

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number **20-903**

APPROVAL LETTER



NDA 20-903

Schering-Plough Research Institute
Attention: Joseph F. Lamendola, Ph.D.
2000 Galloping Hill Road
Kenilworth, NJ 07033

JUN 3 1998

Dear Dr. Lamendola:

Please refer to your December 3, 1997 new drug application, NDA 20-903 submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Intron® A/Rebetol™ (Interferon alfa-2b, recombinant/Ribavirin), 3 million IU injectable/200mg capsule, and amended to provide for the name Rebetron™ Combination Therapy.

We acknowledge receipt of your amendments dated:

September 26, 1997	February 17, 1998	April 24, 1998
January 12, 1998	March 3, 1998	May 8, 1998
January 15, 1998 (2)	March 11, 1998	May 12, 1998
January 20, 1998	March 17, 1998	May 29, 1998
February 16, 1998 (2)	March 26, 1998	

This new drug application provides for the use of ribavirin capsules in combination with interferon alpha 2-b, recombinant for the treatment of chronic hepatitis C in patients with compensated liver disease who have relapsed following alpha interferon therapy.

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for the use as recommended in the enclosed marked-up draft labeling submitted on June 2, 1998. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the June 2, 1998 draft labeling. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit sixteen copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten copies on heavy weight paper or similar material. For administrative purposes this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-903. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

We remind you of your Phase 4 commitments specified in your submissions dated May 13, 1998 and May 29, 1998. These commitments, along with any completion dates agreed upon, are listed below. Further, we acknowledge that the commitments for development of a patient information sheet and package to accommodate dose modification, as stated in your May 13, 1998 submission, have already been completed.

Validation of the regulatory methods has not been completed. At present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any deficiencies that may occur.

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

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

If you have any questions, please contact Ms. Terrie L. Crescenzi, R.Ph., Regulatory Management Officer at (301) 827-2335.

Sincerely yours,

Heidi M Jolson, M.D., M.P.H.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

**APPEARS THIS WAY
ON ORIGINAL**

Concurrence:

HFD-530/DepDir/Birnkrant DB 6/1/98
HFD-530/SMO/Kukich SK 5/29/98
HFD-530/CR/Fleischer AF 5/29/98
HFD-530/StatTL/Flyer OF 5/29/98
HFD-530/Stat/Soon G.S. 5/29/98
HFD-530/MicroTL/Ramsey (P. Ramsey) 6/1/98
HFD-530/Micro/Battula NB 5/29/98
HFD-530/PharmTL/Farrelly 7/5/29/98
HFD-530/Pharm/Morse SM 6/1/98
HFD-530/ChemTL/Miller SM 5/29/98
HFD-530/Chem/Kambhampati R.K. 5/29/98
HFD-530/BiopharmTL/Jenkins MS 5/29/98
HFD-530/Biopharm/Rajagopalan R. 6/1/98
HFD-530/SCSO/DeCicco ID 5-29-98
HFD-530/CSO/Crescenzi C 5/29/98

cc:

Original NDA 20-903
Division File
HF-2/MedWatch (with draft/final labeling)
HF-2/Lumpkin
HFD-80 (with draft/final labeling)
OFFICE FILE (with draft/final labeling)
HFD-40 (with draft/final labeling)
HFD-613 (with draft/final labeling)
HFD-735 (with draft/final labeling)
HFD-21 (with draft/final labeling)
District Office
HFD-830/CChen
HFD-530/Fleischer
HFD-530/Kambhampati
HFD-530/Rajagopalan
HFD-530/Battula
HFD-530/Morse
HFD-530/Soon
HFD-530/Crescenzi

Drafted by: Crescenzi/May 29, 1998

Initialed by:

final:

APPROVAL (AP) [with Phase 4 Commitments]