DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

SUPPLEMENT APPROVAL

NDA 21-511/S-022
BLA 103964/5186

Hoffmann-La Roche, Inc.
Attention: Steven Toma, Pharm.D.
Associate Director
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Dr.Toma:

Please refer to your Supplemental New Drug Application (sNDA) dated December 17, 2009, received December 18, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Copegus® (ribavirin) 200 mg tablets.

Please also refer to your supplement to your biologics license application (BLA) dated December 17, 2009, received December 18, 2009, submitted under section 351 of the Public Health Service Act, for Pegasys® (peginterferon alfa-2a) 180 mcg/1.0 mL vial for single-use and 180 mcg/0.5 mL prefilled syringe for single-use injection.

We acknowledge receipt of your amendments dated February 5, 2010, March 2, 2010, April 19, 2010, April 20, 2010, May 5, 2010, June 15, 2010, July 23, 2010, September 3, 2010, November 2, 2010, June 7, 2011, June 29, 2011, July 28, 2011, August 4, 2011 and August 9, 2011.

The March 23 and 24, 2011, submissions constituted a complete response to our October 1, 2010, action letter.

These Prior Approval supplemental new drug and biologics license applications were submitted to expand the patient population to include chronic hepatitis C patients with renal impairment (creatinine clearance less than 50 mL/min), including those who are receiving chronic hemodialysis.

We have completed our review of these applications, as amended. The applications are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

POSTMARKETING COMMITMENTS

Approval of this supplement fulfills the following postmarketing commitment acknowledged in our December 3, 2002, Copegus® approval letter:

592-3 Determine appropriate dosing recommendations for patients with renal impairment.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, and text for the Medication Guide).

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more

information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Sherly Abraham, R.Ph., Regulatory Project Manager, at (301) 796-3198.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE:
Content of Labeling

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

/s/

JEFFREY S MURRAY
08/09/2011