



NDA 050420/S-091

NDA 050627/S-036

## **SUPPLEMENT APPROVAL**

Sanofi US Services Inc.  
o/b/o Sanofi-aventis U.S. LLC  
Attention: Stephen Canning  
Manager, Global Regulatory Affairs  
450 Water Street  
Cambridge, MA 02141

Dear Stephen Canning:

Please refer to your supplemental new drug applications (sNDAs) dated and received June 28, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

- Rifadin (rifampin) capsules, 150 mg and 300 mg
- Rifadin (rifampin) for injection, 600 mg

These “Changes Being Effected” sNDAs provide for revisions to the prescribing information (PI) as follows:

- Updates to Table 1: Drug Interactions with Rifampin that Affect Concomitant Drug Concentrations
  - In the **PRECAUTIONS** section, **Drug Interactions** subsection,
    - Addition of the following drug classes: *Cortisol Receptor Blocker* and *Progestin Antagonist*
      - Addition of mifepristone to *Cortisol Receptor Blocker* and *Progestin Antagonist*
    - Beneath *Cortisol Receptor Blocker*, mifepristone,
      - Addition of “Avoid concomitant use” under Prevention or Management and addition of “Decrease exposure” under Clinical Effect
    - Beneath *Progestin Antagonist*, mifepristone,
      - Addition of “Refer to the post-treatment assessment in the mifepristone prescribing information to verify that treatment has been successful” under Prevention or Management and addition of “Decrease exposure” under Clinical Effect
  - Updates to the PI, to include the safety labeling changes approved on August 16, 2023 (NDA 050420/S-090 and NDA 050627/S-035)

- Minor editorial revisions

## **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.<sup>1</sup> 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*.<sup>2</sup>

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).

## **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.<sup>3</sup>

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> 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>.

<sup>3</sup> For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at [FDA.gov](http://FDA.gov).<sup>4</sup> Information and Instructions for completing the form can be found at [FDA.gov](http://FDA.gov).<sup>5</sup>

### **PATENT LISTING REQUIREMENTS**

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

### **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, email Lori Kolejian, MS, MSAMB, Regulatory Project Manager, at [Lori.kolejian@fda.hhs.gov](mailto:Lori.kolejian@fda.hhs.gov), or call (301) 796-0881.

Sincerely,

*{See appended electronic signature page}*

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

### **ENCLOSURE:**

- Content of Labeling
  - Prescribing Information

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<sup>4</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

<sup>5</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

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**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.**  
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/s/  
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DMITRI IARIKOV  
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