DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-949/S-033
NDA 19-950/S-033
NDA 20-090/S-015

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

Dear Mr. Granados:

Please refer to your supplemental new drug applications dated April 11, 2001, received on April 12, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Diflucan® (fluconazole) 150-mg Tablets, Injection, and Powder for Oral Suspension.

We acknowledge receipt of your submission dated February 12, 2002.

These supplemental new drug applications provide for a patient package insert.

We have completed the review of these applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the patient package insert submitted February 12, 2002).

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please mount individually ten of the copies on heavyweight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDAs (January 1999). For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 19-949/S-033, NDA 19-950/S-033, and NDA 20-090/S-015." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about these drugs product (i.e., a "Dear Health Care Practitioner" 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 Matthew A. Bacho, Regulatory Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Acting 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/

Marc Cavaille Coll
8/7/02 04:23:43 PM
Signing for Renata Albrecht