DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21511/S-24

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Hoffmann- La-Roche, Inc.
Attention: Steven Toma, Pharm.D.
Associate Director, Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110

Dear Dr. Toma:

Please refer to your Supplemental New Drug Application (sNDA) dated April 1, 2011, received April 1, 2011, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for COPEGUS® (ribavirin) Tablets.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated April 1, 2011.

This supplemental application provides for proposed elimination of the approved REMS.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for COPEGUS® (ribavirin) Tablets was originally approved on June 9, 2009, and the most recent REMS modification was approved on October 8, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for COPEGUS® (ribavirin) Tablets .

Because maintaining the Medication Guide as part of the approved labeling is adequate and meets the standard in 21 CFR 208.1, we have determined that it is no longer necessary to include the Medication Guide as an element of the approved REMS, and that a REMS is no longer necessary to ensure that the benefits of COPEGUS® (ribavirin) Tablets outweigh its risks. Therefore, we agree with your proposal and a REMS for COPEGUS® (ribavirin) Tablets is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

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 Abiola Olagundoye, Pharm.D., Regulatory Project Manager, at (301) 796-3982.

Sincerely,

{See appended electronic signature page}

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

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

/s/

KENDALL A MARCUS
05/09/2011