



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-511S-006

Hoffman-La Roche
Attention: Alan J. Mart
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Mr. Mart:

Please refer to your supplemental new drug application dated November 19, 2004, received November 22, 2004, submitted under section 505(b) of the the Federal Food, Drug, and Cosmetic Act for Copegus® (ribavirin) in combination with Pegasys® (peginterferon alfa-2a) for the treatment of Hepatitis C.

We acknowledge receipt of your submission dated June 17, 2005.

This supplemental new drug application provides for the revision of the Copegus labeling based on the results of a two year oral (intubation) carcinogenicity study in rats (with toxicokinetics), and ; revisions to the HOW SUPPLIED AND STORAGE sections of the last approved Copegus package insert have also been reworded.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use recommended in the labeling submitted November 19, 2004.

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-006.**" 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, HFD-410
FDA
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 Kenny Shade, Regulatory Project Manager, at (301) 827-2361 or (301) 827-2335.

Sincerely,

{See appended electronic signature page}

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

Enclosure: approved draft labeling

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

/s/

Debra Birnkrant
8/22/2005 01:58:16 PM
NDA 21-511