DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-662/S051

Hoffman-La Roche Inc.
Attention: Joanna Waugh, BSc., Hons.
Group Director, Drug Regulatory Affairs
340 Kingsland Street
Nutley, New Jersey 07110

Dear Ms. Waugh:

Please refer to your supplemental new drug application dated May 23, 2002, received May 24, 2002, 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 submission dated June 11, 2002.

Supplemental new drug application S051 provides for the addition of a Pregnancy Testing Table to the Boxed Warning section, and additional wording listing aggressive and/or violent behaviors in the WARNINGS, and ADVERSE REACTIONS sections, Informed Consent, and Medication Guide of the label, and the blister pak container.

We have completed the review of this supplemental application, 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.

We also note your agreement to revising with the next printing, the Prescriber's Brochure, "Recognizing Psychiatric Disorders In Adolescent and Young Adults" with the additional wording of aggressive and/or violent behavior, as well as to issue a "Dear Health Care Professional Letter" which conveys all of the most recent labeling approval information (S043 and S051).

The final printed labeling (FPL) must be identical to the enclosed labeling text. Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Provide Regulatory Submissions in Electronic Format – NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. 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/S051". Approval of this submission by the FDA is not required before the labeling is used.

When the "Dear Health Care Professional Letter" communicating the important information about this drug product 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

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 Kalyani Bhatt, Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Jonathan Wilkin
6/20/02 03:41:51 PM
minor formatting changes needed by sponsor in consent document