ANDA 74-926 April 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,

Douglas L. Sporn
Director
Office of Generic Drugs