

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

18-662 / S-038

Trade Name: Accutane

Generic Name: (isotretinoin)

Sponsor: Hoffman La Roche Inc.

Approval Date: May 1, 2000

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APPLICATION NUMBER:

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APPROVAL LETTER

162.1

NDA 18-662/S-038

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 applications dated September 10, 1999, received September 13, 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 December 22, 1999; and January 17 and 26, February 18 and 24, and April 6 and 18, 2000.

This supplemental new drug application provides for revisions to the labeling regarding the use of contraceptive methods.

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-038." 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:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

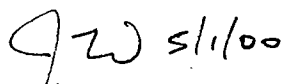
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We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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

Sincerely,

Handwritten signature of Jonathan K. Wilkin, M.D. in black ink, appearing as 'JW 5/1/00'.

Jonathan K. Wilkin, M.D.

Director

Division of Dermatologic and Dental Drug Products

Office of Drug Evaluation V

Center for Drug Evaluation and Research

Enclosure

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