NDA 20-903/NDA 21546 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

A timetable of submission for assessments of the REMS will be no less frequent than by 18 months, 3 years and in the 7th year after FDA approval of the initial REBETOL REMS. The reporting intervals and planned date of assessment submission to the FDA are as follows:

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

2nd FDAAA assessment: 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

Schering-Plough will submit the assessments within 60 days of the close of the interval dates as noted above.