



Pharmaceuticals

September 1, 2000

Mr. Jaime Henriquez
Advisors and Consultant staff
Center for Drug Evaluation and Research
Food and Drug Administration
5630 Fishers Lane
Rockville, Maryland 20857

Ladies and Gentlemen:

Re: NDA 18-662 - Accutane® (isotretinoin) Capsules
General Correspondence: Advisory Committee Meeting Briefing Document

Reference is made to the subject NDA and to the upcoming meeting of the Dermatologic and Ophthalmic Advisory Committee on September 18 and 19, 2000, at which the NDA for Accutane will be discussed.

As requested, enclosed please find 50 copies of the two-volume briefing package for Accutane. The first volume contains the briefing package prepared by Hoffmann-La Roche Inc. The second contains a report prepared by Dr. Allen Mitchell of the Slone Epidemiology Unit, who is the principal investigator in the Survey of Accutane Use in Women.

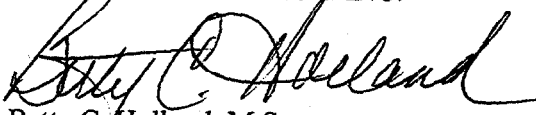
Also provided are two diskettes. Each contains Microsoft Word files of the various portions of the documents that were available electronically.

Also enclosed are two CDs; each contain two Acrobat files (pdf file), one for each complete volume.

Please do not hesitate to contact me if you have any questions regarding this package.

Sincerely,

HOFFMANN-LA ROCHE INC.


Betty C. Holland, M.S.
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BCH/gb
Enclosures

HLR No. 2000-2175

cc: Dr. Janet Woodcock, HFD-001
Dr. Diane Murphy, HFD-002