NDA 214429/S-001

SUPPLEMENT APPROVAL

sanofi-aventis U.S. LLC
A SANOFI COMPANY
Attention: Michael Macalush, MS
Director, U.S. and Global Regulatory Affairs
55 Corporate Drive
Mail Code: 55C-205A
Bridgewater, NJ 08807-5925

Dear Mr. Macalush:

Please refer to your supplemental new drug application (sNDA) dated and received, November 30, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Fexinidazole tablets, 600 mg.

We also refer to our letter dated September 01, 2021, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for nitroimidazole products. This information pertains to the risk of irreversible hepatotoxicity/acute liver failure with fatal outcomes in patients with Cockayne syndrome.

This supplemental new drug application provides for revisions to the labeling for Fexinidazole consistent with our September 01, 2021, safety labeing change notification letter.

The **CONTRAINDICATIONS (4)** section was revised to state that Fexinidazole Tablets are contraindicated in patients with Cockayne syndrome. The **CONTRAINDICATIONS (4)** section was revised to state that fexinidazole is contraindicated in patients with Cockayne syndrome.

Other edits to reflect the change are included in the following sections in the attached Prescribing Information (PI): the **HIGHLIGHTS OF PRESCRIBING INFORMATION**, and the **ADVERSE REACTIONS (6)** section, **Postmarketing Experience (6.2)** subsection.

APPROVAL & LABELING

We have completed our review of this application. 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 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. If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

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).

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).

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.

If you have any questions, call Alison Rodgers, Regulatory Project Manager, at 301-796-0797.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- 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
12/15/2021 09:05:00 AM