NDA 50705/S-017

SUPPLEMENT APPROVAL

sanofi-aventis U.S. LLC
c/o Sanofi US Services, Inc.
Attention: Ying Zheng
Senior Associate, Regulatory Affairs
55 Corporate Drive, Mail Stop: 55C-205A
Bridgewater, NJ 08807

Dear Ms. Zheng:

Please refer to your supplemental new drug application (sNDA) dated May 23, 2019, received May 23, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for RIFATER (rifampin, isoniazid, pyrazinamide USP) Tablets, 120 mg /50 mg/300 mg.

This "Changes Being Effected" supplemental new drug application for **RIFATER** provides for revisions to the **WARNINGS** section and the **ADVERSE REACTIONS** section, **Hepatic** subsection, of the labeling to add information regarding rifampin-associated cholestasis and to the **PRECAUTIONS** section**, Information for Patients** subsection, to add information regarding symptoms/signs of liver injury and use of alcohol, hepatotoxic medications and herbal products. Additionally, the **REFERENCES** section has been removed as information regarding the susceptibility test interpretive criteria (STIC) was removed in a prior supplement approval per the requirements of Section 3044 of the 21st Century Cures Act, that added Section 511A(d)(1) of the FD&C Act.

APPROVAL & LABELING

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also, within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

If you have any questions, call Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

Sincerely,

{See appended electronic signature page}

Joseph G. Toerner, M.D., M.P.H.
Deputy Director for Safety
Division of Anti-Infective 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. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JOSEPH G TOERNER
08/27/2019 04:01:11 PM