DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-662/S-059

Hoffman La-Roche, Inc.
Attention: Maryann Major
Senior Program Manager, Drug Regulatory Affairs
340 Kingland Street
Nutley, NJ 07110

Dear Ms. Major:

Please refer to your supplemental new drug application dated June 24, 2008, received June 27, 2008, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Accutane® (isotretinoin) Capsules.

This supplemental new drug application provides for a revision to the Medication Guide to add the toll-free number for reporting adverse events to FDA per the Food and Drug Administration Amendments Act of 2007.

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

If you have any questions, call Catherine Carr, Regulatory Project Manager, at (301) 796-2311.

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

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

/s/

Susan Walker
11/19/2008 01:50:54 PM