**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103949/5175 **May 8, 2009**

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

Dear Ms. Steiner:

Your request to supplement your biologics license application (BLA) 103949/5175, dated September 22, 2008, and received on September 23, 2008, for PegIntron™(peginterferon alfa-2b) to revise the postmarketing experience subsection of the ADVERSE REACTIONS section, of the package insert, to be consistent with the global product labeling, has been approved.

Within 21 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 103949/5175."

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

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

Sincerely,

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