DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 103949/5217
BLA 103949/5222

SUPPLEMENT BLA APPROVAL
December 22, 2011

Schering Corporation
Attention: Ursula Marek, Pharm.D.
Manager, Global Regulatory Affairs
2000 Galloping Hill Rd.
Kenilworth, NJ 07033

Dear Dr. Marek:

Please refer to your Supplemental Biologics License Application (sBLA), dated June 24, 2011, received on June 28, 2011, for BLA 103949/5217 and your September 15, 2011, submission received on September 20, 2011, for BLA 103949/5222, submitted under section 351 of the Public Health Service Act, for PegIntron™ (Peginterferon alfa-2b).

We acknowledge receipt of your amendments to sBLA 103949/5217, dated October 3, 2011, November 7, 2011, December 8, 2011 and December 20, 2011.

The Prior Approval labeling (BLA 103949/5217) supplement to your biologics license application provides revisions to the Prescribing Information (PI) and Medication Guide (MG) to include the use of PegIntron with hepatitis C virus (HCV) NS3/4A protease inhibitors for the treatment of genotype 1, chronic hepatitis C (CHC) infection. The Changes Being Effected (BLA 103949/5222) supplement to your biologics license application provides for revision to the WARNINGS AND PRECAUTIONS section of the PI to modify the language regarding the use of PegIntron in patients with neuropsychiatric disorders.

We have completed our review of these supplemental applications, as amended. It is approved, effective on the date of this letter, for use as recommended 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, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for PI and MG) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL

files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. For administrative purposes, please designate this submission "**Product Correspondence – Final SPL for approved BLA STN 103949/5222 and STN 103949/5217**."

Also within 14 days, amend all pending supplemental applications for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in MS Word format that includes the changes approved in this supplemental application.

The SPL will be accessible via publicly available labeling repositories.

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
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 601.12(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 601.12(a)(4) to the address above or by fax to 301-847-8444.

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, call Stacey Min, Pharm.D., Regulatory Project Manager, at (301) 796-4253.

Sincerely,

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

ENCLOSURE: Content of Labeling