DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103132/5108

May 2, 2008

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 for Intron A (interferon alfa-2b) to revise the package insert by deleting the 10 MIU single-dose solution vial from the Description, Dosage and Administration and the Preparation and Administration sections and the Medication Guide, and to add information regarding the risk of stroke and the 800 number for MedWatch Adverse Event Reporting to the Medication Guide, has been approved.

FDA previously approved a Medication Guide required for distribution with this product in accordance with 21 CFR Part 208. FDA hereby approves the revised draft Medication Guide you submitted on April 30, 2008.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENT

Title IX, Subtitle A, Section 901 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amends the Federal Food, Drug, and Cosmetic Act (FDCA) to authorize FDA to require the submission of a REMS for an approved drug if the Secretary becomes aware of new safety information and makes a determination that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks (section 505-1(a)(2)). This provision took effect on March 25, 2008.

Since Intron A (interferon alfa-2b) was approved in 1986, FDA has become aware of new safety information, as defined in FDAAA. This new safety information shows that there are cases of cerebrovascular complications due to stroke in patients with few or no expected risk factors for stroke.

In accordance with section 505-1 of the FDCA, as one element of a REMS, FDA may require the development of a Medication Guide as provided for under 21 CFR Part 208. FDA previously approved a Medication Guide required for distribution with Intron A (interferon alfa-2b) in accordance with 21 CFR Part 208. Pursuant to 21 CFR Part 208, FDA has determined that Intron A (interferon alfa-2b) poses a serious and significant public health concern requiring distribution of a Medication Guide. The Medication Guide is necessary for patients' safe and

effective use of Intron A (interferon alfa-2b). FDA has determined that Intron A (interferon alfa-2b) is a product that has serious risks of which patients should be made aware because information concerning the risks could affect patients' decisions to use, or continue to use Intron A (interferon alfa-2b).

The Medication Guide has been revised in response to this new safety information, and is now considered to be part of a REMS.

Your proposed REMS, submitted on April 30, 2008 is approved. The REMS consists of the final Medication Guide approved with this letter and the timetable for submission of assessments of the REMS that was included in your April 30, 2008 submission. The timetable you submitted is as follows:

1st FDAAA assessment:	November 2009 (18 months from approval)
2nd FDAAA assessment:	May 2011 (3 years from approval)
3rd FDAAA assessment:	May 2015(7 years from approval)

Information needed for assessment of the REMS should include but may not be limited to:

a. A survey of patients' understanding of the serious risks of Intron A (interferon alfa-2b)
b. A report on periodic assessments of the distribution and dispensing of the Medication Guide in accordance with 21 CFR 208.24
c. A report on failures to adhere to distribution and dispensing requirements, and corrective actions taken to address noncompliance

Use the following designator to prominently label all submissions, including supplements, relating to this REMS:

Risk Evaluation and Mitigation Strategy (REMS)

Please note that:

- This Medication Guide must be reprinted immediately following the last section of labeling or, alternatively, accompany the prescription drug labeling [21 CFR 201.57(c)(18)] or 21 CFR 201.80(f)(2)];

- You are responsible for ensuring that this Medication Guide is available for distribution to every patient who is dispensed a prescription for this product [21 CFR 208.24];

- The final printed Medication Guide distributed to patients must conform to all conditions described in 21 CFR 208.20, including a minimum of 10 point text; and

- You are responsible for ensuring that the label of each container or package includes a prominent and conspicuous instruction to authorized dispensers to provide a

Medication Guide to each patient to whom the drug is dispensed, and states how the Medication Guide is provided [21 CFR 208.24(d)].

CONTENT OF LABELING

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 103132/5108." In addition, within 21 days of the date of this letter, amend any pending supplements for this BLA with content of labeling in SPL format to include the changes approved in this supplement.

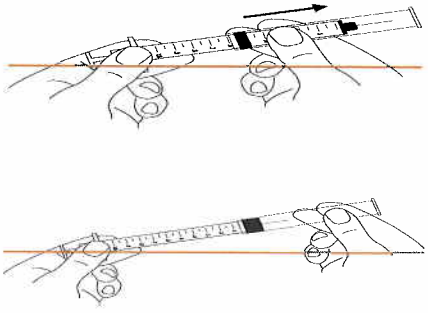
Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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

If you have any questions, contact Victoria Tyson Medlock, Regulatory Project Manager, at 301-796-0827.

Sincerely,

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



- Place all used needles and syringes in a puncture-proof disposable container that is available through your pharmacy or healthcare provider. You may also use a hard plastic container with a screw-on cap (like a laundry detergent container).
- Do not use glass or clear plastic containers for disposal of needles and syringes.
- The container used for the disposal of syringes~~,~~ and needles~~, and Safety-Lok® syringes~~ should be clearly labeled as "USED SYRINGES AND NEEDLES." When the container is almost full, tighten the lid. Tape the cap or lid to make sure it does not come off. Dispose of the container as instructed by your healthcare provider.
  DO NOT throw the container in your household trash and DO NOT recycle.

- **Always keep the container out of reach of children**

Schering Corporation Kenilworth, NJ 07033 USA

U.S. Patent No. 5,935,566 and 6,610,830.

~~Safety-Lok is a registered trademark of Becton, Dickinson and Company.~~

Rev. ~~9/073/08~~5/08

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LRN#030500-INT-SOi-MG-1