DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-662/S041
NDA 18-662/S045

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 S041 dated August 28, 2000, received August 30, 2000, and supplemental new drug application S045 dated November 5, 2001, received November 6, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Accutane (isotretinoin) Capsules, 10 mg, 20 mg, and 40 mg.

Supplemental new drug application S041 provides for a revision to the package insert to add a "**Geriatrics Use"** subsection to the **PRECAUTIONS** Section in accordance with 21 CFR 201.57(f)(10).

Supplemental new drug application S045 provides for revisions to the **CLINICAL PHARMACOLOGY** Section, Lipids subsection to the **WARNINGS** Section, **PRECAUTIONS** Section, **OVERDOSAGE** Section, and the **DOSAGE AND ADMINISTRATION** Section. In addition, the **ADVERSE REACTIONS** Section was revised, to include revising the Medication Guide with this information, in this supplement review.

We have completed the review of these supplemental applications, 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, these supplemental applications are approved effective on the date of this letter.

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/S041 and S045". Approval of this submission by the 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 Professional" 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

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/

Hon-Sum Ko
12/31/01 01:00:14 PM
for Jonathan K. Wilkin, M.D.