DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-903/S-038

Schering Corporation
Attention: Yvette Henderson
2000 Galloping Hill road
Kenilworth, NJ 07033

Dear Ms. Henderson:

Please refer to your supplemental new drug application dated May 26, 2006, received May 30, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rebetol® (ribavirin) capsules and oral solution.

We acknowledge receipt of your Special Supplement "Changes Being Effected, Labeling" dated May 26, 2006.

This "Changes Being Effected" supplemental new drug application updates the WARNINGS and DOSAGE and ADMINISTRATION section of the REBETOL® (ribavirin, USP) capsule and oral solution Product Information Sheet.

We completed our review of this supplemental new drug application. This application is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL). FPL was submitted in an amendment dated August 3, 2006 received August 8, 2006.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Kenny Shade, Regulatory Project Manager, at (301) 796-0807.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant
Division Director
Office of Antiviral Products
Division 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

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