NDA 50420/S-084
NDA 50627/S-027

SUPPLEMENT APPROVAL

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

Dear Ms. Zheng:

Please refer to your supplemental new drug applications (sNDAs) dated January 17, 2020, received January 17, 2020, 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) [NDA 50627].

These Prior Approval supplemental new drug applications, submitted in response to the FDA Supplement Request letter dated December 6, 2019, provide for the removal of the susceptibility test interpretive criteria (STIC) and related information from the approved labeling in accordance with 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 these applications. 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 PI, 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]

[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.

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

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
05/12/2020 09:40:18 AM