NDA 019949/S-074
NDA 019950/S-073
NDA 020090/S-055

SUPPLEMENT APPROVAL

Pfizer Inc
Attention: Michele Burtness
Senior Manager, Pfizer Global Regulatory Sciences
66 Hudson Boulevard East
New York, NY 10001

Dear Ms. Burtness:

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

- NDA 019949/S-074 Diflucan (fluconazole) tablets
- NDA 019950/S-073 Diflucan (fluconazole in dextrose injection and fluconazole in sodium chloride injection) for intravenous use
- NDA 020090/S-055 Diflucan (fluconazole) for oral suspension

These "Changes Being Effected" sNDAs provide for revisions to the prescribing information (PI) and patient package insert (PPI) to incorporate the following labeling changes previously approved on March 9, 2022, and January 17, 2023:

(1) Addition of Ivacaftor and Lurasidone to the **PRECAUTIONS** section, **Drug Interactions** subsection.
(2) Revision of the *HMG-CoA reductase inhibitors* drug interactions text in the **PRECAUTIONS** section, **Drug Interactions** subsection.
(3) Revision of the text regarding voriconazole and addition of new text for abrocitinib in the **CLINICAL PHARMACOLOGY** section, **Drug Interaction Studies** subsection.
(4) Addition of text regarding abrocitinib drug interaction with management strategies to the **PRECAUTIONS** section, **Drug Interactions** subsection.
(5) Revision of the PPI to align with changes made to the Diflucan tablets PI.

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 labeling (text for the Prescribing Information and Patient Package Insert), 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 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).

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).

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[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.

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 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
  - Patient Package Insert

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/

ALISON K RODGERS
07/12/2023 01:46:48 PM

DMITRI IARIKOV
07/12/2023 01:48:50 PM