



NDA 19949/S-069
NDA 19950/S-068
NDA 20090/S-050

SUPPLEMENT APPROVAL

Pfizer Inc.
Attention: Michele Burtness
Senior Manager
Pfizer Global Regulatory Affairs
235 East 42nd Street
New York, NY 10017

Dear Ms. Burtness:

Please refer to your supplemental new drug applications (sNDAs) dated April 3, 2020, received April 3, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 019949/S-069 Diflucan (Fluconazole Tablets), 50 mg, 100 mg, 150 mg, 200 mg
NDA 019950/S-068 Diflucan (Fluconazole in Dextrose Injection and Fluconazole in Sodium Chloride Injection, for intravenous use)
NDA 020090/S-050 Diflucan (Fluconazole for Oral Suspension), 350 mg, 1400 mg

These “Changes Being Effected” supplemental new drug applications provide for revisions to the prescribing information (PI) to add language regarding the potential drug-drug interactions between fluconazole and ibrutinib and fluconazole and tolvaptan. Specifically, the **PRECAUTIONS** section, **Drug Interactions** subsection, *Ibrutinib* and *Tolvaptan* subheadings have been updated and consequential updates have been made to the Patient Package Insert for Diflucan Tablets. Additionally, minor editorial updates have been made throughout the PI.

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](http://www.fda.gov).¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, 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.

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

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).

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

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>.

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
09/08/2020 10:39:37 AM