DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50420/S-078
NDA 50627/S-021

SUPPLEMENT APPROVAL

sanofi-aventis U.S. LLC
A Sanofi Company
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 Applications (sNDAs) dated March 15, 2018, received March 15, 2018, 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 Prior Approval supplemental new drug applications provide for changes to the **CLINICAL PHARMACOLOGY** section, **Isoniazid** subsection, **CONTRAINDICATIONS** section, **WARNINGS** section, and **WARNINGS** section, **Rifampin** subsection, **PRECAUTIONS** section, **Information for Patients/Rifampin**, **Drug Interactions**, and **Pregnancy-Teratogenic Effects** subsections, and the **ADVERSE REACTIONS** section, **Adverse Reactions Reported for Individual Components/Rifampin/Hypersensitivity reactions** subsections of the prescribing information.

The changes include a new contraindication for patients receiving praziquantel therapy, inclusion of acute generalized exanthematous pustulosis in the **WARNINGS** and **ADVERSE REACTIONS** sections, and updated information for clarity regarding drug-drug interactions, teratogenic effects, and hypersensitivity/severe cutaneous adverse reactions in the relevant sections of labeling.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are 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 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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. 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 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 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 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).

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above, by fax to 301-847-8444, or electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft guidance for industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

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}

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:
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/

JOSEPH G TOERNER
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