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APPLICATION NUMBER:

21-024/S-005

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

DWF, 21-024

Food and Drug Administration
Rockville MD 20857

NDA 21-024/S-005

OCT 20 2000

Aventis Pharmaceuticals, Inc.
Attention: Carol Childers, Pharm. D.
U.S. Regulatory Affairs
Marketed Products
10236 Marion Park Drive
P.O. Marion Park Drive
Kansas City, Missouri 64134-0627

Dear Dr. Childers:

Please refer to your supplemental new drug application dated December 17, 1999, received December 21, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Priftin (rifapentine) Tablets, 150 mg.

We acknowledge receipt of your submissions dated August 31, September 27, and October 16 and 19, 2000.

This NDA was approved under the regulations for accelerated approval of new drugs for serious or life-threatening illnesses, specifically, 21 CFR 314.510. At the time of approval you committed to:

1. Submit the final Clinical Study Report issued upon completion of Clinical Study 008 to the Agency for review. The projected timing was June 1999. In this final report both safety and efficacy data for the 2 years of follow-up was to be included.
2. Continue to provide support for USPHS 22, conducted under the Center for Disease Control's (CDC) Investigational New Drug (IND) application for rifapentine, and to provide support for the pharmacokinetic sub-study undertaken in Study 22, developed because of the occurrence of rifampin monoresistance in four HIV-infected patients who relapsed in the rifapentine treatment arm. It was agreed, since this study is being conducted by CDC under a separate IND, that the CDC will submit study results upon completion of the study.

This supplemental new drug application provides for revisions to the Clinical Trials, Indications and Usage, and Adverse Reactions sections of the labeling based upon the Final Clinical Study Report for Protocol 008, "Efficacy and Safety of Rifapentine Combination Therapy Compared to Standard Therapy in the Treatment of Previously Untreated Pulmonary Tuberculosis."

We have completed the review of this 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, this application is approved effective on the date of this letter.

As stated by the Agency during an April 10, 2000 teleconference between Aventis Pharmaceuticals, Inc. and the Agency, submission of both Phase 4 commitments are needed in order to remove Priftin from accelerated approval. Approval of this supplement does not complete fulfillment of your commitments made under 21 CFR 314.510 as the final study report for USPHS 22 has not been submitted to the Agency.

The final printed labeling (FPL) must be identical to the submitted labeling (draft package insert submitted October 19, 2000). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please mount individually ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-024/S-005." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" 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

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 Diana Willard, Regulatory Project Manager, at (301) 827-2387.

Sincerely,

/s/

Mark J. Goldberger, M.D., M.P.H.
Director
Division of Special Pathogen and
Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and
Research