



Pharmaceuticals

August 17, 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 21-177 - Accutane NF™ (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 NF Capsules will be discussed.

As requested, enclosed please find 50 copies of the briefing packaged for Accutane NF. As previously discussed, the information for NDA 18-662 for Accutane (isotretinoin) Capsules will be provided in a separate document.

Also provided are two diskettes, each contains a Microsoft Word file of the document (minus the two attachments) and an Acrobat file (pdf file) of the entire document (with the two attachments).

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.  
Program Director  
Drug Regulatory Affairs  
(973) 562-5549 (phone)

BCH/gb  
Enclosures  
HLR No. 2000-2018

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