DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103949/5125

Schering Corporation
Attention: Rachael Steiner
Associate Director and Liaison
Global Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, NJ 07033

**March 10, 2009**

Dear Ms. Steiner:

Please refer to your supplement to your biologics license application (BLA) 103949/5125, dated July 31, 2006, and received August 1, 2006, for PegIntron™ (peginterferon alfa-2b).

We acknowledge receipt of your amendments to this supplement, dated August 17, 2006, September 15, 2006, February 21, 2007, February 23, 2007, March 6, 2007, September 28, 2007, March 19, 2008, March 28, 2008, April 2, 2008, May 8, 2008, July 16, 2008, September 5, 2008, September 23, 2008, October 17, 2008, January 14, 2009, January 22, 2009, January 26, 2009, February 18, 2009, February 23, 2009, February 27, 2009 and March 4, 2009.

This supplemental application was submitted to expand the indication to include retreatment of chronic hepatitis C patients who failed to respond or relapsed after treatment with combination alpha interferon/ribavirin therapy.

We have completed our review of this application, as amended. This supplemental application is approved, effective on the date of this letter, for use as recommend in the enclosed agreed-upon labeling text.

## CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (package insert submitted March , 2009). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. **For administrative purposes, please designate this submission "SPL for approved BLA 103949/5125."**

In addition, within 21 days of the date of this letter, amend any pending applications for this BLA with content of labeling in structured product labeling (SPL) format to include the changes approved in this application.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved product.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Antiviral Products and two copies of both the promotional materials and the package insert directly 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

**LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this BLA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

If you have any questions, call Victoria Tyson-Medlock, Chief, Project Management Staff, at (301) 796-0827.

Sincerely,

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

Enclosure: Approved PI