

NDA 18-662/S-039  
Hoffmann-La Roche Inc.  
Attention: Betty Holland, M.S.  
Program Director  
340 Kingsland Street  
Nutley, New Jersey 07110-1199

**MAY 1 2000**

Dear Ms. Holland:

Please refer to your supplemental new drug application dated September 22, 1999, received September 24, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Accutane (isotretinoin) Capsules, 10 mg, 20 mg, and 40 mg.

We acknowledge receipt of your submissions dated January 14, 17, 26 and 27, February 11, 18 and 24, and April 6 and 18, 2000.

This supplemental new drug application provides for revisions to the Warnings, Precautions and Adverse Events sections of the package insert.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-662/S-039." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MED WATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

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We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Kevin Darryl White, Project Manager, at (301) 827-2020.

Sincerely,

Jonathan K. Wilkin, M.D.  
Director  
Division of Dermatologic and Dental Drug Products  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research