CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74-926

APPROVAL LETTER

ANDA 74-926

APR 16 1999

Alpharma, U.S. Pharmaceuticals Division
Attention: Ronald Bynum
333 Cassell Drive, Suite 3500
Baltimore, MD 21224

Dear Sir:

This is in reference to your abbreviated new drug application dated July 15, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for M-Zole 3 Combination Pack [Miconazole Nitrate Vaginal Suppositories USP, 200 mg and Miconazole Nitrate Cream USP, 2% (Combination Package)].

Reference is also made to your amendments dated January 29 and March 26, 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 Over-The-Counter (OTC) labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your M-Zole 3 Combination Pack [Miconazole Nitrate Vaginal Suppositories USP, 200 mg and Miconazole Nitrate Cream USP, 2% (Combination Package)] to be bioequivalent to the listed drug (Monistat-3 Combination Pack of Advanced Care Products).

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.

Sincerely yours,

D. L. Sporn 4/16/99

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

ANDA 74-926

JUN 23 1998

Alpharma, U.S. Pharmaceuticals Division
Attention: Ronald Bynum
333 Cassell Drive, Suite 3500
Baltimore, MD 21224

Dear Sir:

This is in reference to your abbreviated new drug application dated July 15, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for M-Zole 3 Combination Pack [Miconazole Nitrate Vaginal Suppositories USP, 200 mg and Miconazole Nitrate Cream USP, 2% (Combination package)].

Reference is also made to your amendments dated August 14, 1996; and February 13, April 3, and April 20, 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 draft 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 drug product referenced in your application is subject to a period of market exclusivity and therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(4)(D) of the Act until the period has expired, i.e., April 16, 1999.

Please provide the Agency, at least 60, but not more than 90 days prior to April 16, 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 change in the conditions outlined in this abbreviated application requires Agency approval before the change may be made effective.

Prior to the 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 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 April 16, 1999, you should amend your application accordingly.

At the time you submit any amendment, you should contact Mr. Joseph Buccine, Project Manager, at (301)827-5848, for further instructions. Please be advised that you are required to submit 12 final printed copies of all labels and labeling as part of the minor amendment noted above. Please note that the Agency reserves the right to request further changes in the labels and/or labeling based upon changes to the approved labeling of the listed drug or upon further review of the application prior to approval.

The introduction or delivery for introduction into interstate commerce of the drug before the effective approval date is prohibited under 21 U.S.C. 311(d).

Sincerely yours,

D. L. Sporn 6/23/98

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