DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

Our STN: BL 103949/5088

OCT 15 2004

Schering Corporation
Attention: Kathy Maglaras
Regulatory Affairs Manager
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Ms. Maglaras:

Your request to supplement your biologics license application for Pegylated Interferon alfa-2b to revise the Clinical Pharmacology and Precautions sections of the package insert, based on the results of a pharmacokinetic study in hepatitis C patients receiving methadone, has been approved.

This fulfills your commitment to evaluate the pharmacokinetic, pharmacodynamic and clinical effects of Peginterferon alfa-2b when administered to patients receiving methadone, as stated in commitment number 4 of the January 19, 2001, approval letter.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

Please refer to http://www.fda.gov/cder biologics/default.htm for important information regarding therapeutic biological products, including the address for submissions. Effective Oct 4, 2004, the new address for all submissions to this application is:

CDER Therapeutic Biological Products Document Room
Center for Drug Evaluation and Research
Food and Drug Administration
12229 Wilkens Avenue
Rockville, Maryland 20852

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

Sincerely,

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Marc Walton, M.D., Ph.D.
Director
Division of Therapeutic Biological
Internal Medicine Products
Office of Drug Evaluation VI
Office of New Drugs
Center for Drug Evaluation and Research