NDA 20-903/NDA 21-546 REBETOL® (Ribavirin, USP)
Antiviral Class

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL(s):

The goal of this REMS is to inform patients about the serious risks associated with the use of REBETOL ® (ribavirin).

II. REMS ELEMENTS:

A. Medication Guide

A Medication Guide will be dispensed with Rebetol prescription in accordance with 21 CFR 208.24. As part of the standard packaging configuration for Rebetol, two Medication Guides are included in each multi-use package and provided to patients with their prescription.

B. Timetable for Submission of Assessments

Schering Corporation will submit REMS Assessments to the FDA at a minimum, by 18 months, by 3 years and in the 7th year from the date of approval of the initial REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Schering Corporation will submit each assessment so that it will be received by the FDA on or before the due date. The reporting intervals and planned date of assessment submission to the FDA are as follows:

1st FDAAA assessment: Submission - November 30, 2009 (18 months from approval)

2nd FDAAA assessment: Submission - May 30, 2011 (3 years from approval)

Reporting Interval: January 30, 2011 - April 1, 2011

April 1, 2011: Complete assessment

May 30, 2011: Report to be submitted

3rd FDAAA assessment: November 6, 2016 (7 years from approval)

Reporting Interval: July 5, 2016 - September 5, 2016

September 5, 2016: Complete assessment

November 6, 2016: Report to be submitted