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APPLICATION NUMBER: 019651/S005

PHARMACOLOGY REVIEW(S)

Pages: 51 through 75

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PLACES V0.200

Oncogenicity Study (24-Months) of 5-ASA in the Diet of Swiss Mice
Project No. 862.09.00-CD
Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	1200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
DIGESTIVE SYSTEM:-											
COLON:											
No abnormality detected		(47)	(49)	(48)	(50)	#	#	(49)	(49)	(50)	#
Metastatic site: HISTIOCYTIC SARCOMA (M)		39	35	43	42	#	#	35	36	40	#
Focal/multifocal acute/chronic inflammation		1	2			#	#	3	2	1	#
Focal vasculitis			1			#	#	1			#
LYMPHOMA (M)		3	2			#	#	2	3	1	#
Focal hemorrhage						#	#		1		#
Multifocal crypt dilation					1	#	#				#
Dilation						#	#				#
Autolysis		3	8	5	6	#	#	7	10	8	#
Multifocal amyloidosis		1			2	#	#	2	1	1	#

Figures in brackets represent the number of animals from which this tissue was examined microscopically .
The absence of a numeral indicates that the lesion specified was not identified

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Oncogenicity Study (24-Months) of 5-ASA in the Diet of Swiss Mice
Project No. 862.09.00-CD
Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
DIGESTIVE SYSTEM:-											
DUODENUM:											
No abnormality detected		(48)	(48)	(49)	(47)	#					#
Metastatic site: HISTIOCYTIC SARCOMA (M)		32	27	34	27	#	26	28	28	28	#
Metastatic site: GRANULOCYTIC LEUKEMIA (M)			1		1	#	2		1		#
Focal/multifocal acute/subacute/chronic transmural/NOS inflammation		1		1		#		2	2	2	#
Multifocal mucosal mineralization						#				1	#
LYMPHOMA (M)		1	1			#	1	1	2	1	#
Multifocal lymphocytic infiltration						#		1	1		#
Diffuse/NOS luminal hemorrhage			1			#				1	#
Multifocal lamina propria fibrosis						#			1		#

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Oncogenicity Study (24-Months) of S-ASA in the Diet of Swiss Mice
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Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
DIGESTIVE SYSTEM:-											
DUODENUM:											
Multifocal crypt dilation		(48)	(48)	(49)	(47)	#	(50)	(49)	(47)	(47)	#
Multifocal lymphatic dilation						#	1		1		#
Dilation						#	1				#
Autolysis		9	13	10	15	#	11	10	10	10	#
Multifocal/diffuse amyloidosis		8	12	6	7	#	16	12	8	8	#
ADENOMA (8)						#				1	#
ESOPHAGUS:						#	(49)	(49)	(49)	(50)	#
No abnormality detected		(48)	(50)	(49)	(47)	#	(49)	(49)	(49)	(50)	#
Focal/multifocal/diffuse mucosal/submucosal/adventitial acute/subacute/chronic inflammation		45	49	45	42	#	47	49	44	49	#
		1		3	3	#			3	1	#

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Oncogenicity Study (24-Months) of 5-ASA in the Diet of Swiss Mice
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Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	INCIDENCE OF OBSERVATION (NUMERIC)											
	MALES						FEMALES					
	TREATMENT	0	200	1000	2000	#	0	200	1000	2000	#	
		mg/kg	mg/kg	mg/kg	mg/kg			mg/kg	mg/kg	mg/kg		
DIGESTIVE SYSTEM:-												
ESOPHAGUS:		(48)	(50)	(49)	(47)			(49)	(49)	(50)		
LYMPHOMA (N)		2		1					2			
Luminal hemorrhage					1							
Dilation												
Autolysis			1					1				
Metastatic site: bronchiolar-alveolar					1							
ADENOCARCINOMA (N)												
Adventitial abscess(es)												
GALLBLADDER:		(46)	(46)	(43)	(46)			(47)	(45)	(47)		
No abnormality detected		27	18	20	20			13	16	15		
Metastatic site: HISTIOCYTIC SARCOMA (N)			1		1			2				

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Oncogenicity Study (24-Months) of S-ASA in the Diet of Swiss Mice
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Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
DIGESTIVE SYSTEM:-											
GALLBLADDER:											
Metastatic site: GRANULOCYTIC LEUKEMIA (N)		(46)	(46)	(43)	(46)	1	(47)	(45)	(46)	(47)	
Focal/multifocal/diffuse acute/subacute/chronic inflammation		13	10	14	12	15	13	13	13	16	
Focal PAPILLOMA (8)		1						1	1		
Diffuse submucosal edema								1			
Diffuse mineralization			1								
LYMPHOMA (N)		1	1			2	2	2	4		
Focal/multifocal papillary hyperplasia					3			1			
Dilation		3	6	3	2	8	2	2	6	9	
Multifocal congestion									1		

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Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
DIGESTIVE SYSTEM:-											
GALLBLADDER:											
Autolysis		(46)	(46)	(43)	(46)	# (47)	(45)	(46)	(47)		
Multifocal amyloidosis		4	10	9	12	# 11	11	7	11		
ILEUM:											
No abnormality detected		(48)	(47)	(49)	(49)	# (47)	(47)	(48)	(50)		
Metastatic site: HISTIOCYTIC SARCOMA (M)		28	18	25	23	# 18	20	26	23		
Metastatic site: GRANULOCYTIC LEUKEMIA (M)			1			# 3	1	2	1		
Focal/multifocal acute/chronic inflammation			1		1	#					
Multifocal lymphocytolysis				2		#	2	2	2		
Focal/multifocal vasculitis						# 1					
		1	1	1		# 1	1				

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Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
DIGESTIVE SYSTEM:-											
ILEUM:											
Metastatic site: MESOTHELIOMA (M)		(48)	(47)	(49)	(49)	0	0	0	0	0	0
LYMPHOMA (M)		1				0	0	0	0	0	0
Multifocal lymphangiectasis		2	1	1	1	0	2	1	1	2	0
Multifocal/diffuse mucosal hemorrhage				2		0	0	1			0
Dilation						0	0	1			0
Autolysis		8	13	10	17	0	0	11	10	10	0
Multifocal/diffuse amyloidosis		12	19	12	11	0	0	21	18	18	0
		(50)	(50)	(49)	(48)	0	0	(49)	(50)	(47)	0
JEJUNUM:											
No abnormality detected		35	26	29	25	0	0	22	24	26	0
Metastatic site: HISTIOCYTIC SARCOMA (M)			1		1	0	0	3	2	2	0

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Oncogenicity Study (24-Months) of 5-ASA in the Diet of Swiss Mice
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Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
DIGESTIVE SYSTEM:-											
JEJUNUM:											
Diffuse submucosal edema		(50)	(50)	(49)	(48)	#	#	#	#	#	#
LYMPHOMA (M)		1		1		#	#	#	#	#	#
Focal/multifocal acute/subacute/chronic granulomatous inflammation			1	1	2	#	#	#	1	2	
Diffuse luminal neutrophilic infiltration				1		#	#	#	#	#	#
Diffuse mesothelial cell hypertrophy				1		#	#	#	#	#	#
Multifocal lymphoid hyperplasia		1				#	#	#	#	#	#
Diffuse hemorrhage				1		#	#	#	#	#	#
Multifocal crypt dilation			1			#	#	#	#	#	#
Multifocal lymphatic dilation						#	#	1		1	

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Oncogenicity Study (24-Months) of 5-ASA in the Diet of Swiss Mice
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Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
DIGESTIVE SYSTEM:-											
JEJUNUM:											
Dilation		(50)	(50)	(49)	(48)	#	#	#	#	#	#
Multifocal congestion				1		#	#	(49)	(48)	(50)	(47)
Autolysis		7	13	10	14	#	#	11	10	10	8
Multifocal/diffuse amyloidosis		8	14	8	9	#	#	15	12	8	11
LIVER:		(50)	(49)	(50)	(50)	#	#	(50)	(50)	(50)	(50)
No abnormality detected		6	5	6	1	#	#	1	2	1	3
Single/focal/multiple basophilic-cell focus(1)		2		2	2	#	#	1	1		
Single/focal vacuolated cell focus(1)			1		1	#	#	1			
Metastatic site: HISTIOCYTIC SARCOMA (M)			2			#	#	4	1	3	3
Primary site: HISTIOCYTIC SARCOMA (M)		1	2		2	#	#	2	2	2	1

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Oncogenicity Study (24-Months) of 5-ASA in the Diet of Swiss Mice
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Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
DIGESTIVE SYSTEM:-											
LIVER:											
Metastatic site: GRANULOCYTIC LEUKEMIA (N)		(50)	(49)	(50)	(50)	1	(50)	(50)	(50)	(50)	
Increased mitotic index		1									
Focal/multifocal/diffuse/centrilobular hepatocellular vacuolation		3	3	5	5	1	1	4	5	3	
Focal telangiectasis				1			1				
Multifocal pigmentation								1	1	1	
Focal/multifocal hepatocellular/single-cell/NOS necrosis		4	2	6	6		7	4	7	11	
Multifocal mineralization							1				
LYMPHOMA (N)		2	2	1	2	3	3	3	3	2	
Multifocal karyomegaly				1							

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Oncogenicity Study (24-Months) of 3-ASA in the Diet of Swiss Mice
Project No. B62.09.00-CD
Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
DIGESTIVE SYSTEM:-											
LIVER:											
Focal/multifocal acute/chronic/chronic-active inflammation		(50)	(49)	(50)	(50)	33	35	38	38	(50)	(50)
Focal/multifocal hepatocellular hypertrophy		1			1						
HEPATOCELLULAR CARCINOMA (M)		6		7	1						
Focal/multifocal/NOS HEPATOCELLULAR ADENOMA (B)		3	3	1	3					2	1
Multifocal hemorrhage					1						
Multifocal extramedullary hematopoiesis											
Metastatic site: HEMANGIOSARCOMA (M)									1	1	
Primary site: HEMANGIOSARCOMA (M)		1		2							

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Oncogenicity Study (24-Months) of 5-ASA in the Diet of Swiss Mice
Project No. 862.09.00-CD
Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
DIGESTIVE SYSTEM:-											
LIVER:											
Focal/NOS HEMANGIOMA (8)		(50)	(49)	(50)	(50)	2	(50)	(50)	(50)	(50)	1
Multifocal centrilobular/NOS fibrosis		2	1	1	1	1	1	1	1	1	1
Focal/multifocal/diffuse sinusoidal dilatation			1	1	1	1					1
Multifocal capsular fibrinous deposition								1			
Focal cyst(s)		2				2	1				
Multifocal/diffuse/NOS congestion				1	2			2			
Autolysis		3	2	5	3	3	5	8	3	6	
Multifocal centrilobular angiectasis					1						
Multifocal amyloidosis		5	13	4	6	5	13	10	7	8	

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Oncogenicity Study (24-Months) of 5-ASA in the Diet of Swiss Mice
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Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
DIGESTIVE SYSTEM:-											
PANCREAS:		(50)	(49)	(50)	(50)	#	(50)	(50)	(50)	(50)	#
No abnormality detected		13	17	16	15	#	11	11	7	6	#
Metastatic site: HISTIOCYTIC SARCOMA (M)			2		2	#	5	1	4	2	#
Metastatic site: GRANULOCYTIC LEUKEMIA (M)			1			#					#
Focal islet subacute inflammation						#			1		#
Focal/multifocal/diffuse interstitial/NOS acute/subacute/chronic inflammation		22	20	24	22	#	19	21	24	27	#
Focal/multifocal vasculitis		2	1	1		#	2	1		1	#
Multifocal/diffuse interstitial edema				1		#	1		2		#
Focal/multifocal vascular mineralization		1	1	2		#					#

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Oncogenicity Study (24-Months) of 5-ASA in the Diet of Swiss Mice
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		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
DIGESTIVE SYSTEM:-											
PANCREAS:											
LYMPHOMA (N)											
Focal/multifocal/MOS peripancratic Inflammation		3	2	1	2	5	4	3	6	4	50
Multifocal islet cell hyperplasia		5	4	3	3	2	2	2	2	2	50
Focal interstitial hemorrhage				1		1					
Focal ductular dilation		1									
Multifocal cyst(s)		1									
Autolysis		4	6	3	4	4	4	9	5	5	50
Focal/multifocal/diffuse acinar atrophy		1	1	1		1	1		1	1	50
Focal/multifocal/MOS islet/interstitial/lobular amyloidosis			2	1	1	2	2	3	2	3	50

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Oncogenicity Study (24-Months) of 5-ASA in the Diet of Swiss Mice
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OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
DIGESTIVE SYSTEM:-											
PANCREAS:											
Focal/multifocal/diffuse acinar cell alteration		(50)	(49)	(50)	(50)	# (50)	(50)	(50)	(50)	(50)	#
		3	6	9	7	# 10	6	7	9	9	#
RECTUM:											
Metastatic site: HISTIOCYTIC SARCOMA (M)					(1)	# (1)					#
Focal hematocyst(s)					1	# 1					#
SALIVARY GLAND(S):											
No abnormality detected		(50)	(50)	(50)	(50)	# (50)	(50)	(49)	(50)	(50)	#
		14	13	14	13	# 9	14	14	12	12	#
Metastatic site: HISTIOCYTIC SARCOMA (M)			3		1	# 1	1	2	2	2	#
Metastatic site: GRANULOCYTIC LEUKEMIA (M)			1		1	#					#
Focal/multifocal/pericapsular acute/subacute/chronic inflammation		25	22	28	27	# 28	26	25	28	28	#

Figures in brackets represent the number of animals from which this tissue was examined microscopically . . .
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		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
DIGESTIVE SYSTEM:-											
SALIVARY GLAND(S):											
Focal/multifocal vasculitis											
Focal mineralization											
LYMPHOMA (M)											
Focal acinar hyperplasia											
Focal/multifocal ductular dilation											
Multifocal acinar dilation											
Multifocal cytomegaly											
Autolysis											
Focal acinar atrophy											
Multifocal amyloidosis											

Figures in brackets represent the number of animals from which this tissue was examined microscopically
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		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
DIGESTIVE SYSTEM:-											
SALIVARY GLAND(S):											
Focal ADENOMA (B)		(50)	(50)	(50)	(50)	# (50)	(50)	(49)	1	(50)	#
STOMACH:											
No abnormality detected						#					
Metastatic site: MISTOCYTIC SARCOMA (M)						#					
Metastatic site: GRANULOCYTIC LEUKEMIA (M)						#					
Focal polyp(s)						#					
Focal/multifocal/diffuse mucosal/submucosal/NOs acute/subacute/chronic inflammation						#					
Focal/multifocal vasculitis						#					
Multifocal vascular thrombosis						#					

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		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
DIGESTIVE SYSTEM:-											
STOMACH:											
SQUAMOUS CELL CARCINOMA (M)		(50)	(50)	(50)	(50)	#	(50)	(50)	(50)	(50)	#
focal/diffuse submucosal edema		1				#					#
focal/multifocal mucosal erosion(s)/ulceration(s)/necrosis		3	5	4	6	#		1		1	#
focal/multifocal mineralization		2	3		1	#			1	3	#
focal glandular squamous metaplasia		3	2	1	2	#		1	4	2	#
LYMPHOMA (M)											
focal luminal neutrophilic infiltration						#					#
focal/multifocal squamous epithelial hyperplasia				2		#			1		#
focal/multifocal/diffuse glandular mucosal hyperplasia		4	1	1	1	#		2	1		#

figures in brackets represent the number of animals from which this tissue was examined microscopically
the absence of a numeral indicates that the lesion specified was not identified

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Oncogenicity Study (24-Months) of 5-ASA in the Diet of Swiss Mice
Project No. 862.09.00-CD
Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
DIGESTIVE SYSTEM:-											
STOMACH:											
Focal glandular hyperplasia		(50)		(50)	(50)	#					#
Focal/multifocal/diffuse/MOS hyperkeratosis		1				#					#
		5	4		5	#		7	9	5	#
Multifocal mucosal hemorrhage				1		#					#
Focal mucosal fibrosis		1	1			#					#
Focal/multifocal glandular dilation		26	27	28	22	#	18	18	21	25	#
CARCINOMA (M)		2				#					#
Autolysis		4	6	5	5	#	5	7	3	7	#
Focal/multifocal/diffuse/MOS glandular mucosal atrophy		2				#	2			1	#
Focal/multifocal/diffuse mucosal/submucosal amyloidosis		7	7	5	5	#	8	3	2	5	#

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Oncogenicity Study (24-Months) of 5-ASA in the Diet of Swiss Mice
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Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
DIGESTIVE SYSTEM:-											
TONGUE:											
No abnormality detected		(50)	(49)	(48)	(50)	#	(49)	(48)	(50)	(48)	#
Metastatic site: HISTIOCYTIC SARCOMA (H)		45	42	45	46	#	40	43	39	42	#
Focal/multifocal/NOS acute/subacute/chronic inflammation		2	3	1	3	#	4	1	3	2	#
Focal/multifocal vasculitis		1	2	1		#	3	4	5	3	#
Multifocal edema		1				#					#
Multifocal myofiber/vascular mineralization					1	#	1				#
LYMPHOMA (H)		1		1		#	1		3		#
Multifocal hemorrhage			1			#					#
Autolysis			1			#					#

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Oncogenicity Study (24-Months) of 5-ASA in the Diet of Swiss Mice
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Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
ENDOCRINE SYSTEM:-											
ADRENAL GLAND(S):		(49)	(48)	(50)	(49)	#	#	(50)	(50)	(50)	#
No abnormality detected		7	4	5	6	#	#	1			#
PHEOCHROMOCYTOMA (M)			1			#	#				#
Focal/NOS MEDULLARY-CELL ADENOMA (S)		1			3	#	1		1		#
One medulla		4	4	8	7	#	5	5	3	6	#
Focal/multiple/NOS CORTICAL-CELL ADENOMA (S)		3	3	3	4	#	#		1		#
Metastatic site: NISTIOCYTIC SARCOMA (M)		1	4		1	#	4	3	4	2	#
No medulla			1	1	2	#	3	2	1		#
Focal/multifocal clear-cell focus(I)		1	1	1		#	#				#
Metastatic site: GRANULOCYTIC LEUKEMIA (M)			1			#	#				#

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Oncogenicity Study (24-Months) of 5-ASA in the Diet of Swiss Mice
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Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
ENDOCRINE SYSTEM:-											
ADRENAL GLAND(S):											
Focal/multifocal/diffuse/NOS pericapsular/capsular/cortical/medullary /NOS acute/subacute/chronic inflammation		(49)	(48)	(50)	(49)	#	(50)	(50)	(50)	(50)	#
		7	4	6	6	#	6	6	5	14	#
One examined		7	7	7	9	#	2	3	1	1	#
Focal/multifocal/diffuse cortical cell vacuolation		8	10	14	9	#	21	21	23	21	#
Focal thrombus						#	1				#
Multifocal medullary edema						#		1			#
Focal/multifocal/NOS medullary/NOS mineralization			1	2	1	#	2	5	1		#
Metastatic site: MESOTHELIOMA (M)		1				#					#
LYMPHOMA (M)		2	2	1	2	#	4	4	4	2	#

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Oncogenicity Study (24-Months) of 5-ASA in the Diet of Swiss Mice
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Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
ENDOCRINE SYSTEM:-											
ADRENAL GLAND(S):											
Focal/multifocal medullary cell hypertrophy		(49)	(48)	(50)	(49)	#	(50)	1	1	1	#
Focal/multifocal/diffuse cortical cell hypertrophy		6	4	5	8	#	2	1			#
Focal/multifocal/diffuse subcapsular cell hyperplasia		25	19	22	18	#	44	48	49	48	#
Focal/multifocal/diffuse medullary cell hyperplasia		1	2	1	4	#	4	4	3	4	#
Focal/multifocal cortical hyperplasia		2	1	4	1	#	3			1	#
Focal/multifocal extramedullary hematopoiesis					1	#		2	1		#
Focal fibrosis		1		1		#					#
Focal/multifocal cortical ectopia		2	5	5	4	#	12	3	8	6	#

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Oncogenicity Study (24-Months) of 5-ASA in the Diet of Swiss Mice
Project No. 862.09.00-CD
Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	200 mg/kg	1000 mg/kg	2000 mg/kg	#
ENDOCRINE SYSTEM:-											
ADRENAL GLAND(S):											
Focal cortical cyst(s)		(49)	(48)	(50)	(49)	#	(50)	(50)	(50)	(50)	#
Multifocal/diffuse/NOS congestion		1	1	1	2	#	1	3	1	2	#
Autolysis			2		2	#		1			#
Diffuse/NOS cortical atrophy		1	3	1	2	#	3	1	1		#
Multifocal/diffuse/NOS amyloidosis		10	13	8	10	#	12	12	9	8	#
Subcapsular-cell ADENOMA (B)						#		1			#
PARATHYROID GLAND(S):						#					#
No abnormality detected		(37)	(43)	(33)	(41)	#	(34)	(37)	(46)	(42)	#
Metastatic site: HISTIOCYTIC SARCOMA (M)		32	34	30	36	#	23	23	32	31	#
Focal/multifocal/diffuse subacute inflammation		2			1	#	1	4	6	4	#

Figures in brackets represent the number of animals from which this tissue was examined microscopically
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Oncogenicity Study (24-Months) of 5-ASA in the Diet of Swiss Mice
Project No. 862.09.00-CD
Pathology Table 7
Summary of all Histomorphologic Findings

OBSERVATIONS	TREATMENT	INCIDENCE OF OBSERVATION (NUMERIC)									
		MALES					FEMALES				
		0 mg/kg	1200 mg/kg	1000 mg/kg	2000 mg/kg	#	0 mg/kg	1000 mg/kg	2000 mg/kg	#	
ENDOCRINE SYSTEM:-											
PARATHYROID GLAND(S):		(37)	(43)	(33)	(41)	#	(34)	(46)	(42)	#	
LYMPHOMA (H)						#	1			#	
Focal/diffuse hyperplasia						#	1	2	1	#	
Ectopia						#	1			#	
Multifocal/diffuse/NOS amyloidosis		3	9	3	4	#	7	8	7	#	
: One examined.		28	30	22	29	#	22	29	28	#	
PITUITARY:		(47)	(50)	(49)	(48)	#	(48)	(47)	(49)	#	
No abnormality detected		41	46	47	42	#	38	39	40	#	
Metastatic site: HISTIOCYTIC SARCOMA (H)						#	1	:		#	
Focal acute/subacute inflammation						#		2		#	
Focal pigmentation						#			1	#	

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