CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-903/S-020

MEDICAL REVIEW

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Division of Antiviral Drug Products
Food and Drug Administration
Rockville MD 20857

DATE: October 16, 2001

TO: NDA 20-903 (Rebetron™ Combination Therapy
Rebetol® Capsules)

FROM: Russell Fleischer, PA-C, MPH
Senior Clinical Analyst, DAVDP

THROUGH: Katherine Laessig, MD
Acting Medical Team Leader, DAVDP

RE: Medical Review of Labeling Supplement (SLR-020)

Background

Schering Corporation submitted this supplement to revise the Rebetol label to include information about its co-administration with PegIntron® for the treatment of patients with chronic hepatitis C virus infection. This revision was prompted by the desire to make the Rebetol label consistent with information contained in the PegIntron label that was recently approved by the Center for Biologic Evaluation and Research (CBER).

Assessment and Recommended Regulatory Action

The labeling submitted by Schering includes revisions to the Indications and Usage, Warnings, Precautions, Adverse Events, and Dosage and Administration sections that are consistent with the information contained in the currently approved PegIntron label. No additional issues of clinical concern were identified in this review. The revised labeling is acceptable; therefore, this labeling supplement should be approved.

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/s/

Russell Fleischer
10/16/01 02:04:57 PM
MEDICAL OFFICER

Labeling supplement to include information about PegIntron in Rebetol label

Kathrine Laessig
10/16/01 04:17:04 PM
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10/16/01 04:34:39 PM
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