DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103964/5147
STN: BL 103964/5163

April 20, 2009

Hoffmann-La Roche Inc.
Attention: Christina Kish
Associate Director Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Kish:

Please refer to your supplements to your biologics license application (BLA) dated February 11, 2008, and February 20, 2009, received February 12, 2008, and February 23, 2009, submitted under section 351 of the Public Health Service Act for Pegasys® (peginterferon alfa-2a).

Reference is also made to your submissions dated December 15, 2008, March 24, 2009 and April 9, 2009.

103964/5147

This supplement provides for revisions to the labeling for Pegasys® (peginterferon alfa-2a) to include the addition of the serious risk of serous retinal detachment in the U.S. Package Insert,***WARNINGS: Ophthalmologic Disorder*** section.

In addition, this supplement provides for a modification to the approved Medication Guide and to the approved REMS. The following sections of the Medication Guide were created or updated to achieve consistency with the U.S. Package Insert: ***Mental health problems and suicide, Heart problems, Eye problems, Body organ problems, Call your healthcare provider immediately if you develop any of these conditions, If you have ever had any of the following conditions or serious medical problems, Tell your healthcare provider before you start taking PEGASYS, What should I avoid while taking PEGASYS, or PEGASYS with COPEGUS, What are the possible side effects of PEGASYS, and PEGASYS taken with COPEGUS***. The reporting of side effects is revised to include **FDA at 1-800-FDA-1088** and a separate statement providing and additional reporting phone number for Roche.

103964/5163

This supplement provides for revisions to the Medication Guide for Pegasys® (peginterferon alfa-2a) to improve patient instructions for handling and injection preparation of the PEGASYS prefilled syringe.

In accordance with section 505-1 of the Federal Food Drug & Cosmetic Act (FDCA), on April 22, 2008, we determined that a REMS was necessary for Pegasys to ensure the benefits of the product outweigh the risks. On October 31, 2008, FDA approved a REMS for Pegasys® (peginterferon alfa-2a). The REMS consisted of a Medication Guide and a timetable for submission of assessments of the REMS.

We have completed our review of these applications, including your proposed modified REMS dated March 24, 2009. These applications and your modified REMS are approved, effective on the date of this letter. Your modified REMS is appended to this letter. The timetable for submission of assessments will remain the same as that approved on October 31, 2008, with the original approval of the REMS.

Prominently identify future submissions containing the REMS assessment or proposed REMS modification with the following appropriate wording in bold capital letters at the top of the first page of the submission:

BLA 103964 REMS ASSESSMENT

NEW SUPPLEMENT FOR BLA 103964 REMS ASSESSMENT

PROPOSED REMS MODIFICATION

Please note that:

- this Medication Guide must be reprinted immediately following the last section of labeling or, alternatively, accompany the prescription drug labeling [21 CFR 201.57(c)(18)] or 21 CFR 201.80(f)(2)];

- you are responsible for ensuring that this Medication Guide is available for distribution to every patient who is dispensed a prescription for this product [21 CFR 208.24];

- the final printed Medication Guide distributed to patients must conform to all conditions described in 21 CFR 208.20, including a minimum of 10 point text; and

- you are responsible for ensuring that the label of each container or package includes a prominent and conspicuous instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed, and states how the Medication Guide is provided [21 CFR 208.24(d)].

Within 14 days of the date of this letter, submit content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public

dissemination. For administrative purposes, please designate this submission "Product Correspondence – Final SPL for approved STN BL 103964/5147 and STN 103964/5163.

Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please refer to http://www.fda.gov/cder/biologics/default.htm for information regarding therapeutic biological products, including the addresses for submissions.

This information will be included in your biologics license application file.

4/20/09

Sincerely,

for D. Birnkrant

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