



Experimental Pathology Laboratories, Inc.

Vinyl Chloride

**AMENDED
PATHOLOGY QUALITY ASSESSMENT
REVIEW AND PWG COORDINATOR'S REPORT
FOR
LIFETIME CARCINOGENICITY STUDY
OF VINYL CHLORIDE
IN SPRAGUE-DAWLEY RATS**

CONDUCTED AT

**THE CANCER RESEARCH CENTER, EUROPEAN RAMAZZINI FOUNDATION
FOR ONCOLOGY AND ENVIRONMENTAL SCIENCES, BOLOGNA, ITALY**

Submitted to:

National Toxicology Program
Research Triangle Park, NC 27709

Submitted by:

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Table of Contents

INTRODUCTION.....	1
EXPERIMENTAL DESIGN AND METHODS.....	2
RESULTS	3
Quality Assessment Review	4
Pathology Working Group Review	4
CONFLICT OF INTEREST STATEMENT	8
REASON FOR CHANGE(S).....	9
SIGNATURE PAGE	10
APPENDIX A	
Slide Review Work Sheets - Males	A-1 – A-25
APPENDIX B	
Slide Review Work Sheets - Females	B-1 – B-32
APPENDIX C	
PWG Participants Curricula Vitae	C-1 – C-91



Vinyl Chloride

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Experimental Pathology Laboratories, Inc.

NARRATIVE



Vinyl Chloride

**AMENDED
PATHOLOGY QUALITY ASSESSMENT REVIEW AND
PATHOLOGY WORKING GROUP (PWG) COORDINATOR'S REPORT
FOR
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Quality Assessment Review: March 14-17, 2011

Date of the Pathology Working Group: April 4 – 8, 2011

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Quality Assessment Pathologist: Peter C. Mann, DVM (EPL)

Study Diagnoses: Ramazzini Institute

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INTRODUCTION

This report by Experimental Pathology Laboratories, Inc. (EPL[®]) presents the results of the Quality Assessment Review and the Pathology Working Group (PWG) which reviewed glass slides subsequent to the Quality Assessment Review of the Vinyl Chloride (VC) study. The VC study was conducted by the Ramazzini Institute by inhalation administration. The study started in 1974 and involved 318 rats.

EXPERIMENTAL DESIGN AND METHODS

One day old Sprague-Dawley rats were exposed to vinyl chloride by inhalation for 4 hours per day, 5 days per week, for a total of 5 weeks and then held without further treatment for their lifetime. The numbers of animals used and their allocation to dose groups are shown in Table 1.

Table 1 – Study Design for Bioassay on Vinyl Chloride Administered in Drinking Water to Male and Female Sprague-Dawley Rats

Dose Group	No. Rat and Sex
10000 ppm	25 Males & 21 Females
6000 ppm	18 Males & 25 Females
0 ppm	109 Males & 120 Females

Results of vinyl chloride study findings have been published previously by the Ramazzini Institute. The publication citations are as follows:

- Maltoni, C. (1977). Recent Findings on the Carcinogenicity of Chlorinated Olefins. Environmental Health Perspectives 21: 1-5.
- Maltoni, C. and Lefemine, G. (1975). Carcinogenicity Bioassays of Vinyl Chloride: Current Results. In: Toxicity of Vinyl Chloride-Polyvinyl Chloride. I.J. Selikoff and E.C. Hammond, Eds. New York Academy of Sciences pp: 195-218.
- Maltoni, C. and Lefemine, G. (1974). Carcinogenicity Bioassays of Vinyl Chloride. I. Research Plan and Early Results. Environmental Research 7: 387-405.
- Maltoni, C., Lefemine, G., Chieco, P. and Carretti, D. (1974). Vinyl Chloride Carcinogenesis: Current Results and Perspectives. Med. Lavoro 65: 421-444.

The peer review consisted of analysis of the Ramazzini Institute data and Quality Assessment (QA) of selected histopathology slides for the chronic lifetime study of vinyl chloride in Sprague-Dawley rats. The request was to review liver sections for hyperplastic and neoplastic changes from all male and female rats in all groups.

All slides with differences of opinion relating to the presence or absence of preneoplastic and neoplastic lesions in the liver between the study and reviewing pathologist were identified for possible review by the Pathology Working Group.

Slide Review Work Sheets were used to document the results of the QA review. These work sheets list in animal number order tissues that were examined by the QA pathologist. In addition, these work sheets list the study pathologist's initial diagnosis for the tissues that were reviewed. The work sheets also record the QA pathologist's comments indicating agreement with the Ramazzini pathologist's diagnosis or a comment when a difference of opinion was noted.

The QA took place March 14-17, 2011 at the Ramazzini Institute. The number of slides examined during the QA review of the vinyl chloride study is listed in Table 2.

Table 2. Number of Slides Reviewed During the QA Review

Group	Males	Females
	Slide Count	Slide Count
10000 ppm	42	35
6000 ppm	34	48
0 ppm	117	129
TOTAL	193	212

The Pathology Working Group (PWG) Panel met on April 6 - 7, 2011 to examine 144 liver sections from 82 rats.

RESULTS

All materials necessary for this review were readily available and well organized. All slides required to be examined by the QA pathologist were present. The histologic quality of the sections was considered to be very good with no deficiencies that interfered with the examination of the tissues present or the interpretation of histopathologic changes that were present. Neither the occasional cases with tissue autolysis nor the use of alcohol fixation presented diagnostic difficulties.

Quality Assessment Review

The quality assessment review resulted in several instances of changes in diagnostic nomenclature. Since the time this study was started in 1974, nomenclature for hepatoproliferative lesions has changed. Ramazzini study pathologist's liver diagnoses of neoplastic nodules and nodular hyperplasia are either no longer used in the case of neoplastic nodule or only rarely used in the case of nodular hyperplasia. What was diagnosed as neoplastic nodule in past years is now consider either focus of cellular alteration or hepatocellular adenoma. Contemporary use of nodular hyperplasia is uncommon and such lesions are typically diagnosed as foci of cellular alteration or regenerative hyperplasia when there is evidence of antecedent or contemporary hepatotoxicity. Furthermore, liver tumors consisting of hepatocellular and cholangiocellular elements are now diagnosed as hepatocholangiomas or hepatocholgiocarcinomas based on changes in nomenclature occurring since this study was completed.

Slide Review Work Sheets used to document the results of the QA review are presented in Appendices A and B. These work sheets list in animal number order tissues that were examined by the QA pathologist from EPL. These work sheets list the initial diagnoses for the tissues which were reviewed and the QA pathologist's agreement or difference of opinion. The QA review consisted of examination of all livers for presence of preneoplastic and neoplastic lesions. When different preneoplastic and neoplastic lesions were present in the same liver, each was diagnosed during the QA review.

Pathology Working Group Review

The primary focus during the PWG review was to confirm the presence of preneoplastic and neoplastic liver lesions for rats where there was a difference in diagnosis between the study and QA pathologist. Many of the diagnostic differences between study and QA pathologists are a reflection of nomenclature changes that have become generally accepted since the present study was completed. Diagnostic criteria for proliferative liver lesions used during the QA and PWG reviews are provided in the following references:

Maronpot, R. R., Harada, T., Murthy, A. S., and Boorman, G. A. (1989). Documenting foci of hepatocellular alteration in two-year carcinogenicity studies: Current practices of the National Toxicology Program. *Toxicol Pathol* 17, 675-683.

Maronpot RR, Montgomery CA, Boorman GA, and McConnell EE, 1986. National Toxicology Program Nomenclature for Hepatoproliferative Lesions of Rats. *Tox. Path.* 14:263-273.

Harada T, Maronpot RR, Boorman GA, Morris RW, and Stitzel KA, 1990. Foci of Cellular Alteration in the Rat Liver: A Review. *Tox. Path.* 3:161-188.

Maronpot RR, 1990. Tumors of the Liver. In: *Atlas of Tumor Pathology of the Fischer Rat*. CRC Press, pp. 193-220.

Goodman DG, Maronpot RR, Newberne PM, Popp JA, and Squire RA, 1994. Proliferative and Selected Other Lesions in the Liver of Rats. In: *Guides for Toxicologic Pathology*. STP/ARP/AFIP, Washington, DC, pp. 1-24.

Thoolen, B., Maronpot, R. R., Harada, T., Nyska, A., Rousseaux, C., Nolte, T., Malarkey, D. E., Kaufmann, W., Kuttler, K., Deschl, U., Nakae, D., Gregson, R., Vinlove, M. P., Brix, A. E., Singh, B., Belpoggi, F., and Ward, J. M. (2010). Proliferative and nonproliferative lesions of the rat and mouse hepatobiliary system. *Toxicol Pathol* 38, 5S-81S.

The PWG Panel members independently reviewed 144 liver slides from 82 rats without knowledge of prior diagnoses by the QA and study pathologists. The liver lesions were complex often with multiple distinct and merging tumors in the same liver and in the same tissue section. The hepatocellular carcinomas tended to have a more glandular component than what is typically seen. When the glandular pattern was sufficiently prominent, the PWG Panel preferred a diagnosis of hepatocholangiocarcinoma, or more rarely hepatocholangioma. There were a number of borderline lesions, particularly involving the lesions ranging from eosinophilic focus of cellular alteration to adenoma to carcinoma. Basophilic foci were hard to identify since they were not tinctorially distinct. Consensus diagnoses for each type of lesion were recorded by the PWG Coordinator. The neoplastic lesions where there was agreement between the study and QA pathologist plus the consensus diagnoses from the PWG Panel review are presented in Tables 3 and 4 for males and females, respectively. Preneoplastic lesions including foci of cellular alteration and angiomatous hyperplasia are tabulated in Slide Review Worksheets in Appendices A and B. Aside from changes in nomenclature for liver lesions since completion of this study, there was good agreement between the QA and study pathologists. A high proportion of

Vinyl Chloride

livers reviewed by the PWG panel had foci of cellular alteration in addition to neoplastic lesions.

Table 3: Liver Tumors in Male Sprague-Dawley Rats Exposed by Inhalation to Vinyl Chloride for a Total of Five Weeks (Four Hours Per Day, Five Days per Week)

Liver Lesion	0 ppm N = 104		6000 ppm N = 18		10000 ppm N = 25	
	SP ^a	QA/PWG ^b	SP ^a	QA/PWG ^b	SP ^a	QA/PWG ^b
Hepatocellular Adenoma	0	0	4	2	7	3
Hepatocellular Carcinoma	0	0	5	8	6	11
Hepatocellular Adenoma and Carcinoma	0	0	0	0	0	1
Hepatocellular Adenoma or Carcinoma	0	0	9	10	13	13
Cholangioma	0	0	9	1	9	2
Cholangiocarcinoma	0	0	0	0	1	1
Cholangioma and Cholangiocarcinoma	0	0	0	0	0	1
Cholangioma or Cholangiocarcinoma	0	0	9	1	10	2
Hepatocholangioma	0	0	0	0	0	1
Hepatocholangiocarcinoma	0	0	0	3	0	5
Hemangioma	0	0	1	1	0	0
Hemangiosarcoma	0	0	5	4	6	4
Hemangioma or Hemangiosarcoma	0	0	6	5	6	4
Neoplastic Nodule	0	0	2	0	7	0

^aLesion frequency represents the study pathologist's diagnoses.

^bLesion frequency represents the QA and PWG Panel consensus.

Vinyl Chloride

Table 4: Liver Tumors in Female Sprague-Dawley Rats Exposed by Inhalation to Vinyl Chloride for a Total of Five Weeks (Four Hours Per Day, Five Days per Week)

Liver Lesion	0 ppm N = 117		6000 ppm N = 25		10000 ppm N = 20	
	SP ^a	QA/PWG ^b	SP ^a	QA/PWG ^b	SP ^a	QA/PWG ^b
Hepatocellular Adenoma	0	0	5	5	2	5
Hepatocellular Carcinoma	0	0	6	7	5	9
Hepatocellular Adenoma and Carcinoma	0	0	0	3	0	1
Hepatocellular Adenoma or Carcinoma	0	0	11	9	7	13
Cholangioma	0	0	7	2	3	0
Cholangiocarcinoma	0	0	1	0	2	2
Hepatocholangioma	0	0	0	1	0	0
Hepatocholangiocarcinoma	0	0	0	3	0	5
Hemangioma	0	0	0	0	0	1
Hemangiosarcoma	0	0	12	7	9	7
Hemangioma or Hemangiosarcoma	0	0	12	7	9	8
Neoplastic Nodule	0	0	4	0	4	0

^aLesion frequency represents the study pathologist's diagnoses.^bLesion frequency represents the QA and PWG Panel consensus.



Vinyl Chloride

CONFLICT OF INTEREST STATEMENT

This statement is to certify that the person listed below, employed by Experimental Pathology Laboratories, Inc., participated in the QA review and Pathology Working Group (PWG) from the Lifetime Carcinogenicity Study of Vinyl Chloride in Sprague-Dawley Rats conducted at the Cancer Research Center, European Ramazzini Foundation for Oncology and Environmental Sciences. He has not been involved in any aspect of the study for any organization other than NTP which conducted the study nor the generation and/or evaluation of materials or data which were reviewed prior to the receipt of materials from the study lab. Hence, his participation in the PWG poses no apparent or actual conflict of interest.

[Redacted]

6 Oct 2011

DATE

ROBERT R. MARONPOT, D.V.M., M.S., M.P.H.
Diplomate, ACVP, ABT
PWG Coordinator

RRM:asc



Vinyl Chloride

REASON FOR CHANGE(S)

Pathology Quality Assessment
Review and PWG Coordinator's Report
For
Lifetime Carcinogenicity Study
Of Vinyl Chloride
In Sprague-Dawley Rats

The amended report is being issued to add the study pathologist's data to Tables 3 and 4, on pages 6 and 7, respectively of the amended report and to include minor editorial changes to the text of the narrative portion of the final report submitted on August 10, 2011. No changes have been made to the Slide Review Work Sheets presented in Appendices A and B.

[Redacted]

ROBERT R. MARONPOT, D.V.M., M.S., M.P.H.
Diplomate, ACVP
Senior Veterinary Pathologist

DATE

6 Oct 2011

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SIGNATURE PAGE



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EPL Project No. 460-500-20

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APPENDIX A
SLIDE REVIEW WORK SHEETS
MALE

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE			Chemical #
Laboratory	CRC			CAS #
Group	3M			Dosage
Sex & Species	MALE	SPRAGUE DAWLEY RAT	TMT 5	0 PPM
				Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1321		0	LIVER - MISSING	AGREE	NOT REVIEWED	
1322		2	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1323		2	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1324		0	LIVER - NORMAL	MISSING SLIDE	NOT REVIEWED	
1325		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1326		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1327		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1328		1	LIVER - ANGiectasis, PRESENT	AGREE	NOT REVIEWED	
1329		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1330		1	LIVER - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE			Chemical #
Laboratory	CRC			CAS #
Group	3M			Dosage
Sex & Species	MALE	SPRAGUE DAWLEY RAT	TMT 5	0 PPM
				Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1331		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1332		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1333		0	LIVER - MISSING	AGREE	NOT REVIEWED	
1334		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1335		0	LIVER - MISSING	AGREE	NOT REVIEWED	
1336		1	LIVER - ANGiectasis, PRESENT	AGREE	NOT REVIEWED	
1337		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1338		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1339		1	LIVER - ANGiectasis, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1340		1				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	3M	Dosage 0 PPM
Sex & Species	MALE	Sacrifice
	SPRAGUE DAWLEY RAT	

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1340		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1341		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1342		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1343		0	LIVER - LYMPH LEUKAEMI, PRESENT	MISSING SLIDE	NOT REVIEWED	
1344		1	LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
1345		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1346		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1347		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1348		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1349		1				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE			Chemical #
Laboratory	CRC			CAS #
Group	3M			Dosage
Sex & Species	MALE	SPRAGUE DAWLEY RAT	TMT 5	0 PPM
				Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1349		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1350		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1351		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1352		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1353		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1354		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1355		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1356		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1357		1	LIVER - ANGiectasis, PRESENT	AGREE	NOT REVIEWED	
1358		1	LIVER - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE			Chemical #
Laboratory	CRC			CAS #
Group	3M			Dosage
Sex & Species	MALE	SPRAGUE DAWLEY RAT	TMT 5	0 PPM
				Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1359		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1360		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1361		1	LIVER - ANGIECTASIS, PRESENT LIVER - FATTY CHANGE, PRESENT	AGREE AGREE	NOT REVIEWED NOT REVIEWED	
1362		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1363		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1364		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1365		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1366		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1367		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1368		1				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE			Chemical #
Laboratory	CRC			CAS #
Group	3M			Dosage
Sex & Species	MALE	SPRAGUE DAWLEY RAT	TMT 5	0 PPM
				Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1368		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1369		1	LIVER - CYST, PRESENT	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1370		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1371		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1372		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1373		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1374		0	LIVER - MISSING	AGREE	NOT REVIEWED	
1375		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1376		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1377		1				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	3M	TMT 5
Sex & Species	MALE	SPRAGUE DAWLEY RAT
		Dosage 0 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1377		1	LIVER - HISTIO SARC, PRESENT	AGREE	NOT REVIEWED	
1378		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1379		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1380		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1381		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1382		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1383		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1384		1	LIVER - ANGiectasis, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1385		1				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	3M	TMT 5
Sex & Species	MALE	SPRAGUE DAWLEY RAT
		Dosage 0 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1385		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1386		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1387		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1388		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1389		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1390		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1391		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1392		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1393		1	LIVER - ANGiectasis, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1394		1				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	3M	TMT 5
Sex & Species	MALE	SPRAGUE DAWLEY RAT
		Dosage 0 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1394		1	LIVER - ANGIO HYP ATYP, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
1395		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1396		1	LIVER - ANGIOMATOUS HY, PRESENT	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
1397		0	LIVER - MISSING	AGREE	NOT REVIEWED	
1398		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1399		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1400		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1401		2				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	3M	TMT 5
Sex & Species	MALE	SPRAGUE DAWLEY RAT
		Dosage 0 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1401		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1402		2	LIVER - HISTIO SARC, PRESENT	AGREE	NOT REVIEWED	
1403		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1404		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1405		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1406		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1407		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1408		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1409		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1410		1	LIVER - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	3M	TMT 5
Sex & Species	MALE	SPRAGUE DAWLEY RAT
		Dosage 0 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1411		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1412		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1413		3	LIVER - DIFFUSED HYPER, PRESENT LIVER - FIBROSIS, PRESENT LIVER - NECROSIS, PRESENT	LIVER - HYPERPLASIA, MULTIFOCAL (-) AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
1414		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1415		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1416		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1417		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1418		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1419		1				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE			Chemical #
Laboratory	CRC			CAS #
Group	3M			Dosage
Sex & Species	MALE	SPRAGUE DAWLEY RAT	TMT 5	0 PPM
				Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1419		1	LIVER - ANGIECTASIS, PRESENT LIVER - DIFFUSED HYPER, PRESENT	AGREE AGREE	NOT REVIEWED NOT REVIEWED	
1420		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1421		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1422		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1423		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1424		2	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1425		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1426		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1427		2	LIVER - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE			Chemical #
Laboratory	CRC			CAS #
Group	3M			Dosage
Sex & Species	MALE	SPRAGUE DAWLEY RAT	TMT 5	0 PPM
				Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1428		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1429		2	LIVER - DIFFUSED HYPER, PRESENT LIVER - NECROSIS, PRESENT	LIVER - HYPERPLASIA, MULTIFOCAL (-) AGREE	NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	2M	TMT 3
Sex & Species	MALE	SPRAGUE DAWLEY RAT
		Dosage 6,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
63		2	LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	LIVER: HEPATOCHOLCARC (-)	
			LIVER - HEPATOCLR CARC, PRESENT <Inserted Finding>	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST LIVER: EOSIN FOCUS (-)	
64		3	LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - NEOPLASTIC NOD, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-)	
65		1	LIVER - ANGIO HYP ATYP, PRESENT	LIVER - ANGIOMATOUS HYPERPLASIA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - CHOLANGIOMA, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - HAEMANGIOMA, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	LIVER: EOSIN FOCUS (-)	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	2M	TMT 3
Sex & Species	MALE	SPRAGUE DAWLEY RAT
		Dosage 6,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
65	Cont'd	1	LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
66		2	LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	LIVER: EOSIN FOCUS (-)	
			LIVER - HEPATOCLR ADEN, PRESENT	AGREE[PWG]	LIVER: HEPATOCHOLCARC (-)	
72		2	LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - NEOPLASTIC NOD, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	LIVER: HEPATOCLR CARC (-)	
73		3	LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	NOT PRESENT IN SECTION (-)	
			LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
74		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	2M	TMT 3
Sex & Species	MALE	SPRAGUE DAWLEY RAT
		Dosage 6,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
75		2	LIVER - CHOLANGIOMA, PRESENT LIVER - HAEMANGIOSARCO, PRESENT LIVER - HEPATOCLR ADEN, PRESENT	AGREE[PWG] AGREE[PWG] LIVER - HEPATOCELLULAR CARCINOMA (-)[PWG]	NOT PRESENT IN SECTION (-) AGREE WITH STUDY PATHOLOGIST AGREE WITH REVIEWING PATHOLOGIST	
83		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
84		1	LIVER - NODULAR HYPERP, PRESENT	NO REMARKABLE LESION (-)	LIVER: EOSIN FOCUS (-)	
88		1	LIVER - CHOLANGIOMA, PRESENT LIVER - HEPATOCLR ADEN, PRESENT	NOT PRESENT IN SECTION (-)[PWG] LIVER - HEPATOCELLULAR CARCINOMA (-)[PWG] LIVER - EOSINOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-) AGREE WITH STUDY PATHOLOGIST AGREE WITH REVIEWING PATHOLOGIST	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	2M	TMT 3
Sex & Species	MALE	SPRAGUE DAWLEY RAT
		Dosage 6,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
89		4	LIVER - CHOLANGIOMA, PRESENT LIVER - HEPATOCLR CARC, PRESENT	LIVER - HEPATOCHOLANGIOPAPILLARY CARCINOMA (-)[PWG] AGREE[PWG]	AGREE WITH REVIEWING PATHOLOGIST AGREE WITH STUDY PATHOLOGIST	
90		1	LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
94		2	LIVER - ANGIOMATOUS HY, PRESENT LIVER - NODULAR HYPERP, PRESENT	NOT PRESENT IN SECTION (-)[PWG] LIVER - BASOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST LIVER: EOSIN FOCUS (-)	
95		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
96		2	LIVER - HAEMANGIOSARCO, PRESENT LIVER - NODULAR HYPERP, PRESENT	LIVER - HAEMANGIOMA (-)[PWG] LIVER - BASOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST LIVER: HEPATOCLR ADEN (-)	
100		2				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	2M	TMT 3
Sex & Species	MALE	SPRAGUE DAWLEY RAT
		Dosage 6,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
100		2	LIVER - ANGIO HYP ATYP, PRESENT	AGREE	NOT REVIEWED	
			LIVER - BLRY DCT FIBRO, PRESENT	AGREE	NOT REVIEWED	
101		2	LIVER - ANGIOMATOUS HY, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - CHOLANGIOMA, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - HEPATOCLR ADEN, PRESENT	LIVER - HEPATOCHOLANGIOPAPILLOMA (-)[PWG]	LIVER: HEPATOCLR CARC (-)	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	1M	TMT 1
Sex & Species	MALE	SPRAGUE DAWLEY RAT
		Dosage 10,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
16		1	LIVER - ANGIOMATOUS HY, PRESENT	AGREE[PWG]	NOT REVIEWED	
			LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	LIVER: HEPATOCHOL (-)	
				LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
			LIVER - HEPATOCLR ADEN, PRESENT	LIVER - EOSINOPHILIC FOCUS (-) New Finding - After[AGREE] {PWG}	AGREE WITH REVIEWING PATHOLOGIST	
17		1	LIVER - NEOPLASTIC NOD, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-)	
18		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-)	
19		1	LIVER - NECROSIS, PRESENT	AGREE	LIVER: HEPATOCLR ADEN (-)	
			LIVER - NEOPLASTIC NOD, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	1M	TMT 1
Sex & Species	MALE	SPRAGUE DAWLEY RAT
		Dosage 10,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
19	Cont'd	1		LIVER - EOSINOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-)	
20		1	LIVER - BILIARY DCT HY, PRESENT LIVER - NEOPLASTIC NOD, PRESENT	AGREE LIVER - EOSINOPHILIC FOCUS (-)[PWG]	NOT REVIEWED AGREE WITH REVIEWING PATHOLOGIST	
24		1	LIVER - HEPATOCLR ADEN, PRESENT <Inserted Finding>	AGREE[PWG]	LIVER: HEPATOCLR CARC (-) LIVER: EOSIN FOCUS (-)	
25		1	LIVER - NEOPLASTIC NOD, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - HEPATOCELLULAR ADENOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
26		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-)	
27		3				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	1M	TMT 1
Sex & Species	MALE	SPRAGUE DAWLEY RAT
		Dosage 10,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
27		3	LIVER - HAEVANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - NEOPLASTIC NOD, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
28		2	LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	LIVER: HEPATOCHOLCARC (-)	
			LIVER - HAEVANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
29		3	LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	LIVER: HEPATOCHOLCARC (-)	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
				LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - BASOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-)	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	1M	TMT 1
Sex & Species	MALE	SPRAGUE DAWLEY RAT
		Dosage 10,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
29	Cont'd	3		LIVER - HEPATOCELLULAR ADENOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
30		2	LIVER - CHOLANGIOMA, PRESENT LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG] AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST AGREE WITH STUDY PATHOLOGIST	
33		1	LIVER - NEOPLASTIC NOD, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
34		4	LIVER - CHOLANGIOMA, PRESENT LIVER - HEPATOCLR CARC, PRESENT LIVER - HISTIO SARC, PRESENT	LIVER, BILE DUCT - CYST (-)[PWG] AGREE[PWG] AGREE[PWG]	NOT PRESENT IN SECTION (-) AGREE WITH STUDY PATHOLOGIST AGREE WITH STUDY PATHOLOGIST	
35		2	LIVER - CHOLANGIOMA, PRESENT LIVER - HEPATOCLR ADEN, PRESENT	AGREE[PWG] LIVER - HEPATOCELLULAR CARCINOMA (-)[PWG]	LIVER: HEPATOCHOLCARC (-) AGREE WITH REVIEWING PATHOLOGIST	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	1M	TMT 1
Sex & Species	MALE	SPRAGUE DAWLEY RAT
		Dosage 10,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
36		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG] LIVER - HEPATOCELLULAR CARCINOMA (-)[VERY SMALL] {PWG}	AGREE WITH REVIEWING PATHOLOGIST AGREE WITH REVIEWING PATHOLOGIST	
37		3	LIVER - CHOLANGIOMA, PRESENT LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG] AGREE[PWG]	NOT PRESENT IN SECTION (-) AGREE WITH STUDY PATHOLOGIST	
38		1	LIVER - CHOLANGIOCARC, PRESENT LIVER - HAEMANGIOSARCO, PRESENT	LIVER, BILE DUCT - CYST MULTilocular (-)[PWG] AGREE[PWG]	NOT PRESENT IN SECTION (-) NOT PRESENT IN SECTION (-)	
43		3	LIVER - HEPATOCLR ADEN, PRESENT LIVER - HAEMANGIOSARCO, PRESENT LIVER - NEOPLASTIC NOD, PRESENT	LIVER - HEPATOCELLULAR CARCINOMA (-)[PWG] AGREE[PWG] LIVER - BASOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST AGREE WITH STUDY PATHOLOGIST NOT PRESENT IN SECTION (-)	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	1M	TMT 1
Sex & Species	MALE	SPRAGUE DAWLEY RAT
		Dosage 10,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
44		2	LIVER - CHOLANGIOMA, PRESENT LIVER - HAEMANGIOSARCO, PRESENT	LIVER - HEPATOCHOLANGiocARCINOMA (-)[PWG] NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH BOTH NOT PRESENT IN SECTION (-)	
				LIVER - CHOLANGIOCARCINOMA (-)[PWG] LIVER - EOSINOPHILIC FOCUS (-)	AGREE WITH REVIEWING PATHOLOGIST AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - HEPATOCLR ADEN, PRESENT	LIVER - HEPATOCELLULAR CARCINOMA (-)[PWG]	NOT PRESENT IN SECTION (-)	
51		0	LIVER - NORMAL	MISSING SLIDE	NOT REVIEWED	
52		3	LIVER - CHOLANGIOMA, PRESENT LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG] AGREE[PWG]	LIVER: HEPATOCHOLCARC (-) AGREE WITH STUDY PATHOLOGIST	
53		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
54		2				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	1M	TMT 1
Sex & Species	MALE	SPRAGUE DAWLEY RAT
		Dosage 10,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
54		2	LIVER - HEPATOCLR ADEN, PRESENT	LIVER - HEPATOCELLULAR CARCINOMA (-)[PWG] LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST AGREE WITH REVIEWING PATHOLOGIST	
58		1	LIVER - HAEMANGIOSARCO, PRESENT LIVER - HEPATOCLR ADEN, PRESENT	AGREE[PWG] NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH STUDY PATHOLOGIST NOT PRESENT IN SECTION (-)	



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APPENDIX B
SLIDE REVIEW WORK SHEETS
FEMALE

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	3F	TMT 6
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT
		Dosage 0 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1201		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1202		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1203		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1204		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1205		2	LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1206		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1207		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1208		0	LIVER - NORMAL	MISSING SLIDE	NOT REVIEWED	
1209		2	LIVER - ANGiectasis, PRESENT	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #	
Laboratory	CRC	CAS #	
Group	3F	Dosage	0 PPM
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT	Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1209	Cont'd	2	LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
1210		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1211		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1212		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1213		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1214		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1215		1	LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
1216		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1217		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1218		1				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #	
Laboratory	CRC	CAS #	
Group	3F	Dosage	0 PPM
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT	Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1218		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - BILIARY DCT HY, PRESENT	AGREE	NOT REVIEWED	
			LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
1219		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1220		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
1221		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1222		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1223		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1224		1				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #	
Laboratory	CRC	CAS #	
Group	3F	Dosage	0 PPM
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT	Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1224		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1225		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1226		0	LIVER - MISSING	AGREE	NOT REVIEWED	
1227		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1228		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1229		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1230		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1231		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1232		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1233		2				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	3F	Dosage 0 PPM
Sex & Species	FEMALE SPRAGUE DAWLEY RAT	Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1233		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1234		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1235		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1236		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1237		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1238		2	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1239		1	LIVER - BILIARY DCT HY, PRESENT	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1240		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1241		1				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #	
Laboratory	CRC	CAS #	
Group	3F	Dosage	0 PPM
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT	Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1241		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
1242		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1243		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
1244		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1245		2	LIVER - DIFFUSED HYPER, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1246		1	LIVER - HISTIO SARC, PRESENT	AGREE	NOT REVIEWED	
1247		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #	
Laboratory	CRC	CAS #	
Group	3F	Dosage	0 PPM
Sex & Species	FEMALE SPRAGUE DAWLEY RAT	Sacrifice	

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1248		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
1249		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1250		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1251		1	LIVER - BILIARY DCT HY, PRESENT	AGREE	NOT REVIEWED	
1252		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1253		1	LIVER - DIFFUSED HYPER, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
1254		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
1255		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (=)	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #	
Laboratory	CRC	CAS #	
Group	3F	Dosage	0 PPM
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT	Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1255	Cont'd	1	LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
1256		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
			LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1257		1	LIVER - ANGIO HYP ATYP, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
1258		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1259		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1260		1				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #	
Laboratory	CRC	CAS #	
Group	3F	Dosage	0 PPM
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT	Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1260		1	LIVER - NECROSIS, PRESENT		NOT REVIEWED	
1261		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1262		1	LIVER - ANGIOMATOUS HY, PRESENT	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
1263		3	LIVER - ANGIOMATOUS HY, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
				LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
1264		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1265		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #	
Laboratory	CRC	CAS #	
Group	3F	Dosage	0 PPM
Sex & Species	FEMALE SPRAGUE DAWLEY RAT	Sacrifice	

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1266		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1267		1	LIVER - DIFFUSED HYPER, PRESENT	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1268		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1269		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1270		2	LIVER - ANGIOMATOUS HY, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
1271		1				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	3F	TMT 6
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT
		Dosage 0 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1271		1	LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1272		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1273		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1274		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
1275		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
1276		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1277		1				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #	
Laboratory	CRC	CAS #	
Group	3F	Dosage	0 PPM
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT	Sacrifice
TMT 6			

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1277		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1278		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1279		1	LIVER - NECROSIS, PRESENT	AGREE LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED NOT REVIEWED	
1280		1	LIVER - DIFFUSED HYPER, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
1281		1	LIVER - NECROSIS, PRESENT LIVER - NODULAR HYPERP, PRESENT	AGREE LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED NOT REVIEWED	
1282		0	LIVER - MISSING	AGREE	NOT REVIEWED	
1283		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1284		0	LIVER - MISSING	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #	
Laboratory	CRC	CAS #	
Group	3F	Dosage	0 PPM
Sex & Species	FEMALE SPRAGUE DAWLEY RAT	Sacrifice	

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1285		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1286		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1287		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1288		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1289		2	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
1290		1	LIVER - ANGIOMATOUS HY, PRESENT	AGREE	NOT REVIEWED	
1291		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1292		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1293		2				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #	
Laboratory	CRC	CAS #	
Group	3F	Dosage	0 PPM
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT	Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1293		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1294		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1295		2	LIVER - NODULAR HYPERP, PRESENT	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
1296		1	LIVER - ANGIOMATOUS HY, PRESENT	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
1297		2	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
1298		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1299		1				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	3F	Dosage 0 PPM
Sex & Species	FEMALE SPRAGUE DAWLEY RAT	Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1299		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1300		1	LIVER - FATTY CHANGE, PRESENT LIVER - NECROSIS, PRESENT	AGREE AGREE	NOT REVIEWED NOT REVIEWED	
1301		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1302		0	LIVER - ANGIECTASIS, PRESENT	MISSING SLIDE	NOT REVIEWED	
1303		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1304		2	LIVER - DIFFUSED HYPER, PRESENT LIVER - NECROSIS, PRESENT	LIVER - EOSINOPHILIC FOCUS (-) AGREE	NOT REVIEWED NOT REVIEWED	
1305		1	LIVER - ANGIOMATOUS HY, PRESENT LIVER - DIFFUSED HYPER, PRESENT	AGREE LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #	
Laboratory	CRC	CAS #	
Group	3F	Dosage	0 PPM
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT	Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1306		1	LIVER - MYELOID LEUKAE, PRESENT	AGREE	NOT REVIEWED	
1307		1	LIVER - ANGIOMATOUS HY, PRESENT	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1308		0	LIVER - NORMAL	MISSING SLIDE	NOT REVIEWED	
1309		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1310		0	LIVER - ANGIECTASIS, PRESENT	MISSING SLIDE	NOT REVIEWED	
1311		1	LIVER - DIFFUSED HYPER, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
			LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #	
Laboratory	CRC	CAS #	
Group	3F	Dosage	0 PPM
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT	Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1311	Cont'd	1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1312		1	LIVER - ANGIECTASIS, PRESENT LIVER - FATTY CHANGE, PRESENT	AGREE AGREE	NOT REVIEWED NOT REVIEWED	
1313		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1314		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1315		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1316		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1317		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
1318		1	LIVER - NORMAL	LIVER - ANGIECTASIS (-) AGREE	NOT REVIEWED NOT REVIEWED	
1319		1				

SLIDE REVIEW WORKSHEET

Study Title VINYL CHLORIDE **Chemical #**
Laboratory CRC **CAS #**
Group 3F **Dosage** 0 PPM
Sex & Species FEMALE SPRAGUE DAWLEY RAT **Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1319		1	LIVER - ANGIOMATOUS HY, PRESENT LIVER - NODULAR HYPERP, PRESENT	AGREE LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED NOT REVIEWED	
1320		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	2F	TMT 4
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT
		Dosage 6,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
59		2	LIVER - CHOLANGIOMA, PRESENT LIVER - HEMANGIOSARCO, PRESENT LIVER - HEPA TO CLR CARC, PRESENT	NOT PRESENT IN SECTION (-)[PWG] AGREE[PWG] LIVER - HEPATOCHOLANGIOPAPILLARY CARCINOMA (-) [PWG] LIVER - EOSINOPHILIC FOCUS (-)[PWG] LIVER - BASOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST LIVER: HEPATOCLR ADEN (-) AGREE WITH BOTH AGREE WITH REVIEWING PATHOLOGIST AGREE WITH REVIEWING PATHOLOGIST	
60		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-)	
61		1	LIVER - CHOLANGIOMA, PRESENT LIVER - HEMANGIOSARCO, PRESENT LIVER - HEPA TO CLR ADEN, PRESENT	LIVER, BILE DUCT - CYST (-)[PWG] NOT PRESENT IN SECTION (-)[PWG] LIVER - EOSINOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-) AGREE WITH REVIEWING PATHOLOGIST AGREE WITH REVIEWING PATHOLOGIST	
62		1				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	2F	TMT 4
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT
		Dosage 6,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
62		1	LIVER - NEOPLASTIC NOD, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG] LIVER - BASOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST NOT PRESENT IN SECTION (-)	
67		1	LIVER - CHOLANGIOMA, PRESENT LIVER - DIFFUSED HYPER, PRESENT	LIVER - HEPATOCHOLANGIOMA (-)[PWG] LIVER - BASOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST NOT PRESENT IN SECTION (-)	
68		1	LIVER - BLRY DCT FIBRO, PRESENT LIVER - HAEMANGIOSARCO, PRESENT LIVER - NODULAR HYPERP, PRESENT	NOT PRESENT IN SECTION (-)[PWG] LIVER - ANGIOMATOUS HYPERPLASIA (-)[PWG] LIVER - BASOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST AGREE WITH REVIEWING PATHOLOGIST LIVER: EOSIN FOCUS (-)	
69		1	LIVER - HEPA TOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	2F	TMT 4
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT
		Dosage 6,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
69	Cont'd	1		LIVER - EOSINOPHILIC FOCUS (-)[PWG] LIVER - BASOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST NOT PRESENT IN SECTION (-)	
70		1	LIVER - ANGIOMATOUS HY, PRESENT LIVER - HEPATOCLR ADEN, PRESENT	AGREE[PWG] AGREE[PWG]	NOT PRESENT IN SECTION (-) NOT PRESENT IN SECTION (-)	
71		1	LIVER - NEOPLASTIC NOD, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG] LIVER - HEPATOCELLULAR ADENOMA (-)[PWG] LIVER - BILIARY DUCTS HYPERPLASIA (-)[PWG]	LIVER: EOSIN FOCUS (-) AGREE WITH REVIEWING PATHOLOGIST LIVER: CHOLANGIOMA (-)	
76		2				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	2F	Dosage 6,000 PPM
Sex & Species	FEMALE SPRAGUE DAWLEY RAT	Sacrifice
		TMT 4

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
76		2	LIVER - CHOLANGIOMA, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - HEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HEPATOCLR CARC, PRESENT	LIVER - HEPATOCHOLANGIOPATHOLOGY (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
77		2	LIVER - CHOLANGIOCARC, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - HEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
78		3	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
79		3	LIVER - HEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	2F	TMT 4
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT
		Dosage 6,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
79	Cont'd	3		LIVER - EOSINOPHILIC FOCUS (-)[PWG] LIVER - BASOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST NOT PRESENT IN SECTION (-)	
80		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG] LIVER - EOSINOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-) AGREE WITH REVIEWING PATHOLOGIST	
81		1	LIVER - CHOLANGIOMA, PRESENT LIVER - HAEMANGIOSARCO, PRESENT LIVER - HEPATOCLR ADEN, PRESENT	NOT PRESENT IN SECTION (-)[PWG] AGREE[PWG] LIVER - HEPATOCHOLANGIOPAPILLARY CARCINOMA (-)[PWG] LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST AGREE WITH STUDY PATHOLOGIST AGREE WITH REVIEWING PATHOLOGIST AGREE WITH REVIEWING PATHOLOGIST	
82		1				

SLIDE REVIEW WORKSHEET

Study Title VINYL CHLORIDE **Chemical #**
Laboratory CRC **CAS #**
Group 2F **Dosage** 6,000 PPM
Sex & Species FEMALE SPRAGUE DAWLEY RAT **Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
82		1	LIVER - HEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
				LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
85		4	LIVER - HEMANGIOSARCO, PRESENT	LIVER - NECROSIS (-)[PWG]	NOT PRESENT IN SECTION (-)	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HISTIO SARC, PRESENT	AGREE[PWG]	NOT PRESENT IN SECTION (-)	
86		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - BASOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-)	
87		3	LIVER - HEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	2F	TMT 4
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT
		Dosage 6,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
87	Cont'd	3	LIVER - HEPATOCLR ADEN, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
91		2	LIVER - ANGIOMATOUS HY, PRESENT	AGREE[PWG]	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	NOT REVIEWED	
92		2	LIVER - CHOLANGIOMA, PRESENT	LIVER, BILE DUCT - CYST (-)[PWG]	LIVER: HEPATOCLR ADEN (-)	
			LIVER - NEOPLASTIC NOD, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
93		3	LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			<Inserted Finding>		LIVER: HEPATOCLR ADEN (-)	
			LIVER - NEOPLASTIC NOD, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
97		2				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	2F	TMT 4
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT
		Dosage 6,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
97		2	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG] LIVER - BASOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST NOT PRESENT IN SECTION (-)	
98		6	LIVER - CHOLANGIOMA, PRESENT LIVER - HAEMANGIOSARCO, PRESENT LIVER - HEPATOCLR ADEN, PRESENT <Inserted Finding>	AGREE[PWG] NOT PRESENT IN SECTION (-)[PWG] AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST LIVER: HEPATOCLR CARC (-) AGREE WITH STUDY PATHOLOGIST LIVER: EOSIN FOCUS (-)	
99		2	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG] LIVER - BASOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST NOT PRESENT IN SECTION (-)	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	1F	TMT 2
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT
		Dosage 10,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
13		1	LIVER - HAEAMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
14		1	LIVER - HAEAMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
15		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	AGREE WITH REVIEWING PATHOLOGIST	
21		1	LIVER - NEOPLASTIC NOD, PRESENT <Inserted Finding>	LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-) LIVER: HEPATOCLR ADEN (-)	
22		2	LIVER - CHOLANGIOCARC, PRESENT LIVER - HAEAMANGIOSARCO, PRESENT LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG] NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH STUDY PATHOLOGIST LIVER: HEPATOCHOLCARC (-)	
23		3		AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	1F	TMT 2
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT
		Dosage 10,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
23		3	LIVER - CHOLANGIOCARC, PRESENT LIVER - HEMANGIOSARCO, PRESENT LIVER - NEOPLASTIC NOD, PRESENT <Inserted Finding>	AGREE[PWG] AGREE[PWG] LIVER - HEPATOCELLULAR ADENOMA (-)[PWG]	LIVER: HEPATOCLR CARC (-) LIVER: HEPATOCHOLCARC (-) LIVER: HEMANGIOMA (-) LIVER: EOSIN FOCUS (-)	
31		1	LIVER - HEPATOCLR ADEN, PRESENT	AGREE[PWG] LIVER - EOSINOPHILIC FOCUS (-)[PWG]	LIVER: HEPATOCLR CARC (-) AGREE WITH REVIEWING PATHOLOGIST	
32		4	LIVER - CHOLANGIOMA, PRESENT LIVER - HEPATOCLR CARC, PRESENT	NOT PRESENT IN SECTION (-) LIVER - HEPATOCHOLANGIOPAPILLARY CARCINOMA (-)	AGREE WITH REVIEWING PATHOLOGIST AGREE WITH BOTH	
39		1	LIVER - HEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	1F	TMT 2
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT
		Dosage 10,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
39	Cont'd	1	LIVER - NODULAR HYPERP, PRESENT	LIVER - HEPATOCELLULAR ADENOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
40		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - HEPATOCELLULAR ADENOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
41		1	LIVER - HEPATOCLR ADEN, PRESENT	LIVER - HEPATOCELLULAR CARCINOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-)	
42		2	LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
				LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
45		1				

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #	
Laboratory	CRC	CAS #	
Group	1F	Dosage	10,000 PPM
Sex & Species	FEMALE	Sacrifice	SPRAGUE DAWLEY RAT

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
45		1	LIVER - ANGIO HYP ATYP, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-)	
46		1	LIVER - NEOPLASTIC NOD, PRESENT	LIVER - HEPATOCELLULAR ADENOMA (-)[PWG]	LIVER: HEPATOCLR CARC (-)	
			<Inserted Finding>		LIVER: BASOPH FOCUS (-)	
47		1	LIVER - ANGIO HYP ATYP, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - BASOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-)	
48		1		LIVER - HEPATOCELLULAR ADENOMA (-)[PWG]	NOT PRESENT IN SECTION (-)	
			LIVER - NECROSIS, PRESENT	AGREE[PWG]	NOT PRESENT IN SECTION (-)	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #
Laboratory	CRC	CAS #
Group	1F	TMT 2
Sex & Species	FEMALE	SPRAGUE DAWLEY RAT
		Dosage 10,000 PPM
		Sacrifice

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
48	Cont'd	1	LIVER - NEOPLASTIC NOD, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG] LIVER - HEPATOCELLULAR CARCINOMA (-)[PWG]	LIVER: EOSIN FOCUS (-) LIVER: HEPATOCLR ADEN (-)	
49		5	LIVER - CHOLANGIOMA, PRESENT LIVER - HAEMANGIOSARCO, PRESENT <Inserted Finding> LIVER - HEPATOCLR CARC, PRESENT <Inserted Finding>	AGREE[PWG] AGREE[PWG] AGREE[PWG]	LIVER: HEPATOCHOLCARC (-) AGREE WITH STUDY PATHOLOGIST LIVER: CHOLANGIOCARC (-) AGREE WITH STUDY PATHOLOGIST LIVER: EOSIN FOCUS (-)	
50		0	LIVER - MISSING	MISSING SLIDE	NOT REVIEWED	
55		4	LIVER - CHOLANGIOMA, PRESENT LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG] New Finding - After[PWG]{AGREE}	LIVER: HEPATOCLR ADEN (-) AGREE WITH STUDY PATHOLOGIST	

SLIDE REVIEW WORKSHEET

Study Title	VINYL CHLORIDE	Chemical #	
Laboratory	CRC	CAS #	
Group	1F	Dosage	10,000 PPM
Sex & Species	FEMALE	Sacrifice	SPRAGUE DAWLEY RAT

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
55	Cont'd	4	LIVER - HEPATOCLR CARC, PRESENT	New Finding - After[PWG] {AGREE}	AGREE WITH STUDY PATHOLOGIST	
				LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: HEPATOCHOLCARC (-)	
56		2	LIVER - HAEAMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
57		1	LIVER - DIFFUSED HYPER, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	NOT REVIEWED	



Experimental Pathology Laboratories, Inc.

APPENDIX C

PWG PARTICIPANTS CURRICULA VITAE

Charles B. Clifford, D.V.M., Ph.D.

email charles.clifford@crl.com

Present Position

Director, Pathology and Technical Services, Charles River

Education

1974	B.S. (Zoology)	Michigan State University
1977	D.V.M.	Michigan State University
1981-1983	Pathology Residency	Walter Reed Army Institute of Research
1988	Ph.D. (Pathology) minors in Immunology and Cell Biology	Cornell University

Professional and Scientific Societies

American College of Veterinary Pathologists (Diplomate, by examination)	1983 - present
Society of Toxicologic Pathologists (Full Member)	1989 - present
American Veterinary Medical Association	1981 - present
American Association of Laboratory Animal Science	1992 - present

Experience

- 1977-1978 Veterinary Officer, Veterinary Detachment, Bayonne, NJ. Supervised approximately 30 civilian and military personnel who inspected most subsistence shipped to the U.S. military in Europe. Conducted sanitary inspection of 5 commissaries and over 80 civilian food processors and suppliers in New York City, Long Island and northern New Jersey. Responsible for zoonosis control at 4 Army posts.
- 1978 Assistant Officer-in-Charge, Team D, 106th Medical Detachment, Pusan, Republic of Korea. Supervised inspection of all subsistence shipped to the U.S. Army in Korea, and managed the only two military veterinary clinics within a 90 mile radius.
- 1978-1979 Officer-in-Charge, Team A, 106th Medical Detachment, Oujongbu, Republic of Korea. Supervised all food inspection for U.S. troops stationed north of Seoul, including along the DMZ, public health consultation for the 2nd Infantry Division. Also was Assistant Chief and Surgeon for the U.S. Army veterinary clinic in Seoul.
- 1979-1980 Course Director, US Army Animal Care Specialist School, Washington, DC, the only school in the U.S. Army to train Animal Health Technicians. Was responsible for course content and administration, counseling and supervision of 5 faculty members, and 120 students per year. Taught courses in pathology, anesthesia, radiology, and the Cardiovascular, Respiratory and Gastrointestinal System.
- 1980-1983 Pathology Resident, Division of Pathology, Walter Reed Army Institute of Research. Provided collaborative histopathology support to the institute, including studies of renal toxicity, pulmonary trauma and toxicity using rodent, lagomorph, canine, and primate models. Served as diagnostic pathologist for the Institute's rodent and primate colonies. Completed all requirements for the board examination of the American College of Veterinary Pathologists.
- 1982-1984 Assistant Senior Army Social Aide to the President of the United States for White House functions, such as receptions and State dinners.
- 1983-1984 Staff Pathologist, Division of Pathology, Walter Reed Army Institute of Research. Developed a rat model and conducted independent research on pathogenesis and healing of pulmonary lesions due to concussive pressure waves. Collaborated in studies of hemorrhagic shock, military systems hazards assessment, and toxicopathology of anti-schistosomal drugs. Assisted in training of 3 pathology residents per year in preparation of the veterinary pathology board examination.
- 1984-1987 Research Assistant (doctoral student), Cornell University. Conducted original research on the ontogeny of neutrophil function and the inflammatory response, comparing fetuses, neonates, and adults. Designed a novel model of *in utero* pulmonary inflammation in the sheep, permitting repetitive blood sampling and bronchoalveolar lavage. Initiated and developed a histopathology training series for

3 veterinary pathology residents from non-English speaking countries. Each resident then successfully completed the veterinary pathology board examination. Completed all requirements for Doctor of Philosophy degree.

- 1987-1991 Research Pathologist and Assistant Chief of Pathology, Letterman Army Institute of Research. Supervised the Institute's postmortem and clinical pathology laboratories. Conducted original research in distribution and toxicity of purified modified hemoglobin solutions. Collaborated with other scientists in model design and pathology support of Good Laboratory Practices Act-compliant toxicity studies (principal pathologist), pathogenesis of neurovascular trauma, hemorrhagic shock and perfusion injury, wound healing, and pre-clinical testing of candidate resuscitative fluids. Served on a rotating duty as diagnostic pathologist for animal postmortem examinations. Member of the Institute's Animal Care and Use Committee.
- 1991-2001 Staff Officer, US Army Medical Research and Materiel Command. Two weeks annual duty as a senior staff member in office with budget and program oversight of all Army biomedical research concerning biological and chemical agents, >\$100 million/annum. Duties included technical review of research proposals, analysis and synopsis of diverse research projects for senior pentagon management. Retired as Colonel.
- 1991-1993 Senior Pathologist, Charles River Laboratories. Oversee all aspects of pathology support of the world's largest supplier of laboratory animals, with approximately \$600 million in annual sales and production facilities in the U.S. and more than 10 other countries. Collaborate in the definition of new animal models, including genetically engineered animals. Supervise extramural development of new diagnostic technologies. Design and conduct pathology service protocols in support of biotechnology and pharmaceutical customers. Address and resolve customer concerns regarding unexpected research findings or other pathology-related issues. Key professional for CRL swine xenotransplantation efforts.
- 1993-present Director, Pathology and Technical Services. (*additional duties to above*) Supervise two other pathologists and the Charles River Technical Assistance Department, which provides information to customers concerning normative data, test procedures, husbandry, health, and all other matters relating to laboratory animals. Oversee corporate toxicology consultant, preparation of technical and reference papers on Historical Control Data..
- 2001-2003 (additional duties) Direct responsibility for Contract Research Services department, approximately \$2 million annual revenue. Specialty areas include oncology, vaccine testing, novel imaging studies.

Licensure

Michigan, #5124, 1977 to present.

Inventions

Hairless Immunodeficient Mouse Model (U.S. application no. 12/047,948)

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11. Korte, D.W., Frost, D.F., Zaucha, G.M., Waring, P.P., **Clifford, C.B.**, and Wheeler, C.R., 28-day Toxicity in Beagle Dogs of Physostigmine Salicylate Administered via Subcutaneously Implanted Alzet Osmotic Minipumps, Proc. West. Pharmacol. Soc., 32:159, 1989.
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13. Runyon, D.E., **Clifford, C.B.**, Bruttig, S.P., Wade, C.E., Dubick, M.A., and Kramer, G.C., Resuscitation of Hypovolemia Using Intraosseous Infusion of a Small Volume of 25% NaCl/24% Dextran-70, Ann. Emerg. Med., 20:480, 1991.
14. Bowman, P.D., **Clifford, C.B.**, McFaul, S.J., Tacha, D., and Johnson, T.W., Distribution of Purified Hemoglobin in Mouse Tissue as a Function of Time after Administration: An Immunocytochemical Study. FASEB, 1991.
15. **Clifford, C.B.**, Gianni, F.J., and White, W.J., *Pneumocystis carinii* and modern methods of rodent breeding and husbandry. Joint meeting of Am Soc Parasitologists and Soc Protozoologists, 1996.
16. Henderson, K.S., **Clifford, C.B.**, and Dionne, J.A., Comparison of the polymerase chain reaction with histological technique for detection of *Pneumocystis carinii*. Joint meeting of Am Soc Parasitologists and Soc Protozoologists, 1996.
17. Kim, N.M., Bailey, L., Olson, T., **Clifford, C.B.**, Benso, F.J., Sgrulloni, S.J., Duenas, E., Cleland, J.L., Putney, S.D., and Riley, M.G.I., Immunogenicity evaluation of ProLease® hGH: A sustained release formulation. Society of Toxicology, 1997.
18. Albers, T.M. and **Clifford, C.B.** Eosinophilic granulomatous pneumonia: A strain-related lesion of high prevalence in the Brown Norway rat, Contemporary Topics, 39(4):61-62, 2000
19. Albers, T. M. and **Clifford, C. B.** Transmission of rat respiratory virus in a rat colony: Gross and histopathological progression of lesions. Contemp Top. Lab Anim Sci 42[4], 73-74. 2003.

Curriculum Vitae

Dr. Sabine FRANCKE-CARROLL

Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

DHHS/CFSAN/FDA/ OFAS/ Senior Science and Policy Staff /Pathology
5100 Paint Branch Parkway HFS-205
College Park MD 20740
(301) 436-1308

EDUCATION:

Ph.D., The Ohio State University, Columbus, OH, USA
Applied Veterinary Pathology Residency, The Ohio State University, Columbus, OH, USA
Dr. Vet. Med., Justus-Liebig University, Giessen, Germany
D.V.M., Justus-Liebig University, Giessen, Germany

PROFESSIONAL ORGANIZATIONS AND MEMBERSHIPS:

Recognized Fellow of the International Academy of Toxicologic Pathology (IATP; 2010 - present)
European Society of Toxicologic Pathology (ESTP; 2009 – present)
US Society of Toxicologic Pathology (STP; 1998 - present)
American College of Toxicology (ACT; 1999 - present)
Association of Government Toxicologists (AGT; 2000- present) – President Elect (2009-11)
Charles Louis Davis D.V.M. Foundation for the Advancement of Veterinary and Comparative Pathology (2000 – present)

United States and Canadian Academy of Pathology, Inc. (USCAP 2000-2010)
American Association for the Advancement of Science (AAAS 1992-2010)
National Society for Histotechnology (NSH 2004-2009)

PROFESSIONAL EXPERIENCE:

CURRENT DUTIES:

Expert Toxicologic Veterinary Regulatory Review Pathologist, Senior Science and Policy Staff / Pathology
Department of Health and Human Services / FDA / CFSAN / OFAS /College Park, MD.

4/10 – present

The incumbent in the Office of Food Additive Safety (OFAS) in CFSAN is recognized by FDA as subject matter expert for Toxicologic Veterinary Regulatory Review Pathology (Veterinary Officer / Pathologist) and serves as an authoritative expert in her field, conducting independent, in-depth regulatory reviews and complex safety evaluations of pathology data from regulatory submissions from all FDA Centers. The incumbent performs independent histo-pathological slide evaluations and serves as authoritative expert in regulatory toxicologic veterinary pathology on Center-, Inter Agency-, and national / international professional committees and provides a regulatory perspective when serving on Pathology Working Groups (PWGs) convened to resolve complex pathology issues.

Supervisor: Dennis Keefe, Ph.D., (Director, SSPS, OFAS, CFSAN/FDA)

Senior Toxicologic Veterinary Pathologist, Senior Science and Policy Staff / Pathology
Department of Health and Human Services / FDA / CFSAN / OFAS /College Park, MD.

2/2007- 3/10. The incumbent serves in the Office of Food Additive Safety (OFAS) in CFSAN as Toxicologic Veterinary Pathologist (Veterinary Officer / Pathologist) conducting independent, in-depth regulatory reviews and complex safety evaluations of pathology data from regulatory submissions from all FDA Centers. The incumbent performs a wide range of administrative functions pertaining to the budget process, property management and pathology contract management.

Supervisor: Dennis Keefe, Ph.D., (Director, SSPS, OFAS, CFSAN/FDA)

Acting Branch Chief, Pathology Branch

Department of Health and Human Services / FDA / CFSAN / OSAS / DGSS / Pathology Branch, College Park, MD.

1/2005-2/2007 Center-wide Reorganization. The incumbent is an experienced regulatory reviewer and applies in-depth professional knowledge and skills as Veterinary Medical Officer / Pathologist conducting independent safety evaluations of pathology data from regulatory petitions for the Division of General Scientific Support (DGSS).

The incumbent manages independently the Pathology Branch and the associated histopathology laboratory, performing a wide range of administrative functions pertaining to daily operations (such as the budget process, property management and contract management). The Pathology Branch and the Pathology Laboratory provide a full range of pathology support functions

Curriculum Vitae

Dr. Sabine FRANCKE-CARROLL

Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

PROFESSIONAL EXPERIENCE (contd.):

for requesting Offices/researchers such as pathology protocol design, monitoring animal-study in-life-phases, performing necropsies, guiding the tissue processing, evaluating histological glass slides and reporting of pathology data. The incumbent instructs and trains laboratory associated personnel and adjunct students from the University of Maryland. The incumbent is solely responsible for the development and application of all immuno-histopathological services provided by the Pathology Laboratory.

Supervisor: Prem Dua, D.V.M., Ph.D., (Director, DGSS, OSAS, CFSAN/FDA)

Senior Staff Toxicologic Pathologist

Department of Health and Human Services / FDA / CFSAN / OSAS / DGSS / Pathology Branch, College Park, MD.

01/2002-12/2004. The incumbent assists the Director of the Division of General Scientific Support (DGSS) with regulatory (food petition) reviews. To do this the incumbent applies knowledge of FDA laws/regulations and extensive experience in pathology data analysis. The incumbent is further involved in administrative matters pertaining to the operation of the Pathology Branch, e.g. the zero based budgeting process. The incumbent's significant research experience involves her extensively as Co-principal investigator in several research projects with Center and/or adjunct scientists from the University of Maryland (UMD). The incumbent serves as student mentor and instructor to laboratory personnel and UMD/JIFSAN students, and promotes the development of immuno-histopathological services provided by the Pathology Laboratory.

Supervisors: Fred Hines, D.V.M., (Pathology Branch Chief), Prem Dua D.V.M., Ph.D., (DGSS Director)

Staff Toxicologic Pathologist

Department of Health and Human Services / FDA / CFSAN / OSAS / DGSS / Pathology Branch, College Park, MD.

01/2001 – 12/2002. The incumbent provides histo-pathological analysis and support to requesting researchers associated with Governmental Offices (e.g. OARSA) and/or joint facilities such as the University of Maryland (under the umbrella of the Joint Institute for Food Safety and Applied Nutrition (JFSAN)). The incumbent participates as Immuno-pathologist and/or as Co-principal-investigator in protocol design, monitors animal-study in-life-phases, performs necropsies, guides the tissue processing, evaluates histological slides and conducts the final pathology-relevant reporting of assigned animal research studies. The incumbent initiates the development of immuno-histopathological services provided by the Pathology Laboratory.

Supervisors: Fred Hines, D.V.M., (Pathology Branch Chief), Prem Dua D.V.M., Ph.D., (DGSS Director)

Toxicologic Pathologist, Novartis Pharmaceuticals Inc. East Hanover, NJ.

11/98 –11/2000. The incumbent generates and evaluates pathology data of assigned acute, subacute and chronic preclinical drug-safety studies which also entailed partial, direct/indirect supervision of technical personnel assigned to these studies. The incumbent is assigned to projects with standard design and/or those requiring an appropriate level of interpretive experience and knowledge. A current knowledge of recent advances and new equipment/procedures is important to achieve optimum results. At the conclusion of each study, the incumbent participates in the data review/analyses to determine target organ toxicity. The incumbent participates in the study design and in the evaluation and implementation of new procedures to improve preclinical drug-safety operations. The incumbent is a member of scientific boards, project teams, and advisory committees and performs other duties as assigned by upper management.

Supervisor: Dr. Pritam Sahota, D.V.M, Ph.D.

Veterinary Research Pathologist, Pathology Associates International (PAI), Immunology and Molecular Pathology Division Frederick, MD 21701

09/1996 – 98. The incumbent evaluates designs and interprets studies assessing the cross-reactivity characteristics of monoclonal antibodies in human and animal tissues (in vivo/in vitro exposure), the localization of monoclonal antibodies by means of immuno-labeling techniques and conducts development and application of molecular and cellular histopathologic technology to characterize and resolve mechanistic problems associated with biopharmaceutical product development.

Supervisor: Bill Hall, V.M.D., Ph.D.

Curriculum Vitae

Dr. Sabine FRANCKE-CARROLL

Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

PROFESSIONAL EXPERIENCE (contd.):

Graduate Research Associate (Ph.D. / Veterinary Pathologist), The Ohio State University, Department of Veterinary Biosciences, Columbus, Ohio

1992-1996 Research conducted evaluates anti-retroviral drug-effects (mainly AZT) on cellular immune responses and immune-cell precursor frequencies. Effector-cell frequency analysis, by limiting dilution analysis (LDA), allows not only qualitative assessment but also quantitation of the effects noted. Two animal models, an outbred feline model for retroviral infection and an inbred mouse model for allograft rejection are utilized in these studies. Research activities: Histopathology, immunology, retro-virology, in-vivo and in-vitro drug testing, immunohistochemistry, vaccine development, cell culture and molecular biology.

Thesis advisor: Lawrence E. Mathes, Ph.D., Professor.

Graduate Teaching Associate and Resident (Veterinary Pathologist / Ph.D.)

1990-1992 (continued services during Ph.D training until 1996) The Ohio State University
Department of Veterinary Biosciences
Columbus, Ohio

Graduate Assistant (Dr.med.Vet.)

1988-1990 Justus-Liebig University
Giessen, Germany

Research performed to obtain a "Dr. Vet. Med." degree centers on the immunohistologic characterization of the cellular immune response to bacterial infection with *Coxiella burnetii* in a murine model. Results illustrated that cellular mechanisms are crucially involved in the pathogenesis of chronic infection with *C. burnetii*.

Thesis advisor: Dr. Wolfgang Baumgaertner, D.V.M., Ph.D., Professor.

Graduation from Veterinary School (DVM)

1988 Justus-Liebig University
Giessen, Germany

LEADERSHIP EXPERIENCE:

- Elected board member to IATP 2011: Vice president 2011-13; President 2013-15
- Recognized as Fellow IATP (International Academy of Toxicologic Pathology) 2009.
- FDA recognized (Agency Peer Review) Expert for Toxicologic Veterinary Regulatory Review Pathology (April 2011)
- President Elect of the Association of Government Toxicologists (AGT term 2010-2011)
- Councilor to the Board of the Association of Government Toxicologists (AGT), 2006 & 2008
- CFSAN Immunotox Redbook working group: chair
- STP SRPC Regulatory Liaison since 2005 till present
 - Hepatic Enzyme Induction working group liaison since 2007/ chair – Dec 2008-10
 - Historical Control Data working group SRPC liaison, 2006-2009
- Pathology Laboratory Chief, and Acting Pathology Branch Chief; providing training, instructions and guidance to Laboratory Technicians and visiting scientists from UMD, regarding duties and functions of the Pathology Branch and its Laboratory.
- Mentor to JIFSAN students; Mentor to UMD and Pathology Laboratory students.
- Histopathology mentor and instructor for Laboratory Biologist: training included pathology terminology, histology, histopathology, tissue trimming, tissue processing, preparation of paraffin blocks, microtoming, H&E staining of routine slides, Immunohistochemical staining, archiving, laboratory administrative work and reagent ordering.

Curriculum Vitae

Dr. Sabine FRANCKE-CARROLL

Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

SERVICES AND RESPONSIBILITIES:

- Regulatory liaison to the Scientific Regulatory and Policy Committee (SRPC) of the Society of Toxicologic Pathology (STP) since 2005
 - SRPC liaison to the Historical Control Data working group; 2006 -09 - Best Practice manuscript published TP 2009; 37(5) 679-93.
 - SRPC liaison to the Hepatic Enzyme Induction Risk Assessment (HEI- RA) working group since 2007; chair since Dec. 2008 – 2010.
 - SRPC liaison to the Joint Regulatory Affairs Committee (JRAC) between STP and the American College of Veterinary Pathology (ACVP); since 2006 - 2009.
 - Invited Member of the STP Regulatory Forum editorial group for the Journal of Toxicologic Pathology since 2007 – ongoing.
- CFSAN Immunotox Redbook committee since 2006
 - Chair: Dec 07 – ongoing.
- Association of Government Toxicologists (AGT)
 - Board member councilor 2005-07; elected for–second term 2008; President elect 2009-10; President 2010-11; Past President 2011-12 – 3 year leadership commitment - ongoing.
- Acting Chief of the Pathology Branch and Laboratory / DGSS (1/2005- until CFSAN reorganization 2/2007).
- CFSAN Cancer Assessment Committee (CAC) Member – Pathologist – since 2004.
- CFSAN Pathology Services and Archiving Contract Project Officer since 2006 – recertified as COTR July 31, 2009.
- Property Management Officer 2005-07.
- CFSAN Science Council Committee Member since 2004.
 - SC Scientific Dissent Resolution policy draft subcommittee 2007-09.
 - SC membership charter following the CFSAN 2007 reorganization subcommittee Scientific Achievement Award-subcommittee (2004, '05, '06, '07, '08).
 - Manuscript clearance subcommittee 2004.
- CFSAN Toxicology Redbook Committee Member since 2003.
- Joint Institute for Food Safety and Applied Nutrition (JIFSAN) steering Committee Member 2002-'07. And JIFSAN Grant – Pathology Support Collaborator to the University of Maryland (UMD), Department of Food Science.

AWARDS / Professional Recognitions

- Recognized FDA Expert for Toxicologic Veterinary Regulatory Review Pathology through Agency peer review March 2010.
- Recognized as Fellow IATP (International Academy of Toxicologic Pathology) 2009.
- FDA / CFSAN Outstanding Customer Service Award, Office of Food Additive Safety for *pathology support to CDRH on the histopathological evaluation of mouse tissues for the distribution of nano-material*, June 2008.
- FDA and Center-level Crosscutting Award that includes CFSAN Employees, FDA Melamine Award, Adulterated protein investigations, analysis, planning, scientific review and emergency response team for *exemplary performance to protect the public health from adulterated protein through actions of investigations, sample analyses, method development, assignment, planning, emergency response, scientific review and risk assessment*, June 2008.
- FDA / CFSAN Honor Award: Aspartame Carcinogenicity Review Team, Office of Food Additive Safety for *exceptional performance in evaluating the results of a number of carcinogenicity studies on aspartame, including the high-profile European Ramazzini Foundation study*, June 2008.
- FDA Outstanding Service Award for *outstanding performance while participating on an expert pathology review panel in response to an Inter-Center pathology support request from CDER* June 2007.
- FDA Outstanding Service Award for *outstanding performance in the regulatory review of pathology issues and in providing critical pathology support to the Office of Food Additive Safety* June 2006.
- FDA Outstanding Service Award for *sustained superior performance in evaluating and resolving complex regulatory pathology review issues as well as supporting collaborating scientists* June 2005.
- FDA Outstanding Service Award for *sustained superior performance in the evaluation of substantial and voluminous regulatory and experimental pathology data* June 2004.
- Team Award as member of the OARSA Food Allergenicity Team for *outstanding team effort in successfully completing pilot studies to evaluate a unique animal model for the study of human food allergenicity* June 2003.
- FDA Outstanding Service Award for *sustained superior performance in the Pathology Branch instituting a food-allergy rat model, leveraging with the UMD and establishing a IH laboratory* June 2003

Curriculum Vitae

Dr. Sabine FRANCKE-CARROLL

Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

- Quality Performance Award for developing methods to quantify "altered crypt foci" in the colon of rats July 2002
 - Quality Performance Award for Pathology support services with the University of Maryland (UMD) June 2002

PUBLICATIONS AND PRESENTATIONS:

Technical Reports: lists on - regulatory review projects (upon request)
- regulatory research projects (upon request).

Poster / Journal presentations and Talks:

Boorman G., Wolf D., Francke-Carroll S., and Maronpot R. Guest Editorial: Pathology Peer Review. *Tox Path* 38:1009-1010, 2010.

Botts S., Ennulat D., Francke-Carroll S., Graham M., Maronpot R., and Mohutsky M. Introduction to Hepatic Drug Metabolizing Enzyme induction in Drug Safety Evaluation Studies. Tox Path 38: 796-798, 2010.

Mohutsky M., Romeike A., Meador V., Lee W., Fowler J. and Francke-Carroll S. (Chair) Introduction to Hepatic Drug Metabolizing Enzyme induction in Drug Safety Evaluation Studies. Tox Path 38: 799-809, 2010.

Griffis L., Twardok L.E., Francke-Carroll S., Biles R., Schroeder R., Bolte H., Hall W., Faust H. and Rojko J. Comparative 90-day dietary study of paraffin wax in Fischer-344 and Sprague-Dawley rats. Food and Chemical Toxicology: 2010, 48: 363-372.

Patri A., Umbreit T., Zeng J., Nagashima K., Goering P., Francke-Carroll S., Golden E., Weaver J., Miller T., Sadrieh N., McNeil S., and Stratmeyer M. Energy dispersive X-ray analysis of titanium dioxide nanoparticle distribution after intravenous and subcutaneous injection in mice. Journal of Applied Toxicology 2009, 29: 667-672.

Keenan C., Elmore S., Francke-Carroll S., Kemp R., Kerlin, Peddada, S., R., Fletcher J., Rinke M., Schmidt S., Taylor I. and Wolf D. Potential for a Global Historical Control Database for Proliferative Rodent Lesions. *Tox Path* 2009; 37(5) 677-8.

Keenan C., Elmore S., Francke-Carroll S., Kemp R., Kerlin, Peddada, S., R., Fletcher J., Rinke M., Schmidt S., Taylor I. and Wolf D. Regulatory Forum: Best Practices for Use of Historical Control Data of Proliferative Rodent Lesions. *Tox Path* 2009; 37(5) 679-93.

Kerlin R, Hutto D, Silverman L, Francke-Carroll S, Vahle J. Regulatory forum for Toxicologic Pathology: an update. *Toxicologic Pathology* 2008; 36(5):760.

Austin C., Umbreit T., Brown K., Barber D., Dair B., Francke-Carroll S., Feswick A., Saint-Louis M., Hikawa H., and Goering P. Distribution of iv-injected silver nanoparticles in pregnant mice and developing embryos. Poster presentation at the Society of Toxicology's 48th annual meeting held in Baltimore MD, March 15-19, 2009.

Invited Talk: Francke-Carroll S., Society of Toxicologic Pathology (STP), 27th annual meeting: As Module of the Effective Communication for the Toxicologic Pathologist - Career Development Courses: "Communicating Pathology Information Effectively to Regulatory Agencies". San Francisco, CA June 20-26, 2008.

Keenan C., Elmore S., Francke-Carroll S., Kemp R., Kerlin R., Pletcher J., Rinke M., Schmidt S., Taylor I., Wolf D. STP Working Group on Historical Control Data of Proliferative Rodent Lesions. Presented at the 26th annual meeting of the Society of Toxicologic Pathology (STP) in San Juan, Rio Mar, Puerto Rico, June 2007.

Umbreit T.H., Goering P.L., Miller T.J., Weaver J.L., Francke-Carroll S., Sadrieh N., Kauffman J., Guthrie J., Robertson J., Stratmeyer M.E.: *Toxicity and Tissue Distribution of Titanium Dioxide (TiO_2) Nanoparticles in subcutaneous and intravenously injected mice over 6 months* Poster presentation at the Society of Toxicology's 47th annual meeting held in Seattle, WA, March 21-26, 2008.

Curriculum Vitae

Dr. Sabine FRANCKE-CARROLL

Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

PUBLICATIONS AND PRESENTATIONS (contd.)

Daly K., Tracy A., Francke-Carroll S., Wang T., Malik M. and Magnuson B.A. Enhanced estrogenic responses and sensitivity to azoxymethane following dietary soy isoflavone supplementation in older female rats. *Food Chem Toxicol* 2007 Apr; 45 (4):628-37.

Umbreit T., Goering P., Francke-Carroll S., Patri A., McNeil S., Weaver J., Miller T., Sadrieh N., and Stratmeyer M. *Energy dispersive X-ray analysis of titanium dioxide nanoparticle distribution in mice*. Poster presentation at the Society of Toxicology's 46th annual meeting held in Charlotte, NC March 25-29, 2007.

Yoon DM, Hawkins EC, Francke-Carroll S., Fisher JP. Effect of construct properties on encapsulated chondrocyte expression of insulin-like growth factor-1. *Biomaterials* 2007 Jan 28 (2); 299-306.

Morton D, Kemp RK, Francke-Carroll S., Jensen K, McCartney J, Monticello TM, Perry R, Pulido O, Roome N, Schafer K, Sellers R, Snyder PW. Best practice for reporting pathology interpretations within GLP toxicology studies. *Tox Path* 2006; 34 (6); 806-9.

Su Y., Yu T., Lala G., Francke-Carroll S., and Magnuson B.A. Protection of side effects of 5-flurouracil by anthocyanin-rich extracts. International Research Conference on Food and Nutrition and Cancer, Washington DC, July 2005. Published in *J. Nutr.* 135.12S:3054.

Ferri, M, Francke-Carroll S. and Magnuson B.A. JIFSAN Student project: Development of immuno-histochemical staining techniques for PCNA and APOPTOSIS tissue markers on rat tissues in the CFSAN Pathology Laboratory. Poster presentation at the 11th Annual FDA Science Forum, 2005, Washington Convention Center, Washington DC.

Hinton D.M., Lorenzo M., Harper S.B. and Francke-Carroll S., (2004). USFDA, CFSAN, Laurel, MD. Progress in the evaluation of an in-bred rat strain ("asthmatic rat") for predicting the allergic potential of food and other Proteins. Seminar presented at OFAS/CFSAN/USFDA Vermont Ave May 6, 2004.

Hinton D.M., Lorenzo M.E., Harper S.B., Francke-Carroll S., O'Neill R.K., Chirtel S.J., Calvo M.S. An In-Bred Rat Strain (the FDA "Asthmatic Rat") for Predicting the Allergic Potential of Proteins and for Evaluating the Efficacy of Drugs and Dietary Supplements in Respiratory (Asthmatic) and Cardiovascular Studies Poster presentation (Board Number B-08) at the 10th Annual FDA Science Forum, 2004, Washington Convention Center, Washington DC.

Magnuson B., Daly K., Malik M., Wang T., Francke-Carroll S.. Enhanced Sensitivity of Female Rats to Azoxymethane following Dietary Soy Isoflavone Supplementation. Poster presentation at the 10th Annual FDA Science Forum, 2004, Washington Convention Center, Washington DC.

Francke-Carroll S., Daly K., Wang T. and Magnuson B.A. Underlying age-related liver pathology increases azoxymethane toxicity in F344 female rats in an aging study on colon cancer chemoprevention with dietary soy. Website publication (Board Number D-PO-01) for the 10th Annual FDA Science Forum, 2004, Washington Convention Center, Washington DC.

Francke-Carroll S., Daly K., Wang T. and Magnuson B.A. Underlying age related liver pathology increases Azoxymethane toxicity in F344 female rats in an aging study on colon cancer and nutrition. Poster presentation # 500 at the Society of Toxicology's 43rd annual meeting held in Baltimore, MD, March 21-26, 2004.

Hinton D.M., Lorenzo M., Harper S.B. and Francke-Carroll S., (2004). USFDA, CFSAN, Laurel, MD. Progress in the evaluation of an in-bred rat strain ("asthmatic rat") for predicting the allergic potential of food and other Proteins. , *The Toxicologist* (Platform Session on Hypersensitivity, Abstract #662, 43rd Annual Meeting of the Society of Toxicology).

Hinton D.M., Myers M.J., Raybourne R.A., Francke-Carroll S., Sotomayor R.E., Shaddock J., Warbritton A., Chou M.W.: Immunotoxicity of Aflatoxin B₁ in Rats: Effects on Lymphocytes and the Inflammatory Response in a Chronic Intermittent Dosing Study. *Toxicological Sciences*; 73, 362-377, 2003.

Curriculum Vitae

Dr. Sabine FRANCKE-CARROLL

Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

PUBLICATIONS AND PRESENTATIONS (contd.)

Humphreys S.H., Dua P., Francke-Carroll S., Bolger P.M., Calamus: Reassessment of Carcinogenicity. *Toxicological Sciences* 66, 1-S, 268, 2002.

Francke S., Orosz C.G., Hsu J, and Mathes L.E.: Immunomodulatory Effect of Zidovudine (ZDV) on Cytotoxic T Lymphocytes Previously Exposed to ZDV. *Antimicrob Agents Chemother* Sept; 46 (9): 2865-71, 2002.

Francke-Carroll, S., Montgomery J.E., Hines F.A., and Magnuson B.A.: The Effect of a Dietary Curcumin Supplement on the Development of Histopathological Age-associated Changes in Male Azoxymethane-Treated F344 Rats. Presented at the twenty-first Annual Symposium of the Society of Toxicologic Pathology, Denver, CO, June. 2-6, 2002.

Francke S., Orosz C.G., Hayes K.A. and Mathes L.E.: Effect of Zidovudine on the primary cytolytic T-lymphocyte response and T-cell effector function. *Antimicrob Agents Chemother* Jul; 44(7): 1900-5, 2000.

Hayes K.A, Phipps A, Francke S. and Mathes L.E.: Antiviral therapy reduces viral burden but does not prevent thymic involution in young cats infected with feline immunodeficiency virus. *Antimicrob Agents Chemother* Sep; 44(9): 2399-2405, 2000.

Mathes L.E., Hayes K.A., Francke S. and Phipps A.: Comparison of pathogenesis of the Mount Airy strain of feline immunodeficiency virus (FIV-MD) in pediatric and adult cats. Presented at the Third International Feline Retrovirus Research Symposium, Ft. Collins, CO, March 6-9, 1998.

Francke S. Evaluation of the Immunomodulatory effects of the anti-retroviral drug Zidovudine (AZT). Presented in partial fulfillment of the requirements for the degree Doctor of Philosophy in the Graduate School of The Ohio State University. The Ohio State University, Columbus, OH, USA, 1996.

Francke, S., Hayes K.A., Orosz C.G., and Mathes L.E.: Frequency Analysis of the Immunosuppressive effect of Zidovudine (AZT) on murine lymphocyte function in vitro by Limiting Dilution Analysis (LDA). Presented at the forty-seventh Annual Meeting of The American College of Veterinary Pathologists, Seattle, WA, Dec. 2-6, 1996.

Hayes, K.A., Francke S., Phipps A and Mathes L.E.: AZT therapy in adult cats chronically infected with FIV-MD. Presented at the Third International Feline Retrovirus Research Symposium, Ft. Collins, Co., March 5-9, 1996.

Francke S. and Capen C.C.: Undifferentiated carcinoma in the anterior mediastinum of a dog. Presented at the Eastern North American Veterinary Diagnostic Pathology Conference, Cobleskill, NY, Oct. 21-22, 1995.

Hayes K.A., Wilkinson J.G., Frick R., Francke S. and Mathes L.E.: Early suppression of viremia by ZDV does not alter the spread of feline immunodeficiency virus infection in cats. *J Acqu Immune Syndr & Hum Retrovir* 9:114-22, 1995.

Francke, S. Histological and immunohistological evaluation of the spleen in Balb/cJ (H-2^d) mice following infection with *Coxiella burnetii*. (*Histologische und immunohistologische Untersuchung der Milz von Balb/cJ (H-2^d)-Maeusen nach Infektion mit Coxiella burnetii*): Inaugural - Dissertation, Veterinary Medicine, Justus-Liebig-University, Giessen, Germany, 1991.

PETER GREAVES MBChB FRCPATH

Dr Greaves is a medical graduate trained in laboratory medicine, specialising in human and experimental histopathology and toxicology. He has over twenty-five years experience in human and experimental pathology as well as toxicology, pre-clinical drug safety evaluation and drug development. He advises both pharmaceutical companies and government in these areas.

PROFESSIONAL HISTORY:

CONSULTING PATHOLOGIST

March 2005 – present:

Advises on preclinical drug safety evaluation and toxicological pathology. Engaged in research in toxicological pathology, carcinogenesis and cancer chemoprevention. Member of the Committee on Carcinogenicity, United Kingdom

MEDICAL RESEARCH COUNCIL TOXICOLOGY UNIT, LEICESTER

March 2000 – February 2005: Senior Research Scientist & Head of Pathology.

Responsibility for the histopathological study of disease models and adverse hepatic effects of drugs in obesity in combination with genetic analysis, laser capture dissection microscopy, in situ hybridisation and immunocytochemistry.

ASTRAZENECA (FORMERLY ZENECA, ICI PHARMACEUTICALS), ALDERLEY PARK, CHESHIRE

March 1990 - February 2000: Head of Safety of Medicines Group

Responsibility for all preclinical safety studies and kinetics and metabolism work with approximately 300 staff in the UK and US in support of the discovery and development of novel drugs for all of ex-ZENECA Pharmaceuticals.

ZENECA (FORMERLY ICI) PHARMACEUTICALS, ALDERLEY PARK, CHESHIRE

January 1989 - February 1990: Head of Pathology

Responsibility for a group of 80 staff conducting histopathological evaluation of toxicity studies.

PARKE-DAVIS RESEARCH INSTITUTE, MISSISSAUGA, ONTARIO, CANADA

January 1987 - December 1988: Director of Research Institute

Responsibility for the Sheridan Park Research Laboratory (60 staff) undertaking preclinical safety studies for Parke-Davis Research centred at Ann Arbor, Michigan.

WELLCOME RESEARCH LABORATORIES, BECKENHAM, KENT, ENGLAND

January 1985 - December 1986: Head of Toxicology and Metabolism

Responsibility for drug safety evaluation, preclinical drug kinetics and radiochemistry at the Beckenham site (50 staff), in collaboration with Experimental Pathology and Toxicology at Research Triangle Park site.

CENTRE DE RECHERCHE, LABORATOIRES PFIZER, AMBOISE, FRANCE

September 1981 - December 1984: Director of Pathology

April 1979 - August 1981 - Pathologist

**WESTMINSTER HOSPITAL MEDICAL SCHOOL & ST STEPHEN'S HOSPITAL,
LONDON**

**September 1976 - March 1979 - Senior Registrar in Histopathology
February 1975 - February 1976 - Registrar in Histopathology**

**MEDIZINISCHE HOCHSCHULE, HANNOVER, GERMANY.
February 1976 - September 1976 - Assistant in Pathology**

**NEWCASTLE GENERAL HOSPITAL, NEWCASTLE-UPON-TYNE
September 1972 - February 1975 - Senior House Officer in Pathology**

**GRAVESEND HOSPITAL, KENT
October 1972 - May 1972 - House Physician**

**CHICHESTER HOSPITAL, WEST SUSSEX
February 1971 - August 1971 - House Surgeon**

EDUCATION AND DEGREES:

- * MBChB University of Birmingham, England, 1969
- * MRCPPath in human histopathology, Royal College of Pathologists, London, 1977
- * FRCPath in histopathology & toxicology, Royal College of Pathologists, London, 1989
- * GMC Registration in Morbid Anatomy and Histopathology under the European Specialist Medical Qualifications order 1995 (number 1491454)
- * Medical Defence Union membership (membership number 095078D)

OTHER ACTIVITIES:

- * Member of the *Committee on Carcinogenicity*, United Kingdom 2008-present
- * Member of *International Life Sciences Institute (ILSI) – Europe* project on data selection for modelling of substances that are genotoxic and carcinogenic 2009-2011
- * Chairman of *International Harmonization of Nomenclature and Diagnostic Criteria* committee for rodent soft tissue pathology 2009-present
- * Member of the *Veterinary Products Committee* of the United Kingdom 2003-2007
- * Member of the editorial board for *Toxicologic Pathology* 2002-2006
- * Member of the editorial board for *Experimental & Toxicologic Pathology* 2000-2007.
- * Chairman of *Zeneca Leisure* 1996-1999: This group managed all the company leisure activities, clubs and leisure facilities, turnover £1 million per annum
- * Member of Personnel steering group for *Zeneca R&D* in the UK 1996-1999
- * Member of Health & Safety Steering Committee for the Alderley Park R&D site 1996-1999
- * Biological Safety Officer, MRC Toxicology Unit 2000-2003

Date: 21 July 2010

PUBLICATIONS:

Books:

Greaves P. and Faccini J.M. (1992): Rat Histopathology: A Glossary for Use in Toxicity and Carcinogenicity Studies, *2nd edition*. Elsevier, Amsterdam.

Greaves P. (2007): Histopathology of Preclinical Toxicity Studies: Interpretation and Relevance in Drug Safety Evaluation. Elsevier, Amsterdam. *3rd edition*.

Main scientific papers:

Greaves P., Filipe M.I. and Branfoot A.C. (1980): Transitional mucosa and survival in human colorectal cancer. *Cancer*, **46**, 764-770.

Greaves P. and Faccini J.M. (1981): Fibrous histiocytic neoplasms spontaneously arising in rats. *Br.J.Cancer*, **43**, 402-411.

Greaves P., Martin J. and Masson M-T. (1982): Spontaneous rat malignant tumors of fibrohistiocytic origin. An ultrastructural study. *Vet.Pathol.*, **19**, 497-505.

Greaves P and Rabémampianina Y. (1982): Choice of rat strain: A comparison of the general pathology and tumour incidence in 2-year old Sprague-Dawley and Long-Evans rats. In: New Toxicology for Old, *Arch.Toxicol.*, Suppl 5, 298-303.

Villanove F. and Greaves P. (1983): Sialoglycoconjugates in normal and neoplastic rat liver: A histochemical study. *Pathol.Res.Pract.*, **178**, 171.

Michel M.C., Greaves P., Martin J. and Greaves P. (1983): Etude ultrastructurale des lymphomes malins non Hodgekiniens gastrointestinaux spontanés chez le hamster Syrien (*Mesocricetus auratus*). *Biol.Cell.*, **48**, 10a.

Greaves P., Martin J., Michel M.C. and Mompon P. (1984): Cardiac hypertrophy in dog and rat induced by oxfenicine an agent which modifies muscle metabolism. In: Diseases, Metabolism and Reproduction in the Toxic Response to Drugs and Other Chemicals. *Arch.Toxicol.*, Suppl. 7, 488-493.

Irisarri E., Kessedjian M.J., Charuel C., Faccini J.M., Greaves P., Monro A.M., Nachbaur J. and Rabémampianina Y. (1984): The preclinical toxicity of Dazoxiben, a specific inhibitor of thromboxane A2 synthetase. In: Disease, Metabolism and Reproduction in the Toxic Response to Drugs and Other Chemicals. *Arch.Toxicol.*, Suppl. 7, 363-364.

Taradach C. and Greaves P. (1984): Spontaneous eye lesions in laboratory animals. Incidence in relation to age. *CRC Crit.Rev.Toxicol.*, **12**, 121-147.

Greaves P. and Boiziau J.L. (1984): Altered patterns of mucin secretion in gastric hyperplasia in mice. *Vet.Pathol.*, **21**, 224-228.

Greaves P., Filipe M.I., Abbas S. and Ormerod M.G. (1984): Sialomucins and carcinoembryonic antigen in the evolution of colorectal cancer. *Histopathology*, **8**, 825-834.

Irisarri E., Kessedjian M.J., Charuel C., Faccini J.M., Greaves P., Monro A.M., Nachbaur J. and Rabémampianina Y. (1985): Dazoxiben, a prototype inhibitor of thromboxane synthesis, has little toxicity in laboratory animals. *Hum.Toxicol.*, **4**, 311-315.

Higgins A.J., Faccini J.M and Greaves P. (1985): Coronary hyperemia and cardiac hypertrophy following inhibition of fatty acid oxidation. Evidence of a regulatory role for cytosolic phosphorylation potential. In: N.S. Dhalla and D.J. Hearse (Eds), *Advances in Myocardiology*, Vol. 6, pp. 329-338, Plenum.

- Greaves P., Martin J.M. and Rabémampianina Y. (1985): Malignant fibrous histiocytoma in rats at site of implanted millipore filters. *Am.J.Pathol.*, **120**, 207-214.
- Spencer A.J. Andreu M. and Greaves P. (1986): Neoplasia and hyperplasia of pancreatic endocrine tissue in the rat: An immunocytochemical study. *Vet.Pathol.*, **23**, 11-15.
- Greaves P., Irisarri E. and Monro A.M. (1986): Hepatic foci of cellular and enzymatic alteration and nodules in rats treated with clofibrate or diethylnitrosamine followed by phenobarbitone: Their rate of onset and their reversibility. *J.N.C.I.*, **76**, 475-484.
- Masson M.T., Villanove F. and Greaves P. (1986): Histological demonstration of wheat germ lectin binding sites in normal and ANIT-treated rats. *Arch.Toxicol.*, **59**, 121-123.
- Spencer A. and Greaves P. (1987): Polyarteritis in a beagle dog colony. *J.Comp.Pathol.*, **97**, 122-128.
- Mompon P., Greaves P., Irisarri E., Monro A.M. and Bridges J.W. (1987): A cytochemical study of the livers of rats treated with diethylnitrosamine/phenobarbital, with benzidine/phenobarbital, with phenobarbital, or with clofibrate. *Toxicology*, **46**, 217-236.
- Greaves P. (1987): Safety evaluation prior to administration of drugs to man. *Lab.Anim.*, **21**, 166.
- Greaves P. (1989): Malignant fibrous histiocytoma, rat. In: Monograph on Pathology of Laboratory Animals. Integument and Mammary Glands. T.C. Jones, U.Mohr and R.D. Hunt (Eds), pp.106-112. Springer-Verlag, Berlin.
- de la Iglesia F.A. and Greaves P. (1989): Role of toxicokinetics in drug safety evaluations. In: Toxicokinetics and New Drug Development. A. Yacobi J.P. Skelly and Y.K. Batra (Eds), chap 2, pp 21-32, Pergamon Press, New York.
- Macallum G.E., Smith G.S., Barsoum N.J., Walker R.M. and Greaves P. (1989): Renal and hepatic toxicity of a benzopyran-4-one in the cynomolgus monkey. *Toxicology*, **59**, 97-108.
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Lazenby C.M., Westwood F.R. and Greaves P. (1993): Crescentic cataracts in Alderley Park rats. *Vet.Pathol.*, **30**, 70-74.

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Green, A.R., Parrott, E.L., Butterworth, M., Jones, P.S., Greaves, P. and White I.N.H. (2001): Comparisons of the effects of tamoxifen, toremifene and raloxifene on enzyme induction and gene expression in the ovariectomized rat uterus. *J.Endocrinol.*, **170**, 555-564.

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prostate (TRAMP) tissue by ^1H -NMR analysis—evidence for unusual phospholipid metabolism. *Prostate*, **68**, 1035–1047.

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[In Press withheld under Exemptions B4 and B6]



Experimental Pathology Laboratories, Inc.

**JERRY F. HARDISTY
CHIEF EXECUTIVE OFFICER/SENIOR PATHOLOGIST**

EDUCATION:

Iowa State University, Pre-Veterinary, 1965-1967

Iowa State University, D.V.M., 1971

Certified by the American College of Veterinary Pathologists, 1976

Adjunct Associate Professor at the School of Veterinary Medicine,
NC State University, 1983

PRESENT POSITION AND EXPERIENCE:

2010 - Present. Chief Executive Officer/Veterinary Pathologist, Experimental Pathology Laboratories, Inc., Research Triangle Park, North Carolina

Responsible for the overall implementation of the strategic goals and objectives of EPL. Provide leadership toward the company's philosophy, mission, strategy, and goals and objectives. Direct the company's business development and marketing efforts. Serve as the Principal Investigator as a Study Pathologist, Peer Review Pathologist and Chairperson for Pathology Working Groups and Scientific Advisory Panels.

1998 - 2010. President and Veterinary Pathologist, Experimental Pathology Laboratories, Inc., Research Triangle Park, North Carolina

Responsible for overall management and direction of contract research pathology laboratories in Virginia and North Carolina. The company serves both government and university research and the safety assessment programs of the pharmaceutical, chemical, and cosmetic industries.

1994 - 1998. Vice President, Operations and Pathologist, Experimental Pathology Laboratories, Inc., Research Triangle Park, North Carolina

Responsible for overall management and direction of pathology research laboratories in North Carolina and Virginia.

1978 - 1994. Director and Pathologist, Experimental Pathology Laboratories, Inc., Research Triangle Park, North Carolina

Responsible for the project management, direction and technical supervision of the North Carolina branch of EPL. Responsible for the microscopic evaluation of toxicological studies. Responsible for the National Toxicology Program's Pathology Quality Assessment Program and Operations of the NTP Archives.

1976 - 1978. Pathologist/Project Manager, Experimental Pathology Laboratories, Inc., Herndon, Virginia

Responsible for the management of EPL's Carcinogenesis Support Laboratory. Project Manager of a program to provide Tracor Jitco with Quality Assurance in the NCI Carcinogenesis Testing Program. Technical supervision of a program to provide pathology support services to the Carcinogenesis Program of the National Cancer Institute. Responsible for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies.



Experimental Pathology Laboratories, Inc.

JERRY F. HARDISTY, DVM, DACVP

PRESENT POSITION AND EXPERIENCE – Continued

1972-1976 Research Pathologist, Veterinary Pathology Branch, Biomedical Laboratory, Edgewood Arsenal, Maryland

Dr. Hardisty was a preceptor in the U.S. Army preceptorship program in Veterinary Pathology. During this time he performed gross and microscopic diagnoses of spontaneous disease and changes produced by experimental procedures in laboratory animals. He prepared reports describing and interpreting these experimental results.

During this time he was principal investigator for the reproductive, mutagenic, teratogenic studies performed at the laboratory. This work consisted of revising previous experimental protocols and designing new experimental protocols to be utilized at the laboratory. The experimental design employed required the gross examination of pregnant female rats and fetuses for evidence of fetal toxicity and teratogenesis. He trained biological technicians to perform timed matings in rats, examine serially sectioned fetuses for malformations, and to examine fetal skeletons for prenatal abnormalities.

1971-1972 Attending Veterinarian, Division of BioSensor Research,
Walter Reed Army Institute of Research

Dr. Hardisty studied the radiographic and morphologic lesions of several musculoskeletal diseases of the German Shepherd Dog. In association with Dr. Wayne Riser, he investigated the pathogenesis and possible genetic relationship of canine hip dysplasia, eosinophilic panosteitis and ununited anconeal processes in an attempt to reduce their incidence through a selective breeding program.

PROFESSIONAL MEMBERSHIPS:

Diplomate, American College of Veterinary Pathologists

ACVP Subspecialty in Toxicologic Pathology

American College of Toxicology

Society of Toxicology

Society of Toxicologic Pathologists

British Society of Toxicologic Pathologists

International Academy of Toxicologic Pathology

American Veterinary Medical Association

North Carolina Society of Toxicology

Charles Louis Davis, D.V.M. Foundation

The Society of Phi Zeta

The Society of Gamma Sigma Delta

The Fraternity of Alpha Zeta

The Fraternity of Omega Tau Sigma

American Association for the Advancement of Science

Standardized System of Nomenclature and Diagnostic Criteria (SSNDC), The



Experimental Pathology Laboratories, Inc.

JERRY F. HARDISTY, DVM, DACVP

PROFESSIONAL ACTIVITIES – Continued

Society of Toxicologic Pathologists, 1987-1995.
Executive Committee, The Society of Toxicologic Pathologists, 1994- 1998.
Executive Committee Chairman, The Society of Toxicologic Pathologists, 1997-1998.
Joint Committee for STPs/ILSI on International Standardization of
Nomenclature and Diagnostic Criteria for Toxicologic Pathology, 1994-1995,
Co-Chairman 1995-Present.
President-Elect, The Society of Toxicologic Pathologists, 1999-2000.
President, The Society of Toxicologic Pathologists, 2000-2001.
Past President, The Society of Toxicologic Pathologists, 2001-2002.
Long Range Planning Committee, American College of Toxicology, 2002.
North American Director, International Academy of Toxicologic Pathology, 2002.
FDA Clinical Pharmacology Subcommittee of the Advisory Committee for
Pharmaceutical Sciences, FDA Center for Drug Evaluation and Research, 2003.

EDITORIAL REVIEW BOARD:

International Agency for Research on Cancer (WHO), Classification of Rodent Tumors, Part II, The Mouse, 1995-2001.

Editorial Review Board for *Fundamental and Applied Toxicology*, Society of Toxicology Board of Publications, 1996-1998.

Editorial Review Board for *Toxicological Sciences*, Society of Toxicology Board of Publications, 1998-2004.

Editorial Review Board for *Experimental and Toxicologic Pathology*, 2000.

Editorial Board of *Toxicologic Pathology*, 2006-2008.

PUBLICATIONS AND PAPERS:

Defining a Noncarcinogenic Dose of Recombinant Human Parathyroid, Hormone 1-84 in a 2-Year Study in Fischer 344 Rats. The Society of Toxicologic Pathology

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JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS – Continued

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JERRY F. HARDISTY, DVM, DACVP

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JERRY F. HARDISTY, DVM, DACVP

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JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS – Continued

The pathologist and pathology data. Hardisty JF. Presented at NCTR in Jefferson, AR on October 31, 2002.

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PUBLICATIONS AND PAPERS – Continued

Current Practices in Toxicologic Pathology, Hardisty JF. Speaker, Presented at The Third Sino-US Pharmaceutical Workshop, Toxicological Pathology in New Product Development, Boda Mansion, Beijing, May 30, 2008.

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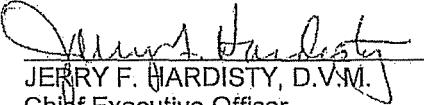
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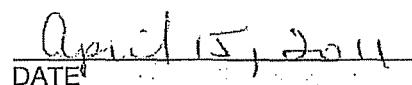
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JERRY F. HARDISTY, D.V.M.

Chief Executive Officer

Senior Pathologist



April 15, 2011

DATE



Experimental Pathology Laboratories, Inc.

**PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P.
VETERINARY PATHOLOGIST**

EDUCATION:

Washington University, St. Louis, Missouri, A.B., English Literature, 1966-1970
University of Missouri, St. Louis, Missouri, Pre-veterinary Studies, 1972-1974
University of Missouri, Columbia, Missouri, D.V.M., 1975-1979

CERTIFICATIONS/LICENSURE:

Certified by the American College of Veterinary Pathologists, 1984

PRESENT POSITION AND EXPERIENCE:

2007 – Present. Manager, EPL Northwest, Seattle, WA.

Responsible for project management and for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies from pharmaceutical, biotechnical, and agricultural clients. Offering histopathology and peer review services as well as organization of Pathology Working Groups. Provide interpretation of ultrastructural pathology. Consultation to clients on regulatory issues.

2002 – 2006. Manager, EPL Northeast, Galena, MD.

Responsible for project management and for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies from pharmaceutical, biotechnical, and agricultural clients. Offering histopathology and peer review services as well as organization of Pathology Working Groups. Provide interpretation of ultrastructural pathology. Consultation to clients on regulatory issues.

2000 – 2002. On-Site Consultant, DuPont Pharmaceuticals Company, Wilmington, DE.

Full-time, on-site consultant to DuPont Pharmaceuticals Company. Provided necropsy supervision and microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies by DuPont Pharmaceuticals Company.



Experimental Pathology Laboratories, Inc.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

1999 – 2000. **Senior Projects Manager**, Experimental Pathology Laboratories, Inc., Research Triangle Park, NC.

Responsible for project management and for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies for both commercial clients and the National Toxicology Program's Pathology Quality Assessment Program and the NTP Archives.

1994 – 1999. **Director and Pathologist**, Experimental Pathology Laboratories, Inc., Research Triangle Park, NC.

Responsible for project management, direction and technical supervision of the North Carolina Branch of EPL. Responsible for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies. Provided support to the National Toxicology Program's Pathology Quality Assessment Program and the NTP Archives.

1990 – 1994. **Veterinary Pathologist**, Experimental Pathology Laboratories, Inc., Research Triangle Park, NC.

Duties included histopathologic interpretation of tissues from various laboratory animals used for toxicology and carcinogenesis studies.

1989 – 1990. **Pathologist**, EPL Scientific Limited, Harrogate, England.

1985 – 1989. **Veterinary Pathologist**, ICI Pharmaceuticals, Division of ICI Americas, Wilmington, Delaware.

1982 – 1989. **Staff Pathologist**, Brandywine Zoo, Wilmington, Delaware.

1982 – 1985. **Senior Lecturer**, Department of Pathobiology, University of Pennsylvania School of Veterinary Medicine.

1979 – 1982. **Resident in Pathology**, National Zoological Park, Washington, DC.



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PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

- 1974 – 1975. **Food Technologist**, Pet Foods Department, Grocery R&D, Ralston Purina Co., St. Louis, MO.
- 1970 – 1971. **Secondary School Teacher**, St. Louis, MO.

PROFESSIONAL MEMBERSHIPS:

American Veterinary Medical Association
American College of Veterinary Pathology
Society of Toxicological Pathology
British Society of Toxicologic Pathologists
C.L. Davis Foundation for the Advancement of Veterinary Pathology
North Carolina Society of Toxicology

SERVICE TO PROFESSIONAL ASSOCIATIONS:

Chairman, STP Nomenclature Subcommittee on the Mammary Gland

Member, STP Nomenclature Subcommittee on the Respiratory System
Adjunct Associate Professor at the School of Veterinary Medicine, NC State University, Department of Microbiology, Pathology and Parasitology
Member, STP Symposium Committee, 1995-1998
Co-Chairman, STP Educational Committee, 1996
Chairman, STP Symposium Committee, 1998
Copy Editor, C.L. Davis Foundation Newsletter, 1998
Member, Advisory Board, C.L. Davis Foundation for the Advancement of Veterinary Pathology, 2000-2004
Member, Executive Committee, Society of Toxicologic Pathology, 2000-2004
Chairman, STP Journal Committee, 2005
Chair, Global Editorial Steering Committee, 2006-2008
President-Elect, Society of Toxicologic Pathology, 2008-2009
President, Society of Toxicologic Pathology, 2009-2010
Member, ILSI/HESI Subcommittee on Distinguishing Adverse from Adaptive, Non-Functional, and Pharmacologic Changes in Toxicology Studies, 2009-2010

SERVICE TO EDITORIAL BOARDS OF SCHOLARY JOURNALS:

Reviewer for Toxicologic Pathology, 1998-2002



Experimental Pathology Laboratories, Inc.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

PROFESSIONAL DEVELOPMENT/SPECIALIZED TRAINING:

Educational Activities/Special Lectures:

- | | |
|-----------|---|
| 1981 | Diseases of zoo mammals and birds. Pathology of Laboratory Animals, Washington, D.C. |
| 1982 | Pathology of zoo animals. Friends of the National Zoo, Washington, D.C. |
| 1982 | Necropsy Service, University of Pennsylvania School of Veterinary Medicine, supervision of senior students and residents in small animal pathology rotation. |
| 1982-1985 | Necropsy Service, University of Pennsylvania School of Veterinary Medicine, supervision of senior students and residents in large animal pathology rotation. |
| 1983 | University of Pennsylvania School of Veterinary Medicine, Course 5402, Skin Diseases of Large Animals. |
| 1983-1984 | Philadelphia College of Pharmacy and Science. Principles of Pathology. |
| 1983-1984 | University of Pennsylvania School of Veterinary Medicine, Course 5001, General Endocrine Pathology. |
| 1983 | University of Pennsylvania School of Veterinary Medicine, Course 4501, Infectious Diseases of Dogs and Cats, Neuroendocrine Pathology. |
| 1984 | University of Pennsylvania School of Veterinary Medicine, Course 5401, Infectious Diseases of Dogs and Cats. |
| 1984 | University of Pennsylvania School of Veterinary Medicine, Course 5402, Skin Diseases of Large Animals, Diseases of Horses. |
| 1985 | University of Pennsylvania School of Veterinary Medicine, Course 5402, Diseases of Horses. |
| 1996 | School of Veterinary Medicine, NC State University, Department of Microbiology, Pathology and Parasitology, VMS 643: Toxicologic Pathology – Lymphoreticular. |



PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

- 1997 School of Veterinary Medicine, NC State University, Department of Microbiology, Pathology and Parasitology, VMS 643: Toxicologic Pathology – Lymphoreticular.
- 1999 Chemical Industry Institute of Toxicology, Pathology Short Course for Toxicologists. Necropsy and Histology Techniques. Pathology of genetically-engineered mouse lines used in new short-term carcinogenesis bioassays.
- 2002 Society of Toxicology, Continuing Education Course: Blood and Lymphoid Tissue: Neoplasia of Blood and Lymphoid Tissue.
- 2003 Society of Toxicology, Continuing Education Course: Integrating Toxicologic Pathology into Compound Evaluation and Risk Assessment II: Diagnostic Drift.
- 2006 International Institute of Biotechnology and Toxicology. Chennai, Tamal Nadu, India: Regulatory Toxicologic Pathology
- 2007 School of Veterinary Medicine, Purdue University. Laboratory Animal Medicine The Use of Genetically-Modified-Mice in Toxicology
- 2008 Beijing Pharma and Biotech Center (BPBC) – Sino American Pharmaceutical Professionals Association (SAPA) Beijing Workshop: Toxicologic Pathology in New Product Development. Fundamentals of General and Toxicologic Pathology and Histopathology of the Respiratory System: Nose, Larynx and Lungs.
- 2010 School of Veterinary Medicine, Purdue University. Laboratory Animal Medicine, The Use of Genetically-Modified-Mice in Toxicology and Trust me, I'm a Pathologist.
- National Institute for the Control of Pharmaceuticals and Biological Products and the Society of Toxicologic Pathology: USA-China Carcinogenicity Studies Workshop. Beijing, China. Reading the Rodent Bioassay: Problems, Pitfalls and Peer Review and Common Background Tumors of Laboratory Rodents.



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PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

Seminars and Presentations:

Canine parvovirus. Johns Hopkins Division of Comparative Medicine, Baltimore, 1980.

Parvo-like enteritis in golden lion tamarins. Primate Pathology Workshop, New Orleans, 1980.

Canine parvovirus in South American canids. American Association of Zoo Veterinarians, Washington, D.C., 1980.

Leiomyomas of the genital tract in large zoo mammals. International Academy of Pathology, Chicago, 1981.

Respiratory distress syndrome in neonatal reindeer (poster). International Academy of Pathology, Chicago, 1981.

Herpesvirus infections in old world primates. Johns Hopkins Division of Comparative Medicine, Baltimore, 1981.

Selected diseases of zoo animals. University of Pennsylvania School of Veterinary Medicine, Philadelphia, 1981.

Tuberculous osteomyelitis in captive marsupials (poster). International Academy of Pathology, Boston, 1982.

Selected diseases of zoo animals. Virginia-Maryland Regional College of Veterinary Medicine, Blacksburg, 1982.

Post mortem examination as a technique in research. Symposium on the effects of oil on birds, Stone Harbour, 1982.

Enzootic nasal tumors in sheep. Pennsylvania Diagnostic Workshop, Harrisburg, 1983.

Gross pathology of zoo animals. Eighth Annual C.L. Davis Conference in Veterinary Pathology, Philadelphia, 1984.

Peer review from the perspective of a consultant pathologist. Society for Quality Assurance Annual Meeting, Phoenix, Arizona, 1995.

Lesions of Dioxin in laboratory animals. Society of Toxicologic Pathologists 15th International Symposium, St. Louis, Missouri, 1996.



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PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

Use of genetically altered mice in short-term bioassays. The 22nd Annual C.L. Davis DVM Foundation Continuing Education Symposium, North Carolina State University, College of Veterinary Medicine, Raleigh, North Carolina, June 14-18, 1998.

Pathology of genetically-engineered mouse lines used in new short-term carcinogenesis bioassays. Pathology of Genetically-Engineered Mice, National Institute of Health, Bethesda, Maryland, February 24-25, 1999.

Pathology of genetically-engineered mouse lines used in new short-term carcinogenesis bioassays. CL Davis Foundation European Pathology Division Symposium, Nantes, France, July 1999.

Pathology of genetically-engineered mouse lines used in new short-term carcinogenesis bioassays. Wyeth Ayerst Research, Chazy, NY, November 1999.

Background pathology of genetically-engineered mouse lines and the significance of strain variability. Pathology of Mutant Animal Models, sponsored by the CL Davis Foundation, Houston, TX, February 17-19, 2000.

Pathology Peer Review: Current Concepts. Society of Quality Assurance, 16th Annual Meeting, Montreal, Canada, October 9-13, 2000.

Background pathology of genetically-engineered mouse lines. American College of Toxicology, 21st Annual Meeting, San Diego, CA, November 13, 2000.

Background pathology of genetically-engineered mouse lines and the significance of strain variability. Pathology of Mutant Animal Models sponsored by the CL Davis Foundation, Houston, TX, February 15-17, 2001.

Pathology of Transgenic Mice. CL Davis Foundation European Division Pathology Symposium (Szent Istvan University, Budapest, Hungary), July 5-7, 2001.

Genetically-engineered mice in toxicology. Pathology of Mutant Animal Models, sponsored by the CL Davis Foundation, Houston, TX, February 13-16, 2002.

Necropsy and Histology: Current Practices in Pathology. Health Canada, Existing Substances Branch, Ottawa, Canada, March 2002.

Pathology Data and Tox-Path Issues. USFDA, May 20, 2002.



Experimental Pathology Laboratories, Inc.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

Necropsy and Histology, Current Practices in Pathology, Pathology of Transgenic Mice, Diagnostic Drift. May 21-22, 2003. Health Canada, Ottawa, Canada.

Necropsy and Histology, Current Practices in Pathology, Pathology of Transgenic Mice, Diagnostic Drift. December 2-3, 2003. Health Canada, Ottawa, Canada.

Diagnostic Dilemmas. Industrial and Toxicologic Pathology Course VI. Chicago, IL, July 18-21, 2004.

Pathology of p53 heterozygous Transgenic Mice, CL Davis Foundation, Northeast Division Meeting, December 10, 2004, Nutley NJ.

Pathology of Transgenic Mice. Korean Society of Toxicology. 2004 Annual Meeting, November 4-5, 2004, Seoul, S. Korea.

Current Practices in Pathology, Peer Review. Korean Institute of Toxicology, November 8, 2004, Daejong, S. Korea.

The PTOX Seminar Series: Transgenic Models. Forest Research Institute, October 21, 2004, Jersey City, NJ.

An Introduction to Toxicologic Pathology, Adolor Corporation, March 4, 2005, Exton, PA.

Adverse vs Non-Adverse Lesions in Toxicology Studies. Korean Institute of Toxicology, June 1, 2005, Daejong, South Korea.

Overview of Neoplastic Lesions in Rodents. Korean Association for Laboratory Animal Science, 21st International Symposium, June 3, 2005, Seoul, South Korea.

Module 3: Carcinogenesis. Alternative Onco Study Models – Update, Lecture and Practical. British Society of Toxicologic Pathology, Modular Education Programme in Toxicologic Pathology, July 15, 2005, Edinburgh, Scotland.

Transgenic Mice: Creation, Pathology and Use in Toxicology Studies. CL Davis Foundation European Division; Annual Meeting, September 6, 2005, Naples, Italy.

The Rodent Bioassay in the 21st Century: Reading the Study – Problems, Pitfalls and Peer Review. CL Davis Foundation, NorthEast Division, November 11, 2005, Nutley, NJ.

INHAND and the GESC – the New Nomenclature Project. Japanese Society of Toxicologic Pathology, February 7, 2008, Nagoya, Japan



Experimental Pathology Laboratories, Inc.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

Pathology of Transgenic Mice. DIMS Institute of Medical Science, February 8, 2008, Ichinomiya, Japan

Trust Me, I'm a Pathologist. American College of Toxicology, Palm Springs, November 1, 2009, Palm Springs, CA.

PUBLICATIONS AND PRESENTATIONS:

Books:

Mann, P.C.: How to Buy a Used Car Without Getting Gyped. New York, New York, Harper and Row, 1975.

Book Chapters:

Salivary, Harderian and Lacrimal Glands, by S. Botts, M.P. Jokinen, E.T. Gaillard, M.R. Elwell, and P.C. Mann. In: Pathology of the Mouse (R.R. Maronpot, G.A. Boorman, and B.W. Gaul, eds), Vienna, IL, Cache River Press, 1999.

Thymus, Spleen and Lymph Nodes, by J.M. Ward, P.C. Mann, H. Morishima, and C.H. Frith. In: Pathology of the Mouse (R.R. Maronpot, G.A. Boorman, and B.W. Gaul, eds), Vienna, IL, Cache River Press, 1999.

Managing Pitfalls in Toxicologic Pathology, by P.C. Mann, J.F. Hardisty, and M.D. Parker. In: Handbook of Toxicologic Pathology (W.M. Haschek, C.G. Rousseaux, and M.A. Wallig, eds), San Diego, CA, Academic Press, 2002.

Principles of Pathology for Toxicology Studies by Steven R. Frame and Peter C. Mann. In: Principles and Methods of Toxicology, Fifth Edition (A. Wallace Hayes, ed), Boca Raton, FL, CRC Press, 2008

Abstracts:

Mann, P.C., Bush, M., Jones, D.M., Griner, L.A., Keuhne, G.R. and Montali, R.J.: Leiomyomas of the genital tract in large zoo mammals. *Laboratory Investigation*, 1981, 44:40A.

Mann, P.C., Montali, R.J. and Bush, M.: Respiratory distress syndrome in neonatal reindeer. *Laboratory Investigation*, 1981, 44:40A-41A.

Mann, P.C., Montali, R.J. and Bush, M.: Tuberculous osteomyelitis in captive marsupials. *Laboratory Investigation*, 1982, 46-51A.

Harrison, I., Tulleners, E., Mann, P.C. and Raker, C.W.: Assessment of partial arytenoidectomy without mucosal closure of the horse. *Vet. Surgery*, 1986, 15:122.



Experimental Pathology Laboratories, Inc.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

Mahler, J.F., Mann, P., Takaoka, M. and Maronpot, R.: Spontaneous lesions of the FVB/N mouse. *Tox. Path.*, 23(6), 1996, 744-745.

Torrey CE, Allen JS, Selinger K, Mann P, Miller RT and Rickert DE. Testing of Clofibrate in a 6-Month Gavage Study Using p53[±] Mice. *Toxicologic Pathology* 29S:205-207, 2001.

Jackson, K., Okasaki, K., Chihaya, Y., Sato, K., Koelling, M., Meyer, S., and Mann, P. Results of a validation carcinogenicity study using transgenic p53 +/- and transgenic ras H2 mice. The Japanese Society of Toxicology, 2004 Annual Meeting, July 2004.

Acute Adverse Effects of the Indenopyridine, CDB-4022 (Racemate), on the Ultrastructure of Sertoli Cells, Spermatocytes, and Spermatids in the Testes of Treated Rats: Comparison to the Known Sertoli Cell Toxicant, Di-n-Pentylphthalate (DPP), 38th Annual Meeting, Society for the Study of Reproduction, July 24-27, 2005, Quebec City, Quebec, Canada.

Scientific Papers:

Wagner, J.E. and Mann, P.C.: Botulism in California sea lions (*Zalophus californianus*), a case report. *Journal of Zoo Animal Medicine*, 1978, 9:142-145.

Kier, A.B., Mann, P.C. and Wagner, J.E.: Disseminated sporotrichosis in a cat. *JAVMA*, 1979, 175:202-204.

Taylor, J.L., Wagner, J.E., Kusewitt, D.F. and Mann, P.C.: *Klossiella* parasites of animals. A literature review. *Veterinary Parasitology*, 1979, 5:137-144.

Wagner, J.E., Burton, C.H., Morehouse, L.G. and Mann, P.C.: A computerized system for retrieval of case information in a veterinary diagnostic laboratory. *American Journal of Veterinary Research*, 1979, 40:336-442.

Mann, P.C., Bush, M., Appel, M.J.G., Beehler, B.A. and Montali, R.J.: Canine parvovirus infection in South American canids. *JAVMA*, 1980, 177:779-783.

Wightman, S.R., Mann, P.C. and Wagner, J.E.: Dihydrostreptomycin toxicity in the Mongolian gerbil. *Lab. Animal Science*, 1980, 30:71-75.

Montali, R.J. and Mann, P.C.: Selected diseases of zoo animals. C.L. Davis Foundation, Training Aid Issue, 1981, Vol. XI.

Montali, R.J., Mann, P.C. and Seidensticker, J.: Rabies in raccoons - Virginia. *Morbidity and Mortality Weekly Report*, 1981, 30:353-355.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

- Mann, P.C., Bush, M., Janssen, D.L. Frank, E.S. and Montali, R.J.: Clinopathologic correlations of tuberculosis in large zoo mammals. JAVMA, 1981, 179:1123-1129.
- Montali, R.J., Mann, P.C., Jones, D.M., Griner, L.A., Keuhne, G.R., Narushima, E. and Bush, M.: Leiomyomas in the genital tract of large zoo mammals. Proceedings XXIV International Symposium on the Disease of Zoo Animals, 1982, Vesprem, 117-122.
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- Reef, V.B., Mann, P.C. and Orsini, P.G.: Echocardiographic detection of tricuspid atresia in two foals. JAVMA, 1987, 191:225-228.
- Morris, C.F., Robertson, J.L., Mann, P.C., Clark, S. and Divers, T.J.: Hemolytic uremic-like syndrome in two horses. JAVMA, 1987, 191:1453-1454.
- Tulleners, E.P., Harrison, I.W., Mann, P.C. and Raker, C.W.: Partial arytenoidectomy in the horse with and without mucosal closure. Vet Surgery, 1988, 17:252-257.
- Orsini, PG, Raker CW, Reid CF, Mann P. Xeroradiographic evaluation of the equine larynx, Am J Vet Res. 1989, 50(6):845-9.
- Tulleners, E., Mann, P., Raker, C.W., Epiglottic augmentation in the horse. Vet. Surgery, 1990, 19:181-190.
- Bader, R., Gembardt, C., Kaufmann, W., Kuttler, K., Mann, P.C., Van Zwieten, M.J. and Zurcher, C.: Part I: The Rat, 5. Integumentary System. In: International Classification of Rodent Tumours, (U. Mohr, ed), pp 1-45. International Agency for Research on Cancer, 1993.
- Hayes, J.R., Wilson, N.H., Roblin, M.C., Mann, P.C. and Kiorpis, A.L.: 28-Day continuous dosing study in minipigs with a SALATRIM structured triacylglycerol composed of stearate, acetate, and propionate. J. Agric. Food Chem., 1994, 42:563-571.



Experimental Pathology Laboratories, Inc.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

Dodd, D.E., Stuart, B.O., Rothenberg, S.J., Kershaw, M., Mann, P.C., James, J.T. and Lam, C.: Acute, 2-Week, and 13-Week Inhalation Toxicity Studies on Dimethylethoxysilane Vapor in Fischer 344 Rats. *Inhalation Toxicology*, 6:151-166, 1994.

Malarkey, D.E., Devereux, T.R., Dinse, G.E., Mann, P.C. and Maronpot, R.R.: hepatocarcinogenicity of chlordane in B6C3F1 and B6D2F1 male mice: evidence for regression in B6C3F1 mice and carcinogenesis independent of ras proto-oncogene activation. *Carcinogenesis*, Vol. 16, No. 11, 2617-2625, 1995.

Mann, P.C., Boorman, G.A., Lollini, L.O., McMurtin, D.N. and Goodman, D.G. Proliferative lesions of the mammary gland in rats, IS-2. In: *Guides for Toxicologic Pathology*, STP/ARP/AFIP, Washington, D.C., 1996.

Mann, P.C. Pathology peer review from the perspective of an external peer review pathologist. *Toxicologic Pathology* ISSN: 0192-6233, Vol. 24, No. 5, 650-653, 1996.

Mahler, J.F., Stokes, W., Mann, P.C., Takaoka, M. and Maronpot, R. Spontaneous lesions in aging FVB/N mice. *Toxicologic Pathology* ISSN: 0192-6233, Vol. 24, No. 6, 710-716, 1996.

Mann, P.C., Selected lesions of dioxin in laboratory rodents. *Toxicologic Pathology* ISSN: 0192-6233, Vol. 25, No. 1, 72-79, 1997.

Gray, L.E., Wolf, C., Mann, P., Ostby, J.S., In utero exposure to low doses of 2,3,7,8-tetrachlorodibenzo-p-dioxin alters reproductive development of female Long Evans hooded rat offspring. *Toxicology and Applied Pharmacology*, Vol 146, No. 2, 237-44, 1997.

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Burns-Naas, L.A., Mast, R.W., Klykken, P.C., McCay, J.A., White, K.L., Mann, P.C. and Naas, D.J., Toxicology and humoral immunity assessment of decamethylcyclo-pentasiloxane (D₅) following a 1-month whole body inhalation exposure in Fischer 344 rats. *Toxicological Sciences*, 43:28-38, 1998.

Burns-Naas, L.A., Mast, R.W., Meeks, R.G., Mann, P.C. and Thevenaz, P., Inhalation toxicology of decamethylcyclo-pentasiloxane (D₅) following a 3-month nose-only exposure in Fischer 344 rats. *Toxicological Sciences*, 43:230-240, 1998.



Experimental Pathology Laboratories, Inc.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

Mahler, JF, Flagler, ND, Malarkey, DE, Mann, PC, Haseman, JK and Eastin, W., Spontaneous and chemically induced proliferative lesions in Tg.AC Transgenic and *p53*-heterozygous mice. *Toxicologic Pathology*, Vol. 26, No. 4, 501-511, 1998.

Boorman, G.A., Anderson, L.E., Morris, J.E., Sasser, L.B., Mann, P.C., Grumbein, S.L., Hailey, J.R., McNally, A., Sills, R.C. and Haseman, J.K., Effect of 26 week magnetic field exposures in a DMBA initiation-promotion mammary gland model in Sprague-Dawley rats. *Carcinogenesis*, Vol. 20, No. 5, 899-904, 1999.

Anderson, L.E., Boorman, G.A., Morris, J.E., Sasser, L.B., Mann, P.C., Grumbein, S.L., Hailey, J.R., McNally, A., Sills, R.C., and Haseman, J.K., Effect of 13-week magnetic field exposures on DMBA initiated mammary gland carcinomas in female Sprague-Dawley rats. *Carcinogenesis*, Vol. 20, No. 8, 1615-20, 1999.

Richardson, F.C., Tennant, B.C., Meyer, D.J., Richardson, K.A., Mann, P.C., McGinty, G.R., Wolf, J.L., Zack, P.M. and Bendele, R.A., An Evaluation of the Toxicities of 2'-Fluorouridine and 2'-Fluorocytidine-HCl in F344 Rats and Woodchucks (*Marmota monax*). *Toxicologic Pathology*, Vol. 27, No. 6, 607-617, 1999.

Ostby, J., Kelce, W.R., Lambright, C., Wolf, C.J., Mann, P., Gray, L.E., Jr., The fungicide procymidone alters sexual differentiation in the male rat by acting as an androgen-specific antagonist *in vivo* and *in vitro*. *Toxicology and Industrial Health*, Vol. 15, Nos. 1-2, 80-93. 1999.

Gary, L.E., Wolf, C., Lambright, C., Mann, P., Price, M., Cooper, R.L., Ostby, J., Administration of potentially antiandrogenic pesticides (procymidone, linuron, iprodione, chlozolinate, p,p'-DDE, and ketoconazole) and toxic substances (dibutyl- and diethylhexyl phthalate, PCB169, and ethane dimethane sulphonate) during sexual differentiation produces diverse profiles of reproductive malformations in the male rat. *Toxicology and Industrial Health*, Vol. 15, Nos. 1-2, 94-118, 1999.

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PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

Floyd, E., Mann, P., Long, G., Ochoa, R., The Trp53 hemizygous mouse in pharmaceutical development: Points to consider for pathologists. *Toxicologic Pathology*, Vol. 30, No. 1, 147-156, 2002.

Lau, C., Narotsky, M.G., Lui, D., Best, D., Setzer, R.W., Mann, P.C., Wubah, J.A., Exposure-disease continuum for 2-chloro-2'-deoxyadenosine (2-CdA), a prototype teratogen: Induction of lumbar hernia in the rat and species comparison for the teratogenic responses. *Teratology*, Vol. 66, No. 1, 6-18, 2002.

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Wolf DC and Mann PC. Confounders in Interpreting Pathology for Safety and Risk Assessment. *Toxicology and Applied Pharmacology*, 202:302-308, 2005.

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Lewis JM, Maslanka JC, Malley LA, Everds NE, Mann PC, Kennedy GL Jr. Oral Toxicity Study of 2-pentenenitrile in rats with reproductive toxicity screening test. *Drug Chem Toxicol* 29(4):345-361, 2006.

Hild SA, Reel JR, Dykstra MJ, Mann PC, Marshalls GR. Acute Adverse Effects of the Indenopyridine CDB-4022 on the Ultrastructure of Sertoli Cells, Spermatocytes, and Spermatids in Rat Testes: Comparison to the Known Sertoli Cell Toxicant Di-n-pentylphthalate (DPP). *J of Androl*, 28:621-629, 2007.

Malley LA, Everds NE, Reynolds J, Mann PC, Lamb I, Rood T, Schmidt J, Layton RJ, Prochaska LM, Hinds M, Locke M, Chui CF, Claussen F, Mattsson JL, Delaney B. Subchronic feeding study of DAS-59122-7 maize grain in Sprague-Dawley rats. *Food Chem Toxicol*. Jul;45(7):1277-92, 2007. Epub 2007 Jan 25.

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Experimental Pathology Laboratories, Inc.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

Hoberman AM, Schreur DK, Leazer T, Daston GP, Carthew P, Re T, Loretz L, Mann P. Lack of effect of butylparaben and methylparaben on the reproductive system in male rats. Birth Defects Res B Dev Reprod Toxicol. 83(2):122-133, 2008.

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[Redacted]

PETER C. MANN, D.V.M.
Diplomate, A.C.V.P.

APRIL 23, 2010
Date

JAMES B. NOLD
Biotechnics

Formal Education:

1985	Colorado State University Fort Collins, CO PhD Pathology
1980	The Armed Forces Institute of Pathology Washington, DC Pathology Residency Diploma
1973	Ohio State University Columbus, OH DVM

Board Certifications and Licensure:

Diplomate, American College of Veterinary Pathologists, 1980

Professional Experience:

WIL Research Laboratories, LLC/Biotechnics
Hillsborough, NC

02/09/09 - Present Position: Senior Pathologist
 Pathology

Performs microscopic examination of material obtained from various in-house studies utilizing different species. These will include acute, subacute and chronic studies. Records the microscopic findings in the on-line computer system utilizing the pathology master list of terms or microscopic lesions established for the given species or organ. Correlates the clinical pathology data with the microscopic observations. Writes the pathology summary, which includes organ weight, gross, microscopic and clinical pathology interpretations on various studies. Provides consultation to the necropsy group during the examination of individual animals sacrificed or which died on study. Provides direction and professional consultation for the department during the absence of the Director. Scientific and technical adviser for necropsy and histology labs. Maintains professional level of expertise by attending scientific meetings,

Professional Experience (Continued):

reading appropriate professional journals, and participating in professional organizations. Special interests in neuropathology include brain morphometry in developmental toxicity studies. Assists with the clinical care of study animals.

GlaxoSmithKline
Research Triangle Park, NC

2003 - 2009

Position: Director of Morphologic Pathology
Safety Assessment, Pathology

Directed the histology and necropsy service function and supervised the Manager of Necropsy and Laboratory Services. Managed the contracted histopathology workload and assisted in scheduling and assignment of studies. Provided pathology support to both research and development functions, including consultation and collaboration on target and chemical class liability, animal model selection, and investigative and regulatory study design, as well as gross, microscopic and molecular pathologic evaluation and data interpretation of target localization and biological profiling, investigational, and regulatory studies.

2001 - 2003

Position: Director of Regulatory & Discovery Pathology
Safety Assessment, Pathology

Provided pathology support to both research and development functions, including consultation and collaboration on target and chemical class liability, animal model selection, and investigative and regulatory study design, as well as gross, microscopic and molecular pathologic evaluation and data interpretation of target localization and biological profiling, investigational, and regulatory studies.

Pathology Associates
A Charles River Company
Durham, NC

1997 - 2001

Position: Division Director

Was responsible for the overall operation of the North Carolina Division for Pathology Associates – A Charles River Company. Served as the senior administrator of the group and directly

Professional Experience (Continued):

supervises five doctorate level scientists and the Division Director. Served as a study pathologist and as a business development representative for the organization. Specialized in general toxicologic pathology and electron microscopy. The North Carolina Division currently has a staff of 20 personnel.

Covance Laboratories, Inc.

Pathology Department

Madison, WI

1993 – 1996

Position: Director of Pathology

Responsible for all administrative functions of the department and for the scientific direction of the Anatomical Pathology Section (which includes necropsy and histology) and the Clinical Pathology Section (which includes hematology and clinical chemistry). Directly supervised five anatomical pathologists, one clinical pathologist, the section supervisors of the Anatomic Pathology Section, and an administrative assistant. Also served as a study pathologist. Special interests in morphometry, immunopathology, and general toxicologic pathology.

Corning Hazleton, Inc.

Pathology Department

Madison, WI

1990 - 1993

Position: Pathologist

Study pathologist for acute, subchronic, chronic, and reproductive toxicology, and oncogenicity studies using rats, mice, dogs, rabbits, nonhuman primates, and domestic livestock as the experimental animals. Supervised the macroscopic examination of the test animals, evaluated the prepared tissues, and wrote the pathology portion of the study reports.

Specialized in morphometry and immunohistochemistry techniques. Radiation pathology, immunopathology, and acute toxicologic pathology were particular areas of interest.

Articles:

Quaile, M.P.; Melich, D.H.; Jordan, H.L.; Nold, J.B.; Chism, J.P.; Polli, J.W.; Smith, G.A.; Rhodes, M.C. Toxicity and toxicokinetics of metformin in rats. *Toxicology and Applied Pharmacology* **2010**, 243, 340-347.

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Herrera, J.; Gage, T.; Vigneulle, R.M.; Nold, J.B.; Dubois, A. Effects of radiation and radioprotection on small intestinal functions in canines. *Dig Dis Sci* **1995**, 40(1), 211-218.

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Keeler, J.R.; Hurt, H.H.; Nold, J.B.; Corcoran, K.D.; Tezak-Reid, I.M. Phosgene-induced lung injury in the sheep. *Inhalation Toxicology* **1990**, *2*, 391-406.

Articles (Continued):

Keeler, J.R.; Hurt, H.H.; Nold, J.B.; Lennox, W.J. Estimation of the LC₅₀ of phosgene in sheep. *Drug and Chemical Toxicology* **1990**, *13(2 and 3)*, 229-239.

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intestinal blood flow. *International Journal of Radiation Biology* **1984**, 45, 65-72.

Nold, J.B.; Powers, B.E.; Eden, E.L., McChesney, A.E. Ameloblastic odontoma in a dog. *Journal of the American Veterinary Medical Association* **1984**, 185, 996-997.

Articles (Continued):

Hamilton, H.B.; Severin, G.A.; Nold, J.B. Pulmonary squamous cell carcinoma with intraocular metastasis in a cat. *Journal of the American Medical Association* **1984**, 185, 307-309.

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Books:

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Abstracts (Continued):

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Assaad, A.; Trotz, M.; Moore, D.; Nold, J.B.; Corcoran, K.; Dewey, H.; Phillips, K.; Said, S. Biochemical markers of acute lung injury in the bronchoalveolar lavage of sheep exposed to a toxic dose of perfluoroisobutylene. *International Journal of Toxicology* 1990, Abstract #P15.

Assaad, A.; Moore, D.; Nold, J.B.; Tucker, S.; Corcoran, K.; Dewey, H.; Phillips, K. Hematology and serum chemistry of sheep exposed to lethal doses of phosgene. *International Journal of Toxicology* 1990, Abstract #P20.

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DeBell, R.M.; Ledney, G.D.; Nold, J.B.; Snyder, S. Diamine oxidase: a marker for intestinal mucosal integrity after trauma. *Journal of Leukocyte Biology* 1986, 40, 238.

Miller, G.K.; Nold, J.B.; Benjamin, S.A. Prenatal and neonatal radiation injury and immunologic development. *Laboratory Investigation* 1986, 54, 43A.

James B. Nold

Date



Experimental Pathology Laboratories, Inc.

**ROBERT R. MARONPOT
SENIOR PATHOLOGIST**

EDUCATION:

Michigan State University, B.S., 1963
Michigan State University, D.V.M., 1965
Michigan State University, M.S., 1966
Harvard University, M.P.H., 1972

PRESENT POSITION AND BACKGROUND:

2008 – Present	Senior Pathologist, Experimental Pathology Laboratories, Inc. Research Triangle Park, NC
2007 – Present	Maronpot Consulting, LLC, 1612 Medfield Road Raleigh, NC
1992 - 2006	Chief, Laboratory of Experimental Pathology, Environmental Toxicology Program, National Institute of Environmental Health Sciences, Research Triangle Park, NC
1991 - 1992	Chief, Experimental Toxicology Branch, National Toxicology Program National Institute of Environmental Health Sciences, Research Triangle Park, NC
1990 - 1991	Head, Cancer Genetics & Molecular Pathology, Experimental Carcinogenesis & Mutagenesis Branch, National Institute of Environmental Health Sciences, Research Triangle Park, NC
1989 - 1993	Board of Directors, American Board of Toxicology, Washington, D.C. University of North Carolina, Chapel Hill, N.C.
1981 - 1990	Head, Experimental Pathology, Chemical Pathology Branch, National Toxicology Program, National Institute of Environmental Health Sciences, Research Triangle Park, NC
1978 - 1981	Senior Fellow, Bushy Run Research Center, Carnegie-Mellon University 4400 Fifth Avenue, Pittsburgh, Pennsylvania
1975 - 1978	Head, Pathology Department, Chemical Hygiene Fellowship, Carnegie-Mellon Institute of Research, 4400 Fifth Avenue, Pittsburgh, Pennsylvania
1974 - 1975	Head, Research Animal Facility
1974 - 1975	Acting Head, Experimental Pathology Division, Naylor Dana Institute for Disease Prevention, American Health Foundation, Valhalla, New York



Experimental Pathology Laboratories, Inc.

ROBERT R. MARONPOT, DVM, MS, MPH

PRESENT POSITION AND BACKGROUND: – Continued

1974 - 1975	Clinical Assistant Professor of Pathology, New York Medical College, Valhalla, New York
1975	Consultant in Veterinary Pathology, Memorial Sloan-Kettering Cancer Research Center, New York, New York
1972 - 1974	Research Fellow in Comparative Pathology, Pathology Department, Harvard Medical School and Angell Memorial Animal Hospital Boston, Massachusetts
1971 - 1972	Research Fellow in Public Health, Microbiology Department, Harvard School of Public Health, Boston Massachusetts Valhalla, New York
1968 - 1971	Head, Veterinary Medicine Department, U.S. Naval Medical Research Unit #3 Cairo, Egypt
1966 - 1968	Veterinary Laboratory Officer, Veterinary Corps, U.S. Army Pathology Division, U.S. Army Medical Research and Nutrition Laboratory, Denver, Colorado
1965 - 1966	NIH Postdoctoral Fellow, Pathology Department, Michigan State University, East Lansing, Michigan

PROFESSIONAL MEMBERSHIPS:

American College of Veterinary Pathologists

Society of Toxicologic Pathologists

Society of Toxicology

SPECIALTY BOARDS & HONORS:

Diplomate, American College of Veterinary Pathologists, 1973

Diplomate, American Board of Toxicology, 1980

Distinguished Postdoctoral Veterinary Alumnus Award from

Michigan State University College of Veterinary Medicine - 2000

President, Society of Toxicologic Pathology - 2001-2002

Editor-in-Chief, Toxicologic Pathology – 2001-2004



Experimental Pathology Laboratories, Inc.

ROBERT R. MARONPOT, DVM, MS, MPH

SELECTED NATIONAL & INTERNATIONAL INVITED PRESENTATIONS SINCE 2007:

2007 Lectures

- Society of Toxicology Annual Meeting
Charlotte, NC – March 2007
Lectured at a Continuing Education Course
Rodent Imaging Overview for the Toxicologist
“Magnetic Resonance Imaging”
- 7th Biennial Industrial Toxicology & Pathology Short Course
University of Illinois – July 2007
“Carcinogenicity Assessment”
and
“Application of Multimodality Imaging in Toxicologic Pathology”
- American Association for Laboratory Animal Science Annual Meeting
Charlotte, NC – October 2007
The Wallace P. Rowe Lecture
“The Cancer Bioassay: Challenges for the Future”
and
Seminar on Current Imaging Modalities for Rodent Xenograft Models
“MRI Imaging Systems”
- National Academy of Science Workshop on Mouse Liver Tumors
Washington, DC – November 2007
“Mouse Models for Carcinogenicity”
- American College of Veterinary Pathologists
Savannah, Georgia – November 2007
Lectured at a Continuing Education Course
Rodent Imaging Overview for the Pathologist
“Magnetic Resonance Imaging”

2008 Lectures

- ILSI Annual Meeting
Rio Grande, Puerto Rico – January 2008
Organized symposium on “Applications of Small Animal Imaging in Toxicology Research and Testing”
Lectured on “Application of Magnetic Resonance Imaging in Toxicology and Toxicologic Pathology”
- NIEHS
February 2008
Lecture on “Comparative Medicine Branch Pathology/Case Presentations”
- Aperio Research Triangle Park Digital Pathology Seminar
May 13, 2008
Lecture on “Digital Pathology for Peer Review and Phenotyping”



Experimental Pathology Laboratories, Inc.

ROBERT R. MARONPOT, DVM, MS, MPH

SELECTED NATIONAL & INTERNATIONAL INVITED PRESENTATIONS SINCE 2007: Continued

- NTP Satellite Symposium, STP Annual meeting
Conundrums in Toxicologic Pathology
June 21, 2008, San Francisco
- 2nd East Mediterranean ICLAS Regional Meeting
“Overview of Imaging Modalities and Control of Small Animal Physiology During Live Imaging” and “Application of MRI in Toxicology and Toxicologic Pathology”
Jerusalem, Israel, December 3-4, 2008.
- TEVA Pharmaceutical Company, Israel
“The Cancer Bioassay: Past, Present, Future”
December 8, 2008

EDITORIAL REVIEW BOARD:

- Editor – Toxicologic Pathology (2001- 2004)
Editorial Board – Toxicologic Pathology (1986-2001)
Section Editor, Laboratory Animal Pathology (1996-2001)
Editorial Board – Drug and Chemical Toxicology (1986-1992)
Editorial Board – Fundamental and Applied Toxicology (1985-1991)
Editorial Review Board – Environmental Health Perspectives (1985-1992) (1994-1997)
Editorial Board – Toxicology (1988-1998)
Senior Advisor – Toxicologic Pathology (2005-present)
Editorial Board – Experimental & Toxicologic Pathology (2001-present)

EDITORIAL ACTIVITIES:

- Ad hoc Reviewer
Comparative Medicine
Carcinogenesis
Molecular Carcinogenesis
Cancer
International Journal of Cancer
Toxicological Sciences
Cancer Research
American Journal of Pathology
Proceedings of the National Academy of Sciences (USA)
American Journal of Respiratory Cell & Molecular Biology
Food and Chemical Toxicology

ROBERT R. MARONPOT, DVM, MS, MPH**PUBLICATIONS AND PAPERS:**

Maronpot RR and Whitehair CK, 1967. Experimental Sprue-like Small Intestinal Lesions in Pigs. Can. J. Comp. Med. 31:309-316.

Maronpot RR, Stedman MA, and Bucci TJ, 1968. Focal Degenerative Myopathy in Turkeys. Avian Dis. 12:96-103.

Stedham MA, Bucci TJ, and Maronpot RR, 1968. Sexual and Asexual Phases of Aspergillus Nidulans in an Egret. Myopath. et Mycologia Appli. 36:289-292.

Maronpot RR and Michael SA, 1968. Toxoplasmosis in Sheep. A Review. J. Egypt. Vet. Med. Assoc. 28:155-163.

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Michael SA, Maronpot RR, and Botros BAM, 1970. Blood Parasites in Egyptian Animals. Proc. 9th Arab Vet. Congress, Cairo, Egypt. pp. 236-254.

Waslien CI, Maronpot RR, and Kozman AR, 1970. Nutritional Studies in the Sand Rat (*Psammomys obesus*). Pahlavi Medical J. 1:228-233.

Maronpot RR, Barsoum IS, and Ezzat E, 1971. Canine Leptospirosis in Cairo. United Arab Republic. The J. of Infectious Diseases. 123:548-550.

Wilson BJ and Maronpot RR, 1971. Causative Fungus Agent of Leukoencephalomalacia in Equine Animals. Vet. Rec. 88:484-486.

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ROBERT R. MARONPOT, DVM, MS, MPH**PUBLICATIONS AND PAPERS: – Continued**

Wilson BJ, Maronpot RR, and Hildebrandt PK, 1973. Equine Leukoencephalomalacia. *J. Amer. Vet. Med. Assoc.* 163:1293-1295.

Maronpot RR, Michael SA, and Botros BAM, 1974. Blood Parasites in Egyptian Domestic Animals. *J. Egypt. Vet. Med. Assoc.* 34:301-308.

Botros BAM and Maronpot RR, 1974. Complement-fixing and Indirect Fluorescent Antibodies in Sera of Dogs Experimentally Infected with Babesia gibsoni. *J. Egypt. Vet. Med. Assoc.* 34:309-321.

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Hecht SS, Thorne RL, Maronpot RR, and Hoffman D, 1975. A Study of Tobacco Carcinogenesis. XIII. Tumor Promoting Subfractions of the Weakly Acidic Fraction. *JNCI* 55:1329-1336.

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Narisawa T, Wong CQ, Maronpot RR, and Weisburger JH, 1976. Large Bowel Carcinogenesis in Mice and Rats by Several Intrarectal doses of Methylnitrosourea and Negative Effect of Nitrite plus Methylurea. *Cancer Res.* 36:505-510.

Maronpot RR and Chavannes JM, 1977. Dacryoadenitis, Conjunctivitis, and Facial Dermatitis of the Mouse. *Lab. Anim. Sci.* 27:277.

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Burton DS, Maronpot RR, and Howard FL, 1979. Frequency of Hydronephrosis in Wistar Rats. *Lab. Anim. Sci.* 29:642-644.

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ROBERT R. MARONPOT, DVM, MS, MPH**PUBLICATIONS AND PAPERS: – Continued**

Maronpot RR, Witschi HP, Smith LH, and McCoy JL, 1983. Recent Experience with the Strain A Mouse Pulmonary Tumor Bioassay Model. In Short-Term Bioassays in the Analysis of Complex Environmental Mixtures III. Environ. Sci. Res. 27:341-350.

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Yang RSH, Garman RH, Maronpot RR, McKelvey JA, Weil CS, and Woodside MD, 1983. Acute and Subchronic Toxicity of Ethylenediamine in Laboratory Animals. Fund. & Appl. Tox. 3:512-520.

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