DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-968

JUN 30 1999

Advanced Care Products
Attention: Diane Herron
Director, Regulatory Affairs
691 Highway 1
North Brunswick, NJ 08902-0724

Dear Ms. Herron:

Please refer to your June 30, 1998 new drug application, NDA 20-968 for MONISTAT® DUAL-PAK™, containing MONISTAT® (miconazole nitrate vaginal insert) Soft Gel Vaginal Insert, 1200 mg, and MONISTAT® (miconazole nitrate cream) External Vulvar Cream, 2%, received June 30, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act. The User Fee goal date for this application is June 30, 1999.

We acknowledge receipt of your submissions and amendments dated:

September 16, 1998	March 30, 1999	June 2, 1999
September 30, 1998	April 19, 1999	June 7, 1999
October 8, 1998	April 27, 1999	June 9, 1999
January 12, 1999	May 3, 1999	June 11, 1999
January 13, 1999	May 4, 1999 (2)	June 15, 1999
February 18, 1999	May 7, 1999	June 23, 1999
March 1, 1999 (2)	May 18, 1999	June 29, 1999,
March 16, 1999		

as well as your faxes dated August 11, 1998; May 25, June 17, 18, and 30, 1999.

This new drug application provides for the use of MONISTAT® DUAL-PAK™ for the treatment of vulvovaginal candidiasis.

We have completed the review of this application, as amended, and we have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved, effective on the date of this letter.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to

contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). We are waiving the pediatric study requirement for this application, because the Agency believes adult clinical trial data can be extrapolated to demonstrate safety and effectiveness in postmenarchal girls, and it is unlikely that premenarchal girls would need to use this medication.

In addition, we remind you of 21 CFR 201.56 (b) which states that labeling shall not be promotional in tone.

The final printed labeling (FPL) must be identical to the submitted draft labeling (text for the physician package insert, text for the patient package insert, blister pack, immediate container of the cream, and carton labels submitted June 29, 1999, as amended by your fax of June 30, 1999). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-968." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:
Christina H. Chi, Ph.D.,
Regulatory Project Manager,
Phone: (301) 827-2127.

Sincerely yours,

Mark J. Goldberger, M.D., M.P.H.
Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research