

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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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

Note: Animals arranged according to days on test.

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

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
Mesentery		+						+			+	+										
Oral Mucosa																						
Squamous Cell Papilloma																						
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Acinus, Adenoma						X																
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

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FISCHER 344 RATS MALE	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	
	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7	
0.0 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	0	0	0	0	0	0	0	0	0	0	0	0	0	0	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	4	3	2	1	4	0	2	0	0	4	4	3	3	2	0	0	0	1	1	1	
	6	2	3	5	2	5	6	9	7	3	7	8	5	2	8	2	5	9	1	4	7	

Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Tooth															+	+	+			+	+

CARDIOVASCULAR SYSTEM

Blood Vessel	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

ENDOCRINE SYSTEM

Adrenal Cortex Carcinoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Fibrous Histiocytoma, Metastatic, Skeletal Muscle										X											
Adrenal Medulla Pheochromocytoma Benign	+	+	+	+	+	+	+	+	+	+	+	+	+	X	+	+	+	+	+	+	+
Bilateral, Pheochromocytoma Benign																				X	+
Islets, Pancreatic Adenoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	X	X	+	+
Parathyroid Gland Adenoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Pituitary Gland Pars Distalis, Adenoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	X	X	X		X	X	X						X	X				X	X	X	X
Thyroid Gland C-cell, Adenoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	X	X	+	+
				X						X								X	X		X

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

Follicular Cell, Adenoma

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

Coagulating Gland

+

Epididymis

+ +

Preputial Gland  
Carcinoma

+ +

Prostate

+ +

Seminal Vesicle

+ +

Testes  
Bilateral, Interstitial Cell, Adenoma  
Interstitial Cell, Adenoma

+  
 X  
 X

HEMATOPOIETIC SYSTEM

Bone Marrow

+ +

Lymph Node

+

Lymph Node, Mandibular

M M

Lymph Node, Mesenteric

+ +

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| DAY ON TEST | FISCHER 344 RATS MALE |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 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 |           |                    |
| 5           | 5                     | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0         |                    |
| 0           | 0                     | 1 | 4 | 8 | 9 | 1 | 1 | 2 | 5 | 7 | 8 | 8 | 9 | 0 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 0         |                    |
| 4           | 4                     | 1 | 5 | 2 | 4 | 0 | 3 | 9 | 1 | 5 | 6 | 9 | 4 | 9 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 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 | 0 | 0 | 0 | 0         |                    |
| 1           | 4                     | 3 | 2 | 1 | 4 | 0 | 2 | 0 | 0 | 4 | 4 | 3 | 3 | 2 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 2 | 0         |                    |
| 6           | 2                     | 3 | 5 | 2 | 5 | 6 | 9 | 7 | 3 | 7 | 8 | 5 | 2 | 8 | 2 | 5 | 9 | 1 | 4 | 7 | 8 | 9 | 2 | 3 | 0         |                    |

|        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|--------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Spleen | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Thymus | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + |  |

**INTEGUMENTARY SYSTEM**

|                                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mammary Gland                    | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Skin                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Dermis, Fibroma                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |
| Epidermis, Basal Cell Adenoma    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Subcutaneous Tissue, Fibroma     |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   | X |   |   |   |   |
| Subcutaneous Tissue, Lipoma      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Subcutaneous Tissue, Liposarcoma |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |

**MUSCULOSKELETAL SYSTEM**

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Osteosarcoma         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |
| Skeletal Muscle      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |
| Fibrous Histiocytoma |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |

**NERVOUS SYSTEM**

|                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Brain            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Peripheral Nerve |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |
| Spinal Cord      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |
| Glioma Malignant |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |

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

**RESPIRATORY SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lung  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Alveolar/Bronchiolar Adenoma                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Alveolar/Bronchiolar Adenoma, Multiple            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Alveolar/Bronchiolar Carcinoma                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Fibrous Histiocytoma, Metastatic, Skeletal Muscle |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mediastinum, Osteosarcoma, Metastatic, Bone       |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |
| Nose  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Trachea   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

**SPECIAL SENSES SYSTEM**

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

**URINARY SYSTEM**

|                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Ureter          |   |   |   | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Urethra         |   |   |   | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

**SYSTEMIC LESIONS**

|                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Multiple Organ | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

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|                              |  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                            |  |  |
|------------------------------|--|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|-------------|----------------------------|--|--|
| <b>FISCHER 344 RATS MALE</b> | DAY ON TEST  | 0<br>5<br>4      | 0<br>5<br>4      | 0<br>5<br>1      | 0<br>5<br>4      | 0<br>5<br>2      | 0<br>5<br>4      | 0<br>6<br>0      | 0<br>6<br>3      | 0<br>6<br>1      | 0<br>6<br>9      | 0<br>6<br>5      | 0<br>6<br>7      | 0<br>6<br>8      | 0<br>6<br>8      | 0<br>6<br>9      | 0<br>7<br>4      | 0<br>7<br>9      | 0<br>7<br>7      | 0<br>7<br>2      | 0<br>7<br>2      | 0<br>7<br>7      | 0<br>7<br>7      | 0<br>7<br>7      | 0<br>7<br>7      | 0<br>7<br>2      | 0<br>7<br>2      | 0<br>7<br>7      | 0<br>7<br>7      | 0<br>7<br>2      | 0<br>7<br>7      | 0<br>7<br>7 | <b>males<br/>(cont...)</b> |  |  |
|                              | ANIMAL ID  | 0<br>0<br>1<br>6 | 0<br>0<br>4<br>2 | 0<br>0<br>3<br>3 | 0<br>0<br>2<br>5 | 0<br>0<br>1<br>2 | 0<br>0<br>4<br>5 | 0<br>0<br>0<br>6 | 0<br>0<br>2<br>9 | 0<br>0<br>0<br>7 | 0<br>0<br>0<br>3 | 0<br>0<br>0<br>7 | 0<br>0<br>4<br>8 | 0<br>0<br>4<br>5 | 0<br>0<br>4<br>8 | 0<br>0<br>3<br>5 | 0<br>0<br>3<br>2 | 0<br>0<br>2<br>8 | 0<br>0<br>0<br>2 | 0<br>0<br>0<br>5 | 0<br>0<br>0<br>9 | 0<br>0<br>0<br>7 | 0<br>0<br>0<br>1 | 0<br>0<br>0<br>4 | 0<br>0<br>1<br>7 | 0<br>0<br>1<br>8 | 0<br>0<br>1<br>9 | 0<br>0<br>2<br>2 | 0<br>0<br>2<br>7 | 0<br>0<br>2<br>7 | 0<br>0<br>2<br>3 |             |                            |  |  |
|                              | Leukemia Mononuclear<br>Lymphoma Malignant<br>Mesothelioma Malignant |                  |                  |                  |                  |                  |                  | 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 | DAY ON TEST |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | * TOTALS |
|-----------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|
|                       | 0727        | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 |          |
| 0.0 G/KG              | 0039        | 0044 | 0046 | 0049 | 0050 | 0004 | 0000 | 0003 | 0000 | 0001 | 0004 | 0006 | 0007 | 0000 | 0004 | 0007 | 0008 | 0000 | 0001 | 0003 | 0008 | 0005 |          |

**ALIMENTARY SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Esophagus   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Intestine Large, Cecum                            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Intestine Large, Colon                            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Intestine Large, Rectum                           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Intestine Small, Duodenum                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Intestine Small, Ileum                            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Intestine Small, Jejunum                          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Liver   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Fibrous Histiocytoma, Metastatic, Skeletal Muscle |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Hepatocellular Adenoma                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Mesentery   |   | + |   |   |   |   |   |   |   |   | + |   |   |   |   |   |   |   |   |   |   |   | 6  |
| Oral Mucosa                                       | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Squamous Cell Papilloma                           | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Pancreas  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Acinus, Adenoma                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Salivary Glands                                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Stomach, Forestomach                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |

\* .. 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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>0.0 G/KG                 | DAY ON TEST |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | * TOTALS |
|---|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|
|   | 077         | 077  | 077  | 077  | 077  | 077  | 077  | 077  | 077  | 077  | 077  | 077  | 077  | 077  | 077  | 077  | 077  | 077  | 077  | 077  | 077  | 077  |          |
| ANIMAL ID   | 0039        | 0044 | 0046 | 0049 | 0050 | 0004 | 0000 | 0003 | 0000 | 0001 | 0001 | 0002 | 0002 | 0002 | 0002 | 0003 | 0003 | 0003 | 0004 | 0004 | 0004 | 0001 |          |
| Stomach, Glandular                                | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 49       |
| Tooth   |             | +    |      |      |      |      |      |      |      | +    |      |      |      |      |      | +    |      | +    |      | +    |      |      | 10       |
| <b>CARDIOVASCULAR SYSTEM</b>                      |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |
| Blood Vessel                                      | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 49       |
| Heart   | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 49       |
| <b>ENDOCRINE SYSTEM</b>                           |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |
| Adrenal Cortex                                    | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 49       |
| Carcinoma   |             |      |      |      | X    |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 1        |
| Fibrous Histiocytoma, Metastatic, Skeletal Muscle |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 1        |
| Adrenal Medulla                                   | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 49       |
| Pheochromocytoma Benign                           |             |      | X    |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | X    |      |      | 4        |
| Bilateral, Pheochromocytoma Benign                |             |      |      |      |      |      |      |      |      |      |      |      |      |      | X    |      |      |      |      |      |      |      | 1        |
| Islets, Pancreatic                                | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 49       |
| Adenoma   |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 4        |
| Parathyroid Gland                                 | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 49       |
| Adenoma   |             |      |      |      | X    |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 1        |
| Pituitary Gland                                   | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 49       |
| Pars Distalis, Adenoma                            |             | X    | X    |      | X    |      |      |      | X    | X    | X    |      |      |      |      |      |      |      | X    | X    |      |      | 21       |
| Thyroid Gland                                     | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 49       |
| C-cell, Adenoma                                   |             |      |      |      |      |      |      |      |      |      |      | X    |      |      |      |      |      | X    |      | X    |      |      | 8        |

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 + .. 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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>0.0 G/KG | DAY ON TEST |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | * TOTALS |
|-----------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|
|                                   | 0727        | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  |          |
| ANIMAL ID                         | 00039       | 00044 | 00046 | 00049 | 00050 | 00054 | 00057 | 00060 | 00063 | 00065 | 00068 | 00071 | 00074 | 00077 | 00080 | 00083 | 00086 | 00089 | 00092 | 00095 | 00098 | 00101 |          |

Follicular Cell, Adenoma

X

1

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

Coagulating Gland

+

2

Epididymis

+ +

49

Preputial Gland  
Carcinoma

+  
X

49  
1

Prostate

+ +

49

Seminal Vesicle

+ +

49

Testes  
Bilateral, Interstitial Cell, Adenoma  
Interstitial Cell, Adenoma

+  
X  
X

49  
29  
8

**HEMATOPOIETIC SYSTEM**

Bone Marrow

+ +

49

Lymph Node

+ + +

4

Lymph Node, Mandibular

M M

0

Lymph Node, Mesenteric

+ +

49

\* .. 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  
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**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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>0.0 G/KG | DAY ON TEST |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | * TOTALS |
|-----------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|
|                                   | 07          | 07    | 07    | 07    | 07    | 07    | 07    | 07    | 07    | 07    | 07    | 07    | 07    | 07    | 07    | 07    | 07    | 07    | 07    | 07    | 07    | 07    |          |
| ANIMAL ID                         | 00039       | 00044 | 00046 | 00049 | 00050 | 00064 | 00070 | 00073 | 00080 | 00081 | 00082 | 00083 | 00084 | 00085 | 00086 | 00087 | 00088 | 00089 | 00091 | 00093 | 00095 | 00097 |          |
| Spleen                            | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | 49       |
| Thymus                            | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | 48       |
| <b>INTEGUMENTARY SYSTEM</b>       |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |
| Mammary Gland                     | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | 48       |
| Skin                              | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | 49       |
| 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  |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | 1        |
| <b>MUSCULOSKELETAL SYSTEM</b>     |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |
| Bone                              | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | 49       |
| Osteosarcoma                      |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | 1        |
| Skeletal Muscle                   |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | 1        |
| Fibrous Histiocytoma              |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | 1        |
| <b>NERVOUS SYSTEM</b>             |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |
| Brain                             | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | 49       |
| Peripheral Nerve                  |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | 2        |
| Spinal Cord                       |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | 2        |
| Glioma 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 | DAY ON TEST           |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       | * TOTALS              |                       |  |
|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|--|
|                       | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                |                       |                       |  |
| 0.0 G/KG              | 2<br>7                | 2<br>7                | 2<br>7                | 2<br>7                | 2<br>7                | 2<br>8                | 2<br>8                | 2<br>8                | 2<br>8                | 2<br>8                | 2<br>8                | 2<br>8                | 2<br>8                | 2<br>8                | 2<br>8                | 2<br>8                | 2<br>8                | 2<br>8                | 2<br>8                | 2<br>9                | 2<br>9                | 2<br>9                | 2<br>9                |                       |                       |  |
|                       | 0<br>0<br>0<br>3<br>9 | 0<br>0<br>0<br>4<br>4 | 0<br>0<br>0<br>4<br>6 | 0<br>0<br>0<br>4<br>9 | 0<br>0<br>0<br>5<br>0 | 0<br>0<br>0<br>1<br>4 | 0<br>0<br>0<br>1<br>0 | 0<br>0<br>0<br>1<br>3 | 0<br>0<br>0<br>2<br>0 | 0<br>0<br>0<br>2<br>0 | 0<br>0<br>0<br>2<br>1 | 0<br>0<br>0<br>2<br>4 | 0<br>0<br>0<br>2<br>6 | 0<br>0<br>0<br>2<br>7 | 0<br>0<br>0<br>3<br>0 | 0<br>0<br>0<br>3<br>4 | 0<br>0<br>0<br>3<br>7 | 0<br>0<br>0<br>4<br>8 | 0<br>0<br>0<br>4<br>0 | 0<br>0<br>0<br>4<br>1 | 0<br>0<br>0<br>4<br>3 | 0<br>0<br>0<br>0<br>1 | 0<br>0<br>0<br>1<br>8 | 0<br>0<br>0<br>1<br>5 | 0<br>0<br>0<br>3<br>1 |  |

**RESPIRATORY SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Lung  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Alveolar/Bronchiolar Adenoma                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   | 1  |
| Alveolar/Bronchiolar Adenoma, Multiple            |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Alveolar/Bronchiolar Carcinoma                    |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Fibrous Histiocytoma, Metastatic, Skeletal Muscle |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Mediastinum, Osteosarcoma, Metastatic, Bone       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Nose  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Trachea   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |

**SPECIAL SENSES SYSTEM**

|                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Eye             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |

**URINARY SYSTEM**

|                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Kidney          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Ureter          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Urethra         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |

**SYSTEMIC LESIONS**

|                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Multiple Organ | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|

\* .. 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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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 | DAY ON TEST |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | ANIMAL ID | males<br>(cont...) |
|-----------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------|--------------------|
|                       | 0030        | 0018 | 0055 | 0057 | 0058 | 0066 | 0066 | 0066 | 0066 | 0066 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 |           |                    |
| 0.1 G/KG              | 0076        | 0003 | 0005 | 0004 | 0005 | 0007 | 0008 | 0003 | 0001 | 0000 | 0007 | 0002 | 0008 | 0005 | 0005 | 0002 | 0003 | 0004 | 0006 | 0008 | 0004 | 0007 | 0006 | 0009 | 0001      |                    |

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 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hepatocellular Adenoma                 |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mesentery                              |   |   |   |   | + | + |   |   |   | + |   | + |   |   |   |   |   |   |   |   |   |   |   |   |
| Oral Mucosa                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Pancreas                               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Mast Cell Tumor Malignant              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Salivary Glands                        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Carcinoma                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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>0.1 G/KG                   | DAY ON TEST |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |   | ANIMAL ID | males<br>(cont...) |
|---|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|---|-----------|--------------------|
|   | 0030        | 0016 | 0052 | 0055 | 0057 | 0066 | 0066 | 0066 | 0066 | 0066 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 |   |           |                    |
| 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 | 0077      |                    |
| Lymph Node, Mesenteric<br>Mast Cell Tumor Malignant | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | + | 0077      |                    |
| Spleen<br>Mast Cell Tumor Malignant                 | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | + | 0077      |                    |
| Thymus  | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | + | 0077      |                    |
| <b>INTEGUMENTARY SYSTEM</b>                         |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |   |           |                    |
| Mammary Gland<br>Fibroadenoma                       | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | + | 0077      |                    |
| Skin<br>Subcutaneous Tissue, Fibroma                | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | + | 0077      |                    |
| Subcutaneous Tissue, Fibrous Histiocytoma           |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |   | 0077      |                    |
| Subcutaneous Tissue, Osteosarcoma                   |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |   | 0077      |                    |
| <b>MUSCULOSKELETAL SYSTEM</b>                       |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |   |           |                    |
| Bone<br>Osteosarcoma                                | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | + | 0077      |                    |
| <b>NERVOUS SYSTEM</b>                               |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |   |           |                    |
| Brain<br>Meningioma Malignant                       | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | + | 0077      |                    |
| <b>RESPIRATORY SYSTEM</b>                           |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |   |           |                    |
| Lung  | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | + | 0077      |                    |

\* .. 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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<br>(cont...) |
|-------------|-----------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------|--------------------|
|             | 0030                  | 0016 | 0052 | 0055 | 0057 | 0066 | 0066 | 0066 | 0066 | 0066 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 |           |                    |
| 0.1 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         |                    |

Alveolar/Bronchiolar Carcinoma  
 Carcinoma, Metastatic, Salivary Glands  
 Fibrous Histiocytoma, Metastatic, Skin  
 Neural Crest Tumor, Metastatic, Ear  
 Osteosarcoma, Metastatic, Skin

X

X

X

X

Nose +

Trachea +

**SPECIAL SENSES SYSTEM**

Ear +  
 Neural Crest Tumor X

Eye +

Harderian Gland +

**URINARY SYSTEM**

Kidney +  
 Nephroblastoma X

Ureter  
 Polyp

Urinary Bladder +

**SYSTEMIC LESIONS**

Multiple Organ +  
 Leukemia Mononuclear X X X X X X X 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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>0.1 G/KG | DAY ON TEST            | 0030 | 0016 | 0052 | 0057 | 0055 | 0066 | 0066 | 0066 | 0066 | 0066 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | 0067 | males<br>(cont...) |
|                                       | ANIMAL ID              | 0076 | 0008 | 0005 | 0004 | 0005 | 0007 | 0008 | 0003 | 0001 | 0000 | 0007 | 0002 | 0008 | 0005 | 0005 | 0002 | 0003 | 0004 | 0006 | 0008 | 0004 | 0007 |                    |
|                                       | Mesothelioma Malignant |      |      |      |      | 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  
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P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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>0.1 G/KG | DAY ON TEST |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | * TOTALS |
|-----------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|
|                                   | 0727        | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  |          |
| ANIMAL ID                         | 00093       | 00094 | 00099 | 00090 | 00051 | 00059 | 00061 | 00066 | 00066 | 00066 | 00066 | 00069 | 00070 | 00078 | 00080 | 00082 | 00086 | 00087 | 00089 | 00092 | 00099 | 00101 | 00103 | 00104 |          |
|                                   | 3           | 4     | 9     | 0     | 1     | 9     | 1     | 2     | 5     | 6     | 9     | 0     | 8     | 0     | 2     | 7     | 6     | 8     | 7     | 2     | 9     | 1     | 3     | 4     | 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 |
| Cholangioma                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Fibrous Histiocytoma, Metastatic, Skin |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Hepatocellular Adenoma                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Mesentery                              |   |   |   | + |   | + | + |   | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 8  |
| Oral Mucosa                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Pancreas                               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Mast Cell Tumor Malignant              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Salivary Glands                        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Carcinoma                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 |      |      |    |
|--|-----------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|------|------|----|
|  | 0727                  | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 |          | 0727 |      |    |
| ANIMAL ID                              | 0093                  | 0094 | 0099 | 0090 | 0051 | 0059 | 0061 | 0066 | 0066 | 0066 | 0066 | 0077 | 0077 | 0088 | 0088 | 0088 | 0099 | 0099 | 0057 | 0077 | 0088     | 0088 | 0099 |    |
| Stomach, Glandular                     | +                     | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | +    | +    | 50 |
| Tooth                                  |                       |      |      |      |      |      |      |      |      |      |      |      |      | +    |      |      |      |      | +    |      | +        | +    |      | 6  |
| <b>CARDIOVASCULAR SYSTEM</b>           |                       |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |      |      |    |
| Blood Vessel                           | +                     | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | +    | +    | 50 |
| Heart                                  | +                     | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | +    | +    | 50 |
| Fibrous Histiocytoma, Metastatic, Skin |                       |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |      |      | 1  |
| <b>ENDOCRINE SYSTEM</b>                |                       |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |      |      |    |
| Adrenal Cortex                         | +                     | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | +    | +    | 50 |
| Adrenal Medulla                        | +                     | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | +    | +    | 50 |
| Pheochromocytoma Benign                |                       |      |      |      | X    |      | X    |      |      | X    |      |      |      |      |      |      | X    |      |      |      |          |      |      | 8  |
| Pheochromocytoma Malignant             |                       |      |      |      |      |      |      |      |      |      |      | X    |      |      |      |      |      |      |      |      |          |      |      | 2  |
| Islets, Pancreatic                     | +                     | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | +    | +    | 50 |
| Adenoma                                |                       |      |      |      |      |      | X    | X    |      |      |      |      |      |      |      |      |      |      |      |      |          |      |      | 2  |
| Parathyroid Gland                      | +                     | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | +    | +    | 50 |
| Adenoma                                |                       |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | X        |      |      | 1  |
| Pituitary Gland                        | +                     | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | +    | +    | 50 |
| Pars Distalis, Adenoma                 | X                     |      | X    | X    | X    |      |      |      | X    |      | X    | X    |      | X    |      | X    |      |      | X    |      | X        |      | X    | 20 |
| Thyroid Gland                          | +                     | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | +    | +    | 50 |
| Bilateral, C-cell, Adenoma             |                       |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |      |      | 1  |
| C-cell, Adenoma                        |                       |      |      |      | X    |      |      |      |      |      |      |      |      | X    |      |      |      |      | X    | X    |          |      |      | 8  |

\* .. 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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>0.1 G/KG | DAY ON TEST |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    | * TOTALS |
|-----------------------------------|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----------|
|                                   | 07          | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 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 | 00 | 01 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 |    |          |
|                                   | 99          | 99 | 99 | 00 | 55 | 55 | 66 | 66 | 66 | 66 | 66 | 77 | 77 | 88 | 88 | 88 | 99 | 99 | 55 | 77 | 77 | 88 | 88 | 99 |          |
|                                   | 34          | 49 |    | 01 | 09 | 11 | 22 | 55 | 66 | 99 | 00 | 88 | 00 | 22 | 77 | 66 | 88 | 77 | 22 | 99 | 11 | 33 | 44 | 00 |          |

**GENERAL BODY SYSTEM**

|                  |   |
|------------------|---|
| Tissue NOS       | 1 |
| Rhabdomyosarcoma | 1 |

**GENITAL SYSTEM**

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Coagulating Gland                      | + | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2  |
| Epididymis                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Fibrous Histiocytoma, Metastatic, Skin |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Preputial Gland                        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Carcinoma                              |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   | 1  |
| Schwannoma Malignant                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Prostate                               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Adenoma                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X | 1  |
| Seminal Vesicle                        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Testes                                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Bilateral, Interstitial Cell, Adenoma  | X |   | X |   | X |   | X | X |   | X | X | X |   | X | X | X | X | X | X |   |   |   | X | 32 |
| Interstitial Cell, Adenoma             |   |   |   | X |   | X |   |   |   |   |   |   | X |   |   |   |   |   |   |   | X | X | X | 12 |

**HEMATOPOIETIC SYSTEM**

|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Bone Marrow                           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Mast Cell Tumor Malignant             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Lymph Node                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3  |
| Pancreatic, 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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>0.1 G/KG                   | DAY ON TEST |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |         | * TOTALS |  |
|---|-------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|---------|----------|--|
|   | 077         | 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     |          |  |
|   | 093         | 094 | 099 | 090 | 051 | 059 | 056 | 066 | 066 | 066 | 066 | 077 | 077 | 088 | 088 | 088 | 099 | 099 | 055 | 077 | 077 | 088 | 088 | 099     |          |  |
| 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<br>Mast Cell Tumor Malignant | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | 50<br>1 |          |  |
| Spleen<br>Mast Cell Tumor Malignant                 | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | 50<br>1 |          |  |
| Thymus  | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | 50      |          |  |
| <b>INTEGUMENTARY SYSTEM</b>                         |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |         |          |  |
| Mammary Gland<br>Fibroadenoma                       | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | 50<br>1 |          |  |
| Skin<br>Subcutaneous Tissue, Fibroma                | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | 50<br>5 |          |  |
| Subcutaneous Tissue, Fibrous Histiocytoma           |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | 1       |          |  |
| Subcutaneous Tissue, Osteosarcoma                   |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | 1       |          |  |
| <b>MUSCULOSKELETAL SYSTEM</b>                       |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |         |          |  |
| Bone<br>Osteosarcoma                                | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | 50<br>1 |          |  |
| <b>NERVOUS SYSTEM</b>                               |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |         |          |  |
| Brain<br>Meningioma Malignant                       | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | 50<br>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  
 BLANK .. Not examined microscopically

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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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>0.1 G/KG      | DAY ON TEST |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | * TOTALS |    |  |
|--|-------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|----------|----|--|
|  | 07          | 07     | 07     | 07     | 07     | 07     | 07     | 07     | 07     | 07     | 07     | 07     | 07     | 07     | 07     | 07     | 07     | 07     | 07     | 07     | 07     | 07     | 07     |        |          |    |  |
| ANIMAL ID                              | 000933      | 000934 | 000939 | 000940 | 000951 | 000959 | 000961 | 000962 | 000965 | 000966 | 000969 | 000970 | 000978 | 000980 | 000982 | 000987 | 000988 | 000989 | 000995 | 000997 | 000999 | 001001 | 001003 | 001004 |          |    |  |
| Alveolar/Bronchiolar Carcinoma         |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | 1        |    |  |
| Carcinoma, Metastatic, Salivary Glands |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | 1        |    |  |
| Fibrous Histiocytoma, Metastatic, Skin |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | 1        |    |  |
| Neural Crest Tumor, Metastatic, Ear    |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | 1        |    |  |
| Osteosarcoma, Metastatic, Skin         |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | 1        |    |  |
| Nose                                   | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | 50       |    |  |
| Trachea                                | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | 50       |    |  |
| <b>SPECIAL SENSES SYSTEM</b>           |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |          |    |  |
| Ear                                    |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |          |    |  |
| Neural Crest Tumor                     |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |          | 2  |  |
| Eye                                    | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +        | 50 |  |
| Harderian Gland                        | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +        | 50 |  |
| <b>URINARY SYSTEM</b>                  |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |          |    |  |
| Kidney                                 | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +        | 50 |  |
| Nephroblastoma                         |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |          | 1  |  |
| Ureter                                 |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |          | 1  |  |
| Polyp                                  |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |          | 1  |  |
| Urinary Bladder                        | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +        | 50 |  |
| <b>SYSTEMIC LESIONS</b>                |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |          |    |  |
| Multiple Organ                         | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +        | 50 |  |
| Leukemia Mononuclear                   |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |          | 8  |  |

\* .. 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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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>0.1 G/KG | DAY ON TEST |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |   |
|-----------------------------------|-------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|---|
|                                   | ANIMAL ID   |  | 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 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7        |   |
|                                   |             |  | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2        |   |
|                                   |             |  | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 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 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |   |
|                                   |             |  | 9 | 9 | 9 | 0 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 8 | 8 | 8 | 9 | 9 | 5 | 7 | 7        |   |
|                                   |             |  | 3 | 4 | 9 | 0 | 1 | 9 | 1 | 2 | 5 | 6 | 9 | 0 | 8 | 0 | 2 | 7 | 6 | 8 | 7 | 2 | 9        |   |
| Mesothelioma Malignant            |             |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X        |   |
|                                   |             |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 4 |

\* .. 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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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 | DAY ON TEST |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    | ANIMAL ID | males<br>(cont...) |    |
|-----------------------|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|-----------|--------------------|----|
|                       | 04          | 05 | 05 | 06 | 06 | 06 | 06 | 06 | 06 | 06 | 06 | 06 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 |           |                    | 07 |
| 0.3 G/KG              | 5           | 9  | 9  | 0  | 1  | 3  | 6  | 6  | 6  | 7  | 8  | 8  | 9  | 0  | 0  | 0  | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 2         | 001                |    |
|                       | 4           | 0  | 8  | 8  | 6  | 0  | 4  | 4  | 4  | 3  | 9  | 9  | 4  | 1  | 2  | 9  | 7  | 7  | 7  | 7  | 7  | 7  | 7  | 004       |                    |    |
|                       | 0           | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 008       |                    |    |
|                       | 1           | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 001       |                    |    |

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 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mesentery                                    |   | + | + |   |   |   |   |   |   | + |   |   |   |   |   |   |   |   |   |   | + |   | + |
| Pancreas                                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Acinus, Adenoma                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |
| Salivary Glands                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Schwannoma Malignant                         |   |   |   |   | X |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |
| Stomach, Forestomach                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Stomach, Glandular                           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Carcinoid Tumor Malignant                    |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |
| Muscularis, Fibrosarcoma                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. 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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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<br>(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 |   |
|                       |           | 4           | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |                    | 7 | 7 |
|                       |           | 5           | 9 | 9 | 0 | 1 | 3 | 6 | 6 | 6 | 7 | 8 | 8 | 9 | 0 | 0 | 0 | 2 | 2 | 2 | 2 |                    | 2 | 2 |
| 0.3 G/KG              |           | 4           | 0 | 8 | 8 | 6 | 0 | 4 | 4 | 4 | 3 | 9 | 9 | 4 | 1 | 2 | 9 | 7 | 7 | 7 | 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 |   |
|                       |           | 1           | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1                  | 1 |   |
|                       |           | 4           | 4 | 3 | 3 | 4 | 0 | 0 | 3 | 4 | 4 | 1 | 3 | 3 | 1 | 1 | 3 | 0 | 0 | 1 | 2 | 2                  | 2 |   |
|                       |           | 8           | 5 | 0 | 9 | 1 | 4 | 3 | 1 | 9 | 2 | 8 | 8 | 3 | 4 | 7 | 2 | 2 | 6 | 6 | 2 | 3                  | 6 |   |

Tooth

+ +

CARDIOVASCULAR SYSTEM

Blood Vessel

+ +

Heart

+ +

ENDOCRINE SYSTEM

Adrenal Cortex

+ +

Adrenal Medulla  
 Pheochromocytoma Benign

+  
 X

Islets, Pancreatic  
 Adenoma  
 Adenoma, Multiple

+  
 X  
 X

Parathyroid Gland

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

Pituitary Gland  
 Pars Distalis, Adenoma

+  
 X X X X X X X X

Thyroid Gland  
 Bilateral, C-cell, Adenoma  
 C-cell, Adenoma  
 C-cell, Carcinoma  
 Follicular Cell, Adenoma  
 Follicular Cell, Carcinoma

+  
 X  
 X  
 X  
 X  
 X

GENERAL BODY 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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<br>(cont...) |
|-------------|-----------------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|------|-----------|--------------------|
|             | 04                    | 05 | 05 | 06 | 06 | 06 | 06 | 06 | 06 | 06 | 06 | 06 | 06 | 06 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07   |           |                    |
| 04          | 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      |                    |
| 05          | 9                     | 9  | 9  | 0  | 1  | 3  | 6  | 6  | 6  | 6  | 7  | 8  | 8  | 9  | 0  | 0  | 0  | 2  | 2  | 2  | 2  | 2  | 2  | 2    | 0002      |                    |
| 08          | 0                     | 0  | 8  | 8  | 6  | 0  | 4  | 4  | 4  | 3  | 9  | 9  | 4  | 1  | 2  | 9  | 7  | 7  | 7  | 7  | 7  | 7  | 7  | 0003 |           |                    |
| 08          | 5                     | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0004 |           |                    |
| 08          | 1                     | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 1  | 0005 |           |                    |
| 08          | 4                     | 4  | 3  | 3  | 4  | 0  | 0  | 3  | 4  | 4  | 1  | 3  | 3  | 1  | 1  | 3  | 0  | 0  | 1  | 2  | 2  | 2  | 2  | 0006 |           |                    |
| 08          | 8                     | 5  | 0  | 9  | 1  | 4  | 3  | 1  | 9  | 2  | 8  | 8  | 3  | 4  | 7  | 2  | 2  | 6  | 6  | 2  | 3  | 6  | 7  | 0007 |           |                    |
| 08          | 8                     | 5  | 0  | 9  | 1  | 4  | 3  | 1  | 9  | 2  | 8  | 8  | 3  | 4  | 7  | 2  | 2  | 6  | 6  | 2  | 3  | 6  | 7  | 0008 |           |                    |

Peritoneum +  
 Paraganglioma X

**GENITAL SYSTEM**

Epididymis +  
 Preputial Gland + + + + + + + + + + + M + + + + + + + + + + + + + +  
 Prostate Adenoma +  
 Seminal Vesicle +  
 Testes Bilateral, Interstitial Cell, Adenoma X  
 Interstitial Cell, Adenoma X

**HEMATOPOIETIC SYSTEM**

Bone Marrow +  
 Lymph Node +  
 Lymph Node, Mandibular M  
 Lymph Node, Mesenteric +  
 Spleen +  
 Thymus +

**INTEGUMENTARY 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

| FISCHER 344 RATS MALE<br>0.3 G/KG | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 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 |                    |
|                                   | 4           | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 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 |                    |
|                                   | 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 |                    |
|                                   | 4           | 4 | 3 | 3 | 4 | 0 | 0 | 3 | 4 | 4 | 1 | 3 | 3 | 1 | 1 | 3 | 0 | 0 | 1 | 2 | 2 | 2 | 2 | 3 |                    |
|                                   | 8           | 5 | 0 | 9 | 1 | 4 | 3 | 1 | 9 | 2 | 8 | 8 | 3 | 4 | 7 | 2 | 2 | 6 | 6 | 2 | 3 | 6 | 7 | 8 |                    |

Mammary Gland  
Fibroadenoma

+ +

Skin  
Basal Cell Adenoma  
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 X  
X X  
X

MUSCULOSKELETAL SYSTEM

Bone

+ +

Skeletal Muscle  
Rhabdomyosarcoma

+  
X

NERVOUS SYSTEM

Brain

+ +

RESPIRATORY SYSTEM

Lung

+ +

Alveolar/Bronchiolar Adenoma  
Carcinoma, Metastatic, Thyroid Gland  
Neural Crest Tumor, Metastatic, Ear  
Osteosarcoma, Metastatic, Skin

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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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>0.3 G/KG | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 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 |   |                    |
|                                       | 4           | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |   |                    |
|                                       | 5           | 9 | 9 | 0 | 1 | 3 | 6 | 6 | 6 | 7 | 8 | 8 | 9 | 0 | 0 | 0 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |                    |
| 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 |   |                    |
|                                       | 4           | 4 | 3 | 3 | 4 | 0 | 0 | 3 | 4 | 4 | 1 | 3 | 3 | 1 | 1 | 3 | 0 | 0 | 1 | 2 | 2 | 2 | 2 |   |                    |
| 8                                     | 5           | 0 | 9 | 1 | 4 | 3 | 1 | 9 | 2 | 8 | 8 | 3 | 4 | 7 | 2 | 2 | 6 | 6 | 2 | 3 | 6 | 7 |   |   |                    |

Schwannoma Malignant, Metastatic, Salivary Glands

X

Squamous Cell Carcinoma, Metastatic, Skin

X

Nose

+ +

Trachea

+ +

SPECIAL SENSES SYSTEM

Ear

Neural Crest Tumor

Eye

+ +

Harderian Gland

+ +

Zymbal's Gland Carcinoma

+  
X

URINARY SYSTEM

Kidney

+ +

Urinary Bladder

+ +

SYSTEMIC LESIONS

Multiple Organ

Leukemia Mononuclear

Lymphoma Malignant

Mesothelioma Malignant

+ +

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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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>0.3 G/KG | DAY ON TEST           |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       | * TOTALS |
|-----------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|----------|
|                                   | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                |                       |          |
| ANIMAL ID                         | 0<br>0<br>1<br>3<br>7 | 0<br>0<br>1<br>4<br>0 | 0<br>0<br>1<br>4<br>3 | 0<br>0<br>1<br>0<br>5 | 0<br>0<br>1<br>0<br>7 | 0<br>0<br>1<br>0<br>8 | 0<br>0<br>1<br>1<br>1 | 0<br>0<br>1<br>1<br>1 | 0<br>0<br>1<br>1<br>1 | 0<br>0<br>1<br>1<br>1 | 0<br>0<br>1<br>1<br>1 | 0<br>0<br>1<br>2<br>0 | 0<br>0<br>1<br>2<br>4 | 0<br>0<br>1<br>2<br>5 | 0<br>0<br>1<br>2<br>9 | 0<br>0<br>1<br>2<br>4 | 0<br>0<br>1<br>2<br>6 | 0<br>0<br>1<br>2<br>0 | 0<br>0<br>1<br>2<br>1 | 0<br>0<br>1<br>2<br>9 | 0<br>0<br>1<br>2<br>0 | 0<br>0<br>1<br>2<br>1 | 0<br>0<br>1<br>3<br>4 | 0<br>0<br>1<br>4<br>7 |          |

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  |
| Mesentery                                    |   |   |   |   |   |   |   | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + | 7  |
| Pancreas                                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Acinus, Adenoma                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Salivary Glands                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Schwannoma Malignant                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2  |
| Stomach, Forestomach                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Stomach, Glandular                           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Carcinoid Tumor Malignant                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Muscularis, Fibrosarcoma                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   | 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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>0.3 G/KG | DAY ON TEST           |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       | * TOTALS |
|-----------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|----------|
|                                   | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                |                       |          |
| ANIMAL ID                         | 0<br>0<br>1<br>3<br>7 | 0<br>0<br>1<br>4<br>0 | 0<br>0<br>1<br>4<br>3 | 0<br>0<br>1<br>0<br>5 | 0<br>0<br>1<br>0<br>7 | 0<br>0<br>1<br>0<br>8 | 0<br>0<br>1<br>1<br>1 | 0<br>0<br>1<br>1<br>2 | 0<br>0<br>1<br>1<br>3 | 0<br>0<br>1<br>1<br>5 | 0<br>0<br>1<br>1<br>9 | 0<br>0<br>1<br>2<br>0 | 0<br>0<br>1<br>2<br>4 | 0<br>0<br>1<br>2<br>5 | 0<br>0<br>1<br>2<br>9 | 0<br>0<br>1<br>2<br>4 | 0<br>0<br>1<br>2<br>6 | 0<br>0<br>0<br>2<br>0 | 0<br>0<br>0<br>0<br>1 | 0<br>0<br>0<br>0<br>9 | 0<br>0<br>0<br>1<br>0 | 0<br>0<br>0<br>2<br>1 | 0<br>0<br>0<br>3<br>4 | 0<br>0<br>0<br>4<br>7 |          |
| Tooth                             |                       |                       |                       |                       | +                     |                       |                       | +                     |                       |                       |                       |                       | +                     |                       |                       |                       | +                     |                       |                       | +                     |                       |                       |                       | 9                     |          |
| <b>CARDIOVASCULAR SYSTEM</b>      |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |
| Blood Vessel                      | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | 50                    |          |
| Heart                             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | 50                    |          |
| <b>ENDOCRINE SYSTEM</b>           |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |
| Adrenal Cortex                    | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | 50                    |          |
| Adrenal Medulla                   | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | 50                    |          |
| Pheochromocytoma Benign           |                       |                       |                       | X                     |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       | 2                     |          |
| Islets, Pancreatic                | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | 50                    |          |
| Adenoma                           |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       | 1                     |          |
| Adenoma, Multiple                 |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       | 1                     |          |
| Parathyroid Gland                 | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | M                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | 48                    |                       |          |
| Pituitary Gland                   | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | 50                    |          |
| Pars Distalis, Adenoma            |                       |                       |                       |                       | X                     |                       |                       | X                     | X                     |                       |                       |                       |                       | X                     |                       |                       | X                     | X                     |                       | X                     |                       |                       |                       | 15                    |          |
| Thyroid Gland                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | 50                    |          |
| Bilateral, C-cell, Adenoma        |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       | 2                     |          |
| C-cell, Adenoma                   | X                     |                       |                       |                       |                       |                       |                       | X                     |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       | X                     |                       |                       |                       | 6                     |          |
| C-cell, Carcinoma                 |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       | 2                     |          |
| Follicular Cell, Adenoma          |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       | 1                     |          |
| Follicular Cell, Carcinoma        |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       | 1                     |          |
| <b>GENERAL BODY SYSTEM</b>        |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |

\* .. 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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>0.3 G/KG | DAY ON TEST           |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       | * TOTALS |
|-----------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|----------|
|                                   | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                | 0<br>7                |                       |          |
| ANIMAL ID                         | 0<br>0<br>1<br>3<br>7 | 0<br>0<br>1<br>4<br>0 | 0<br>0<br>1<br>4<br>3 | 0<br>0<br>1<br>0<br>5 | 0<br>0<br>1<br>0<br>7 | 0<br>0<br>1<br>0<br>8 | 0<br>0<br>1<br>1<br>1 | 0<br>0<br>1<br>1<br>1 | 0<br>0<br>1<br>1<br>1 | 0<br>0<br>1<br>1<br>1 | 0<br>0<br>1<br>1<br>1 | 0<br>0<br>1<br>2<br>0 | 0<br>0<br>1<br>2<br>4 | 0<br>0<br>1<br>2<br>5 | 0<br>0<br>1<br>2<br>9 | 0<br>0<br>1<br>2<br>4 | 0<br>0<br>1<br>2<br>6 | 0<br>0<br>1<br>2<br>0 | 0<br>0<br>1<br>2<br>1 | 0<br>0<br>1<br>2<br>9 | 0<br>0<br>1<br>2<br>0 | 0<br>0<br>1<br>2<br>1 | 0<br>0<br>1<br>3<br>4 | 0<br>0<br>1<br>4<br>7 |          |

Peritoneum 1  
 Paraganglioma 1

**GENITAL SYSTEM**

Epididymis + 50  
 Preputial Gland + 49  
 Prostate + 50  
 Adenoma X 1  
 Seminal Vesicle + 50  
 Testes + 50  
 Bilateral, Interstitial Cell, Adenoma X 40  
 Interstitial Cell, Adenoma X 9

**HEMATOPOIETIC SYSTEM**

Bone Marrow + 50  
 Lymph Node + 2  
 Lymph Node, Mandibular M 0  
 Lymph Node, Mesenteric + 50  
 Spleen + 50  
 Thymus + 50

**INTEGUMENTARY 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 |
|--|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----------|
|  | 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  |          |
|  | Mammary Gland         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | 50       |
| Fibroadenoma                           |                       |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2  |          |
| Skin                                   | +                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |          |
| Basal Cell Adenoma                     |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2  |          |
| Epidermis, Keratoacanthoma             |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   | 1  |          |
| Epidermis, Squamous Cell Carcinoma     |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |          |
| Epidermis, Trichoepithelioma           |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   | 1  |          |
| Subcutaneous Tissue, Fibroma           |                       |   |   | X |   | X |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 7  |          |
| Subcutaneous Tissue, Hemangiosarcoma   |                       |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   | 1  |          |
| Subcutaneous Tissue, Lipoma            |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   | 1  |          |
| Subcutaneous Tissue, Osteosarcoma      |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |          |
| Subcutaneous Tissue, Schwannoma        |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |          |
| Malignant, Metastatic, Salivary Glands |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |          |
| <b>MUSCULOSKELETAL SYSTEM</b>          |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |          |
| Bone                                   | +                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |          |
| Skeletal Muscle                        |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |          |
| Rhabdomyosarcoma                       |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |          |
| <b>NERVOUS SYSTEM</b>                  |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |          |
| Brain                                  | +                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |          |
| <b>RESPIRATORY SYSTEM</b>              |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |          |
| Lung                                   | +                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |          |
| Alveolar/Bronchiolar Adenoma           |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2  |          |
| Carcinoma, Metastatic, Thyroid Gland   |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |          |
| Neural Crest Tumor, Metastatic, Ear    |                       |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   | 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  
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TDMS No. 20007 - 05  
 Test Type: CHRONIC  
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**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 |          |    |
| 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   | 01                    | 01 | 01 | 01 | 01 | 01 | 01 | 01 | 01 | 01 | 01 | 01 | 01 | 01 | 01 | 01 | 01 | 01 | 01 | 01 | 01 | 01 | 01 | 01 |          |    |
|   | 34                    | 44 | 44 | 00 | 00 | 00 | 11 | 11 | 11 | 11 | 11 | 22 | 22 | 22 | 33 | 44 | 55 | 00 | 00 | 11 | 22 | 33 | 44 | 44 |          |    |
|   | 70                    |    | 35 |    | 78 |    | 11 |    | 22 |    | 35 |    | 90 |    | 45 |    | 90 |    | 45 |    | 90 |    | 45 |    |          |    |
| Schwannoma Malignant, Metastatic, Salivary Glands |                       |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    | 1        |    |
| Squamous Cell Carcinoma, Metastatic, Skin         |                       |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    | 1        |    |
| Nose  | +                     | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | 50       |    |
| Trachea   | +                     | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | 50       |    |
| <b>SPECIAL SENSES SYSTEM</b>                      |                       |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |          |    |
| Ear   |                       |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |          |    |
| Neural Crest Tumor                                |                       |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |          | 1  |
| Eye   | +                     | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +        | 50 |
| Harderian Gland                                   | +                     | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +        | 50 |
| Zymbal's Gland                                    |                       |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |          | 1  |
| Carcinoma   |                       |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |          | 1  |
| <b>URINARY SYSTEM</b>                             |                       |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |          |    |
| Kidney  | +                     | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +        | 50 |
| Urinary Bladder                                   | +                     | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +        | 50 |
| <b>SYSTEMIC LESIONS</b>                           |                       |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |          |    |
| Multiple Organ                                    | +                     | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +        | 50 |
| Leukemia Mononuclear                              |                       | X  |    |    |    |    |    |    | X  | X  |    |    | X  |    |    | X  |    |    |    |    |    |    |    |    |          | 7  |
| Lymphoma Malignant                                |                       |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |          | 1  |
| Mesothelioma Malignant                            |                       |    |    |    |    |    |    |    |    |    | X  |    |    |    |    |    |    |    |    |    |    |    |    |    |          | 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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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...) |     |      |     |
|-----------------------------------|-------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----------|--------------------|-----|------|-----|
|                                   | 003         | 004 | 005 | 006 | 007 | 008 | 009 | 010 | 011 | 012 | 013 | 014 | 015 | 016 | 017 | 018 | 019 | 020 | 021 | 022 |           |                    | 023 | 024  | 025 |
|                                   | 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   | 0002 |     |
|                                   | 1           | 1   | 1   | 1   | 1   | 1   | 1   | 1   | 1   | 1   | 1   | 1   | 1   | 1   | 1   | 1   | 1   | 1   | 1   | 1   | 1         | 1                  | 1   | 0003 |     |
|                                   | 9           | 7   | 6   | 8   | 8   | 8   | 5   | 9   | 5   | 5   | 6   | 6   | 8   | 6   | 8   | 7   | 8   | 6   | 5   | 5   | 5         | 5                  | 6   | 0004 |     |
|                                   | 3           | 3   | 0   | 8   | 6   | 3   | 3   | 9   | 4   | 7   | 3   | 8   | 5   | 1   | 4   | 1   | 2   | 7   | 9   | 1   | 2         | 8                  | 0   | 0005 |     |

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 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hepatocellular Adenoma                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |
| Mesentery   |   |   |   |   |   |   |   |   |   | + |   |   |   |   |   |   |   |   |   |   |   |   | + |
| Oral Mucosa                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Squamous Cell Carcinoma                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |
| Pancreas  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Salivary Glands                                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Sarcoma   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |
| 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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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 | 0 | 0 | 0 | 0 |
|---|---|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|   | 0 | 0               | 4 | 4 | 4 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 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 | 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 | 1 | 1 | 1 | 1 |
| FISCHER 344 RATS MALE<br>1.0 G/KG                 | 3 | 3               | 4 | 5 | 5 | 8 | 6 | 9 | 9 | 0 | 5 | 3 | 3 | 9 | 9 | 4 | 3 | 9 | 4 | 9 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |   |
|   | 9 | 7               | 6 | 8 | 8 | 8 | 5 | 9 | 5 | 5 | 6 | 6 | 8 | 6 | 8 | 7 | 8 | 6 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 7 | 0 |
|   |   | males (cont...) |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Stomach, Glandular                                | + |                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Tooth   | + |                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| <b>CARDIOVASCULAR SYSTEM</b>                      |   |                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Blood Vessel                                      | + |                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Heart   | + |                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Fibrous Histiocytoma, Metastatic, Skeletal Muscle | + |                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| <b>ENDOCRINE SYSTEM</b>                           |   |                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Adrenal Cortex                                    | + |                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Adrenal Medulla<br>Pheochromocytoma Benign        | + |                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Islets, Pancreatic<br>Adenoma                     | + |                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Parathyroid Gland                                 | + |                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Pituitary Gland<br>Pars Distalis, Adenoma         | + |                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Thyroid Gland<br>C-cell, Adenoma                  | + |                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| <b>GENERAL BODY SYSTEM</b>                        |   |                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| NONE  |   |                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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<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           | 0                     | 0 | 0 | 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 | 4 | 4 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 0         | 0                  |
| 3           | 0                     | 0 | 7 | 1 | 4 | 8 | 6 | 9 | 9 | 9 | 0 | 5 | 0 | 3 | 3 | 9 | 9 | 4 | 9 | 0 | 7 | 7 | 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                  |
| 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 | 0         | 0                  |
| 9           | 7                     | 6 | 8 | 8 | 8 | 5 | 9 | 5 | 5 | 6 | 6 | 8 | 6 | 8 | 7 | 8 | 6 | 5 | 5 | 5 | 5 | 6 | 6 | 7 | 0         | 0                  |
| 3           | 3                     | 0 | 8 | 6 | 3 | 3 | 9 | 4 | 7 | 3 | 8 | 5 | 1 | 4 | 1 | 2 | 7 | 9 | 1 | 2 | 8 | 6 | 9 | 0 | 0         | 0                  |

**GENITAL SYSTEM**

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

**HEMATOPOIETIC SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Lymph Node  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Deep Cervical, Fibrous Histiocytoma,<br>Metastatic, Skeletal Muscle |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 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 |
| Lymph Node, Mesenteric  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Fibrous Histiocytoma, Metastatic, Skeletal<br>Muscle                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Spleen  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Thymus  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

\* .. 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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<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 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0         | 0                  | 0 |
| 0           | 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                     | 4 | 4 | 5 | 5 | 5 | 5 | 8 | 8 | 4 | 6 | 7 | 7 | 7 | 8 | 9 | 0 | 2 | 2 | 2 | 2         | 1                  | 1 |
| 3           | 0                     | 7 | 1 | 4 | 8 | 6 | 9 | 9 | 9 | 0 | 5 | 0 | 3 | 3 | 9 | 4 | 9 | 4 | 7 | 7 | 7         | 3                  | 3 |

Fibrous Histiocytoma, Metastatic, Skeletal Muscle

X

**INTEGUMENTARY SYSTEM**

Mammary Gland  
 Fibroadenoma

+ +

Skin  
 Basal Cell Adenoma  
 Dermis, Fibroma  
 Subcutaneous Tissue, Fibroma

+  
 X  
 X  
 X

**MUSCULOSKELETAL SYSTEM**

Bone

+ +

Skeletal Muscle  
 Fibrous Histiocytoma

+  
 X

**NERVOUS SYSTEM**

Brain

+ +

**RESPIRATORY SYSTEM**

Lung  
 Alveolar/Bronchiolar Adenoma  
 Fibrous Histiocytoma, Metastatic, Skeletal Muscle

+  
 X

Nose

+ +

\* .. 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  
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P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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

Trachea +

**SPECIAL SENSES SYSTEM**

Eye +

Harderian Gland  
 Carcinoma, Metastatic, Oral Mucosa +  
 X

**URINARY SYSTEM**

Kidney +

Urinary Bladder +

**SYSTEMIC LESIONS**

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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 |
|-----------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|
|                                   | 0727        | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  |          |
| ANIMAL ID                         | 00172       | 00172 | 00172 | 00172 | 00172 | 00172 | 00172 | 00172 | 00172 | 00172 | 00172 | 00172 | 00172 | 00172 | 00172 | 00172 | 00172 | 00172 | 00172 | 00172 | 00172 | 00172 | 00172 | 00172 |          |
|                                   | 24          | 8     | 0     | 9     | 5     | 5     | 2     | 5     | 9     | 1     | 7     | 4     | 6     | 6     | 4     | 5     | 6     | 7     | 0     | 1     | 2     | 7     | 8     | 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 |
| Fibrous Histiocytoma, Metastatic, Skeletal Muscle |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Hepatocellular Adenoma                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Mesentery   |   | + |   |   |   |   |   |   |   |   | + |   | + |   |   |   |   |   |   |   |   |   | + | 6  |
| Oral Mucosa                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Squamous Cell Carcinoma                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Pancreas  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Salivary Glands                                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Sarcoma   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 |       |    |
|---|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|-------|----|
|   | 0727        | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  | 0727  |          | 0727  |    |
| ANIMAL ID   | 00172       | 00174 | 00178 | 00180 | 00189 | 00195 | 00205 | 00212 | 00215 | 00219 | 00228 | 00231 | 00234 | 00237 | 00244 | 00246 | 00254 | 00256 | 00267 | 00269 | 00277    | 00288 |    |
| Stomach, Glandular                                | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | +     | 50 |
| Tooth   |             |       | +     | +     |       |       |       |       |       | +     | +     |       | +     |       |       | +     |       |       |       |       |          |       | 11 |
| <b>CARDIOVASCULAR SYSTEM</b>                      |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |       |    |
| Blood Vessel                                      | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | +     | 50 |
| Heart   | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | +     | 50 |
| Fibrous Histiocytoma, Metastatic, Skeletal Muscle |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |       | 1  |
| <b>ENDOCRINE SYSTEM</b>                           |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |       |    |
| Adrenal Cortex                                    | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | +     | 50 |
| Adrenal Medulla                                   | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | +     | 50 |
| Pheochromocytoma Benign                           |             |       |       |       |       |       |       |       |       |       |       |       | X     |       |       |       |       |       |       |       |          |       | 2  |
| Islets, Pancreatic                                | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | +     | 50 |
| Adenoma   |             |       |       |       |       |       |       |       |       |       |       |       | X     |       |       |       |       |       |       |       | X        |       | 3  |
| Parathyroid Gland                                 | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | +     | 50 |
| Pituitary Gland                                   | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | +     | 50 |
| Pars Distalis, Adenoma                            |             | X     |       |       |       | X     |       |       |       |       |       |       |       |       | X     |       |       | X     |       |       |          |       | 8  |
| Thyroid Gland                                     | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | +     | 50 |
| C-cell, Adenoma                                   |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       | X     |       |       |       | X     |          |       | 2  |
| <b>GENERAL BODY SYSTEM</b>                        |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |       |    |
| NONE  |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |       |    |

\* .. 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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          | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 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 |  |          |
|                                   | 11          | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 |  |          |
|                                   | 77          | 77 | 77 | 88 | 88 | 99 | 55 | 66 | 77 | 77 | 88 | 88 | 99 | 99 | 55 | 66 | 66 | 77 | 77 | 99 | 99 | 99 | 99 |  |          |
|                                   | 24          | 88 | 00 | 09 | 05 | 05 | 02 | 05 | 09 | 01 | 07 | 04 | 06 | 06 | 04 | 05 | 06 | 07 | 00 | 01 | 02 | 07 | 08 |  |          |

**GENITAL SYSTEM**

|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |         |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------|
| Epididymis                            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50      |
| Preputial Gland Adenoma               | + | + | + | + | + | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50<br>1 |
| Prostate                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50      |
| Seminal Vesicle                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50      |
| 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 | X | 43      |
| Interstitial Cell, Adenoma            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3       |

**HEMATOPOIETIC SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |         |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------|
| Bone Marrow   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50      |
| Lymph Node<br>Deep Cervical, Fibrous Histiocytoma,<br>Metastatic, Skeletal Muscle |   |   |   |   |   | + |   |   |   |   |   | + |   |   |   |   |   |   |   |   |   | + |   | 5<br>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 | 0       |
| Lymph Node, Mesenteric<br>Fibrous Histiocytoma, Metastatic, Skeletal<br>Muscle    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>1 |
| Spleen  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50      |
| Thymus  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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   | 077   | 077   | 077   | 077   | 077   | 077   | 077   | 077   | 077   | 077   | 077   | 077   | 077   | 077   | 077   | 077   |          | 077 |
| 1.0 G/KG    | 0                     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0        |     |
| ANIMAL ID   | 00172                 | 00174 | 00178 | 00180 | 00189 | 00195 | 00205 | 00252 | 00255 | 00279 | 00281 | 00288 | 00288 | 00291 | 00294 | 00295 | 00296 | 00297 | 00299 | 00302 | 00307    |     |

Fibrous Histiocytoma, Metastatic, Skeletal Muscle

1

**INTEGUMENTARY SYSTEM**

Mammary Gland  
 Fibroadenoma

+ X + + + X X 50  
 3

Skin  
 Basal Cell Adenoma  
 Dermis, Fibroma  
 Subcutaneous Tissue, Fibroma

+ 50  
 1  
 1  
 1

**MUSCULOSKELETAL SYSTEM**

Bone

+ 50

Skeletal Muscle  
 Fibrous Histiocytoma

1  
 1

**NERVOUS SYSTEM**

Brain

+ 50

**RESPIRATORY SYSTEM**

Lung  
 Alveolar/Bronchiolar Adenoma  
 Fibrous Histiocytoma, Metastatic, Skeletal Muscle

+ 50  
 X + + + + + + + + + + X + + X X 4  
 1

Nose

+ 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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TDMS No. 20007 - 05  
 Test Type: CHRONIC  
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**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 |  |
|------------------------------------|-------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|----------|--|
|                                    | 0727        | 0727   | 0727   | 0727   | 0727   | 0727   | 0727   | 0727   | 0727   | 0727   | 0727   | 0727   | 0727   | 0727   | 0727   | 0727   | 0727   | 0727   | 0727   | 0727   | 0727   | 0727   | 0727   | 0727   |          |  |
| ANIMAL ID                          | 001727      | 000117 | 000077 | 000088 | 000099 | 000055 | 000066 | 000077 | 000088 | 000099 | 000011 | 000022 | 000033 | 000044 | 000055 | 000066 | 000077 | 000088 | 000099 | 000011 | 000022 | 000033 | 000044 | 000055 |          |  |
| Trachea                            | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | 50     |          |  |
| <b>SPECIAL SENSES SYSTEM</b>       |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |          |  |
| Eye                                | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | 50     |          |  |
| Harderian Gland                    | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | 50     |          |  |
| Carcinoma, Metastatic, Oral Mucosa |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | 1      |          |  |
| <b>URINARY SYSTEM</b>              |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |          |  |
| Kidney                             | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | 50     |          |  |
| Urinary Bladder                    | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | 50     |          |  |
| <b>SYSTEMIC LESIONS</b>            |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |          |  |
| Multiple Organ                     | +           | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | 50     |          |  |
| Leukemia Mononuclear               |             |        |        |        |        |        |        |        |        |        |        | X      | X      |        |        |        |        |        |        |        | X      | X      | X      | 11     |          |  |
| Lymphoma Malignant                 |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | 1      |          |  |
| Mesothelioma Malignant             |             |        |        |        |        |        |        |        |        |        |        |        |        | X      |        |        |        |        |        |        | X      |        |        | 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  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | ANIMAL ID | females<br>(cont...) |
|-------------------------------------|-------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----------|----------------------|
|                                     | 009         | 004 | 005 | 005 | 005 | 006 | 006 | 006 | 006 | 006 | 006 | 006 | 006 | 007 | 007 | 007 | 007 | 007 | 007 | 007 | 007 | 007 |           |                      |
|                                     | 0           | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 000       |                      |
|                                     | 2           | 2   | 2   | 2   | 2   | 2   | 2   | 2   | 2   | 2   | 2   | 2   | 2   | 2   | 2   | 2   | 2   | 2   | 2   | 2   | 2   | 2   | 002       |                      |
|                                     | 2           | 2   | 0   | 2   | 3   | 3   | 1   | 4   | 4   | 3   | 2   | 4   | 4   | 2   | 0   | 1   | 0   | 1   | 1   | 2   | 2   | 4   | 002       |                      |
|                                     | 3           | 7   | 9   | 1   | 4   | 6   | 4   | 7   | 5   | 5   | 6   | 1   | 4   | 8   | 1   | 7   | 2   | 3   | 9   | 2   | 5   | 3   | 003       |                      |

**ALIMENTARY SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Cecum  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Colon  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Rectum   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum                                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Liver   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Mesentery   |   |   | + | + | + |   | + |   |   |   |   | + |   |   |   |   |   |   |   |   |   | + |
| Pancreas  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Salivary Glands   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Stomach, Forestomach<br>Sarcoma, Metastatic, Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Stomach, Glandular<br>Sarcoma                                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Tooth   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |   | + |   | + |

**CARDIOVASCULAR 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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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 |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         | ANIMAL ID | females<br>(cont...) |
|-------------------------------------|-------------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|-----------|----------------------|
|                                     | 009         | 004     | 005     | 005     | 005     | 006     | 006     | 006     | 006     | 006     | 006     | 006     | 006     | 007     | 007     | 007     | 007     | 007     | 007     | 007     | 007     | 007     | 007     |           |                      |
|                                     | 0           | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0       | 0         |                      |
|                                     | 9           | 0       | 6       | 0       | 9       | 5       | 1       | 7       | 4       | 9       | 2       | 3       | 3       | 1       | 5       | 5       | 8       | 8       | 8       | 8       | 8       | 8       | 8       | 8         |                      |
|                                     | 0022233     | 0022233 | 0022233 | 0022233 | 0022233 | 0022233 | 0022233 | 0022233 | 0022233 | 0022233 | 0022233 | 0022233 | 0022233 | 0022233 | 0022233 | 0022233 | 0022233 | 0022233 | 0022233 | 0022233 | 0022233 | 0022233 | 0022233 | 0022233   |                      |

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Blood Vessel                            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Heart<br>Fibrosarcoma, Metastatic, Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

ENDOCRINE SYSTEM

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Adrenal Medulla<br>Pheochromocytoma Benign                            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   | X |   |   |   |   |
| Islets, Pancreatic<br>Adenoma   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |
| Parathyroid Gland   | + | + | + | + | + | + | + | + | M | + | + | + | M | + | M | + | M | + | + | + | + | + | + | + |
| Pituitary Gland<br>Pars Distalis, Adenoma<br>Pars Distalis, Carcinoma | + | + | + | + | + | X | X | X | X | X |   | X | X |   | X | X | X |   |   | X |   | X | X | X |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |
| Thyroid Gland<br>C-cell, Adenoma<br>Follicular Cell, Adenoma          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland<br>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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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...) |
|-------------------------------------|-------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|--|----------------------|
|                                     | 009         | 005 | 000 | 005 | 005 | 006 | 006 | 006 | 006 | 006 | 006 | 006 | 006 | 007 | 007 | 007 | 007 | 007 | 007 | 007 | 007 | 007 | 007 |  |                      |
|                                     | 00          | 00  | 00  | 00  | 00  | 00  | 00  | 00  | 00  | 00  | 00  | 00  | 00  | 00  | 00  | 00  | 00  | 00  | 00  | 00  | 00  | 00  | 00  |  |                      |
|                                     | 22          | 22  | 20  | 22  | 33  | 33  | 14  | 44  | 33  | 24  | 44  | 20  | 11  | 72  | 15  | 55  | 88  | 88  | 88  | 88  | 88  | 88  | 88  |  |                      |
|                                     | 37          | 79  |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |  |                      |

|                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Carcinoma                |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Carcinoma, Multiple      |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |
| Ovary                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cystadenoma              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |
| Uterus                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Polyp Stromal            |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X | X |   |   |   |   |
| Sarcoma Stromal          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |
| Bilateral, Polyp Stromal |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 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 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Spleen                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Thymus                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

INTEGUMENTARY SYSTEM

|                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mammary Gland          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Adenoma                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Carcinoma              |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |
| Fibroadenoma           |   | X |   |   |   |   |   | X |   |   |   | X |   |   |   | X |   | X |   |   |   | X | X |
| Fibroadenoma, Multiple |   |   |   |   |   |   |   |   |   |   |   |   |   | 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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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 |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    | ANIMAL ID | females<br>(cont...) |
|-------------------------------------|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|-----------|----------------------|
|                                     | 00          | 04 | 05 | 05 | 05 | 06 | 06 | 06 | 06 | 06 | 06 | 06 | 06 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 |           |                      |
|                                     | 0           | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 00        |                      |
|                                     | 0           | 4  | 5  | 5  | 5  | 6  | 6  | 6  | 6  | 6  | 6  | 6  | 6  | 7  | 7  | 7  | 7  | 7  | 7  | 7  | 7  | 7  | 7  | 7  | 00        |                      |
|                                     | 0           | 5  | 0  | 1  | 1  | 1  | 2  | 3  | 6  | 6  | 9  | 9  | 9  | 0  | 0  | 0  | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 00        |                      |
|                                     | 9           | 0  | 6  | 0  | 9  | 5  | 1  | 7  | 4  | 9  | 2  | 3  | 3  | 1  | 5  | 5  | 8  | 8  | 8  | 8  | 8  | 8  | 8  | 8  | 00        |                      |
|                                     | 0           | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 00        |                      |
|                                     | 0           | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 00        |                      |
|                                     | 2           | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 2  | 00        |                      |
|                                     | 2           | 2  | 0  | 2  | 3  | 3  | 1  | 4  | 4  | 3  | 2  | 4  | 4  | 2  | 0  | 1  | 0  | 1  | 1  | 2  | 2  | 4  | 4  | 0  | 00        |                      |
|                                     | 3           | 7  | 9  | 1  | 4  | 6  | 4  | 7  | 5  | 5  | 6  | 1  | 4  | 8  | 1  | 7  | 2  | 3  | 9  | 2  | 5  | 3  | 9  | 4  | 00        |                      |

Skin  
 Subcutaneous Tissue, Fibroma

+  
 X

MUSCULOSKELETAL SYSTEM

Bone

+ +

Skeletal Muscle

+

NERVOUS SYSTEM

Brain

+ +

RESPIRATORY SYSTEM

Lung  
 Mediastinum, Fibrosarcoma

+  
 X

Nose

+ +

Trachea

+ +

SPECIAL SENSES SYSTEM

Ear  
 Neural Crest Tumor

Eye

+ +

Harderian Gland

+ +

URINARY SYSTEM

\* .. 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

TDMS No. 20007 - 05  
 Test Type: CHRONIC  
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Kava kava extract  
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 Lab: BAT

| DAY ON TEST | FISCHER 344 RATS FEMALE |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | ANIMAL ID | females<br>(cont...) |
|-------------|-------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----------|----------------------|
|             | 009                     | 000 | 005 | 006 | 009 | 005 | 006 | 007 | 006 | 006 | 006 | 006 | 006 | 007 | 007 | 007 | 007 | 007 | 007 | 007 | 007 | 007 | 007 | 007 |           |                      |
| 0.0 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         |                      |
|             | 0                       | 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         |                      |
|             | 2                       | 2   | 0   | 2   | 3   | 3   | 1   | 4   | 4   | 3   | 2   | 4   | 4   | 2   | 0   | 1   | 0   | 1   | 1   | 2   | 2   | 4   | 4   | 0   | 0         |                      |
|             | 3                       | 7   | 9   | 1   | 4   | 6   | 4   | 7   | 5   | 5   | 6   | 1   | 4   | 8   | 1   | 7   | 2   | 3   | 9   | 2   | 5   | 3   | 9   | 4   | 5         |                      |

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

SYSTEMIC LESIONS

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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 |
|-------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|
|                                     | 0729        | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 |          |
| ANIMAL ID                           | 0006        | 0008 | 0006 | 0008 | 0000 | 0004 | 0000 | 0002 | 0003 | 0007 | 0008 | 0006 | 0008 | 0000 | 0003 | 0007 | 0000 | 0001 | 0002 | 0005 | 0009 | 0001 | 0009 | 0000 | 0002     |

**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 |
| Mesentery                               |   |   |   |   | + | + |   | + |   |   |   |   |   |   |   | + |   |   |   |   |   |   |   |   | 10 |
| Pancreas                                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Salivary Glands                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Stomach, Forestomach                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Sarcoma, Metastatic, Stomach, Glandular |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Stomach, Glandular                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Sarcoma                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Tooth                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 5  |

**CARDIOVASCULAR 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 |
|-------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|
|                                     | 0729        | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 |          |
| ANIMAL ID                           | 0006        | 0008 | 0006 | 0008 | 0000 | 0004 | 0000 | 0002 | 0003 | 0007 | 0008 | 0006 | 0008 | 0000 | 0003 | 0007 | 0000 | 0001 | 0002 | 0005 | 0009 | 0001 | 0009 | 0002 |          |

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |         |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------|
| Blood Vessel                            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50      |
| Heart<br>Fibrosarcoma, Metastatic, Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>1 |

**ENDOCRINE SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------------|
| Adrenal Cortex  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50            |
| Adrenal Medulla<br>Pheochromocytoma Benign                            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | X | 50<br>3       |
| Islets, Pancreatic<br>Adenoma   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>1       |
| Parathyroid Gland   | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | M | + | 44            |
| Pituitary Gland<br>Pars Distalis, Adenoma<br>Pars Distalis, Carcinoma | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>29<br>1 |
| Thyroid Gland<br>C-cell, Adenoma<br>Follicular Cell, Adenoma          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>5<br>1  |

**GENERAL BODY SYSTEM**

|      |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| NONE |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|

**GENITAL SYSTEM**

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |         |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------|
| Clitoral Gland<br>Adenoma | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 |
|-------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|
|                                     | 0729        | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 |          |
| ANIMAL ID                           | 0006        | 0008 | 0006 | 0008 | 0000 | 0004 | 0000 | 0002 | 0003 | 0007 | 0008 | 0006 | 0008 | 0000 | 0003 | 0007 | 0000 | 0001 | 0002 | 0005 | 0009 | 0001 | 0009 | 0000 | 0002     |

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

**HEMATOPOIETIC SYSTEM**

|                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Bone Marrow            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  |
| Lymph Node             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50 |
| 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 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  |
| Spleen                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  |
| Thymus                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  |

**INTEGUMENTARY SYSTEM**

|                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Mammary Gland          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  |
| Adenoma                |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |    |
| Carcinoma              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2  |
| Fibroadenoma           |   |   |   | X | X |   | X |   | X | X |   |   |   |   |   |   |   | X |   |   |   | X |   |   |    |
| Fibroadenoma, Multiple | X |   | X |   |   |   |   |   | X |   |   | X | X |   |   | X |   |   |   | X | X |   |   |   |    |
|                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 14 |
|                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 10 |

\* .. 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 |         |
|--------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|---------|
|                                      | 0729        | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 |          |         |
| ANIMAL ID                            | 0006        | 0008 | 0006 | 0008 | 0000 | 0004 | 0000 | 0002 | 0003 | 0003 | 0007 | 0008 | 0006 | 0008 | 0000 | 0003 | 0007 | 0000 | 0001 | 0002 | 0005 | 0009 | 0001 | 0009 | 0000 | 0002     |         |
| Skin<br>Subcutaneous Tissue, Fibroma | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | 50<br>1 |
| <b>MUSCULOSKELETAL SYSTEM</b>        |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |         |
| Bone                                 | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | 50      |
| Skeletal Muscle                      |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          | 1       |
| <b>NERVOUS SYSTEM</b>                |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |         |
| Brain                                | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | 50      |
| <b>RESPIRATORY SYSTEM</b>            |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |         |
| Lung<br>Mediastinum, Fibrosarcoma    | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | 50<br>1 |
| Nose                                 | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | 50      |
| Trachea                              | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | 50      |
| <b>SPECIAL SENSES SYSTEM</b>         |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |         |
| Ear<br>Neural Crest Tumor            |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          | 1<br>1  |
| Eye                                  | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | 50      |
| Harderian Gland                      | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | 50      |
| <b>URINARY SYSTEM</b>                |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |         |

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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 |          |      |  |
| 0.0 G/KG                | ANIMAL ID               |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | * TOTALS |      |  |
|                         | 0006                    | 0008 | 0006 | 0008 | 0000 | 0004 | 0000 | 0002 | 0003 | 0007 | 0008 | 0006 | 0008 | 0000 | 0003 | 0007 | 0000 | 0001 | 0002 | 0005 | 0009 | 0001 | 0009 | 0000 |          | 0002 |  |
| Kidney                  | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |      |  |
| Urinary Bladder         | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |      |  |
| <b>SYSTEMIC LESIONS</b> |                         |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |      |  |
| Multiple Organ          | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |      |  |
| Adenolipoma             |                         |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 1        |      |  |
| Leukemia Mononuclear    |                         |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 5        |      |  |
| 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

| FISCHER 344 RATS FEMALE<br><br>0.1 G/KG | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<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 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |                      |
|   | 5           | 1 | 8 | 5 | 5 | 1 | 3 | 3 | 3 | 3 | 9 | 0 | 8 | 8 | 1 | 5 | 5 | 7 | 8 | 8 | 8 | 8 | 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 |                      |
|   | 2           | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |                      |
|   | 8           | 7 | 7 | 8 | 8 | 7 | 9 | 9 | 5 | 6 | 5 | 8 | 8 | 6 | 9 | 5 | 5 | 6 | 6 | 7 | 7 | 8 | 9 |                      |
|   | 8           | 3 | 0 | 7 | 5 | 1 | 0 | 7 | 2 | 3 | 3 | 4 | 3 | 2 | 3 | 1 | 9 | 5 | 6 | 4 | 8 | 0 | 6 |                      |

**ALIMENTARY SYSTEM**

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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 | 0 | 0 | 0 | 0 | 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 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |  |                          |
|                                |             | 0 | 5 | 5 | 0 | 1 | 3 | 3 | 3 | 3 | 7 | 7 | 8 | 0 | 0 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |  |                          |
| <b>0.1 G/KG</b>                | 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 |  |                          |
|                                |             | 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 | 2 |  |                          |
|                                |             | 8 | 7 | 7 | 8 | 8 | 7 | 9 | 9 | 5 | 6 | 5 | 8 | 8 | 6 | 9 | 5 | 5 | 6 | 6 | 7 | 7 | 8 | 9 | 5 | 5 | 5 |  |                          |
|                                |             | 8 | 3 | 0 | 7 | 5 | 1 | 0 | 7 | 2 | 3 | 3 | 4 | 3 | 2 | 3 | 1 | 9 | 5 | 6 | 4 | 8 | 0 | 6 | 4 | 5 |   |  |                          |
|                                |             |   | + |   |   |   |   |   |   |   |   |   |   |   |   | + |   |   |   |   |   |   |   |   |   |   |   |  | <b>females (cont...)</b> |

Tooth + +

**CARDIOVASCULAR SYSTEM**

|              |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|--------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Blood Vessel | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Heart        | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**ENDOCRINE SYSTEM**

|  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Adrenal Cortex<br>Adenoma<br>Carcinoma                                   | +       |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Adrenal Medulla<br>Pheochromocytoma Benign<br>Pheochromocytoma Malignant | +       |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Islets, Pancreatic<br>Adenoma  | + X       |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Parathyroid Gland  | + + + + + + + + + + + + + M + + + + + + + + M         |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pituitary Gland<br>Pars Distalis, Adenoma                                | + X X X X X X |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Thyroid Gland<br>C-cell, Adenoma   | + + + + + + + + + + + + + + + + X + + + X             |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**GENERAL BODY SYSTEM**

NONE

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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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Date Report Requested: 09/21/2010  
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|   |  |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                      |                                    |                                    |                                    |                                    |
|---|--|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|----------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|
| <b>FISCHER 344 RATS FEMALE</b><br><br><b>0.1 G/KG</b> |  | DAY ON TEST                        |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    |                                    | females<br>(cont...) |                                    |                                    |                                    |                                    |
|   |  | 005050666666666677777777777777     | 0055013333778800000000000000000000 | 0501333377880000000000000000000000 | 0055013333778800000000000000000000 | 0501333377880000000000000000000000 | 0055013333778800000000000000000000 | 0501333377880000000000000000000000 | 0055013333778800000000000000000000 | 0501333377880000000000000000000000 | 0055013333778800000000000000000000 | 0501333377880000000000000000000000 | 0055013333778800000000000000000000 | 0501333377880000000000000000000000 | 0055013333778800000000000000000000 | 0501333377880000000000000000000000 | 0055013333778800000000000000000000 | 0501333377880000000000000000000000 | 0055013333778800000000000000000000 | 0501333377880000000000000000000000 | 0055013333778800000000000000000000 |                      | 0501333377880000000000000000000000 | 0055013333778800000000000000000000 | 0501333377880000000000000000000000 | 0055013333778800000000000000000000 |
|   |  | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 |                      | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 | 0000000000000000000000000000000000 |
| ANIMAL ID   |  | 00288                              | 00277                              | 00207                              | 00205                              | 00201                              | 00203                              | 00203                              | 00203                              | 00203                              | 00203                              | 00203                              | 00203                              | 00203                              | 00203                              | 00203                              | 00203                              | 00203                              | 00203                              | 00203                              | 00203                              | 00203                | 00203                              | 00203                              | 00203                              | 00203                              |

**GENITAL SYSTEM**

|                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Adenoma        |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   | X |   | X |   |   |   | X |   |
| Carcinoma      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Ovary          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Uterus         | + | + | + | + | + | + | + | X | + | + | + | + | + | + | + | + | + | X | + | + | + | + | + | + |
| Polyp Stromal  |   |   |   |   |   |   |   | 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 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Spleen                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Thymus                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Thymoma Benign         |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |

**INTEGUMENTARY SYSTEM**

|               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Adenoma       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Carcinoma     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Fibroadenoma  |   |   |   |   | X |   | X |   | X |   |   |   |   |   | X |   |   |   |   | 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

| FISCHER 344 RATS FEMALE  | DAY ON TEST |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |  | females<br>(cont...) |
|--|-------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|--|----------------------|
|  | 005         | 005 | 008 | 006 | 006 | 006 | 006 | 006 | 006 | 006 | 006 | 007 | 007 | 007 | 007 | 007 | 007 | 007 | 007 | 007 | 007 | 007 | 007 |  |                      |
| 0.1 G/KG   | ANIMAL ID   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |  |                      |
| 288  | 283         | 270 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 |  |                      |
| Fibroadenoma, Multiple   |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | X   |     | X   | X   | X   |     |     |  |                      |
| Skin   | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   |  |                      |
| <b>MUSCULOSKELETAL SYSTEM</b>  |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |  |                      |
| Bone   | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   |  |                      |
| <b>NERVOUS SYSTEM</b>  |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |  |                      |
| Brain  | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   |  |                      |
| <b>RESPIRATORY SYSTEM</b>  |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |  |                      |
| Lung   | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   |  |                      |
| Carcinoma, Metastatic, Mammary Gland<br>Pheochromocytoma Malignant, Metastatic,<br>Adrenal Medulla |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |  |                      |
| Nose   | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   |  |                      |
| Trachea  | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   |  |                      |
| <b>SPECIAL SENSES SYSTEM</b>   |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |  |                      |
| Eye  | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   |  |                      |
| Harderian Gland  | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   |  |                      |
| <b>URINARY SYSTEM</b>  |             |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |  |                      |
| Kidney   | +           | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   | +   |  |                      |

\* .. Total animals with tissue examined microscopically; Total animals with tumor  
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TDMS No. 20007 - 05  
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 First Dose M/F: 08/18/04 / 08/19/04  
 Lab: BAT

| FISCHER 344 RATS FEMALE<br>0.1 G/KG | DAY ON TEST |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | females<br>(cont...) |
|-------------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------------------|
|                                     | 005         | 005   | 005   | 006   | 006   | 006   | 006   | 006   | 006   | 006   | 006   | 006   | 007   | 007   | 007   | 007   | 007   | 007   | 007   | 007   | 007   | 007   | 007   | 007   |                      |
|                                     | 518         | 518   | 518   | 501   | 501   | 501   | 501   | 501   | 501   | 501   | 501   | 501   | 507   | 507   | 507   | 507   | 507   | 507   | 507   | 507   | 507   | 507   | 507   | 507   |                      |
| ANIMAL ID                           | 00288       | 00287 | 00287 | 00288 | 00288 | 00287 | 00289 | 00289 | 00285 | 00286 | 00285 | 00288 | 00288 | 00286 | 00289 | 00285 | 00285 | 00286 | 00286 | 00287 | 00287 | 00288 | 00289 | 00285 |                      |
| Urinary Bladder                     | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     |                      |
| <b>SYSTEMIC LESIONS</b>             |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |                      |
| Multiple Organ                      | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     |                      |
| Leukemia Mononuclear                |             |       |       | X     | X     | X     | X     |       |       | X     |       |       | X     |       | 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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 |          |
| ANIMAL ID                           | 0064        | 0067 | 0072 | 0076 | 0077 | 0079 | 0081 | 0082 | 0086 | 0088 | 0092 | 0094 | 0098 | 0099 | 0100 | 0101 | 0102 | 0103 | 0104 | 0105 | 0106 | 0107 | 0108 | 0109 |          |
|                                     | 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    |          |
|                                     | 9           | 9    | 9    | 9    | 9    | 9    | 9    | 9    | 9    | 9    | 9    | 9    | 9    | 9    | 9    | 9    | 9    | 9    | 9    | 9    | 9    | 9    | 9    | 9    |          |

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 |
| Pheochromocytoma Malignant, Metastatic, Adrenal Medulla |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| X   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
| Mesentery   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 9  |
| Oral Mucosa   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Squamous Cell Papilloma                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Pancreas  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Salivary Glands   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Stomach, Forestomach                                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 |          |
| ANIMAL ID                           | 0064        | 0067 | 0072 | 0076 | 0077 | 0079 | 0081 | 0088 | 0088 | 0088 | 0089 | 0089 | 0089 | 0090 | 0090 | 0090 | 0090 | 0090 | 0090 | 0090 | 0090 | 0090 | 0090 | 0090 |          |
|                                     | 4           | 7    | 2    | 6    | 7    | 9    | 1    | 2    | 6    | 2    | 4    | 8    | 0    | 6    | 7    | 8    | 0    | 1    | 8    | 9    | 5    | 9    | 1    | 5    | 9        |

Tooth + 3

**CARDIOVASCULAR SYSTEM**

Blood Vessel + 50

Heart + 50

**ENDOCRINE SYSTEM**

Adrenal Cortex + 50

Adenoma X 1

Carcinoma X 1

Adrenal Medulla + 50

Pheochromocytoma Benign X 1

Pheochromocytoma Malignant X 1

Islets, Pancreatic + 50

Adenoma 1

Parathyroid Gland + M + 47

Pituitary Gland + 50

Pars Distalis, Adenoma X 20

Thyroid Gland + 50

C-cell, Adenoma X 6

**GENERAL BODY SYSTEM**

NONE

\* .. 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 |              |
| ANIMAL ID                           | 0064        | 0067 | 0072 | 0076 | 0077 | 0079 | 0081 | 0082 | 0086 | 0088 | 0092 | 0094 | 0098 | 0099 | 0100 | 0104 | 0105 | 0106 | 0107 | 0108 | 0109 | 0110 | 0111 | 0112 | 49<br>7<br>1 |

**GENITAL SYSTEM**

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

**HEMATOPOIETIC SYSTEM**

|                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |         |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------|
| Bone Marrow            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50      |
| Lymph Node             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 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 | 0       |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50      |
| Spleen                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50      |
| Thymus Thymoma Benign  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>1 |

**INTEGUMENTARY SYSTEM**

|                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Mammary Gland Adenoma      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Mammary Gland Carcinoma    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Mammary Gland Fibroadenoma |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3  |
|                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 17 |

\* .. 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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 |          |  |
| ANIMAL ID   | 0064                    | 0067 | 0072 | 0076 | 0077 | 0079 | 0081 | 0088 | 0088 | 0088 | 0089 | 0089 | 0089 | 0090 | 0095 | 0095 | 0095 | 0096 | 0096 | 0096 | 0097 | 0098 | 0099 | 0099 | 0099 |          |  |
| Fibroadenoma, Multiple                                  |                         |      |      |      |      | X    |      |      |      |      | X    |      |      |      | X    |      |      |      |      |      |      |      |      |      |      | 7        |  |
| Skin  | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |  |
| <b>MUSCULOSKELETAL SYSTEM</b>                           |                         |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |  |
| Bone  | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |  |
| <b>NERVOUS SYSTEM</b>                                   |                         |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |  |
| Brain   | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |  |
| <b>RESPIRATORY SYSTEM</b>                               |                         |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |  |
| Lung  | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |  |
| Carcinoma, Metastatic, Mammary Gland                    |                         |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 1        |  |
| Pheochromocytoma Malignant, Metastatic, Adrenal Medulla |                         |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 1        |  |
| Nose  | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |  |
| Trachea   | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |  |
| <b>SPECIAL SENSES SYSTEM</b>                            |                         |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |  |
| Eye   | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |  |
| Harderian Gland   | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |  |
| <b>URINARY SYSTEM</b>                                   |                         |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |  |
| Kidney  | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 |          |  |
| ANIMAL ID               | 0064                    | 0067 | 0072 | 0076 | 0079 | 0081 | 0082 | 0086 | 0088 | 0089 | 0092 | 0094 | 0098 | 0100 | 0102 | 0103 | 0104 | 0106 | 0108 | 0109 | 0111 | 0115 | 0118 | 0121 |          |  |
| Urinary Bladder         | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |  |
| <b>SYSTEMIC LESIONS</b> |                         |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |  |
| Multiple Organ          | +                       | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50       |  |
| Leukemia Mononuclear    | X                       |      |      |      |      |      |      |      |      | X    |      |      |      |      |      |      |      |      |      |      |      | X    |      |      | 11       |  |

\* .. 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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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 |
| 0           | 0                       | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0         | 0                    | 0 |
| 4           | 4                       | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6         | 0                    | 0 |
| 9           | 3                       | 1 | 1 | 3 | 3 | 3 | 7 | 1 | 1 | 2 | 2 | 3 | 3 | 4 | 5 | 5 | 5 | 6 | 7 | 8 | 8         | 0                    | 0 |
| 8           | 9                       | 8 | 9 | 2 | 2 | 9 | 9 | 5 | 8 | 8 | 9 | 2 | 9 | 7 | 2 | 3 | 8 | 4 | 2 | 1 | 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 |
| 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           | 1                       | 2 | 0 | 0 | 3 | 1 | 3 | 0 | 0 | 2 | 4 | 4 | 4 | 1 | 3 | 4 | 3 | 3 | 1 | 1 | 5         | 0                    | 2 |
| 3           | 5                       | 3 | 6 | 5 | 9 | 4 | 4 | 7 | 8 | 4 | 7 | 2 | 8 | 5 | 6 | 6 | 0 | 8 | 0 | 7 | 0         | 0                    | 9 |

ALIMENTARY SYSTEM

|                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Periesophageal Tissue, Lipoma |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Intestine Large, Cecum        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Colon        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Rectum       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Liver                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Mesentery                     |   |   |   |   | + |   |   | + |   |   |   |   |   | + |   |   |   |   |   |   |   |   |
| Oral Mucosa                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |
| Squamous Cell Papilloma       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |
| Pancreas                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Adenoma, Mixed Cell           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Acinus, Adenoma               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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...)  |                       |
|-------------------------------------|-------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|-----------|-----------------------|-----------------------|
|                                     | 0<br>9<br>8 | 0<br>4<br>3<br>9 | 0<br>5<br>1<br>8 | 0<br>5<br>1<br>9 | 0<br>5<br>3<br>2 | 0<br>5<br>3<br>2 | 0<br>5<br>3<br>9 | 0<br>5<br>3<br>9 | 0<br>6<br>7<br>5 | 0<br>6<br>1<br>1 | 0<br>6<br>2<br>2 | 0<br>6<br>3<br>3 | 0<br>6<br>3<br>3 | 0<br>6<br>4<br>5 | 0<br>6<br>5<br>5 | 0<br>6<br>5<br>5 | 0<br>6<br>6<br>6 | 0<br>6<br>7<br>8 | 0<br>6<br>8<br>8 | 0<br>7<br>0<br>2 | 0<br>7<br>0<br>5 |           |                       | 0<br>7<br>0<br>5      |
|                                     | 0           | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0         | 0<br>0<br>3<br>0<br>3 | 0<br>0<br>3<br>1<br>3 |

|                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Tooth              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**CARDIOVASCULAR SYSTEM**

|              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Heart        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

**ENDOCRINE SYSTEM**

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Adrenal Medulla<br>Pheochromocytoma Benign                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Islets, Pancreatic   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Parathyroid Gland  | + | + | M | + | + | + | M | + | + | + | + | + | + | + | M | M | + | + | + | + | + | M |
| Pituitary Gland<br>Pars Distalis, Adenoma                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Thyroid Gland<br>C-cell, Adenoma<br>Follicular Cell, Adenoma | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

**GENERAL BODY SYSTEM**

NONE

**GENITAL 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

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

females (cont...)

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland Adenoma                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Ovary Granulosa Cell Tumor Benign                   | + | + | + | + | + | + | + | + | + | + | + | X | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Uterus Carcinosarcoma Polyp Stromal Sarcoma Stromal | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|   |   | 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 | M | M | M | M |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Spleen                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Thymus                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

INTEGUMENTARY SYSTEM

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mammary Gland Carcinoma Fibroadenoma Fibroadenoma, Multiple | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|   |   |   |   |   |   |   |   |   |   | X | X | X |   |   |   |   |   |   | X |   | X |   |   |   | X |   |   |
| 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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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 (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 |           |                   |
| 0.3 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         |                   |
|                         | 9           | 3 | 1 | 1 | 3 | 3 | 3 | 7 | 1 | 1 | 2 | 2 | 3 | 3 | 4 | 5 | 5 | 5 | 6 | 7 | 8 | 8 | 0 | 0 | 0         |                   |
|                         | 8           | 9 | 8 | 9 | 2 | 2 | 9 | 9 | 5 | 8 | 8 | 9 | 2 | 9 | 7 | 2 | 3 | 8 | 4 | 2 | 1 | 8 | 2 | 5 | 0         |                   |
|                         | 0           | 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         |                   |

Subcutaneous Tissue, Fibroma  
 Subcutaneous Tissue, Lipoma  
 Subcutaneous Tissue, Osteosarcoma

X

**MUSCULOSKELETAL SYSTEM**

Bone  
 Osteoma  
 Osteosarcoma  
 Osteosarcoma, Metastatic, Skin

+ X + +  
 X

Skeletal Muscle  
 Rhabdomyosarcoma

**NERVOUS SYSTEM**

Brain  
 Peripheral Nerve  
 Spinal Cord

+  
 +  
 +

**RESPIRATORY SYSTEM**

Lung  
 Alveolar/Bronchiolar Adenoma, Multiple  
 Osteosarcoma, Metastatic, Skin  
 Nose  
 Trachea

+  
 X  
 +  
 +

**SPECIAL SENSES 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

| FISCHER 344 RATS FEMALE<br><br>0.3 G/KG | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<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 |                      |
|   | 9           | 3 | 1 | 1 | 3 | 3 | 3 | 7 | 1 | 1 | 2 | 2 | 3 | 3 | 4 | 5 | 5 | 6 | 7 | 8 | 8 | 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 |                      |
|   | 3           | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |                      |
|   | 0           | 1 | 2 | 0 | 0 | 3 | 1 | 3 | 0 | 0 | 2 | 4 | 4 | 4 | 1 | 3 | 4 | 3 | 3 | 1 | 1 | 5 | 0 |                      |
|   | 3           | 5 | 3 | 6 | 5 | 9 | 4 | 4 | 7 | 8 | 4 | 7 | 2 | 8 | 5 | 6 | 6 | 0 | 8 | 0 | 7 | 0 | 9 |                      |
| Eye                                     | +           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |                      |
| Harderian Gland                         | +           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |                      |
| <b>URINARY SYSTEM</b>                   |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Kidney                                  | +           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |                      |
| Urinary Bladder                         | +           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |                      |
| <b>SYSTEMIC LESIONS</b>                 |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| Multiple Organ                          | +           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |                      |
| Leukemia Mononuclear                    |             |   | X |   |   |   |   |   |   |   |   | X | 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

|   |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |                 |
|---|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|-----------------|
| <b>FISCHER 344 RATS FEMALE</b><br><b>0.3 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 |  | <b>* TOTALS</b> |
|   |             | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |  |                 |
|   |             | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |                 |
|   | ANIMAL ID   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |                 |
|   |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |                 |
|   |             | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |  |                 |
|   |             | 4 | 1 | 3 | 4 | 0 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 3 | 3 | 3 | 4 | 4 | 0 | 2 | 2 | 2 | 2 | 3 |  |                 |
|   |             | 9 | 8 | 3 | 3 | 9 | 1 | 2 | 3 | 9 | 0 | 1 | 8 | 1 | 2 | 5 | 4 | 6 | 2 | 2 | 4 | 5 | 6 | 7 |  |                 |

**ALIMENTARY SYSTEM**

|                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|
| Esophagus                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |
| Periesophageal Tissue, Lipoma |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>  |
| Intestine Large, Cecum        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |
| Intestine Large, Colon        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |
| Intestine Large, Rectum       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |
| Intestine Small, Duodenum     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |
| Intestine Small, Ileum        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |
| Intestine Small, Jejunum      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |
| Liver                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |
| Mesentery                     |   |   | + | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |   | + | <b>7</b>  |
| Oral Mucosa                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |   |   |   |   |   |   |   |   | <b>2</b>  |
| Squamous Cell Papilloma       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>  |
| Pancreas                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |
| Adenoma, Mixed Cell           |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>  |
| Acinus, Adenoma               |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   | <b>1</b>  |
| Salivary Glands               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |
| Stomach, Forestomach          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |

\* .. 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | * TOTALS |      |      |      |              |  |
|--|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|------|------|------|--------------|--|
|  | 078         | 078  | 078  | 078  | 078  | 078  | 078  | 078  | 078  | 078  | 078  | 078  | 078  | 078  | 078  | 078  | 078  | 078  | 078  | 078  |          | 078  |      |      |              |  |
| ANIMAL ID  | 0049        | 0038 | 0033 | 0034 | 0009 | 0001 | 0002 | 0003 | 0009 | 0000 | 0001 | 0008 | 0001 | 0002 | 0005 | 0004 | 0006 | 0002 | 0002 | 0004 | 0005     | 0006 | 0007 | 0001 | 0007         |  |
| Stomach, Glandular   | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | +    | +    | +    | 50           |  |
| Tooth  |             |      |      | +    |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |      |      |      | 4            |  |
| <b>CARDIOVASCULAR SYSTEM</b>                                 |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |      |      |      |              |  |
| Blood Vessel   | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | +    | +    | +    | 50           |  |
| Heart  | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | +    | +    | +    | 50           |  |
| <b>ENDOCRINE SYSTEM</b>                                      |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |      |      |      |              |  |
| Adrenal Cortex   | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | +    | +    | +    | 50           |  |
| Adrenal Medulla<br>Pheochromocytoma Benign                   | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | +    | +    | +    | 50<br>1      |  |
| Islets, Pancreatic   | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | +    | +    | +    | 50           |  |
| Parathyroid Gland  | M           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | +    | +    | +    | 44           |  |
| Pituitary Gland<br>Pars Distalis, Adenoma                    | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | +    | +    | +    | 50<br>24     |  |
| Thyroid Gland<br>C-cell, Adenoma<br>Follicular Cell, Adenoma | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +        | +    | +    | +    | 50<br>5<br>1 |  |
| <b>GENERAL BODY SYSTEM</b>                                   |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |      |      |      |              |  |
| NONE   |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |      |      |      |              |  |
| <b>GENITAL SYSTEM</b>  |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |          |      |      |      |              |  |

\* .. 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       | * TOTALS |      |
|-------------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|------|
|                                     | 0708        | 0708  | 0708  | 0708  | 0709  | 0709  | 0709  | 0709  | 0709  | 0709  | 0709  | 0709  | 0709  | 0709  | 0709  | 0709  | 0709  | 0709  | 0709  | 0709  |          | 0709 |
| ANIMAL ID                           | 00349       | 00349 | 00349 | 00349 | 00349 | 00349 | 00349 | 00349 | 00349 | 00349 | 00349 | 00349 | 00349 | 00349 | 00349 | 00349 | 00349 | 00349 | 00349 | 00349 | 00349    |      |
| Clitoral Gland Adenoma              | +           | +     | +     | X     | +     | +     | +     | +     | +     | +     | X     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | 503  |
| Ovary Granulosa Cell Tumor Benign   | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | 501  |
| Uterus Carcinosarcoma               | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | 501  |
| Polyp Stromal                       |             |       |       |       |       |       |       | X     | X     |       |       |       |       |       |       |       | X     |       |       |       | X        | 8    |
| Sarcoma Stromal                     |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          | 1    |
| <b>HEMATOPOIETIC SYSTEM</b>         |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |      |
| Bone Marrow                         | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | 50   |
| Lymph Node                          |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          | 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        | 0    |
| Lymph Node, Mesenteric              | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | 50   |
| Spleen                              | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | 50   |
| Thymus                              | +           | +     | +     | +     | +     | M     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | 49   |
| <b>INTEGUMENTARY SYSTEM</b>         |             |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |          |      |
| Mammary Gland Carcinoma             | +           | +     | +     | +     | +     | +     | +     | +     | +     | X     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | 501  |
| Fibroadenoma                        | X           |       | X     |       | X     | X     |       |       |       |       |       |       |       |       |       | X     | X     |       |       | X     |          | 13   |
| Fibroadenoma, Multiple              |             |       |       |       |       |       |       |       |       |       |       | X     |       |       |       |       |       | X     |       |       |          | 2    |
| Skin                                | +           | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +     | +        | 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                                | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 |
| <b>0.3 G/KG</b>                | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID                      | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
|                                | 4 | 1 | 3 | 4 | 0 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 3 | 3 | 3 | 4 | 4 | 0 | 2 | 2 | 2 | 2 | 3 |
|                                | 9 | 8 | 3 | 3 | 9 | 1 | 2 | 3 | 9 | 0 | 1 | 8 | 1 | 2 | 5 | 4 | 6 | 2 | 2 | 4 | 5 | 6 | 7 |
| <b>* TOTALS</b>                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

|                                   |   |  |  |  |  |  |  |  |   |  |  |  |  |  |  |  |   |  |  |  |  |  |  |
|-----------------------------------|---|--|--|--|--|--|--|--|---|--|--|--|--|--|--|--|---|--|--|--|--|--|--|
| Subcutaneous Tissue, Fibroma      | X |  |  |  |  |  |  |  |   |  |  |  |  |  |  |  | 1 |  |  |  |  |  |  |
| Subcutaneous Tissue, Lipoma       | X |  |  |  |  |  |  |  | 1 |  |  |  |  |  |  |  |   |  |  |  |  |  |  |
| Subcutaneous Tissue, Osteosarcoma | 1 |  |  |  |  |  |  |  |   |  |  |  |  |  |  |  |   |  |  |  |  |  |  |

**MUSCULOSKELETAL SYSTEM**

|                                |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  |    |
|--------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|--|--|--|--|--|--|----|
| Bone                           | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  | 50 |
| Osteoma                        | 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  |    |
| Osteosarcoma                   | X |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1 |  |  |  |  |  |  |    |
| Osteosarcoma, Metastatic, Skin | 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  |    |
| Skeletal Muscle                | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  | 1  |
| Rhabdomyosarcoma               | X |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  | 1  |

**NERVOUS SYSTEM**

|                  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |    |
|------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|
| Brain            | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50 |
| Peripheral Nerve | 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |    |
| Spinal Cord      | 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |    |

**RESPIRATORY SYSTEM**

|  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  |    |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|--|--|--|--|--|--|----|
| Lung                                   | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  | 50 |
| Alveolar/Bronchiolar Adenoma, Multiple | X |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1 |  |  |  |  |  |  |    |
| Osteosarcoma, Metastatic, Skin         | 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  |    |
| Nose                                   | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  | 50 |
| Trachea                                | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  | 50 |

**SPECIAL SENSES 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 | 0         | <b>* TOTALS</b> |
|-------------------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|-----------------|
| FISCHER 344 RATS FEMALE |  | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |           |                 |
| 0.3 G/KG                |  | 0 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |           |                 |
| ANIMAL ID               |  | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |           |                 |
|                         |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |           |                 |
|                         |  | 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 |           |                 |
|                         |  | 4 | 1 | 3 | 4 | 0 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 3 | 3 | 3 | 4 | 4 | 0 | 2 | 2 | 2 | 2 | 3 | 4 | 4 |           |                 |
|                         |  | 9 | 8 | 3 | 3 | 9 | 1 | 2 | 3 | 9 | 0 | 1 | 8 | 1 | 2 | 5 | 4 | 6 | 2 | 2 | 4 | 5 | 6 | 7 | 1 | 7 |           |                 |
| Eye                     |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |                 |
| Harderian Gland         |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |                 |
| <b>URINARY SYSTEM</b>   |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 |
| Kidney                  |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |                 |
| Urinary Bladder         |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |                 |
| <b>SYSTEMIC LESIONS</b> |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                 |
| Multiple Organ          |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |                 |
| Leukemia Mononuclear    |  | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>6</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  
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**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 FEMALE<br>1.0 G/KG | DAY ON TEST |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | ANIMAL ID | females<br>(cont...) |
|-------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------|----------------------|
|                                     | 0111        | 0112 | 0113 | 0114 | 0115 | 0116 | 0117 | 0118 | 0119 | 0120 | 0121 | 0122 | 0123 | 0124 | 0125 | 0126 | 0127 | 0128 | 0129 | 0130 | 0131 |           |                      |
|                                     | 0           | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 000364    |                      |
|                                     | 1           | 1    | 1    | 2    | 3    | 3    | 4    | 5    | 6    | 6    | 6    | 6    | 6    | 6    | 7    | 7    | 7    | 7    | 7    | 7    | 7    | 000336    |                      |
|                                     | 1           | 4    | 9    | 6    | 8    | 9    | 8    | 5    | 1    | 2    | 6    | 8    | 8    | 8    | 9    | 2    | 2    | 2    | 2    | 2    | 2    | 000336    |                      |
|                                     | 1           | 0    | 4    | 5    | 0    | 9    | 9    | 9    | 6    | 9    | 4    | 7    | 8    | 8    | 4    | 1    | 8    | 8    | 8    | 8    | 8    | 000368    |                      |
|                                     | 0           | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 000336    |                      |
|                                     | 0           | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 0    | 000336    |                      |
|                                     | 3           | 3    | 3    | 3    | 3    | 3    | 3    | 4    | 3    | 3    | 3    | 3    | 3    | 3    | 3    | 3    | 3    | 3    | 3    | 3    | 3    | 000336    |                      |
|                                     | 6           | 8    | 8    | 8    | 9    | 9    | 5    | 0    | 6    | 6    | 8    | 7    | 5    | 6    | 8    | 9    | 5    | 5    | 6    | 7    | 7    | 000336    |                      |
|                                     | 4           | 8    | 7    | 3    | 4    | 9    | 6    | 0    | 7    | 6    | 0    | 5    | 3    | 9    | 4    | 2    | 2    | 9    | 0    | 4    | 6    | 000336    |                      |

**ALIMENTARY SYSTEM**

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Cecum    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Colon    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Rectum   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Liver                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Mesentery                 |   |   |   |   |   |   |   |   | + | + |   |   |   |   | + | + |   |   |   | + |   |   |
| Pancreas                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Salivary Glands           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Stomach, Forestomach      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Stomach, Glandular        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Tooth                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |   |

**CARDIOVASCULAR SYSTEM**

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

\* .. 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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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...) |   |
|-------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|----------------------|---|
|                         | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |           |                      | 0 |
| 1.0 G/KG                | 1           | 1 | 1 | 2 | 3 | 3 | 4 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7         | 0                    |   |
|                         | 1           | 4 | 9 | 6 | 8 | 9 | 8 | 5 | 1 | 2 | 6 | 8 | 8 | 8 | 9 | 2 | 2 | 2 | 2 | 2 | 2         | 0                    |   |
|                         | 1           | 0 | 4 | 5 | 0 | 9 | 9 | 9 | 6 | 9 | 4 | 7 | 8 | 8 | 4 | 1 | 8 | 8 | 8 | 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                    |   |
|                         | 3           | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3         | 0                    |   |
|                         | 6           | 8 | 8 | 8 | 9 | 9 | 5 | 0 | 6 | 6 | 8 | 7 | 5 | 6 | 8 | 9 | 5 | 5 | 6 | 7 | 7         | 0                    |   |
|                         | 4           | 8 | 7 | 3 | 4 | 9 | 6 | 0 | 7 | 6 | 0 | 5 | 3 | 9 | 4 | 2 | 2 | 9 | 0 | 4 | 6         | 0                    |   |

Heart  
 Schwannoma Malignant, Metastatic, Lung

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

ENDOCRINE SYSTEM

Adrenal Cortex

+ +

Adrenal Medulla  
 Pheochromocytoma Benign

+ +

Islets, Pancreatic

+ +

Parathyroid Gland  
 Adenoma

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

Pituitary Gland  
 Pars Distalis, Adenoma

+ X

Thyroid Gland  
 Bilateral, C-cell, Adenoma  
 C-cell, Adenoma  
 Follicular Cell, Adenoma

+ X

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

Clitoral Gland  
 Adenoma

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

Ovary

+ +

\* .. 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 |                              |
| <b>FISCHER 344 RATS FEMALE</b> |             | 1 | 1 | 1 | 2 | 3 | 3 | 4 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |                              |
| <b>1.0 G/KG</b>                |             | 1 | 4 | 9 | 6 | 8 | 9 | 8 | 5 | 1 | 2 | 6 | 8 | 8 | 9 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |                              |
|                                |             | 1 | 0 | 4 | 5 | 0 | 9 | 9 | 9 | 6 | 9 | 4 | 7 | 8 | 8 | 4 | 1 | 8 | 8 | 8 | 8 | 8 | 8 | 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 |                              |
|                                |             | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |                              |
|                                |             | 6 | 8 | 8 | 8 | 9 | 9 | 5 | 0 | 6 | 6 | 8 | 7 | 5 | 6 | 8 | 9 | 5 | 5 | 6 | 7 | 7 | 8 | 9 |                              |
|                                |             | 4 | 8 | 7 | 3 | 4 | 9 | 6 | 0 | 7 | 6 | 0 | 5 | 3 | 9 | 4 | 2 | 2 | 9 | 0 | 4 | 6 | 6 | 3 | <b>females<br/>(cont...)</b> |

Carcinoma, Metastatic, Lung

X

Uterus

Polyp Stromal

Endometrium, Adenoma

+  
 X X X X

**HEMATOPOIETIC SYSTEM**

Bone Marrow

+ +

Lymph Node

Mediastinal, Carcinoma, Metastatic, Lung

+  
X

Lymph Node, Mandibular

M M

Lymph Node, Mesenteric

+ +

Spleen

Carcinoma, Metastatic, Lung

+  
X

Thymus

Schwannoma Malignant, Metastatic, Lung

+ + + + + M +  
X

**INTEGUMENTARY SYSTEM**

Mammary Gland

Fibroadenoma

+  
X X X X

Skin

+ +

**MUSCULOSKELETAL SYSTEM**

Bone

+ +

\* .. 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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
|-------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|
|                         | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
| 1.0 G/KG                | 1           | 1 | 1 | 2 | 3 | 3 | 4 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |                      |
|                         | 1           | 4 | 9 | 6 | 8 | 9 | 8 | 5 | 1 | 2 | 6 | 8 | 8 | 9 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |                      |
|                         | 1           | 0 | 4 | 5 | 0 | 9 | 9 | 9 | 6 | 9 | 4 | 7 | 8 | 8 | 4 | 1 | 8 | 8 | 8 | 8 | 8 | 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 |                      |
|                         | 3           | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |                      |
|                         | 6           | 8 | 8 | 8 | 9 | 9 | 5 | 0 | 6 | 6 | 8 | 7 | 5 | 6 | 8 | 9 | 5 | 5 | 6 | 7 | 7 | 8 | 9 |                      |
|                         | 4           | 8 | 7 | 3 | 4 | 9 | 6 | 0 | 7 | 6 | 0 | 5 | 3 | 9 | 4 | 2 | 2 | 9 | 0 | 4 | 6 | 6 | 3 | females<br>(cont...) |

**NERVOUS SYSTEM**

|                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Brain                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Granular Cell Tumor Benign |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |

**RESPIRATORY SYSTEM**

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lung                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Alveolar/Bronchiolar Adenoma      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Alveolar/Bronchiolar Carcinoma    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |
| Mediastinum, Schwannoma Malignant |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |
| Nose                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Pleura                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |   |   |
| Trachea                           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

**SPECIAL SENSES SYSTEM**

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

**URINARY SYSTEM**

|        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|--------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

\* .. 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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> |
|                                | 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 | 2 | 3 | 3 | 4 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |  |                              |
|                                | 1           | 4 | 9 | 6 | 8 | 9 | 8 | 5 | 1 | 2 | 6 | 8 | 8 | 8 | 9 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |  |                              |
| <b>1.0 G/KG</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 |  |                              |
|                                | 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 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |  |                              |
|                                | 6           | 8 | 8 | 8 | 9 | 9 | 5 | 0 | 6 | 6 | 8 | 7 | 5 | 6 | 8 | 9 | 5 | 5 | 6 | 7 | 7 | 8 | 9 | 6 |  |                              |
| 4                              | 8           | 7 | 3 | 4 | 9 | 6 | 0 | 7 | 6 | 0 | 5 | 3 | 9 | 4 | 2 | 2 | 9 | 0 | 4 | 6 | 6 | 3 | 3 | 1 |  |                              |

Urinary Bladder

+ +

**SYSTEMIC LESIONS**

Multiple Organ  
 Leukemia Mononuclear  
 Lymphoma Malignant

+  
 X X X 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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 FEMALE</b> | <b>1.0 G/KG</b> | 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 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7               | 7 | 7 | 7 |
|                                |                 | 2           | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3               | 3 | 3 |   |
|                                |                 | 9           | 9 | 9 | 9 | 9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 | 0 |   |
|                                |                 | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 | 0 |   |
|                                |                 | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 | 0 |   |
|                                |                 | 3           | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3               | 3 | 3 |   |
|                                |                 | 7           | 8 | 8 | 9 | 9 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 8 | 8               | 9 | 9 |   |
|                                |                 | 8           | 2 | 5 | 5 | 6 | 1 | 4 | 5 | 7 | 8 | 1 | 2 | 5 | 8 | 0 | 2 | 3 | 7 | 9 | 1 | 9               | 0 | 8 |   |
|                                |                 |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>* TOTALS</b> |   |   |   |

**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 |   |
| Mesentery                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + | + |   |   | + | +  | 9 |
| Pancreas                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Salivary Glands           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Stomach, Forestomach      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Stomach, Glandular        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Tooth                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + | 2  |   |

**CARDIOVASCULAR SYSTEM**

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

**P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)**

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 |
|-------------------------------------|-------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|----------|
|                                     | 0729        | 0729   | 0729   | 0729   | 0729   | 0729   | 0729   | 0729   | 0729   | 0729   | 0729   | 0729   | 0729   | 0729   | 0729   | 0729   | 0729   | 0729   | 0729   | 0729   | 0729   | 0729   | 0729   | 0729   |          |
| ANIMAL ID                           | 003788      | 003788 | 003788 | 003788 | 003788 | 003788 | 003788 | 003788 | 003788 | 003788 | 003788 | 003788 | 003788 | 003788 | 003788 | 003788 | 003788 | 003788 | 003788 | 003788 | 003788 | 003788 | 003788 | 003788 |          |

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |         |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------|
| Heart<br>Schwannoma Malignant, Metastatic, Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>1 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------|

**ENDOCRINE SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |         |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------|
| Adrenal Cortex                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50      |
| Adrenal Medulla<br>Pheochromocytoma Benign  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>1 |
| Islets, Pancreatic                          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50      |
| Parathyroid Gland<br>Adenoma                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 47<br>1 |
| Pituitary Gland<br>Pars Distalis, Adenoma   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>8 |
| Thyroid Gland<br>Bilateral, C-cell, Adenoma | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>1 |
| C-cell, Adenoma                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4       |
| Follicular Cell, Adenoma                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1       |

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |         |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------|
| Clitoral Gland<br>Adenoma | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49<br>1 |
| Ovary                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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 |
|-------------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|
|                                     | 0729        | 0729  | 0729  | 0729  | 0729  | 0729  | 0729  | 0729  | 0729  | 0729  | 0729  | 0729  | 0729  | 0729  | 0729  | 0729  | 0729  | 0729  | 0729  | 0729  | 0729  | 0729  | 0729  | 0729  |          |
| ANIMAL ID                           | 00378       | 00378 | 00378 | 00378 | 00378 | 00378 | 00378 | 00378 | 00378 | 00378 | 00378 | 00378 | 00378 | 00378 | 00378 | 00378 | 00378 | 00378 | 00378 | 00378 | 00378 | 00378 | 00378 | 00378 | 00378    |
|                                     | 0           | 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     | 7     | 7     | 7     | 7     | 7     | 7     | 7     | 7     | 7     | 7     | 7     | 7     | 7     | 7     | 7        |
|                                     | 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        |
|                                     | 9           | 9     | 9     | 9     | 9     | 9     | 9     | 9     | 9     | 9     | 9     | 9     | 9     | 9     | 9     | 9     | 9     | 9     | 9     | 9     | 9     | 9     | 9     | 9     | 9        |
|                                     | 0           | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0        |
|                                     | 0           | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0        |
|                                     | 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        |
|                                     | 7           | 8     | 8     | 9     | 9     | 5     | 5     | 5     | 5     | 5     | 6     | 6     | 6     | 6     | 7     | 7     | 7     | 7     | 7     | 8     | 8     | 9     | 9     | 9     | 9        |
|                                     | 8           | 2     | 5     | 5     | 6     | 1     | 4     | 5     | 7     | 8     | 1     | 2     | 5     | 8     | 0     | 2     | 3     | 7     | 9     | 1     | 9     | 0     | 1     | 7     | 8        |

Carcinoma, Metastatic, Lung

1

Uterus

+ +

50

Polyp Stromal

X X X X

8

Endometrium, Adenoma

X

1

HEMATOPOIETIC SYSTEM

Bone Marrow

+ +

50

Lymph Node

+ +

2

Mediastinal, Carcinoma, Metastatic, Lung

1

Lymph Node, Mandibular

M M

0

Lymph Node, Mesenteric

+ +

50

Spleen

+ +

50

Carcinoma, Metastatic, Lung

1

Thymus

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

48

Schwannoma Malignant, Metastatic, Lung

1

INTEGUMENTARY SYSTEM

Mammary Gland

+ +

50

Fibroadenoma

X

4

Skin

+ +

50

MUSCULOSKELETAL SYSTEM

Bone

+ +

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

|  |                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 |   |   |   |   |   |   |   |   |   |   |   |   |
|--|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|
|  |                         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 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 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7               | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |   |
|  | FISCHER 344 RATS FEMALE | 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 | 2 | 2 | 2               | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
|  | 1.0 G/KG                | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9               | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
|  |                         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  | 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 |
|  |                         | 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 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
|  |                         | 7 | 8 | 8 | 8 | 9 | 9 | 9 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 8 | 8 | 9 | 9 | 9 | 9 | 9               | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
|  |                         | 8 | 2 | 5 | 5 | 6 | 1 | 4 | 5 | 7 | 8 | 1 | 2 | 5 | 8 | 0 | 2 | 3 | 7 | 9 | 1 | 9 | 0 | 0 | 1 | 9 | 0 | 0 | 1               | 7 | 8 | 7 | 8 | 8 | 9 | 0 | 1 | 7 | 8 | 8 | 8 |
|  |                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>* TOTALS</b> |   |   |   |   |   |   |   |   |   |   |   |   |

**NERVOUS SYSTEM**

|                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Brain                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Granular Cell Tumor Benign |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |

**RESPIRATORY SYSTEM**

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|
| Lung                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | 50 |
| Alveolar/Bronchiolar Adenoma      |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1  |
| Alveolar/Bronchiolar Carcinoma    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1  |
| Mediastinum, Schwannoma Malignant |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 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            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |

**URINARY SYSTEM**

|        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|--------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 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

P17: NEOPLASMS BY INDIVIDUAL ANIMAL (SYSTEMIC LESIONS ABRIDGED)

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>1.0 G/KG | 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 |          |  |  |
|   | 7           | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 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 |          |  |  |
|   | 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 |          |  |  |
|   | 7           | 8 | 8 | 9 | 9 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 8 | 8 | 9 | 9 | 9 |          |  |  |
|   | 8           | 2 | 5 | 5 | 6 | 1 | 4 | 5 | 7 | 8 | 1 | 2 | 5 | 8 | 0 | 2 | 3 | 7 | 9 | 1 | 9 | 0 | 1 | 7 | 8        |  |  |
| Urinary Bladder                         | +           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50       |  |  |
| <b>SYSTEMIC LESIONS</b>                 |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |  |  |
| Multiple Organ                          | +           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50       |  |  |
| Leukemia Mononuclear                    | X           |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   | X |   |   | X |   |   |   | 9 |          |  |  |
| Lymphoma Malignant                      |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |          |  |  |

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

\* .. 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