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APPLICATION NUMBER:

125196

OTHER REVIEW(S)



REGULATORY PROJECT MANAGER REVIEW

Application Number: BLA 125196/0

Date submitted: June 28, 2006
Date received: July 3, 2006
Date completed: June 10, 2008

Applicant: Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Name of Product: PegIntron™/REBETOL Combo Pack

Materials Reviewed

This application was submitted to provide PegIntron™ and REBETOL® (Pegylated Interferon alfa-2b and Ribavirin, USP) co-packaged. The combined package insert (PI) was compared to the PegIntron package insert approved on March 26, 2008, and the REBETOL PI approved on December 4, 2007.

Background

BLA 103949/0, PegIntron monotherapy was approved on January 19, 2001, for the treatment of chronic hepatitis C in patients who are interferon alpha naïve with compensated liver disease who are at least 18 years of age. On August 7, 2001, the combination therapy, and current standard-of-care, was approved for the treatment of chronic hepatitis C in patients who are interferon alpha naïve with compensated liver disease who are at least 18 years of age.

Package Insert

The Division reviewed the combined PI for PegIntron™ and REBETOL® and compared them to the latest approved PIs for both products. The Division advised the sponsor to update the combined PI to include all information that is in the latest approved PI related to the combination therapy, to include a cross reference to or to include a description of the studies conducted and to

keep the study numbers consistent with the numbers used in the approved package inserts.

Medication Guide

The Division reviewed the combined Medication Guide for PegIntron and REBETOL and compared it to the latest approved Medication Guides for both products. On April 3, 2008, the Division sent a revised labeling proposal to the sponsor that included important information that is in the REBETOL Medication Guide.

Package labeling

The Division reviewed the package labeling for the PegIntronTM/REBETOL[®] Combo Pack and compared them to the latest approved labels for PegIntron RedipenTM and the REBETOL capsules. The Division of Medication Errors also reviewed the labeling and on January 12, 2007, made several recommendations for changes to the labeling. The labeling submitted consists of 56, 70, 84 and 98-200 mg REBETOL capsules, 50 mcg/0.5 mL, 80 mcg/0.5 mL, 120 mcg/0.5 mL and 150 mcg/0.5 mL Redipen labels and the carton labeling for the combined products.

Conclusions/Recommendations:

The revised combined PI and Medication Guide submitted on June 3, 2008, were reviewed and are acceptable to the Division. The package labeling submitted on February 8, 2007, was reviewed and is acceptable. Please see the medical officer's memorandum for concurrence. An approval letter will be sent to the applicant.



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Attachment: annotated labeling