DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-511/S-007

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 January 31, 2005, received February 1, 2005, received submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Copegus® (ribavirin) in combination with Pegasys® (peginterferon alfa-2a) for treatment of Hepatitis C.

We acknowledge receipt of your submission "Changes Being Effected, Labeling" dated January 31, 2005.

This "Changes Being Effected" supplemental new drug application provides for revision to the Adverse Reactions section of the package insert to include thrombotic thrombocytopenic purpura.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted with the supplement.

We remind you that you must comply with the reporting requirements for an approved NDA set forth under 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.
Division Director
Division of Antiviral Drug Products

Enclosure:

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

8/16/2005 02:10:30 PM