020903_S020

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Approval Package

APPLICATION NUMBER:

20-903/S-020

Trade Name: Rebetol®

Generic Name: (ribavirin)

Sponsor: Schering Corporation

Approval Date: March 6, 2002

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APPLICATION NUMBER:

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APPLICATION NUMBER:

20-903/S-020

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-903/S-020

Schering Corporation
Attention: Mary Jane Nehring
Senior Director, Marketed Products, Support and Training
Worldwide Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Ms. Nehring,

Please refer to your supplemental new drug application dated August 13, 2001, received August 14, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for REBETOL® (ribavirin) capsules for use in combination with the approved biologic products Intron®A (interferon alfa 2b) (Rebetron Combination Therapy™), and PEG- Intron® (peg-interferon alfa 2b) powder for injection.

We acknowledge receipt of your submissions dated September 10, 2001, September 25, 2001, and September 27, 2001.

This supplemental new drug application provides for the incorporation of information contained in the PEG- Intron® (peg-interferon alfa 2b) powder for injection package insert into the REBETOL® package insert and Medguide. PEG- Intron® (peg-interferon alfa 2b) powder for injection was approved for use in combination with REBETOL® for the treatment of chronic hepatitis C virus infection on August 7, 2001.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted September 27, 2001, patient package insert submitted September 27, 2001).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-903/S-020." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to

use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Destry M. Sillivan, M.S., Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Jeffrey Murray, M.D.
Acting Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Jeffrey Murray
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