DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 103949/5296

SUPPLEMENT APPROVAL

Schering Corporation
Attention: Nicholas Andrew, M.S.
Director, Worldwide Regulatory Affairs
Merck Sharp and Dohme Corp.
126 East Lincoln Ave.
P.O. Box 2000, RY 33-200
Rahway, NJ 07065

Dear Mr. Andrew:

Please refer to your Supplemental Biologics License Application (sBLA), dated September 12, 2014, received September 12, 2014, submitted under section 351(a) of the Public Health Service Act for Sylatron (peginterferon alfa-2b).

We acknowledge receipt of your amendment dated September 22, 2014.

This Prior Approval labeling supplemental biologics application revises the 300 mcg and 600 mcg cartons for the 5 mL diluent to be in alignment with the 200 mcg carton for the 5 mL diluent approved on August 30, 2014, under BLA 103949/5287.

APPROVAL

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter.

CARTON LABELS

Submit final printed carton labels that are identical to the enclosed carton labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)". Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Diluent Vial Labels for approved BLA 103949/5296**." Approval of this submission by FDA is not required before the labeling is used.

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

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, please call Ms. Sharon Sickafuse, Senior Regulatory Health Project Manager, at (301) 796-2320.

Sincerely,

{See appended electronic signature page}

Jeffery Summers, M.D.
Deputy Director for Safety
Division of Oncology Products 2
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURES:
Carton Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JEFFERY L SUMMERS
10/09/2014