DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-024/S-009

SUPPLEMENT APPROVAL

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

Dear Mr. Cook:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 11, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Priftin® (rifapentine) 150 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for the following changes:

(Additions are underlined; deletions are shown in ~~strikethrough~~ font.)

1. Section **8 USE IN SPECIFIC POPULATIONS, 8.4 Pediatric Use** subsection has been revised as follows:

   The safety and effectiveness of rifapentine in pediatric patients under the age of 12 have not been established. In a pharmacokinetic study conducted in 2 to 12 year-old pediatric patients, the exposure to rifapentine (i.e., AUC and C_{max}) was lower compared with that observed in healthy adults *[see Clinical Pharmacology (12.3)]*.Another ~~A~~ pharmacokinetic study was conducted in 12 to 15 year-old healthy volunteers and the pharmacokinetics of rifapentine were similar to those observed in healthy adults *[see Clinical Pharmacology (12.3)]*

2. Section **12 CLINICAL PHARMACOLOGY**, **12.3 Pharmacokinetics**/ **Pediatric (Adolescents)** subsection has been revised as follows**:**

   In a pharmacokinetic study in pediatric patients (age 2 to 12 years), a single oral dose of 150 mg rifapentine was administered to those weighing <30 kg (n=11) and a single oral dose of 300 mg was administered to those weighing ≥30 kg (n=12). The mean estimates of AUC and C_{max} were approximately 30% to 50% lower in these pediatric patients than those observed in healthy adults administered single oral doses of 600 mg and 900 mg.

In another ~~a~~ pharmacokinetics study of rifapentine in healthy adolescents (age 12 to 15 years), 600 mg rifapentine was administered to those weighing ≥45 kg (n=10) and 450 mg was administered to those weighing <45 kg (n=2). The pharmacokinetics of rifapentine were similar to those observed in healthy adults.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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. Safety Regulatory Project Manager, 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(S):
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21024	SUPPL-9	SANOFI AVENTIS US LLC	PRIFTIN (RIFAPENTINE) 150 MGS TABLETS

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
07/30/2010