DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-024/S-008

Sanofi-Aventis U.S. LLC
Attention: Mr. John Cook
Senior Manager, US Regulatory Affairs Marketed Products
55 Corporate Drive
Bridgewater, NJ 08807

Dear Mr. Cook,

Please refer to your supplemental new drug application dated July 12, 2007, received July 13, 2007, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Priftin® (rifapentine) 150 mg Tablets.

We acknowledge receipt of your submissions dated March 11, 2008, May 9, 2008, May 22, 2008, April 23, 2009 and May 29, 2009.

Your application dated July 12, 2007, contained the results of US Public Health Service (USPHS) Study 22 which addressed the efficacy and relapse rates in subjects in whom rifapentine once-weekly dosing was used for 4 months as a component of the continuation phase of anti-tuberculosis treatment with isoniazid (INH) and compared to the standard continuation regimen of rifampin and INH twice a week for 4 months.

We reviewed this information and on May 13, 2008, issued an approvable letter stating that before the application may be approved, you must submit draft labeling as revised in the package insert enclosed with the approvable letter.

Your submission dated April 23, 2009 constituted a complete response to our May 13, 2008 action letter.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions as agreed in the communication dated June 1, 2009. The revisions are listed below (~~strikethrough~~ = deleted text):

1. The 6th paragraph of section **6.2 Clinical Trials Experience** has been revised a follows:

   Seven patients had adverse reactions~~:~~ **(b) (4)** associated with an overdose. In the rifampin combination group these reactions included hematuria, anorexia, back pain, arthralgia, and myalgia. In the rifapentine combination

group these reactions included hematuria, neutropenia, hyperglycemia, ALT increased, hyperuricemia, pruritus, and arthritis.

2. The labeling should not have the lines in the left margin which denote that new information has been added to the labeling. These lines were deleted from the labeling.

We approved this NDA on June 22, 1998 under 21 CFR 314.510 of Subpart H-Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses. Approval of this supplemental application fulfills your commitments made under 21 CFR 314.510.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. This application was granted Orphan Designation on June 1995 and therefore is exempt from this requirement.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions "**SPL for approved supplements NDA 21-024/S-008**."

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Hyun Son, Pharm.D., Senior Regulatory Management Officer, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Package Insert

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

/s/

Renata Albrecht

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