P.O. Box 1000
North Wales, PA 19454-1099

August 2015

SUBJECT: Merck Voluntarily Discontinuing REBETOL® (ribavirin USP) Capsules, for oral use

Dear Pharmaceutical Purchaser:

The purpose of this communication is to inform you that, for business reasons, Merck is voluntarily discontinuing the manufacture and distribution of REBETOL in the United States, effective February 1, 2016.

Based on current inventory levels and expected demand, Merck anticipates that inventory will be exhausted in or around February 2016, though inventory of certain images may be exhausted as early as the end of the fourth quarter of 2015. For your convenience, impacted NDCs are listed in the table immediately below.

Deleted Product Name / Strength	Description	NDC
REBETOL (ribavirin USP) capsules, for oral use, 200 mg	A bottle containing 56 capsules of REBETOL 200 mg	00085-1351-05
REBETOL (ribavirin USP) capsules, for oral use, 200 mg	A bottle containing 70 capsules of REBETOL 200 mg	00085-1385-07
REBETOL (ribavirin USP) capsules, for oral use, 200 mg	A bottle containing 84 capsules of REBETOL 200 mg	00085-1194-03

Once Merck inventories are depleted, please monitor the inventory of these product images at your distribution centers to maximize service levels until all inventories are exhausted.

Please read the Prescribing Information for REBETOL, including the Boxed Warning about the risk of serious disorders and ribavarin-associated effects. The Medication Guide also is available. REBETOL monotherapy is not effective for the treatment of chronic hepatitis C virus infection and should not be used alone for this indication. The primary toxicity of ribavirin is hemolytic anemia. The anemia associated with REBETOL therapy may result in worsening of cardiac disease that has led to fatal and nonfatal myocardial infarctions. Patients with a history of significant or unstable cardiac disease should not be treated with REBETOL. Significant teratogenic and embryocidal effects have been demonstrated in all animal species exposed to ribavirin. In addition, ribavirin has a multiple-dose half-life of 12 days, and so it may persist in nonplasma compartments for as long as 6 months. Therefore, REBETOL therapy is contraindicated in women who are pregnant and in the male partners of women who are pregnant. Extreme care must be taken to avoid pregnancy during therapy and for 6 months after completion of treatment in both female patients and in female partners of male patients who are taking REBETOL therapy. At least two reliable forms of effective contraception must be utilized during treatment and during the 6-month post-treatment follow-up period.

If you have any questions, please contact your Merck Account Executive or Call the Merck Order Management Center at 800-MERCK-RX (800-637-2579), Monday through Friday, 8:00 AM to 7:00 PM, ET.

If you have any questions, please contact your Merck Account Executive.

Sincerely,

Paul J. Bader, R.Ph.
Director, Pharmacy & Distribution
Merck Sharp & Dohme Corp.