

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

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**  
Kava kava extract  
**CAS Number:** 9000-38-8

**Date Report Requested:** 09/21/2010  
**Time Report Requested:** 09:10:56  
**First Dose M/F:** 08/18/04 / 08/19/04  
**Lab:** BAT

F2\_R2

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

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FISCHER 344 RATS MALE	DAY ON TEST	07	07	06	07	07	06	06	07	07	07	07	05	07	07	07	05	07	07	07	07	07	07	07	07	males (cont...)
		29	27	51	28	27	10	29	29	27	28	27	82	22	28	29	4	27	27	27	88	88	77	22	28	
	ANIMAL ID	0001	0002	0003	0004	0005	0006	0007	0008	0009	0010	0011	0012	0013	0014	0015	0016	0017	0018	0019	0020	0021	0022	0023	0024	

ALIMENTARY SYSTEM

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Lymphoma Malignant																								
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Fibrous Histiocytoma, Metastatic, Skeletal Muscle								X																
Hepatocellular Adenoma		X																						
Leukemia Mononuclear			X			X	X												X	X				
Mesentery			+			+																		
Mesothelioma Malignant																								
Oral Mucosa																								
Squamous Cell Papilloma																								
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Leukemia Mononuclear																							X	

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
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 BLANK .. Not examined microscopically



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 Lab: BAT

FISCHER 344 RATS MALE 0.0 G/KG	DAY ON TEST																									males (cont...)	
	0729	0729	0667	0667	0667	0667	0667	0667	0667	0667	0667	0667	0667	0667	0667	0667	0667	0667	0667	0667	0667	0667	0667	0667	0667		
ANIMAL ID	0001	0002	0003	0004	0005	0006	0007	0008	0009	0010	0011	0012	0013	0014	0015	0016	0017	0018	0019	0020	0021	0022	0023	0024	0025		
Islets, Pancreatic Adenoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Parathyroid Gland Adenoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Pituitary Gland Leukemia Mononuclear Pars Distalis, Adenoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Thyroid Gland C-cell, Adenoma Follicular Cell, Adenoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
GENERAL BODY SYSTEM	NONE																										
GENITAL SYSTEM																											
Coagulating Gland																										+	
Epididymis Mesothelioma Malignant	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Preputial Gland Carcinoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Prostate	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	

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FISCHER 344 RATS MALE 0.0 G/KG	DAY ON TEST																									males (cont...)	
	0729	0727	0671	0778	0777	0660	0667	0772	0779	0777	0778	0522	0772	0778	0779	0504	0772	0777	0777	0778	0778	0777	0777	0778	0778		
ANIMAL ID	0001	0002	0003	0004	0005	0006	0007	0008	0009	0010	0011	0012	0013	0014	0015	0016	0017	0018	0019	0020	0021	0022	0023	0024	0025		
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Mesothelioma Malignant																											
Bilateral, Interstitial Cell, Adenoma				X		X	X		X	X	X		X	X	X			X	X	X		X				X	
Interstitial Cell, Adenoma		X			X			X				X					X						X				
<b>HEMATOPOIETIC SYSTEM</b>																											
Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Lymph Node																											
Deep Cervical, Leukemia Mononuclear																											
Lymph Node, Mandibular	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Leukemia Mononuclear			X					X										X									
Lymphoma Malignant																											
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Leukemia Mononuclear			X			X		X										X	X								
Thymus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Leukemia Mononuclear																											
<b>INTEGUMENTARY SYSTEM</b>																											
Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	

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FISCHER 344 RATS MALE 0.0 G/KG	DAY ON TEST																									ANIMAL ID	males (cont...)
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	7	7	6	7	7	6	6	7	7	7	7	5	7	7	7	5	7	7	7	7	7	7	7	7	5	0	
	2	2	5	2	2	1	2	2	2	2	2	8	2	2	2	0	2	2	2	2	2	2	2	2	2	0	
	9	7	1	8	7	0	9	9	7	8	7	2	8	7	9	4	7	7	7	8	8	8	7	8	0		
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2	2	2	2	2	0		
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	0		

Dermis, Fibroma X  
 Epidermis, Basal Cell Adenoma  
 Subcutaneous Tissue, Fibroma X X  
 Subcutaneous Tissue, Lipoma X  
 Subcutaneous Tissue, Liposarcoma

**MUSCULOSKELETAL SYSTEM**

Bone +  
 Osteosarcoma  
 Skeletal Muscle +  
 Fibrous Histiocytoma X

**NERVOUS SYSTEM**

Brain +  
 Leukemia Mononuclear  
 Peripheral Nerve +  
 Spinal Cord +  
 Glioma Malignant X

**RESPIRATORY SYSTEM**

Lung +  
 Alveolar/Bronchiolar Adenoma X  
 Alveolar/Bronchiolar Adenoma, Multiple X  
 Alveolar/Bronchiolar Carcinoma X

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DAY ON TEST	FISCHER 344 RATS MALE																									ANIMAL ID	males (cont...)																								
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0																										
7	7	6	7	7	6	6	7	7	7	7	5	7	7	7	5	7	7	7	7	7	7	7	7	7	5	0																									
2	2	5	2	2	1	2	2	2	2	2	8	2	2	2	0	2	2	2	2	2	2	2	2	2	2	0																									
9	7	1	8	7	0	9	9	7	8	7	2	8	7	9	4	7	7	7	8	8	7	7	8	8	0																										
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0																									
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0																									
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0																									
0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	2	2	2	2	0																									
1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	0																										
Fibrous Histiocytoma, Metastatic, Skeletal Muscle																									X																										
Leukemia Mononuclear Mediastinum, Osteosarcoma, Metastatic, Bone																									X	X																									
Nose																									+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Trachea																									+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
<b>SPECIAL SENSES SYSTEM</b>																																																			
Eye																									+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Harderian Gland																									+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
<b>URINARY SYSTEM</b>																																																			
Kidney																									+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Leukemia Mononuclear																											X					X													X						
Ureter																																																			+
Urethra																																																			+
Urinary Bladder																									+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
<b>SYSTEMIC LESIONS</b>																																																			
Multiple Organ																									+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Leukemia Mononuclear																											X			X		X													X	X					
Lymphoma Malignant																																																			

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<b>FISCHER 344 RATS MALE</b>	DAY ON TEST	0 7	0 7	0 6	0 7	0 7	0 6	0 6	0 7	0 7	0 7	0 7	0 5	0 7	0 7	0 7	0 5	0 7	0 7	0 7	0 7	0 7	0 7	0 5	
	<b>0.0 G/KG</b>	2 9	2 7	5 1	2 8	2 7	1 0	2 9	2 9	2 7	2 8	2 7	2 2	2 8	2 7	2 9	0 4	2 7	2 7	2 7	2 8	2 8	2 7	2 7	4 5
	ANIMAL ID	0 0 0 1	0 0 0 2	0 0 0 3	0 0 0 4	0 0 0 5	0 0 0 6	0 0 0 7	0 0 0 8	0 0 0 9	0 0 0 0	0 0 0 1	0 0 0 1	0 0 0 1	0 0 0 1	0 0 0 1	0 0 0 1	0 0 0 1	0 0 0 1	0 0 0 2	0 0 0 2	0 0 0 2	0 0 0 2	0 0 0 3	0 0 0 4
																							<b>males</b> <b>(cont...)</b>		

Mesothelioma Malignant

X

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FISCHER 344 RATS MALE 0.0 G/KG	DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	ANIMAL ID	7	7	7	6	7	7	6	5	7	6	7	7	7	7	7	5	7	7	5	7	6	6	7	7
		2	2	0	1	2	2	9	1	2	8	2	2	2	2	2	0	2	2	9	2	7	8	2	2
		8	8	9	3	8	9	4	1	8	9	8	8	7	8	8	4	8	7	4	7	5	6	7	7
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	2	2	2	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	7	8	9	0	1	2	3	4	5	6	7	8	9	0
		* TOTALS																							

ALIMENTARY SYSTEM

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Intestine Small, Ileum Lymphoma Malignant	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49 1
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Fibrous Histiocytoma, Metastatic, Skeletal Muscle																									1
Hepatocellular Adenoma																									1
Leukemia Mononuclear														X									X		7
Mesentery	+																		+		+				6
Mesothelioma Malignant																							X		1
Oral Mucosa																							+		1
Squamous Cell Papilloma																							X		1
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Leukemia Mononuclear																									1

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	078	078	079	061	072	072	069	051	072	068	072	072	072	072	072	050	072	072	059	072	066	067	
ANIMAL ID	000	000	000	000	000	000	000	000	000	000	000	000	000	000	000	000	000	000	000	000	000	000	000
Acinus, Adenoma																							1
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Stomach, Forestomach Leukemia Mononuclear	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49 1
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Tooth													+										10
<b>CARDIOVASCULAR SYSTEM</b>																							
Blood Vessel	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Heart Leukemia Mononuclear	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49 2
<b>ENDOCRINE SYSTEM</b>																							
Adrenal Cortex Carcinoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49 1
Fibrous Histiocytoma, Metastatic, Skeletal Muscle																							1
Leukemia Mononuclear																							3
Adrenal Medulla Leukemia Mononuclear	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49 3
Pheochromocytoma Benign																							4
Bilateral, Pheochromocytoma Benign																							1

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 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

FISCHER 344 RATS MALE 0.0 G/KG	DAY ON TEST																						* TOTALS
	078	078	079	061	072	072	069	051	072	068	072	072	072	072	072	054	072	072	057	066	067	077	
ANIMAL ID	0026	0007	0008	0009	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	
Islets, Pancreatic Adenoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49 4
Parathyroid Gland Adenoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	X	49 1
Pituitary Gland Leukemia Mononuclear Pars Distalis, Adenoma	+	+	+	+	+	+	+	+	+	+	X	+	+	+	+	+	+	+	+	+	+	+	49 2 21
Thyroid Gland C-cell, Adenoma Follicular Cell, Adenoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49 8 1
<b>GENERAL BODY SYSTEM</b>																							
NONE																							
<b>GENITAL SYSTEM</b>																							
Coagulating Gland																						+	2
Epididymis Mesothelioma Malignant	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49 3
Preputial Gland Carcinoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49 1
Prostate	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49

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 Test Type: CHRONIC  
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 Species/Strain: RATS/F 344/N

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 Kava kava extract  
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 Lab: BAT

FISCHER 344 RATS MALE 0.0 G/KG	DAY ON TEST																						* TOTALS
	0728	0728	0709	0601	0722	0722	0609	0501	0721	0608	0722	0722	0722	0722	0500	0722	0722	0509	0722	0607	0606	0722	
ANIMAL ID	00026	00027	00028	00029	00030	00031	00032	00033	00034	00035	00036	00037	00038	00039	00040	00041	00042	00043	00044	00045	00046	00047	00048
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Mesothelioma Malignant														X						X			2
Bilateral, Interstitial Cell, Adenoma		X	X	X	X	X			X	X			X	X	X		X		X	X	X	X	29
Interstitial Cell, Adenoma									X										X				8
<b>HEMATOPOIETIC SYSTEM</b>																							
Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Lymph Node		+																					4
Deep Cervical, Leukemia Mononuclear																							1
Lymph Node, Mandibular	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	0
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Leukemia Mononuclear																							3
Lymphoma Malignant				X																			1
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Leukemia Mononuclear									X												X		7
Thymus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	48
Leukemia Mononuclear																							1
<b>INTEGUMENTARY SYSTEM</b>																							
Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	48
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49

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 + .. Tissue examined microscopically  
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M .. Missing tissue  
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TDMS No. 20007 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344/N

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
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 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

FISCHER 344 RATS MALE 0.0 G/KG	DAY ON TEST																						* TOTALS
	078	078	079	061	072	072	069	051	071	066	077	077	077	077	077	057	077	075	077	066	066	077	
ANIMAL ID	0026	0007	0008	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	

Dermis, Fibroma																							1
Epidermis, Basal Cell Adenoma													X						X				2
Subcutaneous Tissue, Fibroma			X			X			X														6
Subcutaneous Tissue, Lipoma					X																		1
Subcutaneous Tissue, Liposarcoma			X																				1

**MUSCULOSKELETAL SYSTEM**

Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Osteosarcoma																					X		1
Skeletal Muscle																							1
Fibrous Histiocytoma																							1

**NERVOUS SYSTEM**

Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Leukemia Mononuclear											X												1
Peripheral Nerve																							2
Spinal Cord																							2
Glioma Malignant																							1

**RESPIRATORY SYSTEM**

Lung	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Alveolar/Bronchiolar Adenoma																							1
Alveolar/Bronchiolar Adenoma, Multiple																							1
Alveolar/Bronchiolar Carcinoma																							1

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FISCHER 344 RATS MALE 0.0 G/KG	DAY ON TEST																						* TOTALS
	078	078	079	061	072	072	069	051	071	068	072	072	072	072	078	078	048	077	057	077	066	067	
ANIMAL ID	0026	0007	0008	0009	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000
Fibrous Histiocytoma, Metastatic, Skeletal Muscle																							1
Leukemia Mononuclear																							3
Mediastinum, Osteosarcoma, Metastatic, Bone																							1
Nose	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Trachea	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
<b>SPECIAL SENSES SYSTEM</b>																							
Eye	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Harderian Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
<b>URINARY SYSTEM</b>																							
Kidney	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Leukemia Mononuclear																							4
Ureter																							1
Urethra																							1
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
<b>SYSTEMIC LESIONS</b>																							
Multiple Organ	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Leukemia Mononuclear																							7
Lymphoma Malignant																							1

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 Lab: BAT

FISCHER 344 RATS MALE  0.0 G/KG	DAY ON TEST	078	078	079	063	072	076	051	072	068	072	077	077	077	077	054	072	075	077	066	066	077	077	* TOTALS
	ANIMAL ID	0026	0007	0008	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0004	0004	0004	0004	0004	0004	0004	0005	
	Mesothelioma Malignant															X							X	

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 Lab: BAT

FISCHER 344 RATS MALE	DAY ON TEST																				males (cont...)				
	0728	0727	0722	0722	0714	0722	0722	0709	0702	0702	0702	0702	0702	0702	0702	0702	0702	0702	0702	0702		0702			
0.1 G/KG	0051	0052	0053	0054	0055	0056	0057	0058	0059	0060	0061	0062	0063	0064	0065	0066	0067	0068	0069	0070	0071	0072	0073	0074	0075

**ALIMENTARY SYSTEM**

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cholangioma																									
Fibrous Histiocytoma, Metastatic, Skin															X										
Hepatocellular Adenoma																									
Leukemia Mononuclear																		X					X		
Mesentery																									
Mesothelioma Malignant															+										
Oral Mucosa																									
Leukemia Mononuclear																									
Mast Cell Tumor Malignant																									

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 Lab: BAT

FISCHER 344 RATS MALE 0.1 G/KG	DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	ANIMAL ID	
		7	7	7	7	7	7	7	7	6	7	7	1	5	7	7	6	7	7	6	7	6	7	6	7	7		
		2	2	2	2	1	2	2	0	2	7	2	2	6	7	2	2	8	9	7	2	2	6	6	2	1		
		8	7	7	7	4	7	9	9	9	9	8	8	8	1	8	8	9	7	8	3	9	6	6	7	4		
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7		
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5		males (cont...)
Salivary Glands Carcinoma		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		X	
Stomach, Forestomach		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+			
Stomach, Glandular		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+			
Tooth																												
<b>CARDIOVASCULAR SYSTEM</b>																												
Blood Vessel		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+			
Heart		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+			
Fibrous Histiocytoma, Metastatic, Skin																												
Leukemia Mononuclear															X													
<b>ENDOCRINE SYSTEM</b>																												
Adrenal Cortex		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+			
Leukemia Mononuclear																											X	
Adrenal Medulla		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+			
Pheochromocytoma Benign		X	X				X				X					X		X										
Pheochromocytoma Malignant																			X				X					
Islets, Pancreatic		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+			
Adenoma												X	X															
Parathyroid Gland		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+			

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FISCHER 344 RATS MALE 0.1 G/KG	DAY ON TEST																				males (cont...)				
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0			
	7	7	7	7	7	7	7	7	7	7	6	7	7	1	5	7	7	6	7	7		6	7	7	
ANIMAL ID	2	2	2	2	1	2	2	0	2	7	2	2	6	7	2	2	8	2	2	7	2	6	7	7	
	8	7	7	7	4	7	9	9	8	9	8	8	8	1	8	8	9	7	8	8	3	7	6	7	7
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7	7
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
Adenoma																									
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Pars Distalis, Adenoma	X			X			X							X			X	X	X				X	X	
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Bilateral, C-cell, Adenoma																									
C-cell, Adenoma		X				X														X					X
<b>GENERAL BODY SYSTEM</b>																									
Tissue NOS																									
Rhabdomyosarcoma																									
<b>GENITAL SYSTEM</b>																									
Coagulating Gland																									
Epididymis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Fibrous Histiocytoma, Metastatic, Skin														X											
Mesothelioma Malignant																						X			
Preputial Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Carcinoma																									
Schwannoma Malignant																				X					
Prostate	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Adenoma																									
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

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FISCHER 344 RATS MALE 0.1 G/KG	DAY ON TEST																									males (cont...)	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	7	7	7	7	7	7	7	7	7	7	6	7	7	1	5	7	7	6	7	7	6	7	6	7	7		
ANIMAL ID	2	2	2	2	1	2	2	0	2	7	9	8	8	8	1	8	8	9	7	8	3	2	9	6	7		
	8	7	7	7	4	7	9	0	9	8	9	8	8	8	1	8	8	9	7	8	8	7	8	7	7		
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	6	7	7	7	7	7		
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5		
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Mesothelioma Malignant																							X				
Bilateral, Interstitial Cell, Adenoma	X	X	X		X	X	X	X				X	X		X		X	X	X	X	X	X		X			
Interstitial Cell, Adenoma										X	X												X		X		
<b>HEMATOPOIETIC SYSTEM</b>																											
Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Mast Cell Tumor Malignant					X																						
Lymph Node					+																						
Pancreatic, Leukemia Mononuclear																											
Pancreatic, Mast Cell Tumor Malignant					X																						
Lymph Node, Mandibular	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Leukemia Mononuclear																										X	
Mast Cell Tumor Malignant					X																						
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Leukemia Mononuclear		X								X								X							X		
Mast Cell Tumor Malignant					X																						
Thymus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Mesothelioma Malignant																											
<b>INTEGUMENTARY SYSTEM</b>																											
Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically





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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

FISCHER 344 RATS MALE 0.1 G/KG	DAY ON TEST																					* TOTALS			
	0030	0072	0078	0079	0078	0079	0078	0079	0078	0079	0052	0075	0076	0067	0077	0077	0077	0077	0057	0072	0061		0077	0077	
ANIMAL ID	00076	00077	00078	00079	00080	00081	00082	00083	00084	00085	00086	00087	00088	00089	00090	00091	00092	00093	00094	00095	00096	00097	00098	00099	00100

**ALIMENTARY SYSTEM**

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Cholangioma																						X			1
Fibrous Histiocytoma, Metastatic, Skin														X											1
Hepatocellular Adenoma																									1
Leukemia Mononuclear			X					X								X						X			6
Mesentery																									8
Mesothelioma Malignant																	X		X						3
Oral Mucosa																									1
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Leukemia Mononuclear																							X		1
Mast Cell Tumor Malignant																									1

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

FISCHER 344 RATS MALE 0.1 G/KG	DAY ON TEST																								* TOTALS	
	0030	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077		
ANIMAL ID	00076	00077	00078	00079	00080	00081	00082	00083	00084	00085	00086	00087	00088	00089	00090	00091	00092	00093	00094	00095	00096	00097	00098	00099		
Salivary Glands Carcinoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	501		
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Tooth					+	+		+		+														6		
<b>CARDIOVASCULAR SYSTEM</b>																										
Blood Vessel	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Fibrous Histiocytoma, Metastatic, Skin																								1		
Leukemia Mononuclear																							X	1		
<b>ENDOCRINE SYSTEM</b>																										
Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Leukemia Mononuclear																								1		
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Pheochromocytoma Benign																							X	8		
Pheochromocytoma Malignant																								2		
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Adenoma																								2		
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

FISCHER 344 RATS MALE 0.1 G/KG	DAY ON TEST																								* TOTALS		
	0030	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077			
ANIMAL ID	0076	0077	0078	0079	0080	0081	0082	0083	0084	0085	0086	0087	0088	0089	0090	0091	0092	0093	0094	0095	0096	0097	0098	0099	0100		
Adenoma						X																			1		
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Pars Distalis, Adenoma		X			X	X				X	X	X		X	X			X					X	X	20		
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Bilateral, C-cell, Adenoma		X																							1		
C-cell, Adenoma				X		X	X																X		8		
<b>GENERAL BODY SYSTEM</b>																											
Tissue NOS																										1	
Rhabdomyosarcoma																										1	
<b>GENITAL SYSTEM</b>																											
Coagulating Gland																										2	
Epididymis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Fibrous Histiocytoma, Metastatic, Skin																										1	
Mesothelioma Malignant																		X		X						3	
Preputial Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Carcinoma			X																							1	
Schwannoma Malignant																										1	
Prostate	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Adenoma				X																						1	
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	

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 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

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 BLANK .. Not examined microscopically



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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

FISCHER 344 RATS MALE 0.1 G/KG	DAY ON TEST																								* TOTALS		
	0030	0072	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077	0077			
ANIMAL ID	00076	00077	00078	00079	00080	00081	00082	00083	00084	00085	00086	00087	00088	00089	00090	00091	00092	00093	00094	00095	00096	00097	00098	00099	00100		
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Mesothelioma Malignant																			X		X				3		
Bilateral, Interstitial Cell, Adenoma		X		X	X		X					X	X	X	X	X		X		X	X		X	X	32		
Interstitial Cell, Adenoma			X			X		X	X		X					X				X			X		12		
<b>HEMATOPOIETIC SYSTEM</b>																											
Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Mast Cell Tumor Malignant																									1		
Lymph Node			+																				+		3		
Pancreatic, Leukemia Mononuclear																							X		1		
Pancreatic, Mast Cell Tumor Malignant																									1		
Lymph Node, Mandibular	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	0		
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Leukemia Mononuclear																							X		2		
Mast Cell Tumor Malignant																									1		
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Leukemia Mononuclear			X					X							X						X				8		
Mast Cell Tumor Malignant																									1		
Thymus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Mesothelioma Malignant				X																					1		
<b>INTEGUMENTARY SYSTEM</b>																											
Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

FISCHER 344 RATS MALE 0.1 G/KG	DAY ON TEST																								* TOTALS
	0030	0072	0078	0079	0078	0079	0078	0079	0078	0079	0055	0077	0076	0077	0077	0077	0077	0077	0057	0076	0077	0077	0077		
ANIMAL ID	00076	00077	00078	00079	00080	00081	00082	00083	00084	00085	00086	00087	00088	00089	00090	00091	00092	00093	00094	00095	00096	00097	00098	00099	
Fibroadenoma																								1	
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Subcutaneous Tissue, Fibroma			X			X		X			X						X							5	
Subcutaneous Tissue, Fibrous Histiocytoma																								1	
Subcutaneous Tissue, Osteosarcoma																								1	
<b>MUSCULOSKELETAL SYSTEM</b>																									
Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Osteosarcoma																								1	
<b>NERVOUS SYSTEM</b>																									
Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Leukemia Mononuclear																						X		1	
Meningioma Malignant																								1	
<b>RESPIRATORY SYSTEM</b>																									
Lung	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Alveolar/Bronchiolar Carcinoma																			X					1	
Carcinoma, Metastatic, Salivary Glands																								1	
Fibrous Histiocytoma, Metastatic, Skin																								1	
Leukemia Mononuclear										X											X			4	
Mesothelioma Malignant					X																			1	
Neural Crest Tumor, Metastatic, Ear												X												1	
Osteosarcoma, Metastatic, Skin																								1	
Nose	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	

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 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

FISCHER 344 RATS MALE 0.1 G/KG	DAY ON TEST																								* TOTALS
	030	077	077	077	077	077	077	077	077	077	077	077	077	077	077	077	077	077	077	077	077	077	077	077	
ANIMAL ID	000	000	000	000	000	000	000	000	000	000	000	000	000	000	000	000	000	000	000	000	000	000	000	000	
Trachea	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
<b>SPECIAL SENSES SYSTEM</b>																									
Ear																									
Neural Crest Tumor																									
Eye	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Harderian Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
<b>URINARY SYSTEM</b>																									
Kidney	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Leukemia Mononuclear																								3	
Nephroblastoma																								1	
Ureter																								1	
Polyp																								1	
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
<b>SYSTEMIC LESIONS</b>																									
Multiple Organ	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Leukemia Mononuclear																								8	
Mesothelioma Malignant																								4	

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
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M .. Missing tissue  
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TDMS No. 20007 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344/N

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

		DAY ON TEST																				males (cont...)	
<b>FISCHER 344 RATS MALE</b>		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0
	<b>0.3 G/KG</b>	7	7	6	6	7	7	7	7	7	7	7	7	7	7	7	6	7	7	7	7	7	
		2	2	6	3	2	2	2	2	2	2	2	0	2	2	0	8	2	2	2	2	2	
		9	7	4	0	8	7	8	8	9	8	8	1	8	7	2	9	8	8	9	7	7	
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
		0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	2	2	2	2	
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	

**ALIMENTARY SYSTEM**

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Fibrosarcoma, Metastatic, Stomach, Glandular																						
Leukemia Mononuclear												X	X	X					X			
Mesentery									+												+	
Leukemia Mononuclear																						
Lymphoma Malignant																						
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Lymphoma Malignant																						
Acinus, Adenoma																						
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Schwannoma Malignant																						

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
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TDMS No. 20007 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344/N

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

DAY ON TEST	FISCHER 344 RATS MALE																				males (cont...)						
	0 7 2 9	0 7 2 7	0 6 6 4	0 6 3 0	0 7 2 8	0 7 2 7	0 7 2 8	0 7 2 8	0 7 2 8	0 7 2 9	0 7 2 9	0 7 2 8	0 7 2 8	0 7 2 8	0 7 2 8	0 7 2 0	0 6 2 8	0 7 2 8	0 7 2 9	0 7 2 7		0 7 2 2	0 7 2 8	0 7 2 8	0 7 2 8	0 7 2 8	0 7 2 8
ANIMAL ID																					0 0 1 0 1						
Stomach, Forestomach Lymphoma Malignant	+																				+						
Stomach, Glandular Carcinoid Tumor Malignant Lymphoma Malignant Muscularis, Fibrosarcoma	+													X	+							+					
Tooth								+							+							+					
<b>CARDIOVASCULAR SYSTEM</b>																											
Blood Vessel	+																				+						
Heart Lymphoma Malignant	+																				+						
<b>ENDOCRINE SYSTEM</b>																											
Adrenal Cortex Leukemia Mononuclear	+												X	+							X	+					
Adrenal Medulla Leukemia Mononuclear Pheochromocytoma Benign	+										X	+															
Islets, Pancreatic Adenoma Adenoma, Multiple	+																				X						
* .. Total animals with tissue examined microscopically; Total animals with tumor + .. Tissue examined microscopically X .. Lesion present I .. Insufficient tissue M .. Missing tissue A .. Autolysis precludes evaluation BLANK .. Not examined microscopically																											

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

FISCHER 344 RATS MALE 0.3 G/KG	DAY ON TEST																									ANIMAL ID	males (cont...)
	0 7 2 9	0 7 2 7	0 6 6 4	0 6 3 0	0 7 2 8	0 7 2 7	0 7 2 8	0 7 2 8	0 7 2 8	0 7 2 9	0 7 2 9	0 7 2 8	0 7 2 8	0 7 2 8	0 7 2 0	0 7 2 2	0 7 2 0	0 6 8 8	0 7 2 8	0 7 2 8	0 7 2 9	0 7 2 7	0 7 2 2	0 7 2 8	0 7 2 8		
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	0 0 1 0	males (cont...)
Pituitary Gland Pars Distalis, Adenoma	+	+	+	+	+	+	+		X	X	X			X	X	X		X	X					X		0 0 1 0	males (cont...)
Thyroid Gland Bilateral, C-cell, Adenoma C-cell, Adenoma C-cell, Carcinoma Follicular Cell, Adenoma Follicular Cell, Carcinoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		X			0 0 1 0 0	males (cont...)
<b>GENERAL BODY SYSTEM</b>																											
Peritoneum Paraganglioma							+																			0 0 1 0	males (cont...)
<b>GENITAL SYSTEM</b>																											
Epididymis Lymphoma Malignant Mesothelioma Malignant	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	0 0 1 0	males (cont...)
Preputial Gland Lymphoma Malignant	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	0 0 1 0	males (cont...)
Prostate Adenoma Lymphoma Malignant	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	0 0 1 0	males (cont...)
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	0 0 1 0	males (cont...)

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

		DAY ON TEST																							
<b>FISCHER 344 RATS MALE</b>		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		7	7	6	6	7	7	7	7	7	7	7	7	7	7	7	7	7	6	7	7	7	7	7	
<b>0.3 G/KG</b>		2	2	6	3	2	2	2	2	2	2	2	2	2	0	2	2	0	8	2	2	2	2	2	
		9	7	4	0	8	7	8	8	9	9	8	8	8	1	8	7	2	9	8	8	9	7	8	
	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
		0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	2	2	2	2	2	
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	<b>males (cont...)</b>

Lymphoma Malignant

Testes  
 Bilateral, Interstitial Cell, Adenoma  
 Interstitial Cell, Adenoma

	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	X	X	X		X	X	X	X	X		X	X		X	X	X	X	X	X		X	X	
				X							X			X						X			X

**HEMATOPOIETIC SYSTEM**

Bone Marrow

	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
--	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

Lymph Node

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Lymph Node, Mandibular

	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M
--	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

Lymph Node, Mesenteric  
 Leukemia Mononuclear  
 Lymphoma Malignant

	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
																						X	

Spleen  
 Leukemia Mononuclear

	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
											X	X	X								X		

Thymus  
 Lymphoma Malignant

	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
--	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

**INTEGUMENTARY SYSTEM**

Mammary Gland  
 Fibroadenoma

	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
			X									X											

Skin  
 Basal Cell Adenoma

	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
--	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

DAY ON TEST	FISCHER 344 RATS MALE																									ANIMAL ID	males (cont...)
	0729	0727	0664	0663	0772	0777	0777	0777	0777	0777	0777	0777	0777	0777	0777	0777	0777	0777	0777	0777	0777	0777	0777	0777	0777		
0.3 G/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0001	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0002	
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0003	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0004	
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	0005	

Epidermis, Keratoacanthoma  
 Epidermis, Squamous Cell Carcinoma  
 Epidermis, Trichoepithelioma  
 Subcutaneous Tissue, Fibroma  
 Subcutaneous Tissue, Hemangiosarcoma  
 Subcutaneous Tissue, Lipoma  
 Subcutaneous Tissue, Osteosarcoma  
 Subcutaneous Tissue, Schwannoma  
 Malignant, Metastatic, Salivary Glands

X

X

X

X

X

X

X

**MUSCULOSKELETAL SYSTEM**

Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Skeletal Muscle																									
Rhabdomyosarcoma																									

**NERVOUS SYSTEM**

Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
-------	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

**RESPIRATORY SYSTEM**

Lung	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Alveolar/Bronchiolar Adenoma																									
Carcinoma, Metastatic, Thyroid Gland																									
Leukemia Mononuclear																									
Lymphoma Malignant																									
Neural Crest Tumor, Metastatic, Ear																									
Osteosarcoma, Metastatic, Skin																									

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically



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

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

	DAY ON TEST																									males (cont...)
<b>FISCHER 344 RATS MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
<b>0.3 G/KG</b>	7	7	6	6	7	7	7	7	7	7	7	7	7	7	7	7	7	6	7	7	7	7	7	7		
ANIMAL ID	2	2	6	3	2	2	2	2	2	2	2	2	0	2	2	0	8	8	8	8	9	7	7	7		
	9	7	4	0	8	7	8	8	9	9	8	8	1	8	7	2	9	8	8	9	7	7	8	8		
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		
	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2		
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	

Schwannoma Malignant, Metastatic, Salivary Glands  
 Squamous Cell Carcinoma, Metastatic, Skin

X

Nose +

Trachea +

**SPECIAL SENSES SYSTEM**

Ear Neural Crest Tumor + X

Eye +

Harderian Gland +

Zymbal's Gland Carcinoma

**URINARY SYSTEM**

Kidney +

Urinary Bladder Lymphoma Malignant +

**SYSTEMIC LESIONS**

Multiple Organ Leukemia Mononuclear Lymphoma Malignant + + + + + + + + + + + X X X + + + + + X + + + + +

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
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TDMS No. 20007 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344/N

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
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 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	males (cont...)	
FISCHER 344 RATS MALE  0.3 G/KG	DAY ON TEST	7	7	6	6	7	7	7	7	7	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7		
	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		
		9	7	4	0	8	7	8	8	9	9	8	8	8	1	8	7	2	0	8	8	8	8	8	8		
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	
Mesothelioma Malignant																									X		

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

FISCHER 344 RATS MALE 0.3 G/KG	DAY ON TEST		0		1		2		3		4		5		6		7		8		9		* TOTALS	
	ANIMAL ID		0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1		
			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
			7	7	7	7	5	6	7	6	7	7	7	6	6	7	6	6	7	2	5	7	7	
			2	2	2	2	9	6	0	9	2	2	2	8	0	2	1	7	2	9	2	5	6	
			7	7	7	8	8	4	9	4	8	9	7	9	8	7	6	3	7	9	0	8	9	
			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
			1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
			2	2	2	2	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	5	
			6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	0	

**ALIMENTARY SYSTEM**

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Fibrosarcoma, Metastatic, Stomach, Glandular												X											1
Leukemia Mononuclear									X						X				X				7
Mesentery	+			+						+					+			+					7
Leukemia Mononuclear																			X				1
Lymphoma Malignant																X							1
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Lymphoma Malignant																X							1
Acinus, Adenoma	X																						1
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Schwannoma Malignant												X				X							2

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
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TDMS No. 20007 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344/N

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

FISCHER 344 RATS MALE 0.3 G/KG	DAY ON TEST																								* TOTALS		
	07	07	07	07	05	06	07	06	07	07	07	07	06	06	07	06	06	07	06	07	05	07	04	06		07	
ANIMAL ID	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00		
	7	7	7	7	8	4	9	4	9	8	9	7	9	8	7	8	9	7	6	7	9	8	4	6	7		
	1	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		
	2	2	2	2	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5		
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0		
Stomach, Forestomach Lymphoma Malignant	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50 1		
Stomach, Glandular Carcinoid Tumor Malignant Lymphoma Malignant Muscularis, Fibrosarcoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50 1 1 1		
Tooth						+	+												+				+	+	9		
<b>CARDIOVASCULAR SYSTEM</b>																											
Blood Vessel	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Heart Lymphoma Malignant	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50 1		
<b>ENDOCRINE SYSTEM</b>																											
Adrenal Cortex Leukemia Mononuclear	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50 3		
Adrenal Medulla Leukemia Mononuclear Pheochromocytoma Benign	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50 1 2		
Islets, Pancreatic Adenoma Adenoma, Multiple	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50 1 1		

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

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

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

FISCHER 344 RATS MALE 0.3 G/KG	DAY ON TEST																								* TOTALS	
	0727	0727	0727	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728		
ANIMAL ID	001267	001267	001267	001267	001267	001267	001267	001267	001267	001267	001267	001267	001267	001267	001267	001267	001267	001267	001267	001267	001267	001267	001267	001267		
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	48	
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Pars Distalis, Adenoma	X						X	X	X	X										X				15		
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Bilateral, C-cell, Adenoma									X															2		
C-cell, Adenoma											X	X	X											6		
C-cell, Carcinoma							X																	2		
Follicular Cell, Adenoma																								1		
Follicular Cell, Carcinoma					X																			1		
<b>GENERAL BODY SYSTEM</b>																										
Peritoneum																									1	
Paraganglioma																									1	
<b>GENITAL SYSTEM</b>																										
Epididymis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Lymphoma Malignant																			X						1	
Mesothelioma Malignant																									1	
Preputial Gland	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	49	
Lymphoma Malignant																				X					1	
Prostate	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Adenoma																					X				1	
Lymphoma Malignant																				X					1	
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

FISCHER 344 RATS MALE 0.3 G/KG	DAY ON TEST																								* TOTALS		
	0727	0727	0727	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728	0728			
ANIMAL ID	00126	00127	00128	00129	00130	00131	00132	00133	00134	00135	00136	00137	00138	00139	00140	00141	00142	00143	00144	00145	00146	00147	00148	00149	00150		
Lymphoma Malignant																										1	
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Bilateral, Interstitial Cell, Adenoma	X	X	X	X	X		X		X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	40	
Interstitial Cell, Adenoma					X									X	X								X			9	
<b>HEMATOPOIETIC SYSTEM</b>																											
Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Lymph Node																										2	
Lymph Node, Mandibular	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	0	
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Leukemia Mononuclear																										1	
Lymphoma Malignant																										1	
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Leukemia Mononuclear									X							X					X					7	
Thymus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Lymphoma Malignant																										1	
<b>INTEGUMENTARY SYSTEM</b>																											
Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Fibroadenoma																										2	
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Basal Cell Adenoma			X																					X		2	

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

DAY ON TEST	FISCHER 344 RATS MALE																								* TOTALS
	077	077	077	077	056	067	067	067	067	067	067	067	067	067	067	067	067	067	067	067	067	067	067	067	
0.3 G/KG	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	
ANIMAL ID	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	
	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	
	22	22	22	22	33	33	33	33	33	33	33	33	33	33	33	33	44	44	44	44	44	44	44	44	
	66	77	88	99	00	11	22	33	44	55	66	77	88	99	00	11	22	33	44	55	66	77	88	99	

Epidermis, Keratoacanthoma																								X	1	
Epidermis, Squamous Cell Carcinoma																										1
Epidermis, Trichoepithelioma																									X	1
Subcutaneous Tissue, Fibroma							X								X											7
Subcutaneous Tissue, Hemangiosarcoma					X																					1
Subcutaneous Tissue, Lipoma																									X	1
Subcutaneous Tissue, Osteosarcoma																										1
Subcutaneous Tissue, Schwannoma															X											1
Malignant, Metastatic, Salivary Glands																										

**MUSCULOSKELETAL SYSTEM**

Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Skeletal Muscle																										1
Rhabdomyosarcoma																										1

**NERVOUS SYSTEM**

Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
-------	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	----

**RESPIRATORY SYSTEM**

Lung	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Alveolar/Bronchiolar Adenoma		X												X											2
Carcinoma, Metastatic, Thyroid Gland							X																		1
Leukemia Mononuclear																					X				3
Lymphoma Malignant																X									1
Neural Crest Tumor, Metastatic, Ear																									1
Osteosarcoma, Metastatic, Skin																									1

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

DAY ON TEST	FISCHER 344 RATS MALE																								* TOTALS	
	07	07	07	07	05	06	07	06	07	07	07	07	06	06	07	06	06	07	06	07	05	07	04	06		07
ANIMAL ID	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	00	
0.3 G/KG	07	07	07	08	08	04	09	04	08	09	07	07	08	09	08	07	06	03	07	09	00	08	09	04	08	
	01	00	00	01	01	01	00	01	01	01	00	01	01	01	01	01	01	01	01	01	01	01	01	01	01	
	02	02	02	02	03	03	03	03	03	03	03	03	03	03	04	04	04	04	04	04	04	04	04	04	05	
	06	07	08	09	00	01	02	03	04	05	06	07	08	09	00	01	02	03	04	05	06	07	08	09		
Schwannoma Malignant, Metastatic, Salivary Glands															X									1		
Squamous Cell Carcinoma, Metastatic, Skin																								1		
Nose	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Trachea	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
<b>SPECIAL SENSES SYSTEM</b>																										
Ear																								1		
Neural Crest Tumor																								1		
Eye	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Harderian Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Zymbal's Gland																								1		
Carcinoma																								1		
<b>URINARY SYSTEM</b>																										
Kidney	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Lymphoma Malignant																								1		
<b>SYSTEMIC LESIONS</b>																										
Multiple Organ	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Leukemia Mononuclear																								7		
Lymphoma Malignant																								1		

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically



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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

FISCHER 344 RATS MALE  0.3 G/KG	DAY ON TEST	0777	0778	0598	0664	0779	0664	0778	0779	0779	0777	0668	0668	0777	0666	0667	0663	0777	0579	0778	0474	0664	0778
	ANIMAL ID	0012	0012	0013	0013	0012	0013	0014	0015	0016	0017	0018	0019	0020	0021	0022	0023	0024	0025	0026	0027	0028	0029
<b>* TOTALS</b>																							

Mesothelioma Malignant

1

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

		DAY ON TEST																				males (cont...)	
<b>FISCHER 344 RATS MALE</b>		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0
		7	7	5	5	7	7	6	7	7	4	6	7	6	7	7	6	6	7	7	6		7
<b>1.0 G/KG</b>		2	2	5	8	2	2	2	2	0	4	7	2	4	2	2	2	9	6	2	2	3	2
		7	7	6	9	8	9	9	7	9	7	3	8	0	9	9	7	4	5	7	7	9	7
	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
		5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2

**ALIMENTARY SYSTEM**

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Fibrous Histiocytoma, Metastatic, Skeletal Muscle																					X	
Hepatocellular Adenoma																						X
Leukemia Mononuclear									X								X	X	X			
Mesentery																						
Mesothelioma Malignant																						+
Oral Mucosa																						
Squamous Cell Carcinoma																						X
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
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TDMS No. 20007 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344/N

P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

		DAY ON TEST																								males (cont...)
FISCHER 344 RATS MALE	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		7	7	5	5	7	7	6	7	7	4	6	7	6	7	7	7	6	6	7	7	6	7	0	7	
1.0 G/KG		2	7	5	8	2	2	2	0	4	7	2	4	2	2	2	9	6	6	2	2	7	7	3	2	2
		7	7	6	9	8	9	9	7	9	7	3	8	0	9	9	7	4	5	7	7	9	7	0	7	8
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
		5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7	
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5

Sarcoma

Stomach, Forestomach  
 Mesothelioma Malignant

+  
 X

Stomach, Glandular

+ +

Tooth

+ + + + +

CARDIOVASCULAR SYSTEM

Blood Vessel

+ +

Heart  
 Fibrous Histiocytoma, Metastatic, Skeletal  
 Muscle  
 Leukemia Mononuclear

+  
 X

ENDOCRINE SYSTEM

Adrenal Cortex  
 Leukemia Mononuclear

+ + + + + + + + X + + + + + + + + + + X + + + + + + + +

Adrenal Medulla  
 Leukemia Mononuclear  
 Pheochromocytoma Benign

+ + + + + + + + X + + + + + + + + + + + + + + + + +  
 X

Islets, Pancreatic  
 Adenoma

+  
 X

Parathyroid Gland

+ +

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS MALE<br>1.0 G/KG | DAY ON TEST |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | ANIMAL ID | males<br>(cont...) |
|-----------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------|--------------------|
|                                   | 0727        | 0727 | 0556 | 0558 | 0722 | 0722 | 0622 | 0722 | 0722 | 0477 | 0677 | 0677 | 0722 | 0722 | 0722 | 0669 | 0666 | 0727 | 0727 | 0677 | 0722 | 0003 | 0722 | 0727 |      |           |                    |
|                                   | 00          | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 0001 |           |                    |
|                                   | 00          | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 00   | 0002 |           |                    |
|                                   | 11          | 11   | 11   | 11   | 11   | 11   | 11   | 11   | 11   | 11   | 11   | 11   | 11   | 11   | 11   | 11   | 11   | 11   | 11   | 11   | 11   | 11   | 11   | 11   | 0003 |           |                    |
|                                   | 55          | 55   | 55   | 55   | 55   | 55   | 55   | 55   | 55   | 66   | 66   | 66   | 66   | 66   | 66   | 66   | 66   | 66   | 66   | 66   | 66   | 66   | 66   | 66   | 0004 |           |                    |
|                                   | 11          | 12   | 13   | 14   | 15   | 16   | 17   | 18   | 19   | 00   | 01   | 02   | 03   | 04   | 05   | 06   | 07   | 08   | 09   | 00   | 01   | 02   | 03   | 04   | 0005 |           |                    |

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Pituitary Gland<br>Pars Distalis, Adenoma | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | X | X | X | X |
| Thyroid Gland<br>C-cell, Adenoma          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |   |   | X |

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Epididymis<br>Mesothelioma Malignant  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | X | X |   |   |
| Preputial Gland<br>Adenoma            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | X |   |   |   |
| Prostate<br>Lymphoma Malignant        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   | X |   |   |
| Seminal Vesicle                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |   |   |   |
| Testes<br>Mesothelioma Malignant      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | X | X |   |   |
| Bilateral, Interstitial Cell, Adenoma | X | X | X | X | X | X | X | X | X |   | X | X |   | X | X | X | X | X | X | X | X | X | X | X |   |   |   |   |
| Interstitial Cell, Adenoma            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X | X |

**HEMATOPOIETIC SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

|                       |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |           |  |
|-----------------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|--|
| DAY ON TEST           |  | 7 | 7 | 5 | 5 | 7 | 7 | 6 | 7 | 7 | 4 | 6 | 7 | 6 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 6 | 7 | 0 | 0 |           |  |
| FISCHER 344 RATS MALE |  | 2 | 2 | 5 | 8 | 2 | 2 | 2 | 2 | 0 | 4 | 7 | 2 | 4 | 2 | 2 | 2 | 9 | 6 | 2 | 2 | 7 | 2 | 3 | 2 |           |  |
| 1.0 G/KG              |  | 7 | 7 | 6 | 9 | 8 | 9 | 9 | 7 | 9 | 7 | 3 | 8 | 0 | 9 | 9 | 7 | 4 | 5 | 7 | 7 | 9 | 7 | 0 | 7 |           |  |
| ANIMAL ID             |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |           |  |
|                       |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | males     |  |
|                       |  | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | (cont...) |  |
|                       |  | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 |           |  |
|                       |  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5         |  |

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Lymph Node   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Deep Cervical, Fibrous Histiocytoma, Metastatic, Skeletal Muscle |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |
| Mediastinal, Leukemia Mononuclear                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Pancreatic, Leukemia Mononuclear                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |
| Lymph Node, Mandibular   | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M |   |   |
| Lymph Node, Mesenteric   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |   |
| Fibrous Histiocytoma, Metastatic, Skeletal Muscle                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |
| Leukemia Mononuclear   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |
| Spleen   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |   |
| Leukemia Mononuclear   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |
| Lymphoma Malignant   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |
| Thymus   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |   |
| Fibrous Histiocytoma, Metastatic, Skeletal Muscle                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |
| Lymphoma Malignant   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |

INTEGUMENTARY SYSTEM

|                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|--------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Mammary Gland      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Fibroadenoma       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |  |
| Skin               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |  |
| Basal Cell Adenoma |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |  |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

|   |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| <b>FISCHER 344 RATS MALE</b><br><b>1.0 G/KG</b> | DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|   |             | 7 | 7 | 5 | 5 | 7 | 7 | 6 | 7 | 7 | 4 | 6 | 7 | 6 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 6 | 7 | 0 | 7 | 7 |
|   |             | 2 | 2 | 5 | 8 | 2 | 2 | 2 | 2 | 0 | 4 | 7 | 2 | 4 | 2 | 2 | 2 | 9 | 6 | 2 | 2 | 9 | 2 | 3 | 2 | 2 |
|   |             | 7 | 7 | 6 | 9 | 8 | 9 | 9 | 7 | 9 | 7 | 3 | 8 | 0 | 9 | 9 | 7 | 4 | 5 | 7 | 7 | 9 | 7 | 0 | 7 | 8 |
|   | ANIMAL ID   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|   |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|   |             | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   |
|   |             | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 |   |
|   |             | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

males  
(cont...)

Dermis, Fibroma X  
Subcutaneous Tissue, Fibroma

MUSCULOSKELETAL SYSTEM

Bone +  
Skeletal Muscle +  
Fibrous Histiocytoma X

NERVOUS SYSTEM

Brain +

RESPIRATORY SYSTEM

Lung +  
Alveolar/Bronchiolar Adenoma X  
Fibrous Histiocytoma, Metastatic, Skeletal Muscle X  
Leukemia Mononuclear X X X  
Nose +  
Trachea +

SPECIAL SENSES SYSTEM

Eye +  
Harderian Gland +

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
+ .. Tissue examined microscopically  
X .. Lesion present  
I .. Insufficient tissue

M .. Missing tissue  
A .. Autolysis precludes evaluation  
BLANK .. Not examined microscopically

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS MALE<br><br>1.0 G/KG | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | ANIMAL ID | males<br>(cont...) |
|---------------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|--------------------|
|                                       | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |           |                    |
|                                       | 7           | 7 | 5 | 5 | 7 | 7 | 6 | 7 | 7 | 4 | 6 | 7 | 6 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 6 | 7 | 0 | 7 | 7 |           |                    |
|                                       | 2           | 2 | 5 | 8 | 2 | 2 | 2 | 2 | 0 | 4 | 7 | 2 | 4 | 2 | 2 | 2 | 9 | 6 | 6 | 2 | 2 | 7 | 2 | 3 | 2 | 2         |                    |
|                                       | 7           | 7 | 6 | 9 | 8 | 9 | 9 | 7 | 9 | 7 | 3 | 8 | 0 | 9 | 9 | 7 | 4 | 5 | 7 | 7 | 9 | 7 | 0 | 7 | 8 |           |                    |
|                                       | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |           |                    |
|                                       | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |           |                    |
|                                       | 1           | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |           |                    |
|                                       | 5           | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 |   |           |                    |
|                                       | 1           | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |           |                    |

Carcinoma, Metastatic, Oral Mucosa X

**URINARY SYSTEM**

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Leukemia Mononuclear |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Urinary Bladder      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

**SYSTEMIC LESIONS**

|                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Multiple Organ         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Leukemia Mononuclear   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Lymphoma Malignant     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mesothelioma Malignant |   |   | X |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
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TDMS No. 20007 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344/N

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS MALE<br>1.0 G/KG | DAY ON TEST |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | * TOTALS |
|-----------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|
|                                   | 0729        | 0729  | 0729  | 0728  | 0728  | 0728  | 0658  | 0568  | 0667  | 0447  | 0744  | 0747  | 0777  | 0777  | 0777  | 0777  | 0777  | 0777  | 0777  | 0777  | 0777  | 0777  | 0777  | 0577  | 0777  |          |
| ANIMAL ID                         | 00176       | 00177 | 00178 | 00179 | 00180 | 00181 | 00182 | 00183 | 00184 | 00185 | 00186 | 00187 | 00188 | 00189 | 00190 | 00191 | 00192 | 00193 | 00194 | 00195 | 00196 | 00197 | 00198 | 00199 | 00200 |          |

**ALIMENTARY SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Esophagus   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Cecum                            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Colon                            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Rectum                           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Duodenum                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Ileum                            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Jejunum                          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Liver   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Fibrous Histiocytoma, Metastatic, Skeletal Muscle |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Hepatocellular Adenoma                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Leukemia Mononuclear                              |   |   |   |   |   |   | X |   |   |   |   |   | X |   |   |   | X |   | X |   |   |   |   | X |   | 9  |
| Mesentery   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 6  |
| Mesothelioma Malignant                            |   |   |   |   |   |   |   |   |   |   |   |   | + |   |   |   |   |   |   |   |   |   |   |   | + | 1  |
| Oral Mucosa                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Squamous Cell Carcinoma                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Pancreas  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Salivary Glands                                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically



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

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
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 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS MALE<br>1.0 G/KG                                  | DAY ON TEST |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | * TOTALS     |
|--|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|--------------|
|  | 0729        | 0729  | 0727  | 0728  | 0727  | 0728  | 0628  | 0528  | 0626  | 0627  | 0628  | 0428  | 0724  | 0725  | 0722  | 0729  | 0729  | 0729  | 0023  | 0728  | 0727  | 0728  | 0729  | 0529  |              |
| ANIMAL ID  | 00176       | 00177 | 00178 | 00179 | 00180 | 00181 | 00182 | 00183 | 00184 | 00185 | 00186 | 00187 | 00188 | 00189 | 00190 | 00191 | 00192 | 00193 | 00194 | 00195 | 00196 | 00197 | 00198 | 00199 | 00200        |
| Sarcoma  |             |       |       |       |       |       |       |       |       |       |       |       | X     |       |       |       |       |       |       |       |       |       |       |       | 1            |
| Stomach, Forestomach<br>Mesothelioma Malignant                     | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | 50<br>1      |
| Stomach, Glandular   | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | 50           |
| Tooth  |             |       | +     |       | +     | +     |       |       | +     |       |       | +     |       |       |       |       |       |       |       |       | +     |       |       |       | 11           |
| <b>CARDIOVASCULAR SYSTEM</b>                                       |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |              |
| Blood Vessel   | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | 50           |
| Heart<br>Fibrous Histiocytoma, Metastatic, Skeletal<br>Muscle      | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | 50<br>1      |
| Leukemia Mononuclear   |             |       |       |       |       |       |       |       |       |       |       |       | X     |       |       |       |       |       | X     |       |       |       |       |       | 2            |
| <b>ENDOCRINE SYSTEM</b>  |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |              |
| Adrenal Cortex<br>Leukemia Mononuclear                             | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | X     | +     | +     | +     | +     | +     | X     | +     | X     | +     | +     | +     | +     | 50<br>5      |
| Adrenal Medulla<br>Leukemia Mononuclear<br>Pheochromocytoma Benign | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | X     | +     | +     | +     | +     | +     | +     | +     | X     | +     | +     | +     | +     | 50<br>3<br>2 |
| Islets, Pancreatic<br>Adenoma                                      | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | 50<br>3      |
| Parathyroid Gland  | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | 50           |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
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 Test Type: CHRONIC  
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 Species/Strain: RATS/F 344/N

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 Kava kava extract  
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| FISCHER 344 RATS MALE<br>1.0 G/KG         | DAY ON TEST |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | * TOTALS |  |  |
|---|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|--|--|
|   | 0729        | 0729  | 0727  | 0728  | 0727  | 0728  | 0728  | 0728  | 0728  | 0728  | 0728  | 0728  | 0728  | 0728  | 0728  | 0728  | 0728  | 0728  | 0728  | 0728  | 0728  | 0728  | 0728  | 0728  |          |  |  |
| ANIMAL ID                                 | 00176       | 00077 | 00078 | 00079 | 00080 | 00081 | 00082 | 00083 | 00084 | 00085 | 00086 | 00087 | 00088 | 00089 | 00090 | 00091 | 00092 | 00093 | 00094 | 00095 | 00096 | 00097 | 00098 | 00099 | 00100    |  |  |
| Pituitary Gland<br>Pars Distalis, Adenoma | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | 50       |  |  |
|   | X           |       |       |       |       |       |       |       | X     | X     |       |       |       |       |       |       |       |       |       | X     |       |       |       |       | 8        |  |  |
| Thyroid Gland<br>C-cell, Adenoma          | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | 50       |  |  |
|   |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | 2        |  |  |
| <b>GENERAL BODY SYSTEM</b>                |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |  |  |
| NONE                                      |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |  |  |
| <b>GENITAL SYSTEM</b>                     |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |  |  |
| Epididymis<br>Mesothelioma Malignant      | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | 50       |  |  |
|   |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | 3        |  |  |
| Preputial Gland<br>Adenoma                | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | 50       |  |  |
|   |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | 1        |  |  |
| Prostate<br>Lymphoma Malignant            | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | 50       |  |  |
|   |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | 1        |  |  |
| Seminal Vesicle                           | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | 50       |  |  |
| Testes<br>Mesothelioma Malignant          | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | 50       |  |  |
|   |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | 2        |  |  |
| Bilateral, Interstitial Cell, Adenoma     | X           | X     | X     | X     | X     | X     | X     |       | X     | X     |       | X     |       | X     | X     | X     | X     |       | X     | X     | X     | X     | X     | X     | 43       |  |  |
| Interstitial Cell, Adenoma                |             |       |       |       |       |       |       | X     |       |       |       | X     |       |       |       |       |       |       |       |       |       |       |       |       | 3        |  |  |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS MALE<br>1.0 G/KG                                | DAY ON TEST |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          | * TOTALS |          |          |          |          |          |          |
|--|-------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
|  | 07<br>29    | 07<br>29 | 07<br>27 | 07<br>28 | 07<br>27 | 07<br>28 | 07<br>28 | 06<br>09 | 05<br>08 | 06<br>02 | 06<br>03 | 06<br>04 | 07<br>08 | 07<br>04 | 07<br>01 | 07<br>07 | 07<br>09 | 07<br>09 | 07<br>09 | 07<br>03 |          | 07<br>08 | 07<br>08 | 07<br>09 | 07<br>09 | 05<br>02 | 07<br>09 |
| ANIMAL ID  | 00176       | 00077    | 00078    | 00079    | 00080    | 00081    | 00082    | 00083    | 00084    | 00085    | 00086    | 00087    | 00088    | 00089    | 00090    | 00091    | 00092    | 00093    | 00094    | 00095    | 00096    | 00097    | 00098    | 00099    | 00100    | 00101    | 00102    |
| Bone Marrow  | +           | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | 50       |
| Lymph Node   |             |          |          |          |          |          |          |          |          |          |          |          |          | +        |          |          |          |          |          |          |          | +        |          |          |          |          | 5        |
| Deep Cervical, Fibrous Histiocytoma, Metastatic, Skeletal Muscle |             |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          | 1        |
| Mediastinal, Leukemia Mononuclear                                |             |          |          |          |          |          |          |          |          |          |          |          |          | X        |          |          |          |          |          |          |          |          |          |          |          |          | 1        |
| Pancreatic, Leukemia Mononuclear                                 |             |          |          |          |          |          |          |          |          |          |          |          |          | X        |          |          |          |          | X        |          |          |          |          |          |          |          | 3        |
| Lymph Node, Mandibular   | M           | M        | M        | M        | M        | M        | M        | M        | M        | M        | M        | M        | M        | M        | M        | M        | M        | M        | M        | M        | M        | M        | M        | M        | M        | M        | 0        |
| Lymph Node, Mesenteric   | +           | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | 50       |
| Fibrous Histiocytoma, Metastatic, Skeletal Muscle                |             |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          | 1        |
| Leukemia Mononuclear   |             |          |          |          |          |          |          |          |          |          |          |          |          | X        |          |          |          |          |          |          |          |          |          |          |          |          | 3        |
| Spleen   | +           | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | 50       |
| Leukemia Mononuclear   |             |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          | 11       |
| Lymphoma Malignant   |             |          |          |          |          |          |          |          |          |          |          |          |          | X        |          |          |          |          |          |          |          |          |          |          |          |          | 1        |
| Thymus   | +           | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | 50       |
| Fibrous Histiocytoma, Metastatic, Skeletal Muscle                |             |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          | 1        |
| Lymphoma Malignant   |             |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          | 1        |
| <b>INTEGUMENTARY SYSTEM</b>                                      |             |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |
| Mammary Gland  | +           | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | 50       |
| Fibroadenoma   |             |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          | 3        |
| Skin   | +           | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | +        | 50       |
| Basal Cell Adenoma   |             |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          | 1        |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

|                              |           | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |
|------------------------------|-----------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
|                              |           | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
| <b>FISCHER 344 RATS MALE</b> |           | 7           | 7 | 7 | 7 | 7 | 6 | 5 | 6 | 6 | 4 | 7 | 4 | 7 | 7 | 7 | 7 | 0 | 7 | 7 | 2 | 2 | 2 | 7 | 7 | 7        |
|                              |           | 2           | 2 | 2 | 2 | 2 | 8 | 2 | 7 | 7 | 5 | 2 | 5 | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 2 | 2 | 2 | 5 | 2 | 2        |
| <b>1.0 G/KG</b>              |           | 9           | 9 | 7 | 8 | 7 | 8 | 8 | 3 | 0 | 4 | 8 | 1 | 7 | 9 | 9 | 9 | 3 | 8 | 7 | 8 | 9 | 9 | 9 | 9 |          |
|                              |           | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
|                              | ANIMAL ID | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
|                              |           | 1           | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |          |
|                              |           | 7           | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |          |
|                              |           | 6           | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |          |

Dermis, Fibroma 1  
 Subcutaneous Tissue, Fibroma X 1

**MUSCULOSKELETAL SYSTEM**

Bone + 50  
 Skeletal Muscle 1  
 Fibrous Histiocytoma 1

**NERVOUS SYSTEM**

Brain + 50

**RESPIRATORY SYSTEM**

Lung + 50  
 Alveolar/Bronchiolar Adenoma X 4  
 Fibrous Histiocytoma, Metastatic, Skeletal Muscle 1  
 Leukemia Mononuclear X X 8  
 Nose + 50  
 Trachea + 50

**SPECIAL SENSES SYSTEM**

Eye + 50  
 Harderian Gland + 50

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

|                                    |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0  |          |  |
|------------------------------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----------|--|
| DAY ON TEST                        |  | 7 | 7 | 7 | 7 | 7 | 6 | 5 | 6 | 6 | 4 | 7 | 4 | 7 | 7 | 7 | 7 | 7 | 0 | 7 | 7 | 7 | 7 | 5  | 7        |  |
| FISCHER 344 RATS MALE              |  | 2 | 2 | 2 | 2 | 2 | 8 | 2 | 7 | 7 | 5 | 2 | 5 | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 2 | 2 | 5 | 2  |          |  |
| 1.0 G/KG                           |  | 9 | 9 | 7 | 8 | 7 | 8 | 8 | 3 | 0 | 4 | 8 | 1 | 7 | 9 | 9 | 9 | 3 | 8 | 7 | 8 | 9 | 9 | 9  |          |  |
| ANIMAL ID                          |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0  |          |  |
|                                    |  | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2  |          |  |
|                                    |  | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0  |          |  |
|                                    |  | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8  | * TOTALS |  |
| Carcinoma, Metastatic, Oral Mucosa |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |          |  |
| <b>URINARY SYSTEM</b>              |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |          |  |
| Kidney                             |  | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50 |          |  |
| Leukemia Mononuclear               |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2  |          |  |
| Urinary Bladder                    |  | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50 |          |  |
| <b>SYSTEMIC LESIONS</b>            |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |          |  |
| Multiple Organ                     |  | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50 |          |  |
| Leukemia Mononuclear               |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 11 |          |  |
| Lymphoma Malignant                 |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |          |  |
| Mesothelioma Malignant             |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3  |          |  |

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

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
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TDMS No. 20007 - 05  
 Test Type: CHRONIC  
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 Species/Strain: RATS/F 344/N

P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS FEMALE<br>0.0 G/KG | DAY ON TEST           |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       | females<br>(cont...) |
|-------------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|----------------------|
|                                     | 0<br>7<br>0<br>5      | 0<br>7<br>2<br>8      | 0<br>7<br>3<br>0      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>0      | 0<br>7<br>3<br>9      | 0<br>7<br>2<br>0      | 0<br>7<br>2<br>6      | 0<br>7<br>3<br>0      | 0<br>7<br>3<br>0      | 0<br>7<br>3<br>8      | 0<br>7<br>2<br>1      | 0<br>7<br>2<br>3      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>5      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>9      | 0<br>7<br>1<br>0      | 0<br>7<br>2<br>8      | 0<br>7<br>0<br>9      | 0<br>7<br>0<br>2      | 0<br>7<br>2<br>4      | 0<br>7<br>2<br>5      |                       |                      |
| ANIMAL ID                           | 0<br>0<br>2<br>0<br>1 | 0<br>0<br>2<br>0<br>2 | 0<br>0<br>2<br>0<br>3 | 0<br>0<br>2<br>0<br>4 | 0<br>0<br>2<br>0<br>5 | 0<br>0<br>2<br>0<br>6 | 0<br>0<br>2<br>0<br>7 | 0<br>0<br>2<br>0<br>8 | 0<br>0<br>2<br>0<br>9 | 0<br>0<br>2<br>0<br>0 | 0<br>0<br>2<br>0<br>1 | 0<br>0<br>2<br>0<br>2 | 0<br>0<br>2<br>0<br>3 | 0<br>0<br>2<br>0<br>4 | 0<br>0<br>2<br>0<br>5 | 0<br>0<br>2<br>0<br>6 | 0<br>0<br>2<br>0<br>7 | 0<br>0<br>2<br>0<br>8 | 0<br>0<br>2<br>0<br>9 | 0<br>0<br>2<br>0<br>0 | 0<br>0<br>2<br>0<br>1 | 0<br>0<br>2<br>0<br>2 | 0<br>0<br>2<br>0<br>3 | 0<br>0<br>2<br>0<br>4 | 0<br>0<br>2<br>0<br>5 |                      |

ALIMENTARY SYSTEM

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus                               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Cecum                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Colon                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Rectum                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Liver                                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Leukemia Mononuclear                    |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |
| Lymphoma Malignant                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |
| Mesentery                               |   |   | + |   |   |   |   |   | + |   |   |   |   | + |   |   |   |   |   | + | + |   |   | + |   |
| Pancreas                                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Leukemia Mononuclear                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Salivary Glands                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Stomach, Forestomach                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Sarcoma, Metastatic, Stomach, Glandular |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Stomach, Glandular                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| DAY ON TEST                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                            | 0 |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|------------------------------|---|
| <b>FISCHER 344 RATS FEMALE</b> | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 0 | 7                            | 7 |
| <b>0.0 G/KG</b>                | 0 | 2 | 3 | 2 | 2 | 2 | 3 | 2 | 0 | 3 | 3 | 3 | 2 | 2 | 3 | 2 | 0 | 2 | 2 | 2 | 1 | 2 | 0 | 2                            | 2 |
| <b>ANIMAL ID</b>               | 5 | 8 | 0 | 9 | 9 | 9 | 0 | 9 | 6 | 0 | 0 | 0 | 8 | 1 | 0 | 9 | 5 | 9 | 8 | 9 | 0 | 0 | 9 | 8                            | 8 |
|                                | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                            | 0 |
|                                | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                            | 0 |
|                                | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2                            | 2 |
|                                | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2                            | 2 |
|                                | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4                            | 5 |
|                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>females<br/>(cont...)</b> |   |

Sarcoma

Tooth + + + + + + +

### CARDIOVASCULAR SYSTEM

Blood Vessel +

Heart +  
 Fibrosarcoma, Metastatic, Lung  
 Lymphoma Malignant X

### ENDOCRINE SYSTEM

Adrenal Cortex +

Adrenal Medulla +  
 Leukemia Mononuclear X  
 Pheochromocytoma Benign X

Islets, Pancreatic +  
 Adenoma X

Parathyroid Gland M M +

Pituitary Gland +  
 Pars Distalis, Adenoma X  
 Pars Distalis, Carcinoma X

Thyroid Gland +  
 C-cell, Adenoma X X X

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS FEMALE<br>0.0 G/KG | DAY ON TEST           |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       | females<br>(cont...)  |
|-------------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
|                                     | 0<br>7<br>0<br>5      | 0<br>7<br>2<br>8      | 0<br>7<br>3<br>0      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>9      | 0<br>7<br>3<br>0      | 0<br>7<br>2<br>9      | 0<br>7<br>3<br>0      | 0<br>5<br>0<br>6      | 0<br>7<br>3<br>0      | 0<br>7<br>3<br>0      | 0<br>7<br>3<br>0      | 0<br>7<br>2<br>8      | 0<br>6<br>2<br>1      | 0<br>7<br>3<br>0      | 0<br>7<br>2<br>9      | 0<br>7<br>0<br>5      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>9      | 0<br>5<br>1<br>0      | 0<br>7<br>2<br>8      | 0<br>0<br>0<br>9      | 0<br>7<br>0<br>8      | 0<br>0<br>2<br>9      |                       |
| ANIMAL ID                           | 0<br>0<br>2<br>0<br>1 | 0<br>0<br>2<br>0<br>2 | 0<br>0<br>2<br>0<br>3 | 0<br>0<br>2<br>0<br>4 | 0<br>0<br>2<br>0<br>5 | 0<br>0<br>2<br>0<br>6 | 0<br>0<br>2<br>0<br>7 | 0<br>0<br>2<br>0<br>8 | 0<br>0<br>2<br>0<br>9 | 0<br>0<br>2<br>0<br>0 | 0<br>0<br>2<br>0<br>1 | 0<br>0<br>2<br>0<br>2 | 0<br>0<br>2<br>0<br>3 | 0<br>0<br>2<br>0<br>4 | 0<br>0<br>2<br>0<br>5 | 0<br>0<br>2<br>0<br>6 | 0<br>0<br>2<br>0<br>7 | 0<br>0<br>2<br>0<br>8 | 0<br>0<br>2<br>0<br>9 | 0<br>0<br>2<br>0<br>0 | 0<br>0<br>2<br>0<br>1 | 0<br>0<br>2<br>0<br>2 | 0<br>0<br>2<br>0<br>3 | 0<br>0<br>2<br>0<br>4 | 0<br>0<br>2<br>0<br>5 | 0<br>0<br>2<br>0<br>6 |

Follicular Cell, Adenoma X

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland<br>Adenoma<br>Carcinoma<br>Carcinoma, Multiple          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Ovary<br>Cystadenoma   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Uterus<br>Polyp Stromal<br>Sarcoma Stromal<br>Bilateral, Polyp Stromal | + | + | + | + | + | + | + | + | + | + | X | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

**HEMATOPOIETIC SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow<br>Lymphoma Malignant   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Lymph Node<br>Mediastinal, Lymphoma Malignant<br>Pancreatic, Lymphoma Malignant |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Lymph Node, Mandibular  | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically



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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS FEMALE<br><br>0.0 G/KG | DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | females<br>(cont...) |
|---|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|
|   | ANIMAL ID   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
|   |             | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 5 | 7 | 0 | 7 | 7 |                      |
|   |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
|   |             | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |                      |
|   |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
|   |             | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 |                      |

Lymph Node, Mesenteric  
 Leukemia Mononuclear  
 Lymphoma Malignant

+ + + + + + + + + X + + + + + + + + + + + + + + +

Spleen  
 Leukemia Mononuclear  
 Lymphoma Malignant

+ + + + + + + + + X + + + + + + + + + + + + + + +

Thymus  
 Lymphoma Malignant

+ +

**INTEGUMENTARY SYSTEM**

Mammary Gland  
 Adenolipoma  
 Adenoma  
 Carcinoma  
 Fibroadenoma  
 Fibroadenoma, Multiple

+ +

X X X X X X X X X X X

Skin  
 Subcutaneous Tissue, Fibroma

+ +

X

**MUSCULOSKELETAL SYSTEM**

Bone

+ +

Skeletal Muscle

+

**NERVOUS SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
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 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS FEMALE<br>0.0 G/KG | DAY ON TEST |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | females<br>(cont...) |
|-------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------------------|
|                                     | 0705        | 0708 | 0709 | 0712 | 0713 | 0714 | 0715 | 0716 | 0717 | 0718 | 0719 | 0720 | 0721 | 0722 | 0723 | 0724 | 0725 | 0726 | 0727 | 0728 | 0729 | 0730 | 0731 | 0732 |      |                      |
| ANIMAL ID                           | 0001        | 0002 | 0003 | 0004 | 0005 | 0006 | 0007 | 0008 | 0009 | 0010 | 0011 | 0012 | 0013 | 0014 | 0015 | 0016 | 0017 | 0018 | 0019 | 0020 | 0021 | 0022 | 0023 | 0024 | 0025 |                      |
| Brain                               | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    |                      |
| <b>RESPIRATORY SYSTEM</b>           |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |                      |
| Lung                                | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    |                      |
| Leukemia Mononuclear                |             |      |      |      |      |      |      |      |      | X    |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |                      |
| Lymphoma Malignant                  |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | X    |      |      |                      |
| Mediastinum, Fibrosarcoma           |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |                      |
| Nose                                | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    |                      |
| Trachea                             | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    |                      |
| <b>SPECIAL SENSES SYSTEM</b>        |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |                      |
| Ear                                 |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |                      |
| Neural Crest Tumor                  |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |                      |
| Eye                                 | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    |                      |
| Harderian Gland                     | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    |                      |
| <b>URINARY SYSTEM</b>               |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |                      |
| Kidney                              | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    |                      |
| Leukemia Mononuclear                |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |                      |
| Urinary Bladder                     | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    |                      |
| <b>SYSTEMIC LESIONS</b>             |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |                      |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
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TDMS No. 20007 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344/N

P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS FEMALE | DAY ON TEST |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | ANIMAL ID | females<br>(cont...) |     |     |     |
|-------------------------|-------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----------|----------------------|-----|-----|-----|
|                         | 075         | 078 | 070 | 073 | 072 | 072 | 073 | 072 | 079 | 076 | 070 | 077 | 073 | 073 | 072 | 078 | 071 | 070 | 077 | 072 | 072 | 078 | 079 | 070 |           |                      | 075 | 077 | 070 |
| 0.0 G/KG                | 005         | 008 | 000 | 003 | 002 | 002 | 002 | 003 | 002 | 009 | 006 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000       | 000                  | 000 | 000 | 000 |
|                         | 21          | 22  | 23  | 24  | 25  | 26  | 27  | 28  | 29  | 30  | 31  | 32  | 33  | 34  | 35  | 36  | 37  | 38  | 39  | 40  | 41  | 42  | 43  | 44  | 45        | 46                   | 47  | 48  | 49  |

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Multiple Organ       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Adenolipoma          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Leukemia Mononuclear |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Lymphoma Malignant   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
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 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| DAY ON TEST | FISCHER 344 RATS FEMALE |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | * TOTALS |
|-------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|
|             | 0692                    | 0450 | 0773 | 0773 | 0773 | 0773 | 0773 | 0773 | 0773 | 0773 | 0773 | 0773 | 0773 | 0773 | 0773 | 0773 | 0773 | 0773 | 0773 | 0773 | 0773 | 0773 | 0773 | 0773 |          |
| ANIMAL ID   | 0022                    | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 |          |
|             | 67                      | 8    | 9    | 0    | 1    | 2    | 3    | 4    | 5    | 6    | 7    | 8    | 9    | 0    | 1    | 2    | 3    | 4    | 5    | 6    | 7    | 8    | 9    | 0    |          |

**ALIMENTARY SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Esophagus                               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Cecum                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Colon                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Rectum                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Duodenum               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Ileum                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Jejunum                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Liver                                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Leukemia Mononuclear                    |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   | 4  |
| Lymphoma Malignant                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Mesentery                               | + |   |   |   |   |   | + |   | + |   |   |   |   |   |   |   |   |   |   |   |   |   | + |   | 10 |
| Pancreas                                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Leukemia Mononuclear                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   | 1  |
| Salivary Glands                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Stomach, Forestomach                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Sarcoma, Metastatic, Stomach, Glandular |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   | 1  |
| Stomach, Glandular                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| DAY ON TEST | FISCHER 344 RATS FEMALE |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | * TOTALS |      |      |
|-------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|------|------|
|             | 0692                    | 0450 | 0701 | 0703 | 0702 | 0703 | 0709 | 0709 | 0519 | 0669 | 0665 | 0772 | 0772 | 0773 | 0773 | 0663 | 0663 | 0664 | 0779 | 0779 |          | 0778 | 0779 |
| ANIMAL ID   | 0022                    | 0022 | 0022 | 0022 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0034 | 0034 | 0034 | 0034 | 0034 | 0034     | 0034 | 0034 |

Sarcoma X 1

Tooth + 5

**CARDIOVASCULAR SYSTEM**

Blood Vessel + 50

Heart + 50

Fibrosarcoma, Metastatic, Lung X 1

Lymphoma Malignant 1

**ENDOCRINE SYSTEM**

Adrenal Cortex + 50

Adrenal Medulla + 50

Leukemia Mononuclear 1

Pheochromocytoma Benign X X 3

Islets, Pancreatic + 50

Adenoma 1

Parathyroid Gland + + + + + + + + + + + + + + M + + + M M + + + + M 44

Pituitary Gland + 50

Pars Distalis, Adenoma X X X X X X X X X X 29

Pars Distalis, Carcinoma 1

Thyroid Gland + 50

C-cell, Adenoma X X 5

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

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TDMS No. 20007 - 05  
 Test Type: CHRONIC  
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**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| DAY ON TEST | FISCHER 344 RATS FEMALE |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | * TOTALS |
|-------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|
|             | 0692                    | 0450 | 0771 | 0773 | 0777 | 0777 | 0779 | 0779 | 0519 | 0669 | 0667 | 0777 | 0777 | 0777 | 0777 | 0667 | 0777 | 0777 | 0666 | 0666 | 0777 | 0667 | 0777 | 0777 |          |
| 0.0 G/KG    | 0026                    | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 26       |
| ANIMAL ID   | 0026                    | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 26       |

Follicular Cell, Adenoma

1

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

|                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|--------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Clitoral Gland           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Adenoma                  |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   | 2  |
| Carcinoma                |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Carcinoma, Multiple      |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Ovary                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cystadenoma              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Uterus                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Polyp Stromal            |   | X |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 6  |
| Sarcoma Stromal          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Bilateral, Polyp Stromal |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   | 1  |

**HEMATOPOIETIC SYSTEM**

|                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|---------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Bone Marrow                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Lymphoma Malignant              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Lymph Node                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Mediastinal, Lymphoma Malignant |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Pancreatic, Lymphoma Malignant  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Lymph Node, Mandibular          | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | 0  |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS FEMALE<br>0.0 G/KG | DAY ON TEST |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | * TOTALS |  |
|-------------------------------------|-------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|----------|--|
|                                     | 069226      | 045001 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 |          |  |
| ANIMAL ID                           | 002226      | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226   |  |
|                                     | 6           | 7      | 8      | 9      | 0      | 1      | 2      | 3      | 4      | 5      | 6      | 7      | 8      | 9      | 0      | 1      | 2      | 3      | 4      | 5      | 6      | 7      | 8      | 9      | 0        |  |

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |              |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Lymph Node, Mesenteric<br>Leukemia Mononuclear<br>Lymphoma Malignant | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>1<br>1 |
| Spleen<br>Leukemia Mononuclear<br>Lymphoma Malignant                 | + | + | + | + | + | + | + | + | X | + | + | + | + | + | + | + | + | + | + | + | X | X | + | + | + | 50<br>5<br>1 |
| Thymus<br>Lymphoma Malignant   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>1      |

**INTEGUMENTARY SYSTEM**

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                               |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------------------------------|
| Mammary Gland<br>Adenolipoma<br>Adenoma<br>Carcinoma<br>Fibroadenoma<br>Fibroadenoma, Multiple | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>1<br>2<br>1<br>14<br>10 |
| Skin<br>Subcutaneous Tissue, Fibroma   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>1                       |

**MUSCULOSKELETAL SYSTEM**

|                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Bone            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Skeletal Muscle |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |

**NERVOUS SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS FEMALE<br>0.0 G/KG | DAY ON TEST |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | * TOTALS |  |  |
|-------------------------------------|-------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|----------|--|--|
|                                     | 069226      | 045010 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 | 077320 |          |  |  |
| ANIMAL ID                           | 002226      | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226 | 002226   |  |  |
| Brain                               | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | 50       |  |  |
| <b>RESPIRATORY SYSTEM</b>           |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |          |  |  |
| Lung                                | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | 50       |  |  |
| Leukemia Mononuclear                |             |        |        |        |        |        |        |        | X      |        |        |        |        |        |        |        |        |        |        |        | X      |        |        |        | 3        |  |  |
| Lymphoma Malignant                  |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | 1        |  |  |
| Mediastinum, Fibrosarcoma           |             |        | X      |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | 1        |  |  |
| Nose                                | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | 50       |  |  |
| Trachea                             | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | 50       |  |  |
| <b>SPECIAL SENSES SYSTEM</b>        |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |          |  |  |
| Ear                                 |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | 1        |  |  |
| Neural Crest Tumor                  |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | X      |        |        |        | 1        |  |  |
| Eye                                 | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | 50       |  |  |
| Harderian Gland                     | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | 50       |  |  |
| <b>URINARY SYSTEM</b>               |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |          |  |  |
| Kidney                              | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | 50       |  |  |
| Leukemia Mononuclear                |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | X      |        |        | 1        |  |  |
| Urinary Bladder                     | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | 50       |  |  |
| <b>SYSTEMIC LESIONS</b>             |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |          |  |  |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
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TDMS No. 20007 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344/N

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

|   |             |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |                 |
|---|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|-----------------|
| <b>FISCHER 344 RATS FEMALE</b><br><br><b>0.0 G/KG</b> | DAY ON TEST | 06 | 04 | 07 | 07 | 07 | 07 | 07 | 07 | 05 | 06 | 06 | 07 | 07 | 07 | 07 | 06 | 07 | 06 | 06 | 07 | 06 | 07 | 07 | 07 | 07 | <b>* TOTALS</b> |
|   | ANIMAL ID   | 09 | 05 | 00 | 03 | 02 | 03 | 02 | 02 | 01 | 06 | 01 | 02 | 02 | 03 | 03 | 09 | 03 | 03 | 06 | 02 | 09 | 03 | 02 | 02 | 02 |                 |
|   |             | 22 | 22 | 22 | 22 | 33 | 33 | 33 | 33 | 33 | 33 | 33 | 33 | 33 | 33 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 |                 |

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|
| Multiple Organ       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |
| Adenolipoma          |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>  |
| Leukemia Mononuclear |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   | X |   | X |   |   |   |   |   | <b>5</b>  |
| Lymphoma Malignant   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>  |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
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 Species/Strain: RATS/F 344/N

P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS FEMALE | DAY ON TEST |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | females<br>(cont...) |
|-------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------------------|
|                         | 0727        | 0639 | 0678 | 0729 | 0779 | 0770 | 0773 | 0773 | 0783 | 0783 | 0783 | 0783 | 0783 | 0783 | 0783 | 0783 | 0783 | 0783 | 0783 | 0783 | 0783 | 0783 | 0783 | 0783 |                      |
| 0.1 G/KG                | 0051        | 0052 | 0053 | 0054 | 0055 | 0056 | 0057 | 0058 | 0059 | 0060 | 0061 | 0062 | 0063 | 0064 | 0065 | 0066 | 0067 | 0068 | 0069 | 0070 | 0071 | 0072 | 0073 | 0074 |                      |

ALIMENTARY SYSTEM

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Intestine Large, Cecum                                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Intestine Large, Colon                                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Intestine Large, Rectum                                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Intestine Small, Duodenum                               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Intestine Small, Ileum                                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Intestine Small, Jejunum                                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Liver   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Leukemia Mononuclear                                    | X |   |   |   | X |   |   |   |   |   |   |   | X | X | X |   |   | X |   |   | X |   |   |   |
| Pheochromocytoma Malignant, Metastatic, Adrenal Medulla |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mesentery   |   |   |   |   |   | + |   |   | + |   |   |   |   |   |   |   |   |   | + | + |   |   |   |   |
| Oral Mucosa   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Squamous Cell Papilloma                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + | X |
| Pancreas  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Salivary Glands   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Stomach, Forestomach                                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS FEMALE<br>0.1 G/KG | DAY ON TEST |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | ANIMAL ID | females<br>(cont...) |      |   |       |       |  |
|-------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------|----------------------|------|---|-------|-------|--|
|                                     | 0727        | 0668 | 0679 | 0779 | 0779 | 0779 | 0779 | 0779 | 0779 | 0779 | 0779 | 0779 | 0779 | 0779 | 0779 | 0779 | 0779 | 0779 | 0779 | 0779 |           |                      | 0779 |   |       |       |  |
|                                     | 0           | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0         | 00251                |      |   |       |       |  |
|                                     | 7           | 6    | 6    | 7    | 7    | 7    | 7    | 7    | 7    | 7    | 7    | 6    | 7    | 7    | 7    | 7    | 7    | 7    | 5    | 6    | 7         | 0                    | 7    | 7 | 00252 |       |  |
|                                     | 2           | 3    | 7    | 2    | 2    | 3    | 3    | 3    | 2    | 3    | 3    | 0    | 7    | 2    | 2    | 2    | 3    | 3    | 5    | 3    | 2         | 5                    | 2    | 3 | 00253 |       |  |
|                                     | 7           | 9    | 8    | 9    | 9    | 0    | 0    | 0    | 8    | 0    | 0    | 5    | 9    | 8    | 8    | 9    | 0    | 0    | 8    | 1    | 9         | 1                    | 8    | 0 | 00254 |       |  |
|                                     | 0           | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0         | 0                    | 0    | 0 | 00255 |       |  |
|                                     | 0           | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0         | 0                    | 0    | 0 | 00256 |       |  |
|                                     | 2           | 2    | 2    | 2    | 2    | 2    | 2    | 2    | 2    | 2    | 2    | 2    | 2    | 2    | 2    | 2    | 2    | 2    | 2    | 2    | 2         | 2                    | 2    | 2 | 00257 |       |  |
|                                     | 5           | 5    | 5    | 5    | 5    | 5    | 5    | 5    | 5    | 6    | 6    | 6    | 6    | 6    | 6    | 6    | 6    | 6    | 7    | 7    | 7         | 7                    | 7    | 7 | 00258 |       |  |
|                                     | 1           | 2    | 3    | 4    | 5    | 6    | 7    | 8    | 9    | 0    | 1    | 2    | 3    | 4    | 5    | 6    | 7    | 8    | 9    | 0    | 1         | 2                    | 3    | 4 | 5     | 00259 |  |

Stomach, Glandular

+ +

Tooth

+ +

**CARDIOVASCULAR SYSTEM**

Blood Vessel

+ +

Heart

+ +

Leukemia Mononuclear

X X

**ENDOCRINE SYSTEM**

Adrenal Cortex

+ +

Adenoma

X

Carcinoma

X X

Leukemia Mononuclear

X X

Adrenal Medulla

+ +

Leukemia Mononuclear

X X

Pheochromocytoma Benign

X

Pheochromocytoma Malignant

+ +

Islets, Pancreatic

+ +

Adenoma

+ + + + M + + + + + + M + + + + + M + + + + + + + +

Parathyroid Gland

+ +

Pituitary Gland

+ +

Pars Distalis, Adenoma

X X

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS FEMALE<br><br>0.1 G/KG | DAY ON TEST |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | females<br>(cont...) |
|---|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------------------|
|   | 0727        | 0668 | 0679 | 0729 | 0770 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0676 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0538 | 0631 | 0729 | 0729 | 0729 |                      |
| ANIMAL ID                               | 0051        | 0052 | 0053 | 0054 | 0055 | 0056 | 0057 | 0058 | 0059 | 0060 | 0061 | 0062 | 0063 | 0064 | 0065 | 0066 | 0067 | 0068 | 0069 | 0070 | 0071 | 0072 | 0073 | 0074 |                      |
|   | +           | +    | +    | +    | +    | +    | +    | X    | +    | +    | +    | +    | +    | +    | X    | +    | +    | +    | X    | +    | +    | +    | +    | X    |                      |

Thyroid Gland  
C-cell, Adenoma

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland<br>Adenoma<br>Carcinoma          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | X |
| Ovary   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Uterus<br>Leukemia Mononuclear<br>Polyp Stromal | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | X |

**HEMATOPOIETIC SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Lymph Node<br>Mediastinal, Leukemia Mononuclear<br>Pancreatic, Leukemia Mononuclear |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Lymph Node, Mandibular  | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M |
| Lymph Node, Mesenteric  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
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TDMS No. 20007 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344/N

P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| DAY ON TEST                   | FISCHER 344 RATS FEMALE |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    | ANIMAL ID | females<br>(cont...) |
|-------------------------------|-------------------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|-----------|----------------------|
|                               | 07                      | 06 | 06 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 06 | 07 | 07 | 07 | 07 | 07 | 05 | 06 | 07 | 00 | 07 | 07 |    |           |                      |
| 0.1 G/KG                      | 27                      | 39 | 78 | 29 | 29 | 30 | 33 | 33 | 30 | 38 | 00 | 00 | 05 | 09 | 08 | 08 | 09 | 00 | 00 | 08 | 31 | 29 | 51 | 08 | 03 |           |                      |
|                               | 00                      | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 |           |                      |
|                               | 25                      | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 77 | 77 | 77 | 77 | 77 |    |           |                      |
|                               | 11                      | 22 | 33 | 44 | 55 | 66 | 77 | 88 | 99 | 00 | 11 | 22 | 33 | 44 | 55 | 66 | 77 | 88 | 99 | 00 | 11 | 22 | 33 | 44 | 55 |           |                      |
| Leukemia Mononuclear          |                         |    |    |    |    |    |    |    |    |    |    |    | X  |    |    |    |    |    | X  |    | X  |    |    |    |    |           |                      |
| Spleen                        | +                       | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  |    |           |                      |
| Leukemia Mononuclear          | X                       |    |    |    | X  |    |    |    |    |    |    |    | X  | X  |    |    |    |    | X  |    | X  |    |    |    |    |           |                      |
| Thymus                        | +                       | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  |    |           |                      |
| Leukemia Mononuclear          | X                       |    |    |    |    |    |    |    |    |    |    |    | X  |    |    |    |    |    |    | X  |    |    |    |    |    |           |                      |
| Thymoma Benign                |                         |    |    |    |    |    |    |    |    |    | X  |    |    |    |    |    |    |    |    |    |    |    |    |    |    |           |                      |
| <b>INTEGUMENTARY SYSTEM</b>   |                         |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |           |                      |
| Mammary Gland                 | +                       | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  |    |           |                      |
| Adenoma                       |                         |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |           |                      |
| Carcinoma                     |                         |    |    |    |    |    |    |    |    |    | X  |    |    |    |    |    |    |    |    |    |    |    |    |    |    |           |                      |
| Fibroadenoma                  |                         | X  |    |    |    |    |    | X  |    | X  | X  |    |    |    |    |    |    |    | X  |    | X  |    |    |    |    |           |                      |
| Fibroadenoma, Multiple        |                         |    |    |    | X  |    |    | X  |    | X  |    |    | X  | X  |    |    |    |    |    |    |    |    |    |    |    |           |                      |
| Skin                          | +                       | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  |    |           |                      |
| <b>MUSCULOSKELETAL SYSTEM</b> |                         |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |           |                      |
| Bone                          | +                       | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  |    |           |                      |
| <b>NERVOUS SYSTEM</b>         |                         |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |           |                      |
| Brain                         | +                       | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  |    |           |                      |
| Leukemia Mononuclear          |                         |    |    |    |    |    |    |    |    |    |    | X  |    |    |    |    |    |    |    |    |    |    |    |    |    |           |                      |
| <b>RESPIRATORY SYSTEM</b>     |                         |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |           |                      |
| Lung                          | +                       | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  |    |           |                      |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

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TDMS No. 20007 - 05  
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 Kava kava extract  
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Date Report Requested: 09/21/2010  
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 Lab: BAT

| DAY ON TEST   | FISCHER 344 RATS FEMALE |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |  | ANIMAL ID | females<br>(cont...) |
|---|-------------------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|--|-----------|----------------------|
|   | 07                      | 06 | 06 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 06 | 07 | 07 | 07 | 07 | 07 | 05 | 06 | 07 | 00 | 07 | 07 |  |           |                      |
| 0.1 G/KG  | 27                      | 39 | 78 | 29 | 29 | 30 | 33 | 33 | 33 | 28 | 30 | 05 | 00 | 00 | 00 | 00 | 00 | 00 | 08 | 31 | 29 | 11 | 00 | 00 |  |           |                      |
|   | 00                      | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 |  |           |                      |
|   | 25                      | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 77 | 77 | 77 | 77 | 77 |    |  |           |                      |
|   | 11                      | 22 | 33 | 44 | 55 | 66 | 77 | 88 | 99 | 00 | 11 | 22 | 33 | 44 | 55 | 66 | 77 | 88 | 99 | 00 | 11 | 22 | 33 | 44 |  |           |                      |
| Carcinoma, Metastatic, Mammary Gland                    |                         |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |  |           |                      |
| Leukemia Mononuclear                                    | X                       |    |    |    |    |    |    |    |    |    |    |    | X  |    |    |    |    |    |    |    | X  |    |    |    |  |           |                      |
| Pheochromocytoma Malignant, Metastatic, Adrenal Medulla |                         |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |  |           |                      |
| Nose  | +                       | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  |  |           |                      |
| Trachea   | +                       | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  |  |           |                      |
| <b>SPECIAL SENSES SYSTEM</b>                            |                         |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |  |           |                      |
| Eye   | +                       | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  |  |           |                      |
| Harderian Gland   | +                       | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  |  |           |                      |
| <b>URINARY SYSTEM</b>                                   |                         |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |  |           |                      |
| Kidney  | +                       | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  |  |           |                      |
| Leukemia Mononuclear                                    |                         |    |    |    |    |    |    |    |    |    |    |    | X  |    |    |    |    |    |    |    |    | X  |    |    |  |           |                      |
| Urinary Bladder   | +                       | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  |  |           |                      |
| <b>SYSTEMIC LESIONS</b>                                 |                         |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |  |           |                      |
| Multiple Organ  | +                       | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  |  |           |                      |
| Leukemia Mononuclear                                    | X                       |    |    |    | X  |    |    |    |    |    |    |    | X  | X  | X  |    |    | X  |    |    | X  |    |    |    |  |           |                      |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
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M .. Missing tissue  
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TDMS No. 20007 - 05  
 Test Type: CHRONIC  
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P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS FEMALE<br>0.1 G/KG | DAY ON TEST |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          |          | * TOTALS |
|-------------------------------------|-------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
|                                     | 07<br>29    | 07<br>29 | 07<br>28 | 07<br>22 | 07<br>22 | 07<br>22 | 07<br>22 | 07<br>22 | 07<br>22 | 07<br>22 | 07<br>22 | 07<br>22 | 07<br>22 | 07<br>22 | 07<br>22 | 07<br>22 | 07<br>22 | 07<br>22 | 07<br>22 | 07<br>22 | 07<br>22 | 07<br>22 | 07<br>22 | 07<br>22 |          |
| ANIMAL ID                           | 0076        | 0077     | 0078     | 0079     | 0080     | 0081     | 0082     | 0083     | 0084     | 0085     | 0086     | 0087     | 0088     | 0089     | 0090     | 0091     | 0092     | 0093     | 0094     | 0095     | 0096     | 0097     | 0098     | 0099     | 0100     |

ALIMENTARY SYSTEM

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Esophagus   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Cecum                                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Colon                                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Rectum                                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Duodenum                               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Ileum                                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Jejunum                                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Liver   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Leukemia Mononuclear                                    |   |   |   |   |   |   |   |   | X |   |   |   |   | X |   |   |   |   | X |   |   | X |   |   |   | 11 |
| Pheochromocytoma Malignant, Metastatic, Adrenal Medulla |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Mesentery   |   |   | + |   |   | + |   |   |   |   |   |   |   |   | + | + | + |   |   |   |   |   |   |   |   | 9  |
| Oral Mucosa   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Squamous Cell Papilloma                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Pancreas  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Salivary Glands   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Stomach, Forestomach                                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| DAY ON TEST                  | FISCHER 344 RATS FEMALE |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | * TOTALS |  |
|------------------------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|--|
|                              | 0729                    | 0729 | 0728 | 0728 | 0728 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 |          |  |
| ANIMAL ID                    | 0076                    | 0077 | 0078 | 0079 | 0080 | 0081 | 0082 | 0083 | 0084 | 0085 | 0086 | 0087 | 0088 | 0089 | 0090 | 0091 | 0092 | 0093 | 0094 | 0095 | 0096 | 0097 | 0098 | 0099 |          |  |
| Stomach, Glandular           | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |  |
| Tooth                        |                         |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 3        |  |
| <b>CARDIOVASCULAR SYSTEM</b> |                         |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |  |
| Blood Vessel                 | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |  |
| Heart                        | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |  |
| Leukemia Mononuclear         |                         |      |      |      |      |      |      |      |      |      |      |      |      | X    |      |      |      |      |      |      |      |      |      |      | 3        |  |
| <b>ENDOCRINE SYSTEM</b>      |                         |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |  |
| Adrenal Cortex               | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |  |
| Adenoma                      |                         |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 1        |  |
| Carcinoma                    |                         |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | X    |      | 1        |  |
| Leukemia Mononuclear         |                         |      |      |      |      |      |      |      |      |      |      |      |      | X    |      |      |      |      |      |      |      |      |      |      | 4        |  |
| Adrenal Medulla              | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |  |
| Leukemia Mononuclear         |                         |      |      |      |      |      |      |      |      |      |      |      |      | X    |      |      |      |      |      |      |      |      |      |      | 3        |  |
| Pheochromocytoma Benign      |                         |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 1        |  |
| Pheochromocytoma Malignant   |                         |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | X    |      |      |      |      |      | 1        |  |
| Islets, Pancreatic           | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |  |
| Adenoma                      |                         |      | X    |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 1        |  |
| Parathyroid Gland            | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 47       |  |
| Pituitary Gland              | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |  |
| Pars Distalis, Adenoma       |                         |      | X    |      |      | X    |      | X    |      |      |      |      |      |      |      | X    | X    |      | X    | X    |      |      |      |      | 20       |  |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically



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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS FEMALE<br>0.1 G/KG | DAY ON TEST |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | * TOTALS |
|-------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|
|                                     | 0729        | 0729 | 0728 | 0722 | 0722 | 0728 | 0722 | 0729 | 0721 | 0668 | 0665 | 0779 | 0665 | 0705 | 0763 | 0733 | 0729 | 0705 | 0709 | 0703 | 0728 | 0662 | 0772 | 0770 |          |
| ANIMAL ID                           | 0076        | 0077 | 0078 | 0079 | 0080 | 0081 | 0082 | 0083 | 0084 | 0085 | 0086 | 0087 | 0088 | 0089 | 0090 | 0091 | 0092 | 0093 | 0094 | 0095 | 0096 | 0097 | 0098 | 0099 | 0000     |

|                                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |         |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------|
| Thyroid Gland<br>C-cell, Adenoma | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>6 |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------|

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |              |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Clitoral Gland<br>Adenoma<br>Carcinoma          | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49<br>7<br>1 |
| Ovary   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50           |
| Uterus<br>Leukemia Mononuclear<br>Polyp Stromal | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>1<br>9 |

**HEMATOPOIETIC SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |             |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------------|
| Bone Marrow   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50          |
| Lymph Node<br>Mediastinal, Leukemia Mononuclear<br>Pancreatic, Leukemia Mononuclear |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + | X | X |   |   |   |   |   |   |   | 3<br>3<br>2 |
| Lymph Node, Mandibular  | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | 0           |
| Lymph Node, Mesenteric  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50          |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS FEMALE<br>0.1 G/KG | DAY ON TEST |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | * TOTALS |    |  |
|-------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|----|--|
|                                     | 0729        | 0729 | 0728 | 0729 | 0728 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 |          |    |  |
| ANIMAL ID                           | 0076        | 0077 | 0078 | 0079 | 0080 | 0081 | 0082 | 0083 | 0084 | 0085 | 0086 | 0087 | 0088 | 0089 | 0090 | 0091 | 0092 | 0093 | 0094 | 0095 | 0096 | 0097 | 0098 | 0099 | 0100     |    |  |
| Leukemia Mononuclear                |             |      |      |      |      |      |      |      |      |      |      | X    |      |      |      |      |      |      |      |      |      |      |      |      |          | 4  |  |
| Spleen                              | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | 50 |  |
| Leukemia Mononuclear                |             |      |      |      |      |      |      | X    |      |      |      | X    |      |      |      |      |      | X    |      | X    |      |      |      |      |          | 10 |  |
| Thymus                              | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | 50 |  |
| Leukemia Mononuclear                |             |      |      |      |      |      |      |      |      |      |      | X    |      |      |      |      |      |      |      |      |      |      |      |      |          | 4  |  |
| Thymoma Benign                      |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          | 1  |  |
| <b>INTEGUMENTARY SYSTEM</b>         |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |    |  |
| Mammary Gland                       | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | 50 |  |
| Adenoma                             |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | X    |      |      |      |      |      |      |          | 1  |  |
| Carcinoma                           |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | X    |      |      |      | X    |      |      |      |          | 3  |  |
| Fibroadenoma                        |             | X    | X    |      | X    | X    |      |      |      | X    |      |      |      | X    | X    | X    | X    | X    | X    |      |      |      |      | X    |          | 17 |  |
| Fibroadenoma, Multiple              |             |      |      | X    |      |      |      |      |      |      |      |      |      |      |      |      |      | X    |      |      |      |      |      |      |          | 7  |  |
| Skin                                | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | 50 |  |
| <b>MUSCULOSKELETAL SYSTEM</b>       |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |    |  |
| Bone                                | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | 50 |  |
| <b>NERVOUS SYSTEM</b>               |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |    |  |
| Brain                               | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | 50 |  |
| Leukemia Mononuclear                |             |      |      |      |      |      |      |      |      |      |      | X    |      |      |      |      |      |      |      |      |      |      |      |      |          | 2  |  |
| <b>RESPIRATORY SYSTEM</b>           |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |    |  |
| Lung                                | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | 50 |  |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically







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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS FEMALE<br>0.3 G/KG | DAY ON TEST           |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       | females<br>(cont...)  |
|-------------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
|                                     | 0<br>7<br>0<br>5      | 0<br>7<br>3<br>0      | 0<br>0<br>9<br>8      | 0<br>6<br>2<br>8      | 0<br>5<br>3<br>2      | 0<br>5<br>1<br>9      | 0<br>6<br>1<br>5      | 0<br>6<br>1<br>8      | 0<br>7<br>2<br>9      | 0<br>6<br>8<br>1      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>9      | 0<br>5<br>3<br>9      | 0<br>4<br>3<br>9      | 0<br>6<br>5<br>2      | 0<br>6<br>8<br>8      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>9      | 0<br>5<br>3<br>0      | 0<br>7<br>1<br>8      | 0<br>7<br>3<br>0      | 0<br>7<br>3<br>0      |                       |
| ANIMAL ID                           | 0<br>0<br>3<br>0<br>1 | 0<br>0<br>3<br>0<br>2 | 0<br>0<br>3<br>0<br>3 | 0<br>0<br>3<br>0<br>4 | 0<br>0<br>3<br>0<br>5 | 0<br>0<br>3<br>0<br>6 | 0<br>0<br>3<br>0<br>7 | 0<br>0<br>3<br>0<br>8 | 0<br>0<br>3<br>0<br>9 | 0<br>0<br>3<br>0<br>0 | 0<br>0<br>3<br>0<br>1 | 0<br>0<br>3<br>0<br>2 | 0<br>0<br>3<br>0<br>3 | 0<br>0<br>3<br>0<br>4 | 0<br>0<br>3<br>0<br>5 | 0<br>0<br>3<br>0<br>6 | 0<br>0<br>3<br>0<br>7 | 0<br>0<br>3<br>0<br>8 | 0<br>0<br>3<br>0<br>9 | 0<br>0<br>3<br>0<br>0 | 0<br>0<br>3<br>0<br>1 | 0<br>0<br>3<br>0<br>2 | 0<br>0<br>3<br>0<br>3 | 0<br>0<br>3<br>0<br>4 | 0<br>0<br>3<br>0<br>5 |

|                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Thyroid Gland            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| C-cell, Adenoma          |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   | X |   |   |   |
| Follicular Cell, Adenoma |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

|                                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland<br>Adenoma            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Ovary<br>Granulosa Cell Tumor Benign | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Uterus<br>Carcinosarcoma             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Polyp Stromal                        | X | X |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   | X |   |   |   |
| Sarcoma Stromal                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**HEMATOPOIETIC SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow                                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Lymph Node<br>Mediastinal, Leukemia Mononuclear | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |
| Pancreatic, Leukemia Mononuclear                | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |
| Lymph Node, Mandibular                          | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS FEMALE<br>0.3 G/KG            | DAY ON TEST |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | ANIMAL ID | females<br>(cont...) |
|--|-------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----------|----------------------|
|  | 075         | 070 | 068 | 065 | 065 | 066 | 066 | 077 | 066 | 077 | 077 | 077 | 055 | 044 | 066 | 066 | 077 | 077 | 077 | 077 | 033 | 055 | 077 | 077 | 000 |           |                      |
| Lymph Node, Mesenteric<br>Leukemia Mononuclear | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | X   |           |                      |
| Spleen<br>Leukemia Mononuclear                 | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | X   |           |                      |
| Thymus<br>Leukemia Mononuclear                 | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | M   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   |     |           |                      |
| <b>INTEGUMENTARY SYSTEM</b>                    |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |           |                      |
| Mammary Gland<br>Carcinoma                     | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | X   |           |                      |
| Fibroadenoma                                   |             |     |     | X   |     |     | X   | X   |     |     | X   |     |     |     |     |     |     |     |     | X   |     | X   |     | X   |     |           |                      |
| Fibroadenoma, Multiple                         |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |           |                      |
| Skin   | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   |     |           |                      |
| Subcutaneous Tissue, Fibroma                   |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |           |                      |
| Subcutaneous Tissue, Lipoma                    |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | X   |     |           |                      |
| Subcutaneous Tissue, Osteosarcoma              |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |           |                      |
| <b>MUSCULOSKELETAL SYSTEM</b>                  |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |           |                      |
| Bone   | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   |     |           |                      |
| Osteoma  |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |           |                      |
| Osteosarcoma                                   |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | X   |     |           |                      |
| Osteosarcoma, Metastatic, Skin                 |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |           |                      |
| Skeletal Muscle                                |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | +   |     |           |                      |
| Rhabdomyosarcoma                               |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | X   |     |           |                      |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| DAY ON TEST | FISCHER 344 RATS FEMALE |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | ANIMAL ID | females<br>(cont...) |   |   |   |   |   |   |
|-------------|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|----------------------|---|---|---|---|---|---|
|             | 0                       | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |           |                      | 0 |   |   |   |   |   |
| 7           | 7                       | 0 | 6 | 5 | 5 | 6 | 6 | 7 | 6 | 7 | 7 | 7 | 5 | 4 | 6 | 6 | 7 | 7 | 7 | 7 | 5         | 7                    | 7 | 3 | 5 | 7 | 3 | 0 |
| 0           | 3                       | 9 | 2 | 3 | 1 | 1 | 1 | 2 | 8 | 2 | 2 | 2 | 3 | 3 | 5 | 8 | 2 | 2 | 2 | 2 | 3         | 1                    | 3 | 3 | 3 | 3 | 3 | 0 |
| 5           | 0                       | 8 | 8 | 2 | 9 | 5 | 8 | 9 | 1 | 9 | 9 | 9 | 9 | 9 | 2 | 8 | 8 | 9 | 9 | 9 | 9         | 0                    | 8 | 1 | 0 | 0 | 0 | 0 |
| 0           | 0                       | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0         | 0                    | 0 | 0 | 0 | 0 | 0 | 0 |
| 0           | 0                       | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0         | 0                    | 0 | 0 | 0 | 0 | 0 | 0 |
| 3           | 3                       | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3         | 3                    | 3 | 3 | 3 | 3 | 3 | 3 |
| 0           | 0                       | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2         | 2                    | 2 | 2 | 2 | 2 | 2 | 2 |
| 1           | 2                       | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2         | 3                    | 4 | 5 |   |   |   |   |

**NERVOUS SYSTEM**

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Brain  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Peripheral Nerve<br>Trigeminal, Leukemia Mononuclear |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Spinal Cord  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**RESPIRATORY SYSTEM**

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lung   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Alveolar/Bronchiolar Adenoma, Multiple<br>Leukemia Mononuclear<br>Osteosarcoma, Metastatic, Skin | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |
| Nose   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Trachea  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

**SPECIAL SENSES SYSTEM**

|                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Eye             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

**URINARY SYSTEM**

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Leukemia Mononuclear |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically



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

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

|                                |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |                              |
|--------------------------------|-------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------------------------------|
| <b>FISCHER 344 RATS FEMALE</b> | DAY ON TEST |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | <b>females<br/>(cont...)</b> |
|                                | 075         | 070 | 006 | 005 | 005 | 006 | 006 | 007 | 006 | 007 | 007 | 007 | 005 | 004 | 006 | 006 | 007 | 007 | 007 | 007 | 005 | 007 | 007 |     |                              |
|                                | 035         | 039 | 028 | 032 | 031 | 031 | 031 | 022 | 038 | 022 | 022 | 022 | 033 | 033 | 035 | 038 | 028 | 028 | 029 | 029 | 022 | 033 | 018 | 033 |                              |
| <b>0.3 G/KG</b>                | ANIMAL ID   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |                              |
|                                | 000         | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 |                              |
|                                | 330         | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 |                              |

Urinary Bladder +  
 Leukemia Mononuclear

**SYSTEMIC LESIONS**

Multiple Organ +  
 Leukemia Mononuclear X X

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
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TDMS No. 20007 - 05  
 Test Type: CHRONIC  
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 Species/Strain: RATS/F 344/N

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
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 Lab: BAT

| FISCHER 344 RATS FEMALE<br>0.3 G/KG | DAY ON TEST |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | * TOTALS |
|-------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|
|                                     | 0730        | 0622 | 0722 | 0700 | 0672 | 0772 | 0772 | 0772 | 0572 | 0762 | 0762 | 0672 | 0662 | 0562 | 0662 | 0732 | 0632 | 0622 | 0722 | 0722 | 0642 | 0722 | 0632 | 0732 |          |
| ANIMAL ID                           | 0032        | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 |          |
|                                     | 0           | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 50       |
| Thyroid Gland                       | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |
| C-cell, Adenoma                     |             |      |      |      |      |      |      | X    |      |      |      |      |      |      |      |      |      |      |      |      |      |      | X    |      | 5        |
| Follicular Cell, Adenoma            |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 1        |

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

|                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|-----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Clitoral Gland              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Adenoma                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   | 3  |
| Ovary                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Granulosa Cell Tumor Benign |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Uterus                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Carcinosarcoma              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Polyp Stromal               |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   | X | X |   |   |   |   |   | X |   | 8  |
| Sarcoma Stromal             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   | 1  |

**HEMATOPOIETIC SYSTEM**

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Bone Marrow                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Lymph Node                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3  |
| Mediastinal, Leukemia Mononuclear |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2  |
| Pancreatic, Leukemia Mononuclear  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Lymph Node, Mandibular            | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | 0  |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| DAY ON TEST                                 | FISCHER 344 RATS FEMALE |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | * TOTALS |         |   |
|---|-------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|---------|---|
|   | 0730                    | 0629  | 0729  | 0725  | 0672  | 0772  | 0772  | 0772  | 0578  | 0779  | 0663  | 0763  | 0563  | 0667  | 0663  | 0662  | 0767  | 0664  | 0767  | 0667  |          | 0767    |   |
| 0.3 G/KG                                    | ANIMAL ID               |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | * TOTALS |         |   |
|   | 00326                   | 00332 | 00332 | 00332 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 |          | 00333   |   |
| Lymph Node, Mesenteric Leukemia Mononuclear | +                       | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | 50<br>2 |   |
| Spleen Leukemia Mononuclear                 | +                       | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | 50<br>5 |   |
| Thymus Leukemia Mononuclear                 | +                       | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | 49<br>1 |   |
| <b>INTEGUMENTARY SYSTEM</b>                 |                         |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |         |   |
| Mammary Gland Carcinoma                     | +                       | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | 50<br>1 |   |
| Fibroadenoma                                |                         |       |       |       | X     |       |       |       |       |       |       |       |       | X     | X     |       | X     |       |       |       | X        | 13      |   |
| Fibroadenoma, Multiple                      | X                       |       |       |       |       | X     |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          | 2       |   |
| Skin  | +                       | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | 50      |   |
| Subcutaneous Tissue, Fibroma                |                         |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | X        | 1       |   |
| Subcutaneous Tissue, Lipoma                 |                         |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          | 1       |   |
| Subcutaneous Tissue, Osteosarcoma           |                         |       |       |       |       |       |       |       |       |       |       |       |       | X     |       |       |       |       |       |       |          | 1       |   |
| <b>MUSCULOSKELETAL SYSTEM</b>               |                         |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |         |   |
| Bone  | +                       | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | 50      |   |
| Osteoma                                     |                         |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          | X       | 1 |
| Osteosarcoma                                |                         |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |         | 1 |
| Osteosarcoma, Metastatic, Skin              |                         |       |       |       |       |       |       |       |       |       |       |       |       | X     |       |       |       |       |       |       |          |         | 1 |
| Skeletal Muscle                             |                         |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |         | 1 |
| Rhabdomyosarcoma                            |                         |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |         | 1 |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically



















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

P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS FEMALE<br>1.0 G/KG | DAY ON TEST |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | * TOTALS |
|-------------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|
|                                     | 0728        | 0730  | 0732  | 0734  | 0736  | 0738  | 0740  | 0742  | 0744  | 0746  | 0748  | 0750  | 0752  | 0754  | 0756  | 0758  | 0760  | 0762  | 0764  | 0766  | 0768  | 0770  | 0772  | 0774  |          |
| ANIMAL ID                           | 00376       | 00377 | 00378 | 00379 | 00380 | 00381 | 00382 | 00383 | 00384 | 00385 | 00386 | 00387 | 00388 | 00389 | 00390 | 00391 | 00392 | 00393 | 00394 | 00395 | 00396 | 00397 | 00398 | 00399 |          |

**ALIMENTARY SYSTEM**

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Esophagus                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Cecum    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Colon    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Rectum   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Ileum    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Jejunum  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Liver                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Leukemia Mononuclear      |   |   | X |   | X | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X | 9  |
| Lymphoma Malignant        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Mesentery                 | + |   | + |   |   |   |   |   | + |   |   |   |   |   |   |   |   |   |   |   |   |   | + | + | 9  |
| Pancreas                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Salivary Glands           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Stomach, Forestomach      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Stomach, Glandular        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Tooth                     |   |   |   |   |   |   |   |   |   |   |   | + |   |   | + |   |   |   |   |   |   |   |   |   | 2  |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically







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

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS FEMALE<br>1.0 G/KG    | DAY ON TEST |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | * TOTALS |     |    |    |
|--|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|-----|----|----|
|  | 078         | 073   | 072   | 073   | 064   | 070   | 077   | 072   | 065   | 074   | 079   | 072   | 094   | 078   | 077   | 077   | 072   | 078   | 038   | 072   | 072   | 073   | 073   | 039   |          | 055 |    |    |
| ANIMAL ID                              | 00376       | 00037 | 00038 | 00039 | 00040 | 00041 | 00042 | 00043 | 00044 | 00045 | 00046 | 00047 | 00048 | 00049 | 00050 | 00051 | 00052 | 00053 | 00054 | 00055 | 00056 | 00057 | 00058 | 00059 | 00060    |     |    |    |
| Lymphoma Malignant                     |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          | X   | 1  |    |
| Spleen                                 | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | +   | +  | 50 |
| Carcinoma, Metastatic, Lung            |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |     |    | 1  |
| Leukemia Mononuclear                   |             |       |       | X     |       | X     | X     |       |       |       |       |       |       |       |       |       |       |       | X     |       |       |       |       |       |          | X   | 9  |    |
| Lymphoma Malignant                     |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          | X   | 1  |    |
| Thymus                                 | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | M        | +   | 48 |    |
| Leukemia Mononuclear                   |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |     |    | 1  |
| Lymphoma Malignant                     |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          | X   | 1  |    |
| Schwannoma Malignant, Metastatic, Lung |             |       |       |       |       |       |       |       |       | X     |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |     | 1  |    |
| <b>INTEGUMENTARY SYSTEM</b>            |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |     |    |    |
| Mammary Gland                          | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | +   | +  | 50 |
| Fibroadenoma                           |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |     |    | 4  |
| Skin                                   | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | +   | +  | 50 |
| <b>MUSCULOSKELETAL SYSTEM</b>          |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |     |    |    |
| Bone                                   | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | +   | +  | 50 |
| <b>NERVOUS SYSTEM</b>                  |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |     |    |    |
| Brain                                  | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | +   | +  | 50 |
| Granular Cell Tumor Benign             |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |     |    | 1  |
| <b>RESPIRATORY SYSTEM</b>              |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |     |    |    |
| Lung                                   | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | +   | +  | 50 |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
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TDMS No. 20007 - 05  
 Test Type: CHRONIC  
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P04: NEOPLASMS BY INDIVIDUAL ANIMAL  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010  
 Time Report Requested: 09:10:56  
 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS FEMALE<br>1.0 G/KG | DAY ON TEST |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | * TOTALS |
|-------------------------------------|-------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|----------|
|                                     | 078         | 073 | 072 | 073 | 064 | 070 | 072 | 026 | 069 | 074 | 079 | 011 | 014 | 077 | 073 | 073 | 021 | 078 | 022 | 038 | 072 | 033 | 073 | 039 | 055 |          |
| ANIMAL ID                           | 007         | 003 | 002 | 003 | 004 | 000 | 002 | 003 | 004 | 005 | 006 | 007 | 008 | 009 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 |          |
|                                     | 376         | 337 | 338 | 339 | 388 | 381 | 382 | 383 | 384 | 385 | 386 | 387 | 388 | 389 | 390 | 391 | 392 | 393 | 394 | 395 | 396 | 397 | 398 | 399 | 390 |          |

|                                   |  |  |  |   |  |  |  |  |   |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  |   |   |   |
|-----------------------------------|--|--|--|---|--|--|--|--|---|--|--|--|--|--|--|--|--|---|--|--|--|--|--|--|---|---|---|
| Alveolar/Bronchiolar Adenoma      |  |  |  |   |  |  |  |  |   |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  |   | 1 |   |
| Alveolar/Bronchiolar Carcinoma    |  |  |  |   |  |  |  |  |   |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  |   |   | 1 |
| Leukemia Mononuclear              |  |  |  | X |  |  |  |  |   |  |  |  |  |  |  |  |  | X |  |  |  |  |  |  | X | 5 |   |
| Mediastinum, Schwannoma Malignant |  |  |  |   |  |  |  |  | X |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  |   | 1 |   |

|         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|---------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Nose    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Pleura  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |

**SPECIAL SENSES SYSTEM**

|                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|--------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Ear                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Neural Crest Tumor |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Eye                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Harderian Gland    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Zymbal's Gland     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Adenoma            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X | 1  |

**URINARY SYSTEM**

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Kidney               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Leukemia Mononuclear |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X | 2  |
| Urinary Bladder      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |

**SYSTEMIC LESIONS**

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

