DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-773

MAR 2 2005

Taro Pharmaceuticals U.S.A., Inc.
Attention: Kalpana Rao
Vice President, Regulatory Affairs
5 Skyline Drive
Hawthorne, NY 10532

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated June 27, 2003, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Miconazole 3 (Miconazole Nitrate Vaginal Cream, 4%), 3 Day Treatment.

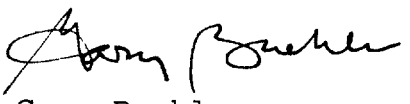
Reference is also made to your amendments dated April 29, July 2, July 23, September 23, and October 6, 2004; and February 4, 2005.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for over-the-counter (OTC) use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Miconazole Nitrate Vaginal Cream, 4%, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Monistat® 3 Vaginal Cream, 4%, of Advanced Care Products).

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.

Postmarketing 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,



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