DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: 103964/5154

Hoffmann-La Roche Inc.
Attention: Ms. Christina Kish
Sr. Program Manager
340 Kingsland Street
Nutley, NJ 07110-1199

September 18, 2008

Dear Ms. Kish:

Please refer to your Biologics License Application (BLA) for Peginterferon alfa-2a submitted under section 351 of the Public Health Service Act. We also refer to the follow labeling supplement:

> BL 103964/5154, submitted September 11, 2008, received September 12, 2008, proposed revisions to the Medication Guide's Appendices to include information related to the green cap needles that will be dispensed with the product.

This supplemental application has been approved.

The final printed labeling (FPL) must be identical to the enclosed labeling. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Within 21 days of the date of this letter, amend any pending supplement(s) for this BLA with content of labeling in SPL format to include the changes approved in this supplement.

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.

Sincerely,

Jeffrey S. Murray for D. Birnkrant

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