DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-511/S-016
NDA 21-511/S-017

Hoffmann-La Roche, Inc.
Attention: Christina Kish
Associate Director, Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Kish:

Please refer to your supplemental new drug applications dated February 11, 2008 and July 29, 2008, received February 12, 2008 and July 30, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act, for COPEGUS® (ribavirin) 200 mg tablets in combination with PEGASYS® (peginterferon alfa-2a).

We also acknowledge receipt of your submissions dated January 14, 2009, February 19, 2009, March 10, 2009 and April 9, 2009.

NDA 21-511/S-016
This supplement provides for revisions to the labeling for COPEGUS® (ribavirin) to include the addition of serous retinal detachment in the U.S. Package Insert, ***ADVERSE REACTIONS:Postmarketing Experience,*** section.

NDA 21-511/S-017
This supplement provides for revisions to the Medication Guide for COPEGUS® (ribavirin), to revise the reporting of side effects information to include FDA's telephone number, **1-800-FDA-1088,** and a separate statement that provides an additional reporting telephone number for Hoffmann-Roche.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, and Medication Guide).

Within 14 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. **For administrative purposes, please designate these submissions "SPL for approved supplements NDA 21-511/S-016 and 21-511/S-017."**

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to

this division, the Division of Antiviral Products, and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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

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

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 Paras M. Patel, Regulatory Project Manager, at (301) 796-3391.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Package Insert and Medication Guide

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

/s/

Kendall Marcus

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