



NDA 19949/S-051
NDA 19950/S-056
NDA 20090/S-034

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Nancy Kirschbaum, Ph.D.
Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Dr. Kirschbaum:

Please refer to your Supplemental New Drug Applications (sNDA's) dated April 16, 2010, received April 16, 2010, 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, 50 mg, 100 mg, and 200 mg	19-949	S-051
Diflucan (fluconazole) I.V., 2 mg/mL	19-950	S-056
Diflucan (fluconazole) for Oral Suspension, 10 mg/mL and 40 mg/mL	20-090	S-034

The December 8, 2010, submission(s) constituted a complete response to our October 15, 2010, action letter.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the **WARNINGS** section, **Use in Pregnancy** subsection, and the **PRECAUTIONS** section, **Pregnancy: Teratogenic Effects** and **Nursing Mothers** subsections of the package insert.

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.

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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the 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 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 submissions, 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 the 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, M.D., M.P.H
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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
06/06/2011