CENTER FOR DRUG EVALUATION AND RESEARCH

75-273

APPLICATION NUMBER:

APPROVAL LETTER

JUN 15 1999

ANDA 75-273

Teva Pharmaceuticals, USA
Attention: Deborah A. Jaskot
1510 Delp Drive
Kulpsville, PA 19443

Dear Madam:

This is in reference to your abbreviated new drug application dated December 12, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ketoconazole Tablets USP, 200 mg.

Reference is made to our Tentative Approval letter dated October 28, 1998, and to your amendment dated March 23, 1999.

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 Ketoconazole Tablets USP, 200 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Nizoral® Tablets, 200 mg, of Janssen Pharmaceutica, Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under 21 CFR 314.70, 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.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253

(Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

D. L. Spoon 6/15/99

Douglas L. Spoon
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 75-273

OCT 28

Teva Pharmaceuticals USA
Attention: Deborah Jaskot
1510 Delp Drive
Kulpsville, PA 19443

Dear Madam:

This is in reference to your abbreviated new drug application dated December 12, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ketoconazole Tablets USP, 200 mg.

Reference is also made to your amendments dated March 27, July 10, and October 5, 1998.

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is, therefore, subject to change on the basis of new information that may come to our attention.

The listed reference drug product upon which you have based your application is subject to a period of patent protection and, therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(4)(B)(ii) of the Act until the period has expired, i.e., June 15, 1999.

Please provide the Agency, at least 60, but not more than 90, days prior to June 15, 1999, an amendment to this application. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as labeling, chemistry, manufacturing, and controls data as appropriate. An amendment should be submitted even if none of these changes were made. This submission should be designated as a MINOR AMENDMENT in your cover letter. In addition to, or instead of, the amendment requested above, the Agency may, at any time prior to the final date of approval, request that you submit an amendment containing the information described above.

Failure to submit such an amendment requested by the Agency will prompt a review of the application which may result in rescission of this tentative approval letter.

Any significant changes in the conditions outlined in this abbreviated application requires Agency approval before the changes may be made effective.

Prior to issuance of a final approval letter by the Agency, your product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list, published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to June 15, 1999, you should amend your application accordingly.

At the time you submit any amendments, you should contact Joseph Buccine, Project Manager, at (301) 827-5848, for further instructions.

The introduction or delivery for introduction into interstate commerce of the drug before the effective approval date is prohibited under 21 U.S.C. 331(d).

Sincerely yours,

D. L. Sporn 10/28/98

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research