DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

BL 103949/5172 **May 8, 2009**

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

Dear Ms. Steiner:

Please refer to your supplement to your biologics license application (BLA) 103949/5172, dated July 7, 2008, and received on July 8, 2008, for PegIntron™ (peginterferon alfa-2b).

We acknowledge receipt of your amendments to this supplement, dated September 30, 2008, October 9, 2008, October 17, 2008, October 21, 2008, and December 10, 2008, January 30, 2009, March 23, 2009 and April 21, 2009, April 29, 2009 and May 1, 2009.

This supplemental application was submitted to update the package insert with the results of the IDEAL study, P03471, which includes adding a two-step dose reduction scheme for PegIntron™ and increasing the dose of REBETOL® to 1200 mg/day for patients who weigh between 81 and 85 kilograms.

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

This fulfills postmarketing commitment number 2 of BLA 103949/5002, outlined in the August 7, 2001, approval letter and described below:

> To assess the safety and efficacy of alternative dose regimens of peginterferon alfa-2b when used in combination with ribavirin in subjects with CHC genotype 1, by directly comparing 1.5 mcg/kg/wk and 1.0 mcg/kg/wk dosages of peginterferon alfa-2b. In this study either a fixed (800 mg) or weight-based dose of ribavirin will be used. Within this study, the safety and efficacy of peginterferon alfa-2b in previously untreated African Americans with chronic hepatitis C will also be evaluated. With the size of the planned study, a minimum of 100 African Americans are expected to be enrolled. Subjects will be stratified by African American versus non-African American to the two treatment groups.

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(1)) in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl/html that is identical to the enclosed labeling (text for the package insert and text for the patient package insert). 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 BL 103949/5172."**

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.

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(s) 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

For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

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

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

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

If you have any questions, call Elizabeth Thompson, M.S., Regulatory Project Manager, at (301) 796-0824.

Sincerely,

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

Enclosures: Approved PI