HUGH E. BLACK & ASSOCIATES, INC.

3 3 7 9 TO JUL 26 P2:05

July 24, 2001

Dockets Management Branch (HFA-305) Food and Drug Administration 12420 Parklawn Drive, Room 1-23 Rockville, Maryland 20857

Dear Sir or Madam:

I wish to support the comments provided by the Society of Toxicologic Pathology on the draft Guidance for Industry, Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals. This response was developed after considerable individual consideration of the Guidance followed by a group debate and comment on the Guidance at the Society's annual meeting held in Orland, Florida in June 2001.

Thank you for the opportunity to comment on the Guidance.

Yours truly,

Hugh E. Black, D.V.M., Ph.D.

heef & Black

Diplomate, American College of Veterinary Pathologists

Diplomate, American Board of Toxicology

Fellow, Academy of Toxicological Sciences

Fellow, International Academy of Toxicologic Pathology Secretary General, International Federation of the Societies

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HEB/jmh

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