DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018662/S-060 **SUPPLEMENT APPROVAL**

Hoffmann-La Roche Inc.
Attention: MaryAnn Major
Senior Program Manager
Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110

Dear Ms. Major:

Please refer to your supplemental new drug application dated August 29, 2008, received September 2, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Accutane® (isotretinoin) Capsules, 10, 20, and 40 mg.

We acknowledge receipt of your submissions dated June 25, August 25, and December 17, 2009 and January 21, 2010.

This Prior Approval supplemental new drug application provides for revisions to question 12 of the *Patient Information/Informed Consent About Birth Defects.* It also provides for changes to the to the "WARNINGS" section to include new information regarding serious skin reactions.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

Within 14 days from the date of this letter, please amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format that includes the changes approved in this supplemental application.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch

Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Dawn Williams, Regulatory Project Manager, at (301) 796-5376.

Sincerely,

{See appended electronic signature page}

Susan J. Walker, M.D., F.A.A.D.
Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure
Content of Labeling
Patient Information/Informed Consent
Medication Guide

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-18662	SUPPL-60	HOFFMANN LA ROCHE INC	ACCUTANE

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

/s/

SUSAN J WALKER
02/01/2010