

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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 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 |

**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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**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 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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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 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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**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
 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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| 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) |

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 |

**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

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 | | | | |
| 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 |

**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
 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 | | | | |
| 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

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 | | | | |
| 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
 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 | | | | |
| 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
Route: DOSED FEED
Species/Strain: RATS/F 344

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

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First Dose M/F: 04/21/03 / 04/21/03
Lab: SRI

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 ***