DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-949/S-037
NDA 19-950/S-039
NDA 20-090/S-019

Pfizer, Inc.
Attention: Corinne Gamper
Director, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Ms. Gamper:

Please refer to your "Changes Being Effected" supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act as follows:

Drug Product	NDA #	Supplement #	Date Submitted	Date Received
Diflucan® (fluconazole) Tablets, 150 mg	19-949	037	December 2, 2003	December 3, 2003
Diflucan® (fluconazole) Injection, 200 mg/100 mL, 400 mg/200 mL	19-950	039	December 2, 2003	December 3, 2003
Diflucan® (fluconazole) Powder for Oral Suspension, 10 mg/mL, 40 mg/mL	20-090	019	December 2, 2003	December 3, 2003

We acknowledge receipt of your submission to each supplement dated March 17, 2004.

These supplemental new drug applications provide for the following changes to the Diflucan® patient package insert. Added text is <u>double underlined</u> and deleted text is ~~strikethrough~~:

> The following drug name was added to the **"What To Tell Your doctor Before You Start Diflucan?"** subsection at the end of the list of drugs that can cause serious problems if taken with Diflucan::
>
> <u>terfenadine (Seldane®); used for allergies</u>

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed label submitted on March 17, 2004 (enclosed). Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Robin Anderson, R.N., M.B.A., Labeling Reviewer, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and
Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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

/s/

Renata Albrecht

3/24/04 06:45:00 PM