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November 1, 1983 2 ps. (ltr + encl)

James T. Stevens, PhD
Manager of Toxicology
CIBA-GEIGY Corporation
Agricultural Division
P. O. Box 18300
Greensboro NC 27419

Dear Jim:

Enclosed is a memo from Dr. Terry Jackson to me concerning the liver histopathology for Study No. 80030, "Two-Year Toxicity and Oncogenicity Study With Metolachlor Technical in Albino Rats." In it he discusses the foci of cellular change and primary neoplasms in the draft expedited liver pathology data and his subsequent review and reclassification of the lesions in some of the animals prior to issuance of the final report.

I trust this explanatory memo will help link the draft data to that presented in the final report.

Sincerely,

Merrill Tisdel
Study Director, Toxicology

MT/tt

Enclosure

cc: T. Jackson
Toxicology

(3820B)

TO: Merrill Tisdel

FROM: T. Jackson

RE: Draft vs. final data for liver, Study No. 80030

DATE: 10/31/83

Sections of liver from all animals in this study were examined during October, 1982 following a special request by CIBA-GEIGY. Draft data, subject to a more timely and thorough examination of the liver sections, were prepared and submitted. This data indicated that a greater number of foci of cellular change and primary liver neoplasms were present in the treated groups, especially the high dose level, than in control groups.

Subsequently, liver sections were reviewed during the examination of all other protocol tissues and it became apparent that some of the "original diagnoses" would have to be changed. Primarily this was because the presence or absence of "compression of surrounding parenchyma" by foci of cells had not been given uniform consideration during the original examination. Where appropriate diagnoses were changed and subsequent data were submitted in the final report. The primary difference in the two sets of data was that some of the lesions originally classified as proliferative foci (neoplastic nodules) were ultimately classified as foci of cellular change due to lack of compression of surrounding parenchyma.

Terry A. Jackson, DVM, PhD
Diplomate, American College of
Veterinary Pathologists

Date