NDA 50420/S-085
NDA 50627/S-028

SUPPLEMENT APPROVAL

sanofi-aventis U.S. LLC
Attention: Praveena Deenumsetti
Manager, Global Regulatory Affairs
55 Corporate Drive, Mailstop: 55C-205A
Bridgewater, NJ 08807

Dear Ms. Deenumsetti:

Please refer to your supplemental new drug applications (sNDAs) dated June 11, 2020, received June 11, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for RIFADIN (rifampin capsules USP), 150 mg and 300 mg [NDA 50420] and RIFADIN IV (rifampin for injection USP), 600 mg [NDA 50627].

These "Changes Being Effected" supplemental new drug applications provide for the following revisions to the **PRECAUTIONS** section of the prescribing information:

(1) Updates to the **Information for Patients** subsection to provide information on concomitant drug exposure, safety and efficacy of rifampin;
(2) Updates to the **Drug Interactions** subsection under the *Effect of Rifampin on Other Drugs* subheading:
    (a) Added information that rifampin may decrease the activity of certain coadministered drugs or increase the activity of a coadministered pro-drug; and
    (b) Updated **Table 1: Drug Interactions with Rifampin that Affect Concomitant Drug Concentrations**" to include an ***Antithrombotic Agents*** section with information on drug-drug interactions with Clopidogrel and Ticagrelor.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are 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 Prescribing Information), 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 these NDAs, 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 these supplemental applications, 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).

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

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, M.D., Ph.D.
Deputy Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
  - Prescribing Information

[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.

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/

DMITRI IARIKOV
06/17/2021 02:08:26 PM