



NDA 19949/S-058
NDA 19950/S-062
NDA 20090/S-042

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Shai Srulovich, PharmD, RPh
Senior Manager, Worldwide Safety and Regulatory
235 East 42nd Street
New York, NY 10017

Dear Dr. Srulovich:

Please refer to your Supplemental New Drug Applications (sNDAs) dated September 24, 2013, received September 24, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Name of Drug Product	NDA Number	Supplement Number
Diflucan (fluconazole) Tablets	19949	S-058
Diflucan (fluconazole) Injection	19950	S-062
Diflucan (fluconazole) Powder for Oral Suspension	20090	S-042

We acknowledge receipt of your amendment dated March 4, 2014.

These supplemental applications, submitted as “Changes Being Effected” supplements, provide for revisions to the following sections of the package insert:

1. **CLINICAL PHARMACOLOGY** Section, **Drug Interaction Studies** subsection to add quinidine.
2. **CONTRAINDICATIONS** Section to add erythromycin.
3. **WARNINGS** Section to provide information about the conditions under which discontinuation of treatment is recommended, if dermatologic reactions occur.
4. **PRECAUTIONS** Section, **Drug Interactions** subsection with information related to use of fluconazole with cyclosporine and quinidine.

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.

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 package insert, text for the patient package insert), with the addition of any labeling changes in pending “Changes Being Effectuated” (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 includes 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 MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in these supplements, 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 package 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 or by fax to 301-847-8444.

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}

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SUMATHI NAMBIAR
03/24/2014