DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-511\S-006
Hoffman-La Roche Inc.
Attention: Alan Mart
Group Director, Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110

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 Federal Food, Drug, and Cosmetic Act for Copegus® (ribavirin) in combination with Pegasys® (peginterferon alfa-2a) for treatment of Hepatitis C.

We have reviewed the referenced material and have the following comments.

1. The approval letter issued by the Division of Antiviral Products on August 22, 2005 for NDA 21-511/S-006 contained the wrong version of the approved draft labeling.

2. Please be advised you will receive a corrected action letter.

3. The date of the action will be unchanged.

If you have any questions, call Kenny Shade, Regulatory Project Manager, at 301-796-0807.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Anti-Viral 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/

Jeffrey Murray

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