
#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%)	0/49	(0%)	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%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	0/699 (0%)			Mean	0%	SD	0%	Total	1/700 (0.14%)			Mean	0.14%	SD	0.53%

#Mammary Gland:																
Adenoma																
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	1/50	(2%)			
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	2/50	(4%)	2/50	(4%)			
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)	0/50	(0%)	4/50	(8%)	0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	0/699 (0%)			Mean	0%	SD	0%	Total	13/700 (1.86%)			Mean	1.86%	SD	2.41%

#Mammary Gland:																
Carcinoma																
		0/50	(0%)	0/50	(0%)	0/50	(0%)	2/50	(4%)	4/50	(8%)	9/50	(18%)			
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)			
		0/50	(0%)	0/50	(0%)	0/50	(0%)	2/50	(4%)	1/50	(2%)	2/50	(4%)			
		1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	2/50	(4%)	3/50	(6%)			
		0/50	(0%)	0/50	(0%)	0/50	(0%)	3/50	(6%)	5/50	(10%)	0/50	(0%)			
Overall Incidence	Total	1/699 (0.14%)			Mean	0.14%	SD	0.53%	Total	35/700 (5%)			Mean	5%	SD	4.69%

#Mammary Gland:																
Carcinoma or Adenoma																
		0/50	(0%)	0/50	(0%)	0/50	(0%)	3/50	(6%)	4/50	(8%)	10/50	(20%)			
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	2/50	(4%)	3/50	(6%)			
		0/50	(0%)	0/50	(0%)	0/50	(0%)	3/50	(6%)	1/50	(2%)	2/50	(4%)			
		1/50	(2%)	0/50	(0%)	0/50	(0%)	3/50	(6%)	2/50	(4%)	3/50	(6%)			
		0/50	(0%)	0/50	(0%)	0/50	(0%)	6/50	(12%)	5/50	(10%)	0/50	(0%)			
Overall Incidence	Total	1/699 (0.14%)			Mean	0.14%	SD	0.53%	Total	47/700 (6.71%)			Mean	6.71%	SD	4.87%

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

		Male				Female			
#Mammary Gland:									
Fibroadenoma									
		3/50 (6%)	2/50 (4%)	2/50 (4%)	26/50 (52%)	25/50 (50%)	27/50 (54%)		
		2/50 (4%)	2/50 (4%)	0/49 (0%)	23/50 (46%)	32/50 (64%)	24/50 (48%)		
		2/50 (4%)	0/50 (0%)	1/50 (2%)	19/50 (38%)	29/50 (58%)	34/50 (68%)		
		0/50 (0%)	1/50 (2%)	1/50 (2%)	24/50 (48%)	36/50 (72%)	14/50 (28%)		
		1/50 (2%)	1/50 (2%)		22/50 (44%)	37/50 (74%)			
Overall Incidence	Total	18/699 (2.58%)	Mean 2.57%	SD 1.83%	Total	372/700 (53.14%)	Mean 53.14%	SD 13.05%	
.....									
#Mammary Gland:									
Fibroma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)		
		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%)	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	0/699 (0%)	Mean 0%	SD 0%	Total	1/700 (0.14%)	Mean 0.14%	SD 0.53%	
.....									
#Mammary Gland:									
Fibroma, Fibroadenoma or Adenoma									
		3/50 (6%)	2/50 (4%)	2/50 (4%)	28/50 (56%)	25/50 (50%)	27/50 (54%)		
		2/50 (4%)	2/50 (4%)	0/49 (0%)	23/50 (46%)	33/50 (66%)	25/50 (50%)		
		2/50 (4%)	0/50 (0%)	1/50 (2%)	19/50 (38%)	29/50 (58%)	34/50 (68%)		
		0/50 (0%)	1/50 (2%)	1/50 (2%)	25/50 (50%)	36/50 (72%)	14/50 (28%)		
		1/50 (2%)	1/50 (2%)		25/50 (50%)	37/50 (74%)			
Overall Incidence	Total	18/699 (2.58%)	Mean 2.57%	SD 1.83%	Total	380/700 (54.29%)	Mean 54.29%	SD 12.84%	
.....									
#Mammary Gland:									
Fibroma, Fibroadenoma, Carcinoma, or Adenoma									
		3/50 (6%)	2/50 (4%)	2/50 (4%)	30/50 (60%)	27/50 (54%)	30/50 (60%)		
		2/50 (4%)	2/50 (4%)	0/49 (0%)	23/50 (46%)	33/50 (66%)	26/50 (52%)		
		2/50 (4%)	0/50 (0%)	1/50 (2%)	21/50 (42%)	30/50 (60%)	34/50 (68%)		
		1/50 (2%)	1/50 (2%)	1/50 (2%)	26/50 (52%)	36/50 (72%)	16/50 (32%)		
		1/50 (2%)	1/50 (2%)		25/50 (50%)	38/50 (76%)			
Overall Incidence	Total	19/699 (2.72%)	Mean 2.71%	SD 1.68%	Total	395/700 (56.43%)	Mean 56.43%	SD 12.06%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 25
 Report Date: 05/24/2013

		Male					Female					
#Mesentery:												
Fibrous Histiocytoma												
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(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%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	1/699 (0.14%)			Mean	0.14%	SD	0.53%	Total	0/700 (0%)		
					Mean	0%	SD	0%				
#Mesentery:												
Schwannoma Malignant												
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(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%)	2/50	(4%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	1/699 (0.14%)			Mean	0.14%	SD	0.53%	Total	2/700 (0.29%)		
					Mean	0.29%	SD	1.07%				
*Nose:												
Adenoma												
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/49	(0%)	1/50	(2%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/48	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	0/697 (0%)			Mean	0%	SD	0%	Total	1/697 (0.14%)		
					Mean	0.14%	SD	0.53%				
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):												
Papilloma Squamous or Papilloma												
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		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%)	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%)	0/50	(0%)	
Overall Incidence	Total	2/699 (0.29%)			Mean	0.29%	SD	0.73%	Total	1/700 (0.14%)		
					Mean	0.14%	SD	0.53%				

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 26
 Report Date: 05/24/2013

		Male				Female			
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma									
		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%)	0/49 (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%)	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%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	3/699 (0.43%)		Mean 0.43%	SD 0.85%	Total	3/700 (0.43%)		Mean 0.43% SD 0.85%

#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma									
		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%)	1/49 (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%)	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%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	5/699 (0.72%)		Mean 0.72%	SD 1%	Total	4/700 (0.57%)		Mean 0.57% SD 0.94%

#Oral Mucosa: Squamous Cell Carcinoma									
		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%)	0/49 (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%)	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%)
		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	2/699 (0.29%)		Mean 0.29%	SD 0.73%	Total	1/700 (0.14%)		Mean 0.14% SD 0.53%

#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%)	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%)	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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/699 (0.14%)		Mean 0.15%	SD 0.55%	Total	0/700 (0%)		Mean 0% SD 0%

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 27
 Report Date: 05/24/2013

	Male		Female			
*Ovary:						
Cystadenoma						
	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%)
	0/50	(0%)	0/50	(0%)	0/50	(0%)
	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total 1/700 (0.14%)		Mean 0.14%		SD 0.53%	
.....						
*Ovary:						
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%)
	0/50	(0%)	0/50	(0%)	0/50	(0%)
	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total 1/700 (0.14%)		Mean 0.14%		SD 0.53%	
.....						
*Ovary:						
Granulosa Cell Tumor Benign						
	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%)
	1/50	(2%)	0/50	(0%)	0/50	(0%)
	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total 2/700 (0.29%)		Mean 0.29%		SD 0.73%	
.....						
*Ovary:						
Granulosa Cell Tumor 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%)	0/50	(0%)
	0/50	(0%)	0/50	(0%)	0/50	(0%)
	1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total 2/700 (0.29%)		Mean 0.29%		SD 0.73%	

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 28
 Report Date: 05/24/2013

	Male		Female			
*Ovary:						
Granulosa Cell Tumor: Benign, Malignant, NOS						
	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%)
	1/50	(2%)	0/50	(0%)	0/50	(0%)
	1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total 4/700 (0.57%)		Mean 0.57%		SD 0.94%	
.....						
*Ovary:						
Granulosa-Theca Tumor Malignant						
	0/50	(0%)	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%)	0/50	(0%)	0/50	(0%)
	0/50	(0%)	1/50	(2%)		
Overall Incidence	Total 3/700 (0.43%)		Mean 0.43%		SD 1.16%	
.....						
*Ovary:						
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%)	0/50	(0%)
	0/50	(0%)	0/50	(0%)		
Overall Incidence	Total 1/700 (0.14%)		Mean 0.14%		SD 0.53%	
.....						
*Ovary:						
Sertoli 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%)	0/50	(0%)
	0/50	(0%)	1/50	(2%)		
Overall Incidence	Total 1/700 (0.14%)		Mean 0.14%		SD 0.53%	

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 29
 Report Date: 05/24/2013

		Male				Female								
*Ovary:														
 Tubulostromal Adenoma														
					0/50	(0%)	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	1/700	(0.14%)	Mean	0.14%	SD	0.53%			

*Pancreas:														
 Adenoma														
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/49	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)	1/49	(2%)	0/50	(0%)	0/50	(0%)			
		0/49	(0%)	0/50	(0%)	1/49	(2%)	0/49	(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%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	4/696	(0.57%)	Mean	0.58%	SD	0.95%	Total	1/698	(0.14%)	Mean	0.14%	SD	0.53%

*Pancreas:														
 Carcinoma or Adenoma														
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/49	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)	1/49	(2%)	0/50	(0%)	0/50	(0%)			
		0/49	(0%)	0/50	(0%)	1/49	(2%)	0/49	(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%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	4/696	(0.57%)	Mean	0.58%	SD	0.95%	Total	1/698	(0.14%)	Mean	0.14%	SD	0.53%

*Pancreas:														
 Mixed Tumor Benign														
		1/50	(2%)	0/50	(0%)	0/49	(0%)	0/49	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)			
		0/49	(0%)	0/50	(0%)	0/49	(0%)	0/49	(0%)	0/50	(0%)			
		0/50	(0%)	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	3/696	(0.43%)	Mean	0.43%	SD	0.85%	Total	0/698	(0%)	Mean	0%	SD	0%

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

		Male				Female			
*Parathyroid Gland:									
Adenoma									
		0/48 (0%)	0/46 (0%)	0/48 (0%)		0/47 (0%)	0/47 (0%)	1/43 (2%)	
		0/47 (0%)	0/50 (0%)	1/49 (2%)		1/38 (3%)	0/48 (0%)	0/44 (0%)	
		0/49 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/47 (0%)	
		0/50 (0%)	0/35 (0%)	0/48 (0%)		0/49 (0%)	0/48 (0%)	0/49 (0%)	
		0/45 (0%)	0/50 (0%)			0/45 (0%)	0/49 (0%)		
Overall Incidence	Total	1/664 (0.15%)	Mean 0.15%	SD 0.55%	Total	3/654 (0.46%)	Mean 0.5%	SD 1%	

*Pituitary Gland: Pars Distalis or Unspecified Site:									
Adenoma									
		24/50 (48%)	37/50 (74%)	31/50 (62%)		25/50 (50%)	35/50 (70%)	29/50 (58%)	
		38/50 (76%)	20/50 (40%)	21/49 (43%)		34/50 (68%)	16/50 (32%)	29/50 (58%)	
		33/50 (66%)	23/50 (46%)	28/50 (56%)		31/50 (62%)	31/50 (62%)	30/50 (60%)	
		33/50 (66%)	16/50 (32%)	36/50 (72%)		25/50 (50%)	22/50 (44%)	36/49 (73%)	
		34/49 (69%)	34/50 (68%)			36/50 (72%)	32/50 (64%)		
Overall Incidence	Total	408/698 (58.45%)	Mean 58.45%	SD 14.21%	Total	411/699 (58.8%)	Mean 58.82%	SD 11.58%	

*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	2/50 (4%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		2/50 (4%)	0/50 (0%)	1/50 (2%)	
		2/50 (4%)	1/50 (2%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/49 (0%)	0/50 (0%)			2/50 (4%)	1/50 (2%)		
Overall Incidence	Total	4/698 (0.57%)	Mean 0.57%	SD 1.22%	Total	11/699 (1.57%)	Mean 1.57%	SD 1.79%	

*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma or Adenoma									
		24/50 (48%)	37/50 (74%)	31/50 (62%)		26/50 (52%)	35/50 (70%)	31/50 (62%)	
		38/50 (76%)	20/50 (40%)	21/49 (43%)		36/50 (72%)	16/50 (32%)	30/50 (60%)	
		35/50 (70%)	24/50 (48%)	28/50 (56%)		33/50 (66%)	31/50 (62%)	30/50 (60%)	
		33/50 (66%)	16/50 (32%)	37/50 (74%)		25/50 (50%)	22/50 (44%)	36/49 (73%)	
		34/49 (69%)	34/50 (68%)			38/50 (76%)	33/50 (66%)		
Overall Incidence	Total	412/698 (59.03%)	Mean 59.02%	SD 14.43%	Total	422/699 (60.37%)	Mean 60.39%	SD 12.29%	

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

		Male				Female			
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Ganglioneuroma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		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%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/698 (0.14%)		Mean 0.14%	SD 0.53%	Total	1/699 (0.14%)		Mean 0.14% SD 0.53%

*Pituitary Gland: Pars Intermedia:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/49 (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%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/49 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	2/698 (0.29%)		Mean 0.29%	SD 0.73%	Total	3/699 (0.43%)		Mean 0.43% SD 0.85%

*Pituitary Gland: Pars Intermedia:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/49 (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%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/49 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	2/698 (0.29%)		Mean 0.29%	SD 0.73%	Total	3/699 (0.43%)		Mean 0.43% SD 0.85%

*Pituitary Gland: Pars Nervosa:									
Craniopharyngioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/49 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	0/698 (0%)		Mean 0%	SD 0%	Total	1/699 (0.14%)		Mean 0.14% SD 0.53%

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 32
 Report Date: 05/24/2013

		Male				Female			
*Prostate:									
Adenoma									
		2/50	(4%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	1/50	(2%)	0/49	(0%)		
		0/50	(0%)	0/50	(0%)	0/49	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	3/698 (0.43%)		Mean 0.43%		SD 1.16%			

*Prostate:									
Carcinoma or Adenoma									
		2/50	(4%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	1/50	(2%)	0/49	(0%)		
		0/50	(0%)	0/50	(0%)	0/49	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	3/698 (0.43%)		Mean 0.43%		SD 1.16%			

*Salivary Glands:									
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%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	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	2/699 (0.29%)		Mean 0.29%		SD 0.73%		Total	0/700 (0%)
								Mean	0%
								SD	0%

*Salivary Glands:									
Carcinoma or 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%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	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	2/699 (0.29%)		Mean 0.29%		SD 0.73%		Total	0/700 (0%)
								Mean	0%
								SD	0%

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 33
 Report Date: 05/24/2013

		Male					Female					
*Salivary Glands:												
Sarcoma												
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(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%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	1/699 (0.14%)			Mean	0.14%	SD	0.53%	Total	0/700 (0%)		
					Mean	0%	SD	0%				
*Salivary Glands:												
Schwannoma Malignant												
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(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%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	1/699 (0.14%)			Mean	0.14%	SD	0.53%	Total	0/700 (0%)		
					Mean	0%	SD	0%				
#Seminal Vesicle:												
Adenoma												
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	1/50	(2%)	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%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	1/699 (0.14%)			Mean	0.14%	SD	0.53%	Total	0/700 (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%)	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%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	1/699 (0.14%)			Mean	0.15%	SD	0.55%	Total	0/700 (0%)		
					Mean	0%	SD	0%				

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 34
 Report Date: 05/24/2013

		Male					Female									
#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%)	0/49	(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%)	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	1/699 (0.14%)			Mean	0.14%	SD	0.53%	Total	0/700 (0%)			Mean	0%	SD	0%
#Skin:																
Basal Cell Adenoma																
		1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)			
		1/50	(2%)	1/50	(2%)	2/49	(4%)	0/50	(0%)	1/50	(2%)	0/50	(0%)			
		0/50	(0%)	1/50	(2%)	1/50	(2%)	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%)	1/50	(2%)			1/50	(2%)	1/50	(2%)	1/50	(2%)			
Overall Incidence	Total	9/699 (1.29%)			Mean	1.29%	SD	1.28%	Total	5/700 (0.71%)			Mean	0.71%	SD	0.99%
#Skin:																
Basal Cell Adenoma or Basosquamous Tumor Benign																
		1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)			
		1/50	(2%)	1/50	(2%)	2/49	(4%)	0/50	(0%)	1/50	(2%)	0/50	(0%)			
		0/50	(0%)	1/50	(2%)	1/50	(2%)	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%)	1/50	(2%)			1/50	(2%)	1/50	(2%)	1/50	(2%)			
Overall Incidence	Total	9/699 (1.29%)			Mean	1.29%	SD	1.28%	Total	5/700 (0.71%)			Mean	0.71%	SD	0.99%
#Skin:																
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma																
		3/50	(6%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)			
		1/50	(2%)	1/50	(2%)	2/49	(4%)	0/50	(0%)	1/50	(2%)	0/50	(0%)			
		0/50	(0%)	1/50	(2%)	1/50	(2%)	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%)	2/50	(4%)			1/50	(2%)	1/50	(2%)	1/50	(2%)			
Overall Incidence	Total	12/699 (1.72%)			Mean	1.72%	SD	1.91%	Total	5/700 (0.71%)			Mean	0.71%	SD	0.99%

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 35
 Report Date: 05/24/2013

		Male				Female			
#Skin:									
Basal Cell Carcinoma									
		1/50 (2%)	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%)	0/49 (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%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	3/50 (6%)	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	7/699 (1%)	Mean 1%	SD 1.71%	Total	3/700 (0.43%)	Mean 0.43%	SD 0.85%	

#Skin:									
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)									
		1/50 (2%)	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%)	0/49 (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%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	3/50 (6%)	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	7/699 (1%)	Mean 1%	SD 1.71%	Total	3/700 (0.43%)	Mean 0.43%	SD 0.85%	

#Skin:									
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma									
		4/50 (8%)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	2/49 (4%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	4/50 (8%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	3/50 (6%)		1/50 (2%)	1/50 (2%)			
Overall Incidence	Total	19/699 (2.72%)	Mean 2.72%	SD 2.79%	Total	8/700 (1.14%)	Mean 1.14%	SD 1.29%	

#Skin:									
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma									
		9/50 (18%)	1/50 (2%)	1/50 (2%)	2/50 (4%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		2/50 (4%)	2/50 (4%)	2/49 (4%)	1/50 (2%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		7/50 (14%)	4/50 (8%)	6/50 (12%)	0/50 (0%)	2/50 (4%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		3/50 (6%)	4/50 (8%)	5/50 (10%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		5/50 (10%)	9/50 (18%)		1/50 (2%)	2/50 (4%)			
Overall Incidence	Total	60/699 (8.58%)	Mean 8.58%	SD 5.4%	Total	17/700 (2.43%)	Mean 2.43%	SD 1.6%	

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

		Male				Female			
#Skin:									
Fibroma									
		11/50 (22%)	3/50 (6%)	1/50 (2%)	2/50 (4%)	2/50 (4%)	1/50 (2%)		
		1/50 (2%)	2/50 (4%)	7/49 (14%)	1/50 (2%)	0/50 (0%)	1/50 (2%)		
		5/50 (10%)	6/50 (12%)	3/50 (6%)	3/50 (6%)	1/50 (2%)	2/50 (4%)		
		1/50 (2%)	5/50 (10%)	3/50 (6%)	1/50 (2%)	0/50 (0%)	0/50 (0%)		
		4/50 (8%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	53/699 (7.58%)	Mean 7.59%	SD 5.75%	Total	15/700 (2.14%)	Mean 2.14%	SD 1.83%	
.....									
#Skin:									
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma									
		16/50 (32%)	3/50 (6%)	2/50 (4%)	2/50 (4%)	2/50 (4%)	1/50 (2%)		
		2/50 (4%)	3/50 (6%)	7/49 (14%)	1/50 (2%)	0/50 (0%)	1/50 (2%)		
		7/50 (14%)	6/50 (12%)	4/50 (8%)	3/50 (6%)	4/50 (8%)	2/50 (4%)		
		1/50 (2%)	5/50 (10%)	6/50 (12%)	1/50 (2%)	0/50 (0%)	0/50 (0%)		
		4/50 (8%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	67/699 (9.59%)	Mean 9.59%	SD 7.67%	Total	18/700 (2.57%)	Mean 2.57%	SD 2.41%	
.....									
#Skin:									
Fibrosarcoma									
		3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		2/50 (4%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	3/50 (6%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	3/50 (6%)	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	9/699 (1.29%)	Mean 1.29%	SD 2.3%	Total	3/700 (0.43%)	Mean 0.43%	SD 1.6%	
.....									
#Skin:									
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma									
		6/50 (12%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		1/50 (2%)	1/50 (2%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		2/50 (4%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	3/50 (6%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	3/50 (6%)	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	15/699 (2.15%)	Mean 2.14%	SD 3.37%	Total	3/700 (0.43%)	Mean 0.43%	SD 1.6%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 37
 Report Date: 05/24/2013

		Male				Female			
#Skin:									
Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	1/50 (2%)	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%)	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	3/699 (0.43%)	Mean 0.43%	SD 0.85%	Total	0/700 (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%)	0/49 (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%)	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	1/699 (0.14%)	Mean 0.14%	SD 0.53%	Total	0/700 (0%)	Mean 0%	SD 0%	

#Skin:									
Keratoacanthoma									
		5/50 (10%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)	
		2/50 (4%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)	
		4/50 (8%)	3/50 (6%)	5/50 (10%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		2/50 (4%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		4/50 (8%)	3/50 (6%)			0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	31/699 (4.43%)	Mean 4.43%	SD 3.69%	Total	7/700 (1%)	Mean 1%	SD 1.3%	

#Skin:									
Lipoma									
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/49 (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%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	6/699 (0.86%)	Mean 0.86%	SD 1.51%	Total	0/700 (0%)	Mean 0%	SD 0%	

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 38
 Report Date: 05/24/2013

		Male					Female									
#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%)	1/49	(2%)	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%)	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	1/699 (0.14%)			Mean	0.15%	SD	0.55%	Total	1/700 (0.14%)			Mean	0.14%	SD	0.53%
.....																
#Skin:																
Neural Crest Tumor																
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)	0/49	(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%)	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	1/699 (0.14%)			Mean	0.14%	SD	0.53%	Total	1/700 (0.14%)			Mean	0.14%	SD	0.53%
.....																
#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%)	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%)	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%)			
Overall Incidence	Total	0/699 (0%)			Mean	0%	SD	0%	Total	1/700 (0.14%)			Mean	0.14%	SD	0.53%
.....																
#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%)			
		1/50	(2%)	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%)	0/50	(0%)	1/50	(2%)	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%)			
Overall Incidence	Total	2/699 (0.29%)			Mean	0.29%	SD	0.73%	Total	2/700 (0.29%)			Mean	0.29%	SD	0.73%

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 39
 Report Date: 05/24/2013

		Male				Female			
#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%)
		1/50 (2%)	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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/699 (0.29%)		Mean 0.29%	SD 0.73%	Total 3/700 (0.43%)		Mean 0.43%	SD 0.85%

#Skin:									
Sarcoma									
		3/50 (6%)	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%)	0/49 (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%)	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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/699 (0.43%)		Mean 0.43%	SD 1.6%	Total 0/700 (0%)		Mean 0%	SD 0%

#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%)
		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%)	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%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/699 (0%)		Mean 0%	SD 0%	Total 1/700 (0.14%)		Mean 0.14%	SD 0.53%

#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%)
		1/50 (2%)	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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/699 (0.29%)		Mean 0.29%	SD 0.73%	Total 2/700 (0.29%)		Mean 0.29%	SD 0.73%

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 40
 Report Date: 05/24/2013

		Male				Female			
#Skin:									
Squamous Cell Carcinoma									
		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%)	1/50 (2%)	0/49 (0%)	1/50 (2%)	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%)	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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/699 (0.43%)		Mean 0.43%	SD 0.85%	Total 2/700 (0.29%)		Mean 0.29%	SD 0.73%

#Skin:									
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma									
		1/50 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/49 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	3/50 (6%)	1/50 (2%)	0/50 (0%)	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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	10/699 (1.43%)		Mean 1.43%	SD 1.83%	Total 5/700 (0.71%)		Mean 0.71%	SD 0.99%

#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%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	8/699 (1.14%)		Mean 1.14%	SD 1.88%	Total 1/700 (0.14%)		Mean 0.14%	SD 0.53%

#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%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	8/699 (1.14%)		Mean 1.14%	SD 1.88%	Total 1/700 (0.14%)		Mean 0.14%	SD 0.53%

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 41
 Report Date: 05/24/2013

		Male				Female			
#Skin:									
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma									
		5/50 (10%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)		
		2/50 (4%)	1/50 (2%)	0/49 (0%)	1/50 (2%)	3/50 (6%)	0/50 (0%)		
		6/50 (12%)	3/50 (6%)	5/50 (10%)	0/50 (0%)	1/50 (2%)	0/50 (0%)		
		3/50 (6%)	4/50 (8%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	1/50 (2%)		
		5/50 (10%)	6/50 (12%)		0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	42/699 (6.01%)	Mean 6%	SD 4.37%	Total	10/700 (1.43%)	Mean 1.43%	SD 1.65%	

#Skin:									
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma									
		5/50 (10%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)		
		2/50 (4%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	3/50 (6%)	0/50 (0%)		
		5/50 (10%)	3/50 (6%)	5/50 (10%)	0/50 (0%)	1/50 (2%)	0/50 (0%)		
		3/50 (6%)	4/50 (8%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)		
		5/50 (10%)	6/50 (12%)		0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	39/699 (5.58%)	Mean 5.57%	SD 4.52%	Total	8/700 (1.14%)	Mean 1.14%	SD 1.7%	

#Skin:									
Trichoepithelioma									
		2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/49 (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%)	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	3/699 (0.43%)	Mean 0.43%	SD 1.16%	Total	0/700 (0%)	Mean 0%	SD 0%	

#Skin: Sebaceous Gland:									
Adenoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/49 (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%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	4/699 (0.57%)	Mean 0.57%	SD 1.22%	Total	1/700 (0.14%)	Mean 0.14%	SD 0.53%	

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

		Male					Female									
#Skin: Sebaceous Gland:																
Carcinoma or Adenoma																
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)	0/49	(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%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)	2/50	(4%)	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	4/699 (0.57%)			Mean	0.57%	SD	1.22%	Total	1/700 (0.14%)			Mean	0.14%	SD	0.53%
#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%)	1/49	(2%)	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%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	1/699 (0.14%)			Mean	0.15%	SD	0.55%	Total	1/700 (0.14%)			Mean	0.14%	SD	0.53%
#Stomach, Glandular:																
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%)	0/49	(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%)			
		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	1/699 (0.14%)			Mean	0.14%	SD	0.53%	Total	0/700 (0%)			Mean	0%	SD	0%
#Stomach, Glandular:																
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%)	0/49	(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%)			
		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	1/699 (0.14%)			Mean	0.14%	SD	0.53%	Total	0/700 (0%)			Mean	0%	SD	0%

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

		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%)	0/49 (0%)		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%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/699 (0%)	Mean 0%	SD 0%	Total	1/700 (0.14%)	Mean 0.14%	SD 0.53%	
.....									
*Testes:									
Adenoma									
		35/50 (70%)	34/50 (68%)	36/50 (72%)					
		37/50 (74%)	45/50 (90%)	37/49 (76%)					
		34/50 (68%)	40/50 (80%)	35/50 (70%)					
		37/50 (74%)	41/50 (82%)	29/50 (58%)					
		27/50 (54%)	32/50 (64%)						
Overall Incidence	Total	499/699 (71.39%)	Mean 71.39%	SD 9.31%					
.....									
*Testes:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)	0/50 (0%)	0/49 (0%)					
		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	2/699 (0.29%)	Mean 0.29%	SD 0.73%					
.....									
*Thymus:									
Thymoma Benign									
		0/44 (0%)	0/43 (0%)	0/44 (0%)		0/48 (0%)	1/46 (2%)	0/48 (0%)	
		1/47 (2%)	0/50 (0%)	0/48 (0%)		1/50 (2%)	0/48 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%)	0/47 (0%)	0/49 (0%)	
		0/47 (0%)	1/48 (2%)	0/47 (0%)		1/50 (2%)	0/50 (0%)	0/44 (0%)	
		0/45 (0%)	0/42 (0%)			0/47 (0%)	0/46 (0%)		
Overall Incidence	Total	2/654 (0.31%)	Mean 0.3%	SD 0.76%	Total	4/673 (0.59%)	Mean 0.58%	SD 0.96%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 44
 Report Date: 05/24/2013

		Male				Female			
*Thymus:									
Thymoma Malignant									
		0/44 (0%)	0/43 (0%)	0/44 (0%)		0/48 (0%)	0/46 (0%)	0/48 (0%)	
		0/47 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	1/48 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/47 (0%)	0/49 (0%)	
		0/47 (0%)	1/48 (2%)	0/47 (0%)		0/50 (0%)	1/50 (2%)	0/44 (0%)	
		0/45 (0%)	0/42 (0%)			0/47 (0%)	0/46 (0%)		
Overall Incidence	Total	1/654 (0.15%)	Mean 0.15%	SD 0.56%	Total	2/673 (0.3%)	Mean 0.29%	SD 0.74%	

*Thymus:									
Thymoma NOS									
		0/44 (0%)	0/43 (0%)	0/44 (0%)		0/48 (0%)	0/46 (0%)	1/48 (2%)	
		0/47 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/48 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/47 (0%)	0/49 (0%)	
		0/47 (0%)	0/48 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/44 (0%)	
		0/45 (0%)	0/42 (0%)			0/47 (0%)	0/46 (0%)		
Overall Incidence	Total	0/654 (0%)	Mean 0%	SD 0%	Total	1/673 (0.15%)	Mean 0.15%	SD 0.56%	

*Thymus:									
Thymoma: Benign, Malignant, NOS									
		0/44 (0%)	0/43 (0%)	0/44 (0%)		0/48 (0%)	1/46 (2%)	1/48 (2%)	
		1/47 (2%)	0/50 (0%)	0/48 (0%)		1/50 (2%)	1/48 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%)	0/47 (0%)	0/49 (0%)	
		0/47 (0%)	2/48 (4%)	0/47 (0%)		1/50 (2%)	1/50 (2%)	0/44 (0%)	
		0/45 (0%)	0/42 (0%)			0/47 (0%)	0/46 (0%)		
Overall Incidence	Total	3/654 (0.46%)	Mean 0.45%	SD 1.21%	Total	7/673 (1.04%)	Mean 1.02%	SD 1.06%	

*Thyroid Gland: C-Cell:									
Adenoma									
		6/46 (13%)	5/50 (10%)	7/50 (14%)		4/42 (10%)	3/50 (6%)	4/50 (8%)	
		10/50 (20%)	11/50 (22%)	8/49 (16%)		11/49 (22%)	6/50 (12%)	5/50 (10%)	
		6/46 (13%)	11/50 (22%)	12/50 (24%)		7/50 (14%)	9/49 (18%)	10/50 (20%)	
		9/50 (18%)	12/50 (24%)	5/50 (10%)		7/50 (14%)	6/50 (12%)	3/50 (6%)	
		8/50 (16%)	4/50 (8%)			3/50 (6%)	3/50 (6%)		
Overall Incidence	Total	114/691 (16.5%)	Mean 16.46%	SD 5.37%	Total	81/690 (11.74%)	Mean 11.74%	SD 5.48%	

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 45
 Report Date: 05/24/2013

		Male				Female			
*Thyroid Gland: C-Cell: Carcinoma									
		0/46 (0%)	4/50 (8%)	1/50 (2%)		3/42 (7%)	1/50 (2%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
		0/46 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/49 (0%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	3/50 (6%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	13/691 (1.88%)	Mean 1.86%	SD 2.54%	Total	6/690 (0.87%)	Mean 0.94%	SD 1.97%	

*Thyroid Gland: C-Cell: Carcinoma or Adenoma									
		6/46 (13%)	9/50 (18%)	8/50 (16%)		7/42 (17%)	4/50 (8%)	4/50 (8%)	
		11/50 (22%)	11/50 (22%)	8/49 (16%)		11/49 (22%)	6/50 (12%)	5/50 (10%)	
		6/46 (13%)	11/50 (22%)	13/50 (26%)		8/50 (16%)	9/49 (18%)	11/50 (22%)	
		9/50 (18%)	12/50 (24%)	6/50 (12%)		7/50 (14%)	6/50 (12%)	3/50 (6%)	
		8/50 (16%)	7/50 (14%)			3/50 (6%)	3/50 (6%)		
Overall Incidence	Total	125/691 (18.09%)	Mean 18.03%	SD 4.47%	Total	87/690 (12.61%)	Mean 12.68%	SD 5.75%	

*Thyroid Gland: Follicular Cell: Adenoma									
		0/46 (0%)	0/50 (0%)	0/50 (0%)		0/42 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	0/50 (0%)	1/49 (2%)		1/49 (2%)	0/50 (0%)	1/50 (2%)	
		0/46 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	1/49 (2%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	5/691 (0.72%)	Mean 0.72%	SD 1.27%	Total	6/690 (0.87%)	Mean 0.86%	SD 1.03%	

*Thyroid Gland: Follicular Cell: Carcinoma									
		0/46 (0%)	0/50 (0%)	0/50 (0%)		0/42 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
		2/46 (4%)	0/50 (0%)	1/50 (2%)		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%)	0/50 (0%)		
Overall Incidence	Total	4/691 (0.58%)	Mean 0.6%	SD 1.3%	Total	0/690 (0%)	Mean 0%	SD 0%	

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

		Male				Female			
*Thyroid Gland: Follicular Cell:									
Carcinoma or Adenoma									
		0/46 (0%)	0/50 (0%)	0/50 (0%)		0/42 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	1/50 (2%)	1/49 (2%)		1/49 (2%)	0/50 (0%)	1/50 (2%)	
		2/46 (4%)	1/50 (2%)	1/50 (2%)		1/50 (2%)	1/49 (2%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	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%)	
Overall Incidence	Total	9/691 (1.3%)	Mean 1.31%	SD 1.54%	Total	6/690 (0.87%)	Mean 0.86%	SD 1.03%	

#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%)	0/49 (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%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	1/699 (0.14%)	Mean 0.14%	SD 0.53%	Total	2/700 (0.29%)	Mean 0.29%	SD 0.73%	

#Tongue:									
Squamous Cell Carcinoma or Papilloma Squamous									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (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%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	2/699 (0.29%)	Mean 0.29%	SD 0.73%	Total	3/700 (0.43%)	Mean 0.43%	SD 0.85%	

#Tongue:									
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%)	0/49 (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%)	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	1/699 (0.14%)	Mean 0.14%	SD 0.53%	Total	1/700 (0.14%)	Mean 0.14%	SD 0.53%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 47
 Report Date: 05/24/2013

		Male					Female									
#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%)	0/49	(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%)	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	1/699 (0.14%)			Mean	0.14%	SD	0.53%	Total	0/700 (0%)			Mean	0%	SD	0%

*Urinary Bladder:																
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%)	0/49	(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%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/49	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	1/698 (0.14%)			Mean	0.14%	SD	0.53%	Total	0/700 (0%)			Mean	0%	SD	0%

*Urinary Bladder:																
Carcinoma or Papilloma																
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)	0/49	(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%)			
		1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/49	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	3/698 (0.43%)			Mean	0.43%	SD	0.85%	Total	1/700 (0.14%)			Mean	0.14%	SD	0.53%

*Urinary Bladder:																
Hemangiosarcoma																
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)	0/49	(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%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/49	(0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	1/698 (0.14%)			Mean	0.14%	SD	0.53%	Total	0/700 (0%)			Mean	0%	SD	0%

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 48
 Report Date: 05/24/2013

		Male				Female				
*Urinary Bladder:										
Papilloma										
		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%)	0/49 (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%)	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%)	
		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/698 (0.29%)		Mean 0.29%	SD 0.73%	Total	1/700 (0.14%)		Mean 0.14%	SD 0.53%
.....										
#Uterus:										
Adenoma										
						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%)	1/50 (2%)		
						0/50 (0%)	0/50 (0%)	1/50 (2%)		
Overall Incidence						Total	2/700 (0.29%)		Mean 0.29%	SD 0.73%
.....										
#Uterus:										
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%)	1/50 (2%)		
						0/50 (0%)	0/50 (0%)	1/50 (2%)		
Overall Incidence						Total	2/700 (0.29%)		Mean 0.29%	SD 0.73%
.....										
#Uterus:										
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%)	1/50 (2%)		
						0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence						Total	1/700 (0.14%)		Mean 0.14%	SD 0.53%

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 49
 Report Date: 05/24/2013

	Male		Female		
#Uterus:					
Polyp Stromal					
	17/50	(34%)	8/50	(16%)	8/50 (16%)
	3/50	(6%)	8/50	(16%)	7/50 (14%)
	10/50	(20%)	3/50	(6%)	8/50 (16%)
	7/50	(14%)	6/50	(12%)	6/50 (12%)
	9/50	(18%)	11/50	(22%)	
Overall Incidence	Total	111/700 (15.86%)	Mean	15.86%	SD 6.9%
.....					
#Uterus:					
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%)
	1/50	(2%)	0/50	(0%)	0/50 (0%)
	0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	1/700 (0.14%)	Mean	0.14%	SD 0.53%
.....					
#Uterus:					
Sarcoma Stromal					
	0/50	(0%)	2/50	(4%)	0/50 (0%)
	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	3/700 (0.43%)	Mean	0.43%	SD 1.16%
.....					
#Uterus:					
Sarcoma Stromal or Polyp Stromal					
	17/50	(34%)	10/50	(20%)	8/50 (16%)
	3/50	(6%)	8/50	(16%)	7/50 (14%)
	10/50	(20%)	3/50	(6%)	8/50 (16%)
	7/50	(14%)	6/50	(12%)	6/50 (12%)
	9/50	(18%)	11/50	(22%)	
Overall Incidence	Total	113/700 (16.14%)	Mean	16.14%	SD 6.99%

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 50
 Report Date: 05/24/2013

	Male		Female			
#Uterus:						
Schwannoma Malignant						
	0/50	(0%)	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%)
	0/50	(0%)	0/50	(0%)		
Overall Incidence	Total 2/700 (0.29%)		Mean 0.29%		SD 0.73%	
.....						
#Vagina:						
Polyp						
	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%)
	1/50	(2%)	0/50	(0%)		
Overall Incidence	Total 2/700 (0.29%)		Mean 0.29%		SD 0.73%	
.....						
#Vagina:						
Sarcoma						
	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%)	0/50	(0%)		
Overall Incidence	Total 1/700 (0.14%)		Mean 0.14%		SD 0.53%	
.....						
#Vagina:						
Schwannoma Malignant						
	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%)	0/50	(0%)
	0/50	(0%)	0/50	(0%)		
Overall Incidence	Total 1/700 (0.14%)		Mean 0.14%		SD 0.53%	

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 51
 Report Date: 05/24/2013

		Male				Female							
#Zymbal's Gland:													
Adenoma													
		0/50	(0%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)		
		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%)	0/50	(0%)	0/50	(0%)		
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	3/699 (0.43%)		Mean 0.43%		SD 1.16%		Total	0/700 (0%)		Mean 0%	SD 0%	

#Zymbal's Gland:													
Carcinoma													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)	0/49	(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%)
		1/50	(2%)	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	5/699 (0.72%)		Mean 0.71%		SD 0.99%		Total	2/700 (0.29%)		Mean 0.29%	SD 0.73%	

#Zymbal's Gland:													
Carcinoma or Adenoma													
		0/50	(0%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)	0/49	(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%)
		1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	8/699 (1.14%)		Mean 1.14%		SD 1.29%		Total	2/700 (0.29%)		Mean 0.29%	SD 0.73%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied