



NDA 21-511 / S-008

Hoffmann-La Roche Inc.
Attn: Duane L. Voss
Program Director, Drug Regulatory Affairs
340 Kingsland Street
Nutley, New Jersey 07110-1199

Dear Ms. Voss:

Please refer to your supplemental new drug application dated February 23, 2005, received February 25, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for COPEGUSTM (ribavirin, USP) Tablets, 200 mg.

We acknowledge receipt of your submission dated March 24, 2005.

This supplemental new drug application provides for a new strength (400 mg) of Copegus Tablets.

We completed our review of this supplemental new drug application. This supplement 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 submitted labeling for the package insert.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulator 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/SN008.**” Approval of this submission by FDA is not required before the labeling is used.

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

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Food and Drug Administration
Rockville MD 20857

If you have any questions, please call Kenny Shade, RN, JD, Regulatory Project Manager, at (301) 827-2361 or (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Stephen P. Miller, Ph.D.
Chemistry Team Leader for the
Division of Antiviral Drug Products, (HFD-530)
DNDC III, Office of New Drug Chemistry
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/

Stephen Paul Miller
6/21/05 08:46:30 PM
NDA 21-511 / S-008 is approved