

TDMS No. 99007 - 05
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Goldenseal root powder
CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
Time Report Requested: 08:34:31
First Dose M/F: 04/21/03 / 04/21/03
Lab: SRI

F1_R2

C Number: C99007B
Lock Date: 08/07/2006
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.0.0

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HISTORICAL CONTROL STUDIES From October 2007 Report

SAME ROUTE

88138-03 -- Benzophenone (ORAL FEED)
99027-03 -- Chromium picolinate monohydrate (ORAL FEED)
05174-05 -- Cresols (ORAL FEED)
92012-05 -- 2-Methylimidazole (ORAL FEED)
92013-05 -- 4-Methylimidazole (ORAL FEED)

ALL ROUTES

88138-03 -- Benzophenone (ORAL FEED)
99027-03 -- Chromium picolinate monohydrate (ORAL FEED)
05174-05 -- Cresols (ORAL FEED)
96011-05 -- Cumene (INHALATION AIR)
97003-07 -- 1,2-Dibromo-2,4-dicyanobutane (SKIN ETHANOL)
93020-07 -- Diisopropylcarbodiimide (SKIN ETHANOL)
88004-05 -- Divinylbenzene (INHALATION AIR)
88123-05 -- Formamide (GAVAGE WATER)
95011-07 -- 5-(Hydroxymethyl)-2-furfural (GAVAGE WATER)
88105-03 -- Isoeugenol (GAVAGE CORN OIL)
97006-01 -- Methyl isobutyl ketone (INHALATION AIR)
91005-07 -- Methylene blue trihydrate (GAVAGE METHYLCELLULOSE)
92012-05 -- 2-Methylimidazole (ORAL FEED)
92013-05 -- 4-Methylimidazole (ORAL FEED)
88006-03 -- alpha-Methylstyrene (INHALATION AIR)
99023-03 -- beta-Myrcene (GAVAGE CORN OIL)
97008-05 -- Propargyl alcohol (INHALATION AIR)
20114-07 -- Sodium dichromate dihydrate (VI) (ORAL WATER)
96001-05 -- Stoddard solvent (type IIC) (INHALATION AIR)
96019-05 -- Water disinfection byproducts (Bromochloroacetic acid) (ORAL WATER)

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HISTORICAL CONTROL STUDIES
From October 2007 Report

96018-03 -- Water disinfection byproducts (Bromodichloromethane) (ORAL WATER)
96017-05 -- Water disinfection byproducts (Dibromoacetic acid) (ORAL WATER)
96015-05 -- Water disinfection byproducts (Dibromoacetonitrile) (ORAL WATER)
96010-03 -- Water disinfection byproducts (Sodium chlorate) (ORAL WATER)

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**FOR ALL DOSES THE TUMOR RATES IN THE FOLLOWING TISSUES/ORGANS ARE BASED ON NUMBER OF TISSUES EXAMINED.
IN OTHER TISSUES/ORGANS RATES ARE BASED ON THE NUMBER OF ANIMALS NECROPSIED.**

Adrenal Cortex
Adrenal Medulla
Bone Marrow
Brain
Clitoral/Preputial Gland
Heart
Islets, Pancreatic
Kidney
Liver
Lung
Ovary
Pancreas
Pituitary Gland
Prostate
Salivary Glands
Spleen
Testes
Thymus
Thyroid Gland
Urinary Bladder

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SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF Goldenseal root powder

MALE RATS

Organ

Adrenal Medulla

Clitoral/Preputial Gland

Liver

Pituitary Gland: Pars Distalis or Unspecified Site

Skin: Sebaceous Gland

All Organs

Morphology

Pheochromocytoma Malignant

Pheochromocytoma: Benign, Complex, Malignant, NOS

Adenoma

Hepatocellular Adenoma

Hepatocellular Carcinoma or Hepatocellular Adenoma

Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma

Adenoma

Carcinoma or Adenoma

Adenoma

Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated

Mesothelioma: Benign, Malignant, NOS

Mesothelioma: Malignant

Malignant Tumors

FEMALE RATS

Organ

Clitoral/Preputial Gland

Liver

Mammary Gland

Pituitary Gland: Pars Distalis or Unspecified Site

Skin

All Organs

Morphology

Carcinoma

Carcinoma or Adenoma

Hepatocellular Adenoma

Hepatocellular Carcinoma or Hepatocellular Adenoma

Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma

Carcinoma or Adenoma

Fibroadenoma

Fibroma, Fibroadenoma or Adenoma

Fibroma, Fibroadenoma, Carcinoma, or Adenoma

Adenoma

Carcinoma

Carcinoma or Adenoma

Sarcoma

Benign Tumors

Malignant and Benign Tumors

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex
 Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/42.29	0/41.55	1/43.4	0/40.1
POLY-3 PERCENT (g)	0%	0%	2.3%	0%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	1/30 (3%)	0/25 (0%)
FIRST INCIDENCE	---	---	729 (T)	---
HC TUMORS SAME RTE	1/250 (0%)			
HC TUMORS ALL RTES	6/1197 (1%)			

STATISTICAL TESTS

POLY 3	P=0.789	(e)	P=0.505	(e)
POLY 1.5	P=0.793N	(e)	P=0.503	(e)
POLY 6	P=0.780	(e)	P=0.506	(e)
COCH-ARM / FISHERS	P=0.790N	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.402	(e)	P=0.165	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Medulla
 Pheochromocytoma Benign**

TUMOR RATES

OVERALL (a)	5/49 (10%)	7/49 (14%)	7/50 (14%)	5/48 (10%)
POLY-3 RATE (b)	5/42.19	7/40.85	7/44.03	5/39.3
POLY-3 PERCENT (g)	11.9%	17.1%	15.9%	12.7%
TERMINAL (d)	4/33 (12%)	6/28 (21%)	3/30 (10%)	3/25 (12%)
FIRST INCIDENCE	600	645	659	653
HC TUMORS SAME RTE	40/250 (16%)			
HC TUMORS ALL RTES	181/1196 (15%)			

STATISTICAL TESTS

POLY 3	P=0.507N	P=0.355	P=0.409	P=0.586
POLY 1.5	P=0.495N	P=0.366	P=0.403	P=0.598
POLY 6	P=0.526N	P=0.336	P=0.411	P=0.567
COCH-ARM / FISHERS	P=0.472N	P=0.380	P=0.394	P=0.617
MAX-ISO-POLY-3	P=0.531	P=0.251	P=0.297	P=0.452
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Medulla
 Pheochromocytoma Malignant**

TUMOR RATES

OVERALL (a)	1/49 (2%)	6/49 (12%)	2/50 (4%)	0/48 (0%)
POLY-3 RATE (b)	1/41.75	6/41.86	2/43.51	0/38.89
POLY-3 PERCENT (g)	2.4%	14.3%	4.6%	0%
TERMINAL (d)	1/33 (3%)	4/28 (14%)	1/30 (3%)	0/25 (0%)
FIRST INCIDENCE	729 (T)	506	701	---
HC TUMORS SAME RTE	3/250 (1%)			
HC TUMORS ALL RTES	27/1196 (2%)			

STATISTICAL TESTS

POLY 3	P=0.091N	P=0.055	P=0.514	P=0.514N
POLY 1.5	P=0.087N	P=0.056	P=0.512	P=0.510N
POLY 6	P=0.097N	P=0.053	P=0.514	P=0.521N
COCH-ARM / FISHERS	P=0.085N	P=0.056	P=0.508	P=0.505N
MAX-ISO-POLY-3	P=0.084N	P=0.023*	P=0.295	P=0.174N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Medulla
 Pheochromocytoma: Benign, Complex, Malignant, NOS**

TUMOR RATES

OVERALL (a)	6/49 (12%)	13/49 (27%)	9/50 (18%)	5/48 (10%)
POLY-3 RATE (b)	6/42.19	13/42.16	9/44.14	5/39.3
POLY-3 PERCENT (g)	14.2%	30.8%	20.4%	12.7%
TERMINAL (d)	5/33 (15%)	10/28 (36%)	4/30 (13%)	3/25 (12%)
FIRST INCIDENCE	600	506	659	653
HC TUMORS SAME RTE	45/250 (18%)			
HC TUMORS ALL RTES	209/1196 (18%)			

STATISTICAL TESTS

POLY 3	P=0.190N	P=0.056	P=0.319	P=0.550N
POLY 1.5	P=0.179N	P=0.058	P=0.312	P=0.536N
POLY 6	P=0.208N	P=0.050*	P=0.322	P=0.571N
COCH-ARM / FISHERS	P=0.162N	P=0.062	P=0.303	P=0.515N
MAX-ISO-POLY-3	P=0.226N	P=0.031*	P=0.229	P=0.422N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Bone
 Osteosarcoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/42.77	0/41.55	1/43.66	0/40.1
POLY-3 PERCENT (g)	4.7%	0%	2.3%	0%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	611	---	659	---
HC TUMORS SAME RTE	0/250 (0%)			
HC TUMORS ALL RTES	8/1199 (1%)			

STATISTICAL TESTS

POLY 3	P=0.263N	P=0.243N	P=0.493N	P=0.251N
POLY 1.5	P=0.262N	P=0.240N	P=0.495N	P=0.246N
POLY 6	P=0.265N	P=0.249N	P=0.493N	P=0.262N
COCH-ARM / FISHERS	P=0.259N	P=0.247N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.098N	P=0.082N	P=0.276N	P=0.090N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Clitoral/Preputial Gland
 Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	3/50 (6%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	0/42.29	3/42.08	2/43.51	2/40.1
POLY-3 PERCENT (g)	0%	7.1%	4.6%	5%
TERMINAL (d)	0/33 (0%)	2/29 (7%)	1/30 (3%)	2/25 (8%)
FIRST INCIDENCE	---	565	701	729 (T)
HC TUMORS SAME RTE	8/250 (3%)			
HC TUMORS ALL RTES	43/1193 (4%)			

STATISTICAL TESTS

POLY 3	P=0.405	P=0.117	P=0.243	P=0.225
POLY 1.5	P=0.416	P=0.118	P=0.241	P=0.230
POLY 6	P=0.387	P=0.115	P=0.244	P=0.217
COCH-ARM / FISHERS	P=0.433	P=0.121	P=0.247	P=0.247
MAX-ISO-POLY-3	P=0.180	P=0.038*	P=0.082	P=0.075
HISTCONT SAME RTE	P=0.219	P=0.043*	P=0.100	P=0.092
HISTCONT ALL RTES	P=0.208	P=0.040*	P=0.094	P=0.086

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Clitoral/Preputial Gland
 Carcinoma**

TUMOR RATES

OVERALL (a)	2/50 (4%)	2/50 (4%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	2/42.29	2/41.86	1/43.4	4/41.35
POLY-3 PERCENT (g)	4.7%	4.8%	2.3%	9.7%
TERMINAL (d)	2/33 (6%)	1/29 (3%)	1/30 (3%)	1/25 (4%)
FIRST INCIDENCE	729 (T)	642	729 (T)	523
HC TUMORS SAME RTE	1/250 (0%)			
HC TUMORS ALL RTES	16/1193 (1%)			

STATISTICAL TESTS

POLY 3	P=0.194	P=0.691	P=0.491N	P=0.326
POLY 1.5	P=0.197	P=0.692	P=0.494N	P=0.330
POLY 6	P=0.190	P=0.687	P=0.490N	P=0.318
COCH-ARM / FISHERS	P=0.201	P=0.691N	P=0.500N	P=0.339
MAX-ISO-POLY-3	P=0.202	P=0.495	P=0.275N	P=0.194
HISTCONT SAME RTE	P=0.026*	P=0.126	P=0.328	P=0.050*
HISTCONT ALL RTES	P=0.005**	P=0.172	P=0.499	P=0.015*

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Clitoral/Preputial Gland
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	2/50 (4%)	5/50 (10%)	3/50 (6%)	6/50 (12%)
POLY-3 RATE (b)	2/42.29	5/42.4	3/43.51	6/41.35
POLY-3 PERCENT (g)	4.7%	11.8%	6.9%	14.5%
TERMINAL (d)	2/33 (6%)	3/29 (10%)	2/30 (7%)	3/25 (12%)
FIRST INCIDENCE	729 (T)	565	701	523
HC TUMORS SAME RTE	9/250 (4%)			
HC TUMORS ALL RTES	57/1193 (5%)			

STATISTICAL TESTS

POLY 3	P=0.154	P=0.216	P=0.513	P=0.124
POLY 1.5	P=0.158	P=0.216	P=0.508	P=0.127
POLY 6	P=0.146	P=0.214	P=0.515	P=0.118
COCH-ARM / FISHERS	P=0.166	P=0.218	P=0.500	P=0.134
MAX-ISO-POLY-3	P=0.106	P=0.119	P=0.337	P=0.065
HISTCONT SAME RTE	P=0.090	P=0.145	P=0.374	P=0.078
HISTCONT ALL RTES	P=0.054	P=0.139	P=0.425	P=0.073

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Heart
 Schwannoma Malignant**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/42.29	0/41.55	2/44.11	0/40.1
POLY-3 PERCENT (g)	0%	0%	4.5%	0%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	---	534	---
HC TUMORS SAME RTE	2/250 (1%)			
HC TUMORS ALL RTES	4/1199 (0%)			

STATISTICAL TESTS

POLY 3	P=0.715	(e)	P=0.246	(e)
POLY 1.5	P=0.720N	(e)	P=0.243	(e)
POLY 6	P=0.700	(e)	P=0.249	(e)
COCH-ARM / FISHERS	P=0.710N	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.272	(e)	P=0.085	(e)
HISTCONT SAME RTE	P=0.331	(e)	P=0.094	(e)
HISTCONT ALL RTES	P=0.231	(e)	P=0.005**	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Intestine Small: Site Unspecified
 Carcinoma or Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/42.29	0/41.55	1/43.71	2/40.51
POLY-3 PERCENT (g)	0%	0%	2.3%	4.9%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	1/25 (4%)
FIRST INCIDENCE	---	---	644	612
HC TUMORS SAME RTE	1/250 (0%)			
HC TUMORS ALL RTES	1/1199 (0%)			

STATISTICAL TESTS

POLY 3	P=0.076	(e)	P=0.507	P=0.227
POLY 1.5	P=0.077	(e)	P=0.504	P=0.231
POLY 6	P=0.073	(e)	P=0.508	P=0.221
COCH-ARM / FISHERS	P=0.081	(e)	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.079	(e)	P=0.167	P=0.075
HISTCONT SAME RTE	P=0.049*	(e)	P=0.152	P=0.068
HISTCONT ALL RTES	P<0.001**	(e)	P=0.005**	P<0.001**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Islets, Pancreatic
 Adenoma**

TUMOR RATES

OVERALL (a)	7/50 (14%)	3/50 (6%)	4/49 (8%)	2/50 (4%)
POLY-3 RATE (b)	7/43.41	3/41.99	4/43.11	2/40.27
POLY-3 PERCENT (g)	16.1%	7.1%	9.3%	5%
TERMINAL (d)	4/33 (12%)	1/29 (3%)	1/30 (3%)	1/25 (4%)
FIRST INCIDENCE	571	663	696	684
HC TUMORS SAME RTE	6/249 (2%)			
HC TUMORS ALL RTES	73/1194 (6%)			

STATISTICAL TESTS

POLY 3	P=0.126N	P=0.169N	P=0.263N	P=0.096N
POLY 1.5	P=0.121N	P=0.164N	P=0.267N	P=0.089N
POLY 6	P=0.136N	P=0.179N	P=0.264N	P=0.109N
COCH-ARM / FISHERS	P=0.113N	P=0.159N	P=0.274N	P=0.080N
MAX-ISO-POLY-3	P=0.076N	P=0.101N	P=0.171N	P=0.054N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Islets, Pancreatic
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	7/50 (14%)	3/50 (6%)	5/49 (10%)	2/50 (4%)
POLY-3 RATE (b)	7/43.41	3/41.99	5/43.11	2/40.27
POLY-3 PERCENT (g)	16.1%	7.1%	11.6%	5%
TERMINAL (d)	4/33 (12%)	1/29 (3%)	2/30 (7%)	1/25 (4%)
FIRST INCIDENCE	571	663	696	684
HC TUMORS SAME RTE	8/249 (3%)			
HC TUMORS ALL RTES	100/1194 (8%)			

STATISTICAL TESTS

POLY 3	P=0.134N	P=0.169N	P=0.383N	P=0.096N
POLY 1.5	P=0.127N	P=0.164N	P=0.387N	P=0.089N
POLY 6	P=0.145N	P=0.179N	P=0.384N	P=0.109N
COCH-ARM / FISHERS	P=0.118N	P=0.159N	P=0.394N	P=0.080N
MAX-ISO-POLY-3	P=0.083N	P=0.101N	P=0.272N	P=0.054N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
 Hepatocellular Adenoma

TUMOR RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	10/50 (20%)
POLY-3 RATE (b)	1/42.29	1/41.72	2/43.65	10/41.31
POLY-3 PERCENT (g)	2.4%	2.4%	4.6%	24.2%
TERMINAL (d)	1/33 (3%)	0/29 (0%)	1/30 (3%)	5/25 (20%)
FIRST INCIDENCE	729 (T)	684	663	612
HC TUMORS SAME RTE	3/250 (1%)			
HC TUMORS ALL RTES	10/1199 (1%)			

STATISTICAL TESTS

POLY 3	P<0.001**	P=0.758	P=0.511	P=0.003**
POLY 1.5	P<0.001**	P=0.759	P=0.507	P=0.003**
POLY 6	P<0.001**	P=0.755	P=0.514	P=0.003**
COCH-ARM / FISHERS	P<0.001**	P=0.753N	P=0.500	P=0.004**
MAX-ISO-POLY-3	P<0.001**	P=0.495	P=0.292	P<0.001**
HISTCONT SAME RTE	P<0.001**	P=0.450	P=0.175	P<0.001**
HISTCONT ALL RTES	P<0.001**	P=0.316	P=0.060	P<0.001**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Liver
 Hepatocellular Carcinoma or Hepatocellular Adenoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	11/50 (22%)
POLY-3 RATE (b)	1/42.29	1/41.72	2/43.65	11/41.59
POLY-3 PERCENT (g)	2.4%	2.4%	4.6%	26.5%
TERMINAL (d)	1/33 (3%)	0/29 (0%)	1/30 (3%)	5/25 (20%)
FIRST INCIDENCE	729 (T)	684	663	612
HC TUMORS SAME RTE	3/250 (1%)			
HC TUMORS ALL RTES	12/1199 (1%)			

STATISTICAL TESTS

POLY 3	P<0.001**	P=0.758	P=0.511	P<0.001**
POLY 1.5	P<0.001**	P=0.759	P=0.507	P=0.002**
POLY 6	P<0.001**	P=0.755	P=0.514	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.753N	P=0.500	P=0.002**
MAX-ISO-POLY-3	P<0.001**	P=0.495	P=0.292	P<0.001**
HISTCONT SAME RTE	P<0.001**	P=0.450	P=0.175	P<0.001**
HISTCONT ALL RTES	P<0.001**	P=0.356	P=0.072	P<0.001**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
 Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma

TUMOR RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	11/50 (22%)
POLY-3 RATE (b)	1/42.29	1/41.72	2/43.65	11/41.59
POLY-3 PERCENT (g)	2.4%	2.4%	4.6%	26.5%
TERMINAL (d)	1/33 (3%)	0/29 (0%)	1/30 (3%)	5/25 (20%)
FIRST INCIDENCE	729 (T)	684	663	612
HC TUMORS SAME RTE	3/250 (1%)			
HC TUMORS ALL RTES	12/1199 (1%)			

STATISTICAL TESTS

POLY 3	P<0.001**	P=0.758	P=0.511	P<0.001**
POLY 1.5	P<0.001**	P=0.759	P=0.507	P=0.002**
POLY 6	P<0.001**	P=0.755	P=0.514	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.753N	P=0.500	P=0.002**
MAX-ISO-POLY-3	P<0.001**	P=0.495	P=0.292	P<0.001**
HISTCONT SAME RTE	P<0.001**	P=0.450	P=0.175	P<0.001**
HISTCONT ALL RTES	P<0.001**	P=0.356	P=0.072	P<0.001**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung
 Alveolar/Bronchiolar Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.29	2/41.57	0/43.4	2/40.1
POLY-3 PERCENT (g)	0%	4.8%	0%	5%
TERMINAL (d)	0/33 (0%)	1/29 (3%)	0/30 (0%)	2/25 (8%)
FIRST INCIDENCE	---	723	---	729 (T)
HC TUMORS SAME RTE	7/250 (3%)			
HC TUMORS ALL RTES	31/1199 (3%)			

STATISTICAL TESTS

POLY 3	P=0.268	P=0.233	(e)	P=0.225
POLY 1.5	P=0.273	P=0.235	(e)	P=0.230
POLY 6	P=0.259	P=0.229	(e)	P=0.217
COCH-ARM / FISHERS	P=0.282	P=0.247	(e)	P=0.247
MAX-ISO-POLY-3	P=0.121	P=0.076	(e)	P=0.075
HISTCONT SAME RTE	P=0.147	P=0.092	(e)	P=0.092
HISTCONT ALL RTES	P=0.140	P=0.086	(e)	P=0.086

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung
 Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	3/50 (6%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	1/42.29	3/41.57	0/43.4	3/40.1
POLY-3 PERCENT (g)	2.4%	7.2%	0%	7.5%
TERMINAL (d)	1/33 (3%)	2/29 (7%)	0/30 (0%)	3/25 (12%)
FIRST INCIDENCE	729 (T)	723	---	729 (T)
HC TUMORS SAME RTE	9/250 (4%)			
HC TUMORS ALL RTES	46/1199 (4%)			

STATISTICAL TESTS

POLY 3	P=0.309	P=0.299	P=0.495N	P=0.286
POLY 1.5	P=0.316	P=0.302	P=0.497N	P=0.294
POLY 6	P=0.299	P=0.292	P=0.494N	P=0.273
COCH-ARM / FISHERS	P=0.327	P=0.309	P=0.500N	P=0.309
MAX-ISO-POLY-3	P=0.212	P=0.151	P=0.158N	P=0.146
HISTCONT SAME RTE	P=0.257	P=0.192	(e)	P=0.186
HISTCONT ALL RTES	P=0.245	P=0.180	(e)	P=0.174

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Mammary Gland Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.29	0/41.55	0/43.4	0/40.1
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	1/250 (0%)			
HC TUMORS ALL RTES	5/1199 (0%)			

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Mammary Gland Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.29	0/41.55	0/43.4	0/40.1
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/250 (0%)			
HC TUMORS ALL RTES	8/1199 (1%)			

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Mammary Gland Carcinoma or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.29	0/41.55	0/43.4	0/40.1
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	1/250 (0%)			
HC TUMORS ALL RTES	13/1199 (1%)			

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Mammary Gland Fibroadenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	1/42.29	1/41.55	4/43.51	1/40.1
POLY-3 PERCENT (g)	2.4%	2.4%	9.2%	2.5%
TERMINAL (d)	1/33 (3%)	1/29 (3%)	3/30 (10%)	1/25 (4%)
FIRST INCIDENCE	729 (T)	729 (T)	701	729 (T)
HC TUMORS SAME RTE	7/250 (3%)			
HC TUMORS ALL RTES	43/1199 (4%)			

STATISTICAL TESTS

POLY 3	P=0.608	P=0.757	P=0.187	P=0.749
POLY 1.5	P=0.619	P=0.759	P=0.184	P=0.754
POLY 6	P=0.589	P=0.753	P=0.188	P=0.741
COCH-ARM / FISHERS	P=0.614N	P=0.753N	P=0.181	P=0.753N
MAX-ISO-POLY-3	P=0.348	P=0.494	P=0.091	P=0.485
HISTCONT SAME RTE	P=0.422	P=0.635	P=0.112	P=0.624
HISTCONT ALL RTES	P=0.404	P=0.624	P=0.105	P=0.613

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Mammary Gland Fibroma, Fibroadenoma or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	1/42.29	1/41.55	4/43.51	1/40.1
POLY-3 PERCENT (g)	2.4%	2.4%	9.2%	2.5%
TERMINAL (d)	1/33 (3%)	1/29 (3%)	3/30 (10%)	1/25 (4%)
FIRST INCIDENCE	729 (T)	729 (T)	701	729 (T)
HC TUMORS SAME RTE	8/250 (3%)			
HC TUMORS ALL RTES	49/1199 (4%)			

STATISTICAL TESTS

POLY 3	P=0.608	P=0.757	P=0.187	P=0.749
POLY 1.5	P=0.619	P=0.759	P=0.184	P=0.754
POLY 6	P=0.589	P=0.753	P=0.188	P=0.741
COCH-ARM / FISHERS	P=0.614N	P=0.753N	P=0.181	P=0.753N
MAX-ISO-POLY-3	P=0.348	P=0.494	P=0.091	P=0.485
HISTCONT SAME RTE	P=0.422	P=0.635	P=0.112	P=0.624
HISTCONT ALL RTES	P=0.404	P=0.624	P=0.105	P=0.613

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Mammary Gland Fibroma, Fibroadenoma, Carcinoma, or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	1/42.29	1/41.55	4/43.51	1/40.1
POLY-3 PERCENT (g)	2.4%	2.4%	9.2%	2.5%
TERMINAL (d)	1/33 (3%)	1/29 (3%)	3/30 (10%)	1/25 (4%)
FIRST INCIDENCE	729 (T)	729 (T)	701	729 (T)
HC TUMORS SAME RTE	8/250 (3%)			
HC TUMORS ALL RTES	55/1199 (5%)			

STATISTICAL TESTS

POLY 3	P=0.608	P=0.757	P=0.187	P=0.749
POLY 1.5	P=0.619	P=0.759	P=0.184	P=0.754
POLY 6	P=0.589	P=0.753	P=0.188	P=0.741
COCH-ARM / FISHERS	P=0.614N	P=0.753N	P=0.181	P=0.753N
MAX-ISO-POLY-3	P=0.348	P=0.494	P=0.091	P=0.485
HISTCONT SAME RTE	P=0.422	P=0.635	P=0.112	P=0.624
HISTCONT ALL RTES	P=0.404	P=0.624	P=0.105	P=0.613

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)
 Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/42.83	1/41.55	0/43.4	0/40.1
POLY-3 PERCENT (g)	4.7%	2.4%	0%	0%
TERMINAL (d)	1/33 (3%)	1/29 (3%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	563	729 (T)	---	---
HC TUMORS SAME RTE	2/250 (1%)			
HC TUMORS ALL RTES	8/1199 (1%)			

STATISTICAL TESTS

POLY 3	P=0.158N	P=0.511N	P=0.234N	P=0.252N
POLY 1.5	P=0.158N	P=0.506N	P=0.235N	P=0.246N
POLY 6	P=0.158N	P=0.519N	P=0.235N	P=0.262N
COCH-ARM / FISHERS	P=0.156N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.098N	P=0.292N	P=0.076N	P=0.090N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pituitary Gland: Pars Distalis or Unspecified Site
 Adenoma**

TUMOR RATES

OVERALL (a)	8/50 (16%)	18/50 (36%)	16/49 (33%)	13/50 (26%)
POLY-3 RATE (b)	8/44.21	18/44	16/44.11	13/41.87
POLY-3 PERCENT (g)	18.1%	40.9%	36.3%	31.1%
TERMINAL (d)	4/33 (12%)	10/29 (35%)	11/30 (37%)	8/25 (32%)
FIRST INCIDENCE	407	437	563	523
HC TUMORS SAME RTE	65/249 (26%)			
HC TUMORS ALL RTES	541/1192 (45%)			

STATISTICAL TESTS

POLY 3	P=0.373	P=0.014*	P=0.043*	P=0.123
POLY 1.5	P=0.404	P=0.016*	P=0.043*	P=0.137
POLY 6	P=0.330	P=0.013*	P=0.044*	P=0.105
COCH-ARM / FISHERS	P=0.460	P=0.020*	P=0.044*	P=0.163
MAX-ISO-POLY-3	P=0.061	P=0.008**	P=0.026*	P=0.084
HISTCONT SAME RTE	P=0.073	P=0.008**	P=0.028*	P=0.103
HISTCONT ALL RTES	P=0.070	P=0.008**	P=0.027*	P=0.097

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pituitary Gland: Pars Distalis or Unspecified Site
 Carcinoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.29	1/41.55	0/42.86	0/40.1
POLY-3 PERCENT (g)	0%	2.4%	0%	0%
TERMINAL (d)	0/33 (0%)	1/29 (3%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	729 (T)	---	---
HC TUMORS SAME RTE	0/249 (0%)			
HC TUMORS ALL RTES	6/1192 (1%)			

STATISTICAL TESTS

POLY 3	P=0.576N	P=0.496	(e)	(e)
POLY 1.5	P=0.574N	P=0.498	(e)	(e)
POLY 6	P=0.579N	P=0.493	(e)	(e)
COCH-ARM / FISHERS	P=0.572N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.404N	P=0.158	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pituitary Gland: Pars Distalis or Unspecified Site
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	8/50 (16%)	19/50 (38%)	16/49 (33%)	13/50 (26%)
POLY-3 RATE (b)	8/44.21	19/44	16/44.11	13/41.87
POLY-3 PERCENT (g)	18.1%	43.2%	36.3%	31.1%
TERMINAL (d)	4/33 (12%)	11/29 (38%)	11/30 (37%)	8/25 (32%)
FIRST INCIDENCE	407	437	563	523
HC TUMORS SAME RTE	65/249 (26%)			
HC TUMORS ALL RTES	547/1192 (46%)			

STATISTICAL TESTS

POLY 3	P=0.413	P=0.008**	P=0.043*	P=0.123
POLY 1.5	P=0.444	P=0.009**	P=0.043*	P=0.137
POLY 6	P=0.368	P=0.007**	P=0.044*	P=0.105
COCH-ARM / FISHERS	P=0.500	P=0.012*	P=0.044*	P=0.163
MAX-ISO-POLY-3	P=0.051	P=0.004**	P=0.026*	P=0.084
HISTCONT SAME RTE	P=0.062	P=0.004**	P=0.028*	P=0.103
HISTCONT ALL RTES	P=0.059	P=0.004**	P=0.027*	P=0.097

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Prostate
 Adenoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	1/42.29	1/41.55	3/43.4	2/40.2
POLY-3 PERCENT (g)	2.4%	2.4%	6.9%	5%
TERMINAL (d)	1/33 (3%)	1/29 (3%)	3/30 (10%)	1/25 (4%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	703
HC TUMORS SAME RTE	0/249 (0%)			
HC TUMORS ALL RTES	4/1197 (0%)			

STATISTICAL TESTS

POLY 3	P=0.363	P=0.757	P=0.314	P=0.482
POLY 1.5	P=0.372	P=0.759	P=0.311	P=0.489
POLY 6	P=0.349	P=0.753	P=0.315	P=0.471
COCH-ARM / FISHERS	P=0.386	P=0.753N	P=0.309	P=0.500
MAX-ISO-POLY-3	P=0.349	P=0.494	P=0.163	P=0.270
HISTCONT SAME RTE	P=0.062	P=0.107	P=0.034*	P=0.050*
HISTCONT ALL RTES	P=0.002**	P=0.143	P=0.003**	P=0.016*

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin
 Basal Cell Carcinoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.29	1/41.55	0/43.4	2/40.44
POLY-3 PERCENT (g)	0%	2.4%	0%	5%
TERMINAL (d)	0/33 (0%)	1/29 (3%)	0/30 (0%)	1/25 (4%)
FIRST INCIDENCE	---	729 (T)	---	635
HC TUMORS SAME RTE	0/250 (0%)			
HC TUMORS ALL RTES	6/1199 (1%)			

STATISTICAL TESTS

POLY 3	P=0.142	P=0.496	(e)	P=0.227
POLY 1.5	P=0.145	P=0.498	(e)	P=0.231
POLY 6	P=0.138	P=0.493	(e)	P=0.221
COCH-ARM / FISHERS	P=0.149	P=0.500	(e)	P=0.247
MAX-ISO-POLY-3	P=0.079	P=0.158	(e)	P=0.075
HISTCONT SAME RTE	P=0.051	P=0.040*	(e)	P=0.041*
HISTCONT ALL RTES	P=0.032*	P=0.182	(e)	P=0.022*

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Skin
 Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/42.29	1/41.55	1/43.66	2/40.44
POLY-3 PERCENT (g)	0%	2.4%	2.3%	5%
TERMINAL (d)	0/33 (0%)	1/29 (3%)	0/30 (0%)	1/25 (4%)
FIRST INCIDENCE	---	729 (T)	659	635
HC TUMORS SAME RTE	3/250 (1%)			
HC TUMORS ALL RTES	25/1199 (2%)			

STATISTICAL TESTS

POLY 3	P=0.177	P=0.496	P=0.506	P=0.227
POLY 1.5	P=0.181	P=0.498	P=0.504	P=0.231
POLY 6	P=0.170	P=0.493	P=0.508	P=0.221
COCH-ARM / FISHERS	P=0.187	P=0.500	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.123	P=0.158	P=0.166	P=0.075
HISTCONT SAME RTE	P=0.133	P=0.201	P=0.212	P=0.092
HISTCONT ALL RTES	P=0.142	P=0.188	P=0.199	P=0.086

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

	Males			
DOSE	0 PPM	3000 PPM	9000 PPM	25000 PPM

Skin
 Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	5/50 (10%)	6/50 (12%)	4/50 (8%)
POLY-3 RATE (b)	2/43.04	5/41.55	6/43.66	4/40.6
POLY-3 PERCENT (g)	4.7%	12%	13.7%	9.9%
TERMINAL (d)	1/33 (3%)	5/29 (17%)	5/30 (17%)	2/25 (8%)
FIRST INCIDENCE	456	729 (T)	659	635
HC TUMORS SAME RTE	21/250 (8%)			
HC TUMORS ALL RTES	112/1199 (9%)			

STATISTICAL TESTS

POLY 3	P=0.419	P=0.201	P=0.136	P=0.310
POLY 1.5	P=0.434	P=0.208	P=0.135	P=0.320
POLY 6	P=0.398	P=0.191	P=0.136	P=0.296
COCH-ARM / FISHERS	P=0.461	P=0.218	P=0.134	P=0.339
MAX-ISO-POLY-3	P=0.231	P=0.112	P=0.072	P=0.186
HISTCONT SAME RTE	P=0.282	P=0.140	P=0.087	P=0.238
HISTCONT ALL RTES	P=0.269	P=0.131	P=0.082	P=0.225

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Skin				
Fibroma				
TUMOR RATES	#	#	#	#
OVERALL (a)	5/50 (10%)	4/50 (8%)	2/50 (4%)	5/50 (10%)
POLY-3 RATE (b)	5/42.56	4/42.11	2/43.4	5/40.46
POLY-3 PERCENT (g)	11.8%	9.5%	4.6%	12.4%
TERMINAL (d)	4/33 (12%)	2/29 (7%)	2/30 (7%)	4/25 (16%)
FIRST INCIDENCE	656	563	729 (T)	627
HC TUMORS SAME RTE	20/250 (8%)			
HC TUMORS ALL RTES	121/1199 (10%)			

STATISTICAL TESTS

POLY 3	P=0.485	P=0.507N	P=0.207N	P=0.599
POLY 1.5	P=0.494	P=0.503N	P=0.211N	P=0.611
POLY 6	P=0.470	P=0.516N	P=0.208N	P=0.578
COCH-ARM / FISHERS	P=0.511	P=0.500N	P=0.218N	P=0.630N
MAX-ISO-POLY-3	P=0.459	P=0.368N	P=0.115N	P=0.466
HISTCONT SAME RTE	P=0.557	P=0.599	P=1.000	P=0.432
HISTCONT ALL RTES	P=0.540	P=1.000	P=1.000	P=0.571

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin
 Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	5/50 (10%)	5/50 (10%)	4/50 (8%)	5/50 (10%)
POLY-3 RATE (b)	5/42.56	5/42.24	4/43.53	5/40.46
POLY-3 PERCENT (g)	11.8%	11.8%	9.2%	12.4%
TERMINAL (d)	4/33 (12%)	2/29 (7%)	3/30 (10%)	4/25 (16%)
FIRST INCIDENCE	656	563	696	627
HC TUMORS SAME RTE	24/250 (10%)			
HC TUMORS ALL RTES	146/1199 (12%)			

STATISTICAL TESTS

POLY 3	P=0.543	P=0.626	P=0.486N	P=0.599
POLY 1.5	P=0.556	P=0.628	P=0.491N	P=0.611
POLY 6	P=0.523	P=0.620	P=0.486N	P=0.578
COCH-ARM / FISHERS	P=0.577	P=0.630N	P=0.500N	P=0.630N
MAX-ISO-POLY-3	P=0.650	P=0.494	P=0.350N	P=0.466
HISTCONT SAME RTE	P=0.712	P=0.547	P=1.000	P=0.514
HISTCONT ALL RTES	P=0.763	P=0.624	P=1.000	P=0.591

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Skin				
Fibrosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/42.29	0/41.55	2/43.53	0/40.1
POLY-3 PERCENT (g)	0%	0%	4.6%	0%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	1/30 (3%)	0/25 (0%)
FIRST INCIDENCE	---	---	696	---
HC TUMORS SAME RTE	2/250 (1%)			
HC TUMORS ALL RTES	14/1199 (1%)			

STATISTICAL TESTS

POLY 3	P=0.715	(e)	P=0.243	(e)
POLY 1.5	P=0.720N	(e)	P=0.241	(e)
POLY 6	P=0.700	(e)	P=0.244	(e)
COCH-ARM / FISHERS	P=0.710N	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.269	(e)	P=0.082	(e)
HISTCONT SAME RTE	P=0.327	(e)	P=0.100	(e)
HISTCONT ALL RTES	P=0.312	(e)	P=0.094	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin
 Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/42.29	1/41.68	2/43.53	0/40.1
POLY-3 PERCENT (g)	0%	2.4%	4.6%	0%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	1/30 (3%)	0/25 (0%)
FIRST INCIDENCE	---	696	696	---
HC TUMORS SAME RTE	4/250 (2%)			
HC TUMORS ALL RTES	26/1199 (2%)			

STATISTICAL TESTS

POLY 3	P=0.550N	P=0.497	P=0.243	(e)
POLY 1.5	P=0.542N	P=0.498	P=0.241	(e)
POLY 6	P=0.563N	P=0.494	P=0.244	(e)
COCH-ARM / FISHERS	P=0.530N	P=0.500	P=0.247	(e)
MAX-ISO-POLY-3	P=0.349	P=0.158	P=0.082	(e)
HISTCONT SAME RTE	(h)	(h)	(h)	(e)
HISTCONT ALL RTES	(h)	(h)	(h)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Skin				
Keratoacanthoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	4/50 (8%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	2/43.04	4/41.55	5/43.4	2/40.26
POLY-3 PERCENT (g)	4.7%	9.6%	11.5%	5%
TERMINAL (d)	1/33 (3%)	4/29 (14%)	5/30 (17%)	1/25 (4%)
FIRST INCIDENCE	456	729 (T)	729 (T)	688
HC TUMORS SAME RTE	16/250 (6%)			
HC TUMORS ALL RTES	71/1199 (6%)			

STATISTICAL TESTS

POLY 3	P=0.478N	P=0.320	P=0.219	P=0.670
POLY 1.5	P=0.463N	P=0.328	P=0.218	P=0.679
POLY 6	P=0.499N	P=0.309	P=0.216	P=0.657
COCH-ARM / FISHERS	P=0.438N	P=0.339	P=0.218	P=0.691N
MAX-ISO-POLY-3	P=0.402	P=0.191	P=0.122	P=0.473
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Skin				
Lipoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/42.29	0/41.55	2/43.94	0/40.1
POLY-3 PERCENT (g)	2.4%	0%	4.6%	0%
TERMINAL (d)	1/33 (3%)	0/29 (0%)	1/30 (3%)	0/25 (0%)
FIRST INCIDENCE	729 (T)	---	563	---
HC TUMORS SAME RTE	1/250 (0%)			
HC TUMORS ALL RTES	11/1199 (1%)			

STATISTICAL TESTS

POLY 3	P=0.472N	P=0.504N	P=0.513	P=0.511N
POLY 1.5	P=0.467N	P=0.502N	P=0.508	P=0.506N
POLY 6	P=0.481N	P=0.507N	P=0.517	P=0.518N
COCH-ARM / FISHERS	P=0.458N	P=0.500N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.353N	P=0.163N	P=0.295	P=0.172N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Skin				
Sarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.29	0/41.55	0/43.4	0/40.1
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	1/250 (0%)			
HC TUMORS ALL RTES	7/1199 (1%)			

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin
 Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	4/50 (8%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	2/43.04	4/41.55	5/43.4	2/40.26
POLY-3 PERCENT (g)	4.7%	9.6%	11.5%	5%
TERMINAL (d)	1/33 (3%)	4/29 (14%)	5/30 (17%)	1/25 (4%)
FIRST INCIDENCE	456	729 (T)	729 (T)	688
HC TUMORS SAME RTE	18/250 (7%)			
HC TUMORS ALL RTES	91/1199 (8%)			

STATISTICAL TESTS

POLY 3	P=0.478N	P=0.320	P=0.219	P=0.670
POLY 1.5	P=0.463N	P=0.328	P=0.218	P=0.679
POLY 6	P=0.499N	P=0.309	P=0.216	P=0.657
COCH-ARM / FISHERS	P=0.438N	P=0.339	P=0.218	P=0.691N
MAX-ISO-POLY-3	P=0.402	P=0.191	P=0.122	P=0.473
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin
 Squamous Cell Papilloma, Papilloma, or Keratoacanthoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	4/50 (8%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	2/43.04	4/41.55	5/43.4	2/40.26
POLY-3 PERCENT (g)	4.7%	9.6%	11.5%	5%
TERMINAL (d)	1/33 (3%)	4/29 (14%)	5/30 (17%)	1/25 (4%)
FIRST INCIDENCE	456	729 (T)	729 (T)	688
HC TUMORS SAME RTE	17/250 (7%)			
HC TUMORS ALL RTES	87/1199 (7%)			

STATISTICAL TESTS

POLY 3	P=0.478N	P=0.320	P=0.219	P=0.670
POLY 1.5	P=0.463N	P=0.328	P=0.218	P=0.679
POLY 6	P=0.499N	P=0.309	P=0.216	P=0.657
COCH-ARM / FISHERS	P=0.438N	P=0.339	P=0.218	P=0.691N
MAX-ISO-POLY-3	P=0.402	P=0.191	P=0.122	P=0.473
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin: Sebaceous Gland
 Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.29	0/41.55	0/43.4	2/41.27
POLY-3 PERCENT (g)	0%	0%	0%	4.9%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	---	---	450
HC TUMORS SAME RTE	0/250 (0%)			
HC TUMORS ALL RTES	8/1199 (1%)			

STATISTICAL TESTS

POLY 3	P=0.040*	(e)	(e)	P=0.231
POLY 1.5	P=0.040*	(e)	(e)	P=0.234
POLY 6	P=0.039*	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.034*	(e)	(e)	P=0.076
HISTCONT SAME RTE	P=0.035*	(e)	(e)	P=0.039*
HISTCONT ALL RTES	P=0.039*	(e)	(e)	P=0.058

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Testes
 Adenoma

TUMOR RATES

OVERALL (a)	42/50 (84%)	43/50 (86%)	44/50 (88%)	42/50 (84%)
POLY-3 RATE (b)	42/46.32	43/46.86	44/48.1	42/45.82
POLY-3 PERCENT (g)	90.7%	91.8%	91.5%	91.7%
TERMINAL (d)	32/33 (97%)	28/29 (97%)	28/30 (93%)	25/25 (100%)
FIRST INCIDENCE	456	506	431	478
HC TUMORS SAME RTE	234/250 (94%)			
HC TUMORS ALL RTES	1035/1199 (86%)			

STATISTICAL TESTS

POLY 3	P=0.549	P=0.583	P=0.599	P=0.593
POLY 1.5	P=0.558	P=0.533	P=0.492	P=0.575
POLY 6	P=0.557	P=0.670	P=0.624N	P=0.643
COCH-ARM / FISHERS	P=0.510N	P=0.500	P=0.387	P=0.607N
MAX-ISO-POLY-3	P=0.656	P=0.414	P=0.438	P=0.421
HISTCONT SAME RTE	P=0.777	P=0.540	P=0.569	P=0.548
HISTCONT ALL RTES	P=0.771	P=0.526	P=0.553	P=0.537

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thyroid Gland: C-Cell
 Adenoma**

TUMOR RATES

OVERALL (a)	7/50 (14%)	5/50 (10%)	6/50 (12%)	3/50 (6%)
POLY-3 RATE (b)	7/42.41	5/42.4	6/43.58	3/41.09
POLY-3 PERCENT (g)	16.5%	11.8%	13.8%	7.3%
TERMINAL (d)	5/33 (15%)	2/29 (7%)	4/30 (13%)	1/25 (4%)
FIRST INCIDENCE	711	632	688	547
HC TUMORS SAME RTE	41/245 (17%)			
HC TUMORS ALL RTES	151/1185 (13%)			

STATISTICAL TESTS

POLY 3	P=0.169N	P=0.378N	P=0.479N	P=0.168N
POLY 1.5	P=0.165N	P=0.379N	P=0.487N	P=0.165N
POLY 6	P=0.178N	P=0.379N	P=0.476N	P=0.176N
COCH-ARM / FISHERS	P=0.156N	P=0.380N	P=0.500N	P=0.159N
MAX-ISO-POLY-3	P=0.171N	P=0.267N	P=0.363N	P=0.100N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thyroid Gland: C-Cell
 Carcinoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	3/50 (6%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/42.29	3/42.2	0/43.4	1/40.1
POLY-3 PERCENT (g)	2.4%	7.1%	0%	2.5%
TERMINAL (d)	1/33 (3%)	1/29 (3%)	0/30 (0%)	1/25 (4%)
FIRST INCIDENCE	729 (T)	632	---	729 (T)
HC TUMORS SAME RTE	7/245 (3%)			
HC TUMORS ALL RTES	38/1185 (3%)			

STATISTICAL TESTS

POLY 3	P=0.433N	P=0.304	P=0.495N	P=0.749
POLY 1.5	P=0.428N	P=0.305	P=0.497N	P=0.754
POLY 6	P=0.440N	P=0.302	P=0.494N	P=0.741
COCH-ARM / FISHERS	P=0.421N	P=0.309	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.294N	P=0.153	P=0.158N	P=0.485
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thyroid Gland: C-Cell
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	8/50 (16%)	7/50 (14%)	6/50 (12%)	4/50 (8%)
POLY-3 RATE (b)	8/42.41	7/42.71	6/43.58	4/41.09
POLY-3 PERCENT (g)	18.9%	16.4%	13.8%	9.7%
TERMINAL (d)	6/33 (18%)	3/29 (10%)	4/30 (13%)	2/25 (8%)
FIRST INCIDENCE	711	632	688	547
HC TUMORS SAME RTE	48/245 (20%)			
HC TUMORS ALL RTES	188/1185 (16%)			

STATISTICAL TESTS

POLY 3	P=0.156N	P=0.494N	P=0.364N	P=0.189N
POLY 1.5	P=0.151N	P=0.497N	P=0.373N	P=0.185N
POLY 6	P=0.166N	P=0.491N	P=0.361N	P=0.199N
COCH-ARM / FISHERS	P=0.143N	P=0.500N	P=0.387N	P=0.178N
MAX-ISO-POLY-3	P=0.203N	P=0.381N	P=0.264N	P=0.120N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
All Organs				
Histiocytic Sarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/42.29	1/42.05	2/44.2	1/40.68
POLY-3 PERCENT (g)	0%	2.4%	4.5%	2.5%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	576	594	547
HC TUMORS SAME RTE	0/250 (0%)			
HC TUMORS ALL RTES	8/1199 (1%)			

STATISTICAL TESTS

POLY 3	P=0.460	P=0.499	P=0.247	P=0.492
POLY 1.5	P=0.467	P=0.500	P=0.243	P=0.495
POLY 6	P=0.448	P=0.497	P=0.250	P=0.487
COCH-ARM / FISHERS	P=0.479	P=0.500	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.248	P=0.158	P=0.085	P=0.158
HISTCONT SAME RTE	P=0.160	P=0.039*	P=0.034*	P=0.042*
HISTCONT ALL RTES	P=0.137	P=0.188	P=0.033*	P=0.188

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

All Organs
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated

TUMOR RATES	#	#	#	#
OVERALL (a)	21/50 (42%)	16/50 (32%)	24/50 (48%)	28/50 (56%)
POLY-3 RATE (b)	21/46.19	16/45.17	24/47.73	28/45.61
POLY-3 PERCENT (g)	45.5%	35.4%	50.3%	61.4%
TERMINAL (d)	11/33 (33%)	5/29 (17%)	11/30 (37%)	12/25 (48%)
FIRST INCIDENCE	456	355	316	478
HC TUMORS SAME RTE	91/250 (36%)			
HC TUMORS ALL RTES	465/1199 (39%)			

STATISTICAL TESTS

POLY 3	P=0.018*	P=0.220N	P=0.397	P=0.089
POLY 1.5	P=0.019*	P=0.210N	P=0.383	P=0.094
POLY 6	P=0.019*	P=0.239N	P=0.396	P=0.085
COCH-ARM / FISHERS	P=0.025*	P=0.204N	P=0.344	P=0.115
MAX-ISO-POLY-3	P=0.029*	P=0.165N	P=0.322	P=0.060
HISTCONT SAME RTE	P=0.035*	P=1.000	P=0.242	P=0.072
HISTCONT ALL RTES	P=0.033*	P=1.000	P=0.356	P=0.067

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**All Organs
 Mesothelioma: Benign, Malignant, NOS**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	3/50 (6%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/42.29	3/41.55	2/43.48	0/40.1
POLY-3 PERCENT (g)	0%	7.2%	4.6%	0%
TERMINAL (d)	0/33 (0%)	3/29 (10%)	1/30 (3%)	0/25 (0%)
FIRST INCIDENCE	---	729 (T)	709	---
HC TUMORS SAME RTE	5/250 (2%)			
HC TUMORS ALL RTES	35/1199 (3%)			

STATISTICAL TESTS

POLY 3	P=0.319N	P=0.115	P=0.243	(e)
POLY 1.5	P=0.311N	P=0.117	P=0.241	(e)
POLY 6	P=0.333N	P=0.112	P=0.244	(e)
COCH-ARM / FISHERS	P=0.299N	P=0.121	P=0.247	(e)
MAX-ISO-POLY-3	P=0.245	P=0.038*	P=0.082	(e)
HISTCONT SAME RTE	(h)	(h)	(h)	(e)
HISTCONT ALL RTES	(h)	(h)	(h)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**All Organs
 Mesothelioma: Malignant**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	3/50 (6%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/42.29	3/41.55	2/43.48	0/40.1
POLY-3 PERCENT (g)	0%	7.2%	4.6%	0%
TERMINAL (d)	0/33 (0%)	3/29 (10%)	1/30 (3%)	0/25 (0%)
FIRST INCIDENCE	---	729 (T)	709	---
HC TUMORS SAME RTE	5/250 (2%)			
HC TUMORS ALL RTES	34/1199 (3%)			

STATISTICAL TESTS

POLY 3	P=0.319N	P=0.115	P=0.243	(e)
POLY 1.5	P=0.311N	P=0.117	P=0.241	(e)
POLY 6	P=0.333N	P=0.112	P=0.244	(e)
COCH-ARM / FISHERS	P=0.299N	P=0.121	P=0.247	(e)
MAX-ISO-POLY-3	P=0.245	P=0.038*	P=0.082	(e)
HISTCONT SAME RTE	(h)	(h)	(h)	(e)
HISTCONT ALL RTES	(h)	(h)	(h)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**All Organs
 Osteosarcoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/42.77	0/41.55	1/43.66	0/40.1
POLY-3 PERCENT (g)	4.7%	0%	2.3%	0%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	611	---	659	---
HC TUMORS SAME RTE	1/250 (0%)			
HC TUMORS ALL RTES	11/1199 (1%)			

STATISTICAL TESTS

POLY 3	P=0.263N	P=0.243N	P=0.493N	P=0.251N
POLY 1.5	P=0.262N	P=0.240N	P=0.495N	P=0.246N
POLY 6	P=0.265N	P=0.249N	P=0.493N	P=0.262N
COCH-ARM / FISHERS	P=0.259N	P=0.247N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.098N	P=0.082N	P=0.276N	P=0.090N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**All Organs
 Osteosarcoma or Osteoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/42.77	0/41.55	1/43.66	0/40.1
POLY-3 PERCENT (g)	4.7%	0%	2.3%	0%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	611	---	659	---
HC TUMORS SAME RTE	3/250 (1%)			
HC TUMORS ALL RTES	13/1199 (1%)			

STATISTICAL TESTS

POLY 3	P=0.263N	P=0.243N	P=0.493N	P=0.251N
POLY 1.5	P=0.262N	P=0.240N	P=0.495N	P=0.246N
POLY 6	P=0.265N	P=0.249N	P=0.493N	P=0.262N
COCH-ARM / FISHERS	P=0.259N	P=0.247N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.098N	P=0.082N	P=0.276N	P=0.090N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**All Organs
 Benign Tumors**

TUMOR RATES	#	#	#	#
OVERALL (a)	47/50 (94%)	48/50 (96%)	48/50 (96%)	47/50 (94%)
POLY-3 RATE (b)	47/48.24	48/48.46	48/49.08	47/47.6
POLY-3 PERCENT (g)	97.4%	99.1%	97.8%	98.7%
TERMINAL (d)	33/33 (100%)	29/29 (100%)	29/30 (97%)	25/25 (100%)
FIRST INCIDENCE	407	437	431	450
HC TUMORS SAME RTE	247/250 (99%)			
HC TUMORS ALL RTES	1166/1199 (97%)			

STATISTICAL TESTS

POLY 3	P=0.589	P=0.596	P=0.740	P=0.662
POLY 1.5	P=0.588	P=0.511	P=0.600	P=0.603
POLY 6	P=0.656	P=0.891	P=0.714N	P=0.909
COCH-ARM / FISHERS	P=0.520N	P=0.500	P=0.500	P=0.661N
MAX-ISO-POLY-3	P=0.422	P=0.179	P=0.442	P=0.241
HISTCONT SAME RTE	P=0.514	P=0.229	P=0.573	P=0.311
HISTCONT ALL RTES	P=0.491	P=0.215	P=0.555	P=0.296

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**All Organs
 Malignant Tumors**

TUMOR RATES	#	#	#	#
OVERALL (a)	29/50 (58%)	29/50 (58%)	31/50 (62%)	37/50 (74%)
POLY-3 RATE (b)	29/49.08	29/47.89	31/49.29	37/48.31
POLY-3 PERCENT (g)	59.1%	60.6%	62.9%	76.6%
TERMINAL (d)	14/33 (42%)	12/29 (41%)	13/30 (43%)	15/25 (60%)
FIRST INCIDENCE	422	355	316	208
HC TUMORS SAME RTE	127/250 (51%)			
HC TUMORS ALL RTEs	686/1199 (57%)			

STATISTICAL TESTS

POLY 3	P=0.029*	P=0.524	P=0.429	P=0.049*
POLY 1.5	P=0.031*	P=0.549	P=0.429	P=0.055
POLY 6	P=0.028*	P=0.492	P=0.421	P=0.044*
COCH-ARM / FISHERS	P=0.037*	P=0.580N	P=0.419	P=0.069
MAX-ISO-POLY-3	P=0.047*	P=0.441	P=0.349	P=0.031*
HISTCONT SAME RTE	P=0.030*	P=0.307	P=0.237	P=0.035*
HISTCONT ALL RTEs	P=0.053	P=0.559	P=0.442	P=0.032*

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**All Organs
 Malignant and Benign Tumors**

TUMOR RATES	#	#	#	#
OVERALL (a)	50/50 (100%)	50/50 (100%)	50/50 (100%)	49/50 (98%)
POLY-3 RATE (b)	50/50	50/50	50/50	49/49.24
POLY-3 PERCENT (g)	100%	100%	100%	99.5%
TERMINAL (d)	33/33 (100%)	29/29 (100%)	30/30 (100%)	25/25 (100%)
FIRST INCIDENCE	407	355	316	208
HC TUMORS SAME RTE	250/250 (100%)			
HC TUMORS ALL RTES	1195/1199 (100%)			

STATISTICAL TESTS

POLY 3	P=0.967N	(e)	(e)	P=0.999N
POLY 1.5	P=0.525N	(e)	(e)	P=0.852N
POLY 6	P=1.000N	(e)	(e)	P=1.000N
COCH-ARM / FISHERS	P=0.210N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	P=0.127N	(e)	(e)	P=0.161N
HISTCONT SAME RTE	(h)	(e)	(e)	(h)
HISTCONT ALL RTES	(h)	(e)	(e)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex
 Adenoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	1/44.86	1/44.94	3/45.91	2/46.07
POLY-3 PERCENT (g)	2.2%	2.2%	6.5%	4.3%
TERMINAL (d)	1/30 (3%)	1/36 (3%)	3/42 (7%)	2/36 (6%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
HC TUMORS SAME RTE	8/199 (4%)			
HC TUMORS ALL RTES	17/1098 (2%)			

STATISTICAL TESTS

POLY 3	P=0.401	P=0.760N	P=0.314	P=0.509
POLY 1.5	P=0.393	P=0.759	P=0.307	P=0.503
POLY 6	P=0.413	P=0.759N	P=0.325	P=0.518
COCH-ARM / FISHERS	P=0.386	P=0.753N	P=0.309	P=0.500
MAX-ISO-POLY-3	P=0.353	P=0.499N	P=0.163	P=0.291
HISTCONT SAME RTE	P=0.435	P=1.000	P=0.211	P=0.384
HISTCONT ALL RTES	P=0.232	P=0.570	P=0.124	P=0.299

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Medulla
 Pheochromocytoma Benign**

TUMOR RATES

OVERALL (a)	0/48 (0%)	2/50 (4%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.73	2/44.94	0/44.91	0/46.07
POLY-3 PERCENT (g)	0%	4.5%	0%	0%
TERMINAL (d)	0/30 (0%)	2/36 (6%)	0/41 (0%)	0/36 (0%)
FIRST INCIDENCE	---	729 (T)	---	---
HC TUMORS SAME RTE	3/197 (2%)			
HC TUMORS ALL RTES	27/1091 (3%)			

STATISTICAL TESTS

POLY 3	P=0.365N	P=0.243	(e)	(e)
POLY 1.5	P=0.367N	P=0.243	(e)	(e)
POLY 6	P=0.362N	P=0.244	(e)	(e)
COCH-ARM / FISHERS	P=0.365N	P=0.258	(e)	(e)
MAX-ISO-POLY-3	P=0.254N	P=0.080	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Medulla
 Pheochromocytoma Malignant**

TUMOR RATES

OVERALL (a)	0/48 (0%)	0/50 (0%)	1/49 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/43.73	0/44.94	1/44.91	0/46.07
POLY-3 PERCENT (g)	0%	0%	2.2%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	1/41 (2%)	0/36 (0%)
FIRST INCIDENCE	---	---	729 (T)	---
HC TUMORS SAME RTE	3/197 (2%)			
HC TUMORS ALL RTES	8/1091 (1%)			

STATISTICAL TESTS

POLY 3	P=0.783N	(e)	P=0.505	(e)
POLY 1.5	P=0.785N	(e)	P=0.502	(e)
POLY 6	P=0.780N	(e)	P=0.511	(e)
COCH-ARM / FISHERS	P=0.786N	(e)	P=0.505	(e)
MAX-ISO-POLY-3	P=0.397	(e)	P=0.164	(e)
HISTCONT SAME RTE	(h)	(e)	(h)	(e)
HISTCONT ALL RTES	(h)	(e)	(h)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Medulla
 Pheochromocytoma: Benign, Complex, Malignant, NOS**

TUMOR RATES

OVERALL (a)	0/48 (0%)	2/50 (4%)	1/49 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/43.73	2/44.94	1/44.91	0/46.07
POLY-3 PERCENT (g)	0%	4.5%	2.2%	0%
TERMINAL (d)	0/30 (0%)	2/36 (6%)	1/41 (2%)	0/36 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---
HC TUMORS SAME RTE	6/197 (3%)			
HC TUMORS ALL RTES	36/1091 (3%)			

STATISTICAL TESTS

POLY 3	P=0.379N	P=0.243	P=0.505	(e)
POLY 1.5	P=0.383N	P=0.243	P=0.502	(e)
POLY 6	P=0.372N	P=0.244	P=0.511	(e)
COCH-ARM / FISHERS	P=0.381N	P=0.258	P=0.505	(e)
MAX-ISO-POLY-3	P=0.334N	P=0.080	P=0.164	(e)
HISTCONT SAME RTE	(h)	(h)	(h)	(e)
HISTCONT ALL RTES	(h)	(h)	(h)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Bone				
Osteosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	1/200 (1%)			
HC TUMORS ALL RTES	5/1100 (1%)			

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Clitoral/Preputial Gland
 Adenoma**

TUMOR RATES

OVERALL (a)	5/50 (10%)	9/50 (18%)	4/49 (8%)	3/50 (6%)
POLY-3 RATE (b)	5/45.26	9/45.27	4/44.91	3/46.07
POLY-3 PERCENT (g)	11.1%	19.9%	8.9%	6.5%
TERMINAL (d)	2/30 (7%)	8/36 (22%)	4/41 (10%)	3/36 (8%)
FIRST INCIDENCE	663	639	729 (T)	729 (T)
HC TUMORS SAME RTE	26/200 (13%)			
HC TUMORS ALL RTES	104/1096 (10%)			

STATISTICAL TESTS

POLY 3	P=0.116N	P=0.191	P=0.505N	P=0.347N
POLY 1.5	P=0.121N	P=0.189	P=0.514N	P=0.354N
POLY 6	P=0.109N	P=0.193	P=0.490N	P=0.337N
COCH-ARM / FISHERS	P=0.125N	P=0.194	P=0.513N	P=0.357N
MAX-ISO-POLY-3	P=0.147N	P=0.122	P=0.367N	P=0.225N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Clitoral/Preputial Gland
 Carcinoma**

TUMOR RATES

OVERALL (a)	4/50 (8%)	3/50 (6%)	1/49 (2%)	0/50 (0%)
POLY-3 RATE (b)	4/45.02	3/45.22	1/44.91	0/46.07
POLY-3 PERCENT (g)	8.9%	6.6%	2.2%	0%
TERMINAL (d)	2/30 (7%)	2/36 (6%)	1/41 (2%)	0/36 (0%)
FIRST INCIDENCE	703	653	729 (T)	---
HC TUMORS SAME RTE	6/200 (3%)			
HC TUMORS ALL RTES	29/1096 (3%)			

STATISTICAL TESTS

POLY 3	P=0.034N*	P=0.498N	P=0.179N	P=0.057N
POLY 1.5	P=0.035N*	P=0.502N	P=0.185N	P=0.060N
POLY 6	P=0.033N*	P=0.492N	P=0.170N	P=0.054N
COCH-ARM / FISHERS	P=0.037N*	P=0.500N	P=0.187N	P=0.059N
MAX-ISO-POLY-3	P=0.032N*	P=0.345N	P=0.085N	P=0.019N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Clitoral/Preputial Gland
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	9/50 (18%)	11/50 (22%)	5/49 (10%)	3/50 (6%)
POLY-3 RATE (b)	9/45.42	11/45.55	5/44.91	3/46.07
POLY-3 PERCENT (g)	19.8%	24.2%	11.1%	6.5%
TERMINAL (d)	4/30 (13%)	9/36 (25%)	5/41 (12%)	3/36 (8%)
FIRST INCIDENCE	663	639	729 (T)	729 (T)
HC TUMORS SAME RTE	32/200 (16%)			
HC TUMORS ALL RTES	133/1096 (12%)			

STATISTICAL TESTS

POLY 3	P=0.016N*	P=0.403	P=0.198N	P=0.056N
POLY 1.5	P=0.018N*	P=0.397	P=0.206N	P=0.059N
POLY 6	P=0.015N*	P=0.409	P=0.185N	P=0.052N
COCH-ARM / FISHERS	P=0.019N*	P=0.402	P=0.205N	P=0.061N
MAX-ISO-POLY-3	P=0.026N*	P=0.309	P=0.127N	P=0.029N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Heart
 Schwannoma Malignant**

TUMOR RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/44.94	0/44.94	0/45.91	1/46.07
POLY-3 PERCENT (g)	2.2%	0%	0%	2.2%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	1/36 (3%)
FIRST INCIDENCE	709	---	---	729 (T)
HC TUMORS SAME RTE	1/200 (1%)			
HC TUMORS ALL RTES	4/1099 (0%)			

STATISTICAL TESTS

POLY 3	P=0.549	P=0.500N	P=0.496N	P=0.755N
POLY 1.5	P=0.546	P=0.501N	P=0.499N	P=0.759N
POLY 6	P=0.552	P=0.499N	P=0.490N	P=0.750N
COCH-ARM / FISHERS	P=0.544	P=0.500N	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.405N	P=0.158N	P=0.158N	P=0.492N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Intestine Small: Site Unspecified
 Carcinoma or Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/200 (0%)			
HC TUMORS ALL RTES	0/1100 (0%)			

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Islets, Pancreatic
 Adenoma**

TUMOR RATES

OVERALL (a)	0/49 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.89	1/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	2.2%	0%	0%
TERMINAL (d)	0/30 (0%)	1/36 (3%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	729 (T)	---	---
HC TUMORS SAME RTE	2/198 (1%)			
HC TUMORS ALL RTES	21/1092 (2%)			

STATISTICAL TESTS

POLY 3	P=0.569N	P=0.505	(e)	(e)
POLY 1.5	P=0.570N	P=0.503	(e)	(e)
POLY 6	P=0.567N	P=0.507	(e)	(e)
COCH-ARM / FISHERS	P=0.570N	P=0.505	(e)	(e)
MAX-ISO-POLY-3	P=0.390N	P=0.163	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Islets, Pancreatic
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	0/49 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.89	1/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	2.2%	0%	0%
TERMINAL (d)	0/30 (0%)	1/36 (3%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	729 (T)	---	---
HC TUMORS SAME RTE	4/198 (2%)			
HC TUMORS ALL RTES	25/1092 (2%)			

STATISTICAL TESTS

POLY 3	P=0.569N	P=0.505	(e)	(e)
POLY 1.5	P=0.570N	P=0.503	(e)	(e)
POLY 6	P=0.567N	P=0.507	(e)	(e)
COCH-ARM / FISHERS	P=0.570N	P=0.505	(e)	(e)
MAX-ISO-POLY-3	P=0.390N	P=0.163	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Liver
 Hepatocellular Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	8/50 (16%)
POLY-3 RATE (b)	0/44.86	0/44.94	1/45.91	8/46.48
POLY-3 PERCENT (g)	0%	0%	2.2%	17.2%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	1/42 (2%)	6/36 (17%)
FIRST INCIDENCE	---	---	729 (T)	666
HC TUMORS SAME RTE	3/200 (2%)			
HC TUMORS ALL RTES	14/1099 (1%)			

STATISTICAL TESTS

POLY 3	P<0.001**	(e)	P=0.505	P=0.004**
POLY 1.5	P<0.001**	(e)	P=0.501	P=0.004**
POLY 6	P<0.001**	(e)	P=0.511	P=0.005**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.500	P=0.003**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.164	P=0.002**
HISTCONT SAME RTE	P<0.001**	(e)	P=0.213	P=0.002**
HISTCONT ALL RTES	P<0.001**	(e)	P=0.195	P=0.002**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Liver
 Hepatocellular Carcinoma or Hepatocellular Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	8/50 (16%)
POLY-3 RATE (b)	0/44.86	0/44.94	1/45.91	8/46.48
POLY-3 PERCENT (g)	0%	0%	2.2%	17.2%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	1/42 (2%)	6/36 (17%)
FIRST INCIDENCE	---	---	729 (T)	666
HC TUMORS SAME RTE	3/200 (2%)			
HC TUMORS ALL RTES	14/1099 (1%)			

STATISTICAL TESTS

POLY 3	P<0.001**	(e)	P=0.505	P=0.004**
POLY 1.5	P<0.001**	(e)	P=0.501	P=0.004**
POLY 6	P<0.001**	(e)	P=0.511	P=0.005**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.500	P=0.003**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.164	P=0.002**
HISTCONT SAME RTE	P<0.001**	(e)	P=0.213	P=0.002**
HISTCONT ALL RTES	P<0.001**	(e)	P=0.195	P=0.002**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Liver				
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	8/50 (16%)
POLY-3 RATE (b)	0/44.86	0/44.94	1/45.91	8/46.48
POLY-3 PERCENT (g)	0%	0%	2.2%	17.2%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	1/42 (2%)	6/36 (17%)
FIRST INCIDENCE	---	---	729 (T)	666
HC TUMORS SAME RTE	3/200 (2%)			
HC TUMORS ALL RTES	14/1099 (1%)			

STATISTICAL TESTS

POLY 3	P<0.001**	(e)	P=0.505	P=0.004**
POLY 1.5	P<0.001**	(e)	P=0.501	P=0.004**
POLY 6	P<0.001**	(e)	P=0.511	P=0.005**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.500	P=0.003**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.164	P=0.002**
HISTCONT SAME RTE	P<0.001**	(e)	P=0.213	P=0.002**
HISTCONT ALL RTES	P<0.001**	(e)	P=0.195	P=0.002**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Lung
 Alveolar/Bronchiolar Adenoma

TUMOR RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.86	1/45.02	0/45.91	0/46.07
POLY-3 PERCENT (g)	2.2%	2.2%	0%	0%
TERMINAL (d)	1/30 (3%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	729 (T)	709	---	---
HC TUMORS SAME RTE	5/200 (3%)			
HC TUMORS ALL RTES	24/1099 (2%)			

STATISTICAL TESTS

POLY 3	P=0.290N	P=0.760N	P=0.495N	P=0.495N
POLY 1.5	P=0.291N	P=0.760	P=0.499N	P=0.498N
POLY 6	P=0.289N	P=0.758N	P=0.489N	P=0.490N
COCH-ARM / FISHERS	P=0.290N	P=0.753N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.257N	P=0.498N	P=0.158N	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung
 Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.86	1/45.02	0/45.91	0/46.07
POLY-3 PERCENT (g)	2.2%	2.2%	0%	0%
TERMINAL (d)	1/30 (3%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	729 (T)	709	---	---
HC TUMORS SAME RTE	5/200 (3%)			
HC TUMORS ALL RTES	29/1099 (3%)			

STATISTICAL TESTS

POLY 3	P=0.290N	P=0.760N	P=0.495N	P=0.495N
POLY 1.5	P=0.291N	P=0.760	P=0.499N	P=0.498N
POLY 6	P=0.289N	P=0.758N	P=0.489N	P=0.490N
COCH-ARM / FISHERS	P=0.290N	P=0.753N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.257N	P=0.498N	P=0.158N	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Mammary Gland Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/44.86	2/45.31	0/45.91	1/46.07
POLY-3 PERCENT (g)	4.5%	4.4%	0%	2.2%
TERMINAL (d)	2/30 (7%)	1/36 (3%)	0/42 (0%)	1/36 (3%)
FIRST INCIDENCE	729 (T)	627	---	729 (T)
HC TUMORS SAME RTE	3/200 (2%)			
HC TUMORS ALL RTES	15/1100 (1%)			

STATISTICAL TESTS

POLY 3	P=0.363N	P=0.690N	P=0.232N	P=0.491N
POLY 1.5	P=0.366N	P=0.693	P=0.236N	P=0.497N
POLY 6	P=0.360N	P=0.686N	P=0.225N	P=0.482N
COCH-ARM / FISHERS	P=0.367N	P=0.691N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.271N	P=0.495N	P=0.076N	P=0.275N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Mammary Gland Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	4/50 (8%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	4/45.11	1/45.02	1/46.44	2/46.17
POLY-3 PERCENT (g)	8.9%	2.2%	2.2%	4.3%
TERMINAL (d)	3/30 (10%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	663	709	565	716
HC TUMORS SAME RTE	6/200 (3%)			
HC TUMORS ALL RTES	60/1100 (6%)			

STATISTICAL TESTS

POLY 3	P=0.433N	P=0.179N	P=0.170N	P=0.326N
POLY 1.5	P=0.436N	P=0.181N	P=0.177N	P=0.334N
POLY 6	P=0.428N	P=0.177N	P=0.160N	P=0.316N
COCH-ARM / FISHERS	P=0.441N	P=0.181N	P=0.181N	P=0.339N
MAX-ISO-POLY-3	P=0.136N	P=0.084N	P=0.081N	P=0.195N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Mammary Gland Carcinoma or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	6/50 (12%)	3/50 (6%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	6/45.11	3/45.39	1/46.44	3/46.17
POLY-3 PERCENT (g)	13.3%	6.6%	2.2%	6.5%
TERMINAL (d)	5/30 (17%)	1/36 (3%)	0/42 (0%)	1/36 (3%)
FIRST INCIDENCE	663	627	565	716
HC TUMORS SAME RTE	9/200 (5%)			
HC TUMORS ALL RTES	75/1100 (7%)			

STATISTICAL TESTS

POLY 3	P=0.277N	P=0.239N	P=0.051N	P=0.230N
POLY 1.5	P=0.280N	P=0.244N	P=0.055N	P=0.239N
POLY 6	P=0.272N	P=0.232N	P=0.046N*	P=0.218N
COCH-ARM / FISHERS	P=0.284N	P=0.243N	P=0.056N	P=0.243N
MAX-ISO-POLY-3	P=0.079N	P=0.145N	P=0.023N*	P=0.141N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Mammary Gland Fibroadenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	30/50 (60%)	20/50 (40%)	11/50 (22%)	17/50 (34%)
POLY-3 RATE (b)	30/46.42	20/46	11/45.91	17/47
POLY-3 PERCENT (g)	64.6%	43.5%	24%	36.2%
TERMINAL (d)	21/30 (70%)	17/36 (47%)	11/42 (26%)	13/36 (36%)
FIRST INCIDENCE	611	585	729 (T)	568
HC TUMORS SAME RTE	106/200 (53%)			
HC TUMORS ALL RTEs	574/1100 (52%)			

STATISTICAL TESTS

POLY 3	P=0.015N*	P=0.029N*	P<0.001N**	P=0.004N**
POLY 1.5	P=0.018N*	P=0.033N*	P<0.001N**	P=0.005N**
POLY 6	P=0.012N*	P=0.026N*	P<0.001N**	P=0.003N**
COCH-ARM / FISHERS	P=0.026N*	P=0.036N*	P<0.001N**	P=0.008N**
MAX-ISO-POLY-3	P<0.001N**	P=0.018N*	P<0.001N**	P=0.002N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Mammary Gland Fibroma, Fibroadenoma or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	30/50 (60%)	21/50 (42%)	11/50 (22%)	18/50 (36%)
POLY-3 RATE (b)	30/46.42	21/46.36	11/45.91	18/47
POLY-3 PERCENT (g)	64.6%	45.3%	24%	38.3%
TERMINAL (d)	21/30 (70%)	17/36 (47%)	11/42 (26%)	14/36 (39%)
FIRST INCIDENCE	611	585	729 (T)	568
HC TUMORS SAME RTE	108/200 (54%)			
HC TUMORS ALL RTES	583/1100 (53%)			

STATISTICAL TESTS

POLY 3	P=0.024N*	P=0.043N*	P<0.001N**	P=0.007N**
POLY 1.5	P=0.027N*	P=0.050N*	P<0.001N**	P=0.010N**
POLY 6	P=0.020N*	P=0.038N*	P<0.001N**	P=0.005N**
COCH-ARM / FISHERS	P=0.036N*	P=0.055N	P<0.001N**	P=0.014N*
MAX-ISO-POLY-3	P<0.001N**	P=0.027N*	P<0.001N**	P=0.004N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Mammary Gland Fibroma, Fibroadenoma, Carcinoma, or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	31/50 (62%)	22/50 (44%)	12/50 (24%)	19/50 (38%)
POLY-3 RATE (b)	31/46.67	22/46.44	12/46.44	19/47.06
POLY-3 PERCENT (g)	66.4%	47.4%	25.8%	40.4%
TERMINAL (d)	21/30 (70%)	17/36 (47%)	11/42 (26%)	14/36 (39%)
FIRST INCIDENCE	611	585	565	568
HC TUMORS SAME RTE	111/200 (56%)			
HC TUMORS ALL RTES	619/1100 (56%)			

STATISTICAL TESTS

POLY 3	P=0.025N*	P=0.045N*	P<0.001N**	P=0.008N**
POLY 1.5	P=0.028N*	P=0.051N	P<0.001N**	P=0.010N**
POLY 6	P=0.021N*	P=0.041N*	P<0.001N**	P=0.006N**
COCH-ARM / FISHERS	P=0.037N*	P=0.054N	P<0.001N**	P=0.014N*
MAX-ISO-POLY-3	P<0.001N**	P=0.028N*	P<0.001N**	P=0.004N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)
 Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/44.86	0/44.94	0/45.91	1/46.07
POLY-3 PERCENT (g)	2.2%	0%	0%	2.2%
TERMINAL (d)	1/30 (3%)	0/36 (0%)	0/42 (0%)	1/36 (3%)
FIRST INCIDENCE	729 (T)	---	---	729 (T)
HC TUMORS SAME RTE	0/200 (0%)			
HC TUMORS ALL RTES	10/1100 (1%)			

STATISTICAL TESTS

POLY 3	P=0.549	P=0.500N	P=0.495N	P=0.755N
POLY 1.5	P=0.547	P=0.501N	P=0.499N	P=0.759N
POLY 6	P=0.552	P=0.498N	P=0.489N	P=0.749N
COCH-ARM / FISHERS	P=0.544	P=0.500N	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.405N	P=0.158N	P=0.158N	P=0.492N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pituitary Gland: Pars Distalis or Unspecified Site
 Adenoma**

TUMOR RATES

OVERALL (a)	25/50 (50%)	20/50 (40%)	16/50 (32%)	16/50 (32%)
POLY-3 RATE (b)	25/46.29	20/46.35	16/46.43	16/46.33
POLY-3 PERCENT (g)	54%	43.2%	34.5%	34.5%
TERMINAL (d)	19/30 (63%)	16/36 (44%)	15/42 (36%)	13/36 (36%)
FIRST INCIDENCE	537	589	569	687
HC TUMORS SAME RTE	93/197 (47%)			
HC TUMORS ALL RTES	613/1093 (56%)			

STATISTICAL TESTS

POLY 3	P=0.058N	P=0.198N	P=0.042N*	P=0.043N*
POLY 1.5	P=0.062N	P=0.212N	P=0.049N*	P=0.048N*
POLY 6	P=0.052N	P=0.180N	P=0.033N*	P=0.036N*
COCH-ARM / FISHERS	P=0.066N	P=0.211N	P=0.052N	P=0.052N
MAX-ISO-POLY-3	P=0.042N*	P=0.144N	P=0.026N*	P=0.027N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pituitary Gland: Pars Distalis or Unspecified Site
 Carcinoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	4/50 (8%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/44.86	4/44.95	2/46.44	1/46.07
POLY-3 PERCENT (g)	0%	8.9%	4.3%	2.2%
TERMINAL (d)	0/30 (0%)	3/36 (8%)	1/42 (2%)	1/36 (3%)
FIRST INCIDENCE	---	726	565	729 (T)
HC TUMORS SAME RTE	3/197 (2%)			
HC TUMORS ALL RTES	13/1093 (1%)			

STATISTICAL TESTS

POLY 3	P=0.460N	P=0.060	P=0.245	P=0.505
POLY 1.5	P=0.468N	P=0.060	P=0.240	P=0.502
POLY 6	P=0.447N	P=0.061	P=0.254	P=0.510
COCH-ARM / FISHERS	P=0.472N	P=0.059	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.170	P=0.019*	P=0.083	P=0.165
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pituitary Gland: Pars Distalis or Unspecified Site
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	25/50 (50%)	24/50 (48%)	18/50 (36%)	17/50 (34%)
POLY-3 RATE (b)	25/46.29	24/46.36	18/46.97	17/46.33
POLY-3 PERCENT (g)	54%	51.8%	38.3%	36.7%
TERMINAL (d)	19/30 (63%)	19/36 (53%)	16/42 (38%)	14/36 (39%)
FIRST INCIDENCE	537	589	565	687
HC TUMORS SAME RTE	96/197 (49%)			
HC TUMORS ALL RTES	626/1093 (57%)			

STATISTICAL TESTS

POLY 3	P=0.044N*	P=0.497N	P=0.091N	P=0.067N
POLY 1.5	P=0.048N*	P=0.511N	P=0.107N	P=0.075N
POLY 6	P=0.039N*	P=0.478N	P=0.071N	P=0.058N
COCH-ARM / FISHERS	P=0.051N	P=0.500N	P=0.113N	P=0.078N
MAX-ISO-POLY-3	P=0.071N	P=0.411N	P=0.062N	P=0.043N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin
 Basal Cell Carcinoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	1/200 (1%)			
HC TUMORS ALL RTES	3/1100 (0%)			

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Skin
 Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.86	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	1/30 (3%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	729 (T)	---	---	---
HC TUMORS SAME RTE	3/200 (2%)			
HC TUMORS ALL RTES	12/1100 (1%)			

STATISTICAL TESTS

POLY 3	P=0.450N	P=0.500N	P=0.495N	P=0.495N
POLY 1.5	P=0.448N	P=0.501N	P=0.499N	P=0.498N
POLY 6	P=0.453N	P=0.498N	P=0.489N	P=0.490N
COCH-ARM / FISHERS	P=0.448N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.126N	P=0.158N	P=0.158N	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Skin
 Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.86	1/45.22	0/45.91	0/46.07
POLY-3 PERCENT (g)	2.2%	2.2%	0%	0%
TERMINAL (d)	1/30 (3%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	729 (T)	653	---	---
HC TUMORS SAME RTE	7/200 (4%)			
HC TUMORS ALL RTES	24/1100 (2%)			

STATISTICAL TESTS

POLY 3	P=0.290N	P=0.759N	P=0.495N	P=0.495N
POLY 1.5	P=0.291N	P=0.760	P=0.499N	P=0.498N
POLY 6	P=0.289N	P=0.756N	P=0.489N	P=0.490N
COCH-ARM / FISHERS	P=0.290N	P=0.753N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.257N	P=0.497N	P=0.158N	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Skin Fibroma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	4/50 (8%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	1/44.86	4/46.05	3/46.14	1/46.3
POLY-3 PERCENT (g)	2.2%	8.7%	6.5%	2.2%
TERMINAL (d)	1/30 (3%)	1/36 (3%)	2/42 (5%)	0/36 (0%)
FIRST INCIDENCE	729 (T)	568	666	666
HC TUMORS SAME RTE	5/200 (3%)			
HC TUMORS ALL RTES	19/1100 (2%)			

STATISTICAL TESTS

POLY 3	P=0.331N	P=0.187	P=0.315	P=0.754N
POLY 1.5	P=0.340N	P=0.181	P=0.308	P=0.758N
POLY 6	P=0.318N	P=0.194	P=0.329	P=0.747N
COCH-ARM / FISHERS	P=0.345N	P=0.181	P=0.309	P=0.753N
MAX-ISO-POLY-3	P=0.346N	P=0.091	P=0.165	P=0.490N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin
 Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	5/50 (10%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	3/45.74	5/46.05	3/46.14	1/46.3
POLY-3 PERCENT (g)	6.6%	10.9%	6.5%	2.2%
TERMINAL (d)	1/30 (3%)	2/36 (6%)	2/42 (5%)	0/36 (0%)
FIRST INCIDENCE	575	568	666	666
HC TUMORS SAME RTE	6/200 (3%)			
HC TUMORS ALL RTES	25/1100 (2%)			

STATISTICAL TESTS

POLY 3	P=0.130N	P=0.360	P=0.658N	P=0.301N
POLY 1.5	P=0.133N	P=0.355	P=0.660	P=0.305N
POLY 6	P=0.125N	P=0.367	P=0.647N	P=0.294N
COCH-ARM / FISHERS	P=0.133N	P=0.357	P=0.661N	P=0.309N
MAX-ISO-POLY-3	P=0.166N	P=0.235	P=0.495N	P=0.152N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Skin				
Fibrosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	2/45.47	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	4.4%	0%	0%
TERMINAL (d)	0/30 (0%)	1/36 (3%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	568	---	---
HC TUMORS SAME RTE	1/200 (1%)			
HC TUMORS ALL RTES	5/1100 (1%)			

STATISTICAL TESTS

POLY 3	P=0.364N	P=0.240	(e)	(e)
POLY 1.5	P=0.368N	P=0.238	(e)	(e)
POLY 6	P=0.359N	P=0.243	(e)	(e)
COCH-ARM / FISHERS	P=0.370N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.256N	P=0.079	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin
 Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/45.74	2/45.47	0/45.91	0/46.07
POLY-3 PERCENT (g)	4.4%	4.4%	0%	0%
TERMINAL (d)	0/30 (0%)	1/36 (3%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	575	568	---	---
HC TUMORS SAME RTE	1/200 (1%)			
HC TUMORS ALL RTES	6/1100 (1%)			

STATISTICAL TESTS

POLY 3	P=0.113N	P=0.692	P=0.236N	P=0.236N
POLY 1.5	P=0.114N	P=0.690	P=0.239N	P=0.238N
POLY 6	P=0.112N	P=0.693	P=0.232N	P=0.232N
COCH-ARM / FISHERS	P=0.114N	P=0.691N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.121N	P=0.497	P=0.076N	P=0.076N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Skin				
Keratoacanthoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	3/200 (2%)			
HC TUMORS ALL RTES	8/1100 (1%)			

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Skin				
Lipoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/200 (0%)			
HC TUMORS ALL RTES	1/1100 (0%)			

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Skin				
Sarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/45.74	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	4.4%	0%	0%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	575	---	---	---
HC TUMORS SAME RTE	0/200 (0%)			
HC TUMORS ALL RTES	0/1100 (0%)			

STATISTICAL TESTS

POLY 3	P=0.215N	P=0.241N	P=0.236N	P=0.236N
POLY 1.5	P=0.216N	P=0.241N	P=0.239N	P=0.238N
POLY 6	P=0.215N	P=0.242N	P=0.232N	P=0.232N
COCH-ARM / FISHERS	P=0.220N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.034N*	P=0.080N	P=0.076N	P=0.076N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin
 Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	1/45.22	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	2.2%	0%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	653	---	---
HC TUMORS SAME RTE	4/200 (2%)			
HC TUMORS ALL RTES	12/1100 (1%)			

STATISTICAL TESTS

POLY 3	P=0.570N	P=0.502	(e)	(e)
POLY 1.5	P=0.572N	P=0.500	(e)	(e)
POLY 6	P=0.568N	P=0.504	(e)	(e)
COCH-ARM / FISHERS	P=0.572N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.390N	P=0.161	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin
 Squamous Cell Papilloma, Papilloma, or Keratoacanthoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	1/45.22	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	2.2%	0%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	653	---	---
HC TUMORS SAME RTE	4/200 (2%)			
HC TUMORS ALL RTES	11/1100 (1%)			

STATISTICAL TESTS

POLY 3	P=0.570N	P=0.502	(e)	(e)
POLY 1.5	P=0.572N	P=0.500	(e)	(e)
POLY 6	P=0.568N	P=0.504	(e)	(e)
COCH-ARM / FISHERS	P=0.572N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.390N	P=0.161	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin: Sebaceous Gland
 Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/200 (0%)			
HC TUMORS ALL RTES	1/1100 (0%)			

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thyroid Gland: C-Cell
 Adenoma**

TUMOR RATES

OVERALL (a)	4/50 (8%)	4/50 (8%)	3/50 (6%)	4/50 (8%)
POLY-3 RATE (b)	4/44.86	4/45.28	3/45.91	4/46.07
POLY-3 PERCENT (g)	8.9%	8.8%	6.5%	8.7%
TERMINAL (d)	4/30 (13%)	3/36 (8%)	3/42 (7%)	4/36 (11%)
FIRST INCIDENCE	729 (T)	635	729 (T)	729 (T)
HC TUMORS SAME RTE	26/195 (13%)			
HC TUMORS ALL RTEs	124/1086 (11%)			

STATISTICAL TESTS

POLY 3	P=0.578N	P=0.638N	P=0.487N	P=0.629N
POLY 1.5	P=0.585N	P=0.642	P=0.498N	P=0.638N
POLY 6	P=0.567N	P=0.631N	P=0.469N	P=0.615N
COCH-ARM / FISHERS	P=0.585	P=0.643N	P=0.500N	P=0.643N
MAX-ISO-POLY-3	P=0.639N	P=0.494N	P=0.337N	P=0.484N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thyroid Gland: C-Cell
 Carcinoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.86	1/45.43	0/45.91	0/46.07
POLY-3 PERCENT (g)	2.2%	2.2%	0%	0%
TERMINAL (d)	1/30 (3%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	729 (T)	585	---	---
HC TUMORS SAME RTE	2/195 (1%)			
HC TUMORS ALL RTES	18/1086 (2%)			

STATISTICAL TESTS

POLY 3	P=0.290N	P=0.758N	P=0.495N	P=0.495N
POLY 1.5	P=0.291N	P=0.760N	P=0.499N	P=0.498N
POLY 6	P=0.289N	P=0.755N	P=0.489N	P=0.490N
COCH-ARM / FISHERS	P=0.290N	P=0.753N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.257N	P=0.496N	P=0.158N	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thyroid Gland: C-Cell
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	5/50 (10%)	5/50 (10%)	3/50 (6%)	4/50 (8%)
POLY-3 RATE (b)	5/44.86	5/45.76	3/45.91	4/46.07
POLY-3 PERCENT (g)	11.2%	10.9%	6.5%	8.7%
TERMINAL (d)	5/30 (17%)	3/36 (8%)	3/42 (7%)	4/36 (11%)
FIRST INCIDENCE	729 (T)	585	729 (T)	729 (T)
HC TUMORS SAME RTE	28/195 (14%)			
HC TUMORS ALL RTES	141/1086 (13%)			

STATISTICAL TESTS

POLY 3	P=0.414N	P=0.618N	P=0.344N	P=0.483N
POLY 1.5	P=0.421N	P=0.627N	P=0.355N	P=0.495N
POLY 6	P=0.404N	P=0.605N	P=0.326N	P=0.467N
COCH-ARM / FISHERS	P=0.424N	P=0.630N	P=0.357N	P=0.500N
MAX-ISO-POLY-3	P=0.458N	P=0.486N	P=0.223N	P=0.349N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
Uterus				
Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	14/50 (28%)	11/50 (22%)	16/50 (32%)	10/50 (20%)
POLY-3 RATE (b)	14/47.47	11/46.27	16/46.15	10/46.61
POLY-3 PERCENT (g)	29.5%	23.8%	34.7%	21.5%
TERMINAL (d)	7/30 (23%)	8/36 (22%)	15/42 (36%)	9/36 (25%)
FIRST INCIDENCE	404	568	663	563
HC TUMORS SAME RTE	40/200 (20%)			
HC TUMORS ALL RTES	203/1100 (19%)			

STATISTICAL TESTS

POLY 3	P=0.274N	P=0.348N	P=0.377	P=0.255N
POLY 1.5	P=0.276N	P=0.345N	P=0.379	P=0.256N
POLY 6	P=0.269N	P=0.352N	P=0.382	P=0.254N
COCH-ARM / FISHERS	P=0.268N	P=0.322N	P=0.414	P=0.241N
MAX-ISO-POLY-3	P=0.311N	P=0.269N	P=0.299	P=0.188N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
All Organs				
Histiocytic Sarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.86	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	1/30 (3%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	729 (T)	---	---	---
HC TUMORS SAME RTE	3/200 (2%)			
HC TUMORS ALL RTES	9/1100 (1%)			

STATISTICAL TESTS

POLY 3	P=0.450N	P=0.500N	P=0.495N	P=0.495N
POLY 1.5	P=0.448N	P=0.501N	P=0.499N	P=0.498N
POLY 6	P=0.453N	P=0.498N	P=0.489N	P=0.490N
COCH-ARM / FISHERS	P=0.448N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.126N	P=0.158N	P=0.158N	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

All Organs
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated

TUMOR RATES	#	#	#	#
OVERALL (a)	9/50 (18%)	9/50 (18%)	7/50 (14%)	6/50 (12%)
POLY-3 RATE (b)	9/45.61	9/46.75	7/46.88	6/47.35
POLY-3 PERCENT (g)	19.7%	19.3%	14.9%	12.7%
TERMINAL (d)	4/30 (13%)	3/36 (8%)	5/42 (12%)	1/36 (3%)
FIRST INCIDENCE	611	635	474	563
HC TUMORS SAME RTE	43/200 (22%)			
HC TUMORS ALL RTES	265/1100 (24%)			

STATISTICAL TESTS

POLY 3	P=0.198N	P=0.581N	P=0.369N	P=0.261N
POLY 1.5	P=0.208N	P=0.596N	P=0.386N	P=0.276N
POLY 6	P=0.186N	P=0.558N	P=0.345N	P=0.240N
COCH-ARM / FISHERS	P=0.216N	P=0.602N	P=0.393N	P=0.288N
MAX-ISO-POLY-3	P=0.302N	P=0.476N	P=0.275N	P=0.183N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**All Organs
 Mesothelioma: Benign, Malignant, NOS**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/200 (0%)			
HC TUMORS ALL RTES	4/1100 (0%)			

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**All Organs
 Mesothelioma: Malignant**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/200 (0%)			
HC TUMORS ALL RTES	3/1100 (0%)			

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

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 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
All Organs				
Osteosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	1/200 (1%)			
HC TUMORS ALL RTES	5/1100 (1%)			

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**All Organs
 Osteosarcoma or Osteoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	1/200 (1%)			
HC TUMORS ALL RTES	5/1100 (1%)			

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
All Organs				
Benign Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	46/50 (92%)	44/50 (88%)	40/50 (80%)	36/50 (72%)
POLY-3 RATE (b)	46/49.34	44/48.69	40/47.45	36/48
POLY-3 PERCENT (g)	93.2%	90.4%	84.3%	75%
TERMINAL (d)	29/30 (97%)	33/36 (92%)	36/42 (86%)	28/36 (78%)
FIRST INCIDENCE	404	568	565	563
HC TUMORS SAME RTE	178/200 (89%)			
HC TUMORS ALL RTES	966/1100 (88%)			

STATISTICAL TESTS

POLY 3	P=0.003N**	P=0.439N	P=0.130N	P=0.010N**
POLY 1.5	P=0.003N**	P=0.457N	P=0.121N	P=0.011N*
POLY 6	P=0.003N**	P=0.412N	P=0.139N	P=0.010N**
COCH-ARM / FISHERS	P=0.004N**	P=0.370N	P=0.074N	P=0.009N**
MAX-ISO-POLY-3	P=0.006N**	P=0.298N	P=0.075N	P=0.005N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
All Organs				
Malignant Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	19/50 (38%)	18/50 (36%)	13/50 (26%)	12/50 (24%)
POLY-3 RATE (b)	19/46.83	18/47.85	13/48.24	12/47.6
POLY-3 PERCENT (g)	40.6%	37.6%	27%	25.2%
TERMINAL (d)	10/30 (33%)	8/36 (22%)	8/42 (19%)	5/36 (14%)
FIRST INCIDENCE	575	568	474	563
HC TUMORS SAME RTE	73/200 (37%)			
HC TUMORS ALL RTES	428/1100 (39%)			

STATISTICAL TESTS

POLY 3	P=0.061N	P=0.467N	P=0.116N	P=0.083N
POLY 1.5	P=0.065N	P=0.491N	P=0.132N	P=0.092N
POLY 6	P=0.058N	P=0.436N	P=0.098N	P=0.074N
COCH-ARM / FISHERS	P=0.067N	P=0.500N	P=0.142N	P=0.097N
MAX-ISO-POLY-3	P=0.091N	P=0.384N	P=0.082N	P=0.055N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Goldenseal root powder
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 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
All Organs				
Malignant and Benign Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	48/50 (96%)	47/50 (94%)	45/50 (90%)	39/50 (78%)
POLY-3 RATE (b)	48/49.49	47/49	45/49	39/48.57
POLY-3 PERCENT (g)	97%	95.9%	91.8%	80.3%
TERMINAL (d)	29/30 (97%)	34/36 (94%)	38/42 (91%)	28/36 (78%)
FIRST INCIDENCE	404	568	474	563
HC TUMORS SAME RTE	186/200 (93%)			
HC TUMORS ALL RTES	1039/1100 (95%)			

STATISTICAL TESTS

POLY 3	P<0.001N**	P=0.604N	P=0.246N	P=0.008N**
POLY 1.5	P<0.001N**	P=0.637N	P=0.279N	P=0.009N**
POLY 6	P<0.001N**	P=0.553N	P=0.210N	P=0.007N**
COCH-ARM / FISHERS	P<0.001N**	P=0.500N	P=0.218N	P=0.007N**
MAX-ISO-POLY-3	P<0.001N**	P=0.383N	P=0.129N	P=0.003N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 05
Test Type: CHRONIC
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Species/Strain: RATS/F 344

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LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
 - (b) Number of tumor-bearing animals/Poly-3 number
 - (d) Observed incidence at terminal kill.
 - (e) Value of Statistic cannot be computed.
 - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
 - (g) Poly-3 adjusted lifetime tumor incidence.
 - (h) Value of Historical Controls statistic is only calculated when Poly-3 trend is positive and when there is more than one tumor in the treatment groups.
 - (I) Interim sacrifice
 - (T) Terminal sacrifice
 - # Tumor rates based on numbers of animals necropsied.
 - * To the right of any statistical result, indicates significance at ($P \leq 0.05$).
 - ** To the right of any statistical result, indicates significance at ($P \leq 0.01$).
 - N Indicates a negative trend for all tests
- The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

*** END OF REPORT ***