DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-511/S-014

Hoffmann-La Roche, Inc.
Attention: Alan Mart
Group Director, Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110

Dear Mr. Mart:

Please refer to your supplemental new drug application dated December 15, 2006, received, December 19, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for COPEGUS®, (ribavirin) 200 mg tablets.

We acknowledge receipt of your submission dated June 12, 2007.

This supplemental new drug application provides for revisions to the WARNINGS – Hypersensitivity, ADVERSE REACTIONS - Postmarketing Experience, and OVERDOSAGE sections of the package insert and revisions to the Medication Guide's section entitled, "What are the possible side effects of COPEGUS?".

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 agreed-upon labeling text.

Within 21 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.

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

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-511/S-014**." Approval of this submission by FDA is not required before the labeling is used.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Karen Winestock, Regulatory Project Manager, at (301) 796-0834.

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

Enclosures

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

/s/

Jeffrey Murray

6/19/2007 02:05:30 PM