DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-903/S-039

Schering Corporation
Attention: Rachael Steiner
Associate Director and Liaison
Global Regulatory Affairs
200 Galloping Hill Road
Kenilworth, NJ 07033

Dear Ms. Steiner:

Please refer to your supplemental new drug application dated November 21, 2006, received November 22, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rebetol® (ribavirin) Capsules and Oral solution.

W acknowledge receipt of your amendments dated November 21, 2006, February 6, 2007, March 13, 2007 and March 28, 2007.

This "Changes Being Effected in 30 days" supplemental new drug application includes adding a Postmarketing Experiences subsection to the ADVERSE REACTIONS section and revising the statement regarding monitoring subjects with renal impairment to include subjects over the age of 50 with respect to anemia in the DOSAGE AND ADMINISTRATION section.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text in the enclosed labeling.

Please submit an electronic version of the final printed labeling (FPL) according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-903/S-039**" Approval of this submission by FDA is not required before the labeling is used. The FPL must be identical to the enclosed labeling package insert submitted March 28, 2007.

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 text/submitted labeling dated March 28, 2007. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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

Sincerely,

{See appended electronic signature page}

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

Enclosure:

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

/s/

Jeffrey Murray
4/13/2007 10:51:53 AM