DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020903/S-048
NDA 021546/S-004

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Schering Corporation
Attention: Ripal Shah, Pharm D.
Manager, Global Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Dr. Shah:

Please refer to your Supplemental New Drug Application (sNDA) dated March 24, 2011, received March 25, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for REBETOL (ribavirin), 200 mg Capsules and 40 mg/mL Oral Solution.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated November 24, 2009.

These supplemental new drug applications propose to eliminate the requirement for the REBETOL REMS.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for REBETOL (ribavirin) Capsules and Oral Solution was originally approved on November 6, 2009, and a REMS modification was approved on October 28, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for REBETOL (ribavirin) Capsules and Oral Solution.

We have determined that it is no longer necessary to include the Medication Guide as an element of the approved REMS, and that a REMS is no longer necessary to ensure that the benefits of REBETOL (ribavirin) Capsules and Oral Solution outweigh their risks. Therefore, we agree with your proposal, and a REMS for REBETOL (ribavirin) Capsules and Oral Solution is no longer required. We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

REPORTING REQUIREMENTS

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, Chief, Project Management Staff, at (301) 796-0827.

Sincerely,

{See appended electronic signature page}

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

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

/s/

KENDALL A MARCUS
05/06/2011