



NDA 21-511/S-015

CBE-30/CBE-0 SUPPLEMENT

Hoffmann-La Roche, Inc.
Attention: Ms. Christina Kish
Sr. Program Manager
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Kish

Please refer to your supplemental new drug application dated October 12, 2007, received, October 15, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for COPEGUS[®], (ribavirin) 200 mg tablets.

Reference is also made to your amendment dated November 26, 2007, received, November 27, 2007 in response to a letter from the FDA dated November 19, 2007 requesting a full explanation for the basis of the addition of dehydration and the data upon which the change was based.

This "Changes Being Effectuated" supplemental new drug application provides for a revision to the ADVERSE REACTIONS - Postmarketing Experience section to include dehydration.

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.

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

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).

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If you have any questions, call Kwadwo (Kojo) Awuah, Regulatory Project Manager, at (301) 796-0608.

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:

Package Insert

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/

Jeffrey Murray
4/17/2008 04:12:55 PM