



DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-665

Food and Drug Administration  
Rockville MD 20857

JUL 29 2004

Apotex Corp.  
Attention: Marcy Macdonald  
U.S. Agent for: Apotex Inc.  
616 Heathrow Drive  
Lincolnshire, IL 60069

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated February 13, 2003, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Fluconazole Tablets, 50 mg, 100 mg, 150 mg and 200 mg.

Reference is also made to the Tentative Approval letter issued by this office on July 20, 2004, and to your amendments dated December 19, 2003; and February 20, March 11, May 19, and July 20, 2004.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Fluconazole Tablets, 50 mg, 100 mg, 150 mg and 200 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Diflucan<sup>®</sup> Tablets, 50 mg, 100 mg, 150 mg, and 200 mg, respectively, of Pfizer Central Research). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration  
Division of Drug Marketing, Advertising, and Communications, HFD-42  
5600 Fishers Lane  
Rockville, MD 20857

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours, 

(b)(6)

Gary Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research