DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 74-681

Food and Drug Administration
Rockville MD 20857

JUL 29 2004

TEVA Pharmaceuticals USA
Attention: Deborah A. Jaskot
U.S. Agent for: Novopharm Limited
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated June 5, 1995, 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 our Tentative Approval letters dated June 18, 1999 and January 28, 2004, and to your amendments dated October 18, 1996; February 24, 2000; April 17, 2002; and January 29, and May 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 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