DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103132/5095

May 22, 2007

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, to revise the package insert by adding a Postmarketing Experience subsection to the ADVERSE REACTIONS section and to add information on monitoring subjects with impaired renal function to the DOSAGE AND ADMINISTRATION section, has been approved.

The final printed labeling (FPL) must be identical to the enclosed labeling. Marketing product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug. Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] 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 dated May 22, 2007. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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

Sincerely,

for D. BIRNKRANT

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