20827

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER: **20-827**

Trade Name: Monistat 3 Vaginal Cream

Generic Name: Miconazole Nitrate 4% Vaginal Cream

Sponsor: Advanced Care Products

Approval Date: March 30, 1998

Indication(s): Treatment of vulvovaginal candidiasis

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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-827

MAR 30 1998

Advanced Care Products
Attention: Diane Herron
691 Highway 1, P.O. Box 6024
North Brunswick, New Jersey 08902-0724

Dear Ms. Herron:

Please refer to your March 31, 1997, new drug application (NDA) for Monistat® 3 Vaginal Cream (miconazole nitrate cream), 4%, NDA 20-827, received March 31, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act.

We acknowledge receipt of your submissions and amendments dated April 3, May 9, July 17, August 12, September 23, October 7, and 8, November 12, 17, 18, and 19, and December 4, 1997, and January 29 (2), February 5 (2), 6, and 19, and March 5, 6, 23 (2), 24, 25, 26, 27 (2), and 30, 1998. The User Fee goal date for this application is March 31, 1998.

This new drug application provides for a 3-day therapy with miconazole nitrate cream for the over-the-counter treatment of vulvovaginal candidiasis.

We have completed the review of this application, and we conclude that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling in the submission dated March 27, 1998, with the revisions listed below. Accordingly, the application is approved, effective on the date of this letter. As discussed by telephone conference on March 30, 1998, between Ms. Williams and members of the Agency, the labeling revisions are as follows:

1. The generic name will be stated throughout all labeling and associated materials for the drug product as "miconazole nitrate cream."

2. In the "Directions For Use" section of the Educational Brochure, the spelling of the word "grey" will be changed to "gray."

3. In the "Directions For Use" section of the Educational Brochure, the recumbent position will be used in all diagrams.

4. The tradename of the drug product will be stated as "MONISTAT 3 Vaginal Cream" throughout all labeling and associated materials for the drug product.

5. In the "What Is a Vaginal Yeast Infection (Candidiasis)" section of the Educational Brochure, the last sentence should be revised to read, "The CDC phone numbers are: 1-800-342-AIDS..."

These revisions are terms of the NDA approval. Marketing the product before making the revisions, exactly as requested, in the products's final printed labeling (FPL) may render the product misbranded and an unapproved new drug. Please be advised that no promotional materials may be attached to any part of the labeling for this drug product.

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 "FINAL PRINTED LABELING" for approved NDA 20-827. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

We remind you of your Phase 4 commitment specified in your submissions dated September 23, 1997 and March 30, 1998. This commitment, along with any completion date agreed upon, is listed below:

A label comprehension study as proposed by the FDA, and agreed upon, on October 1, 1997, to be completed within 1 year of this product's approval. Please refer to our communication dated March 4, 1998, in which we specified the Agency's recommendations, in response to your protocol dated November 17, 1997.

Protocols, data, and final reports should be submitted to your IND and NDA for this product. In addition, we request under 21 CFR 314.81(b)(2)(vii) that you include in your annual report to this application, a status summary of each commitment. The status summary should include the number of subjects entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

In addition, please submit four copies of the introductory promotional material 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 the Division of Over-the-Counter Drug Products (DOTCDP), one copy to the Division of Special Pathogens and Immunologic Drug

Products (DSPIDP), and two copies of both the promotional material and the package insert directly to:

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

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.

Please submit two market packages of the drug product, when they are available, to each of the two Divisions (DOTCDP and DSPIDP).

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.
Project Manager
Phone: (301) 827-2125.

Sincerely yours,

/S/

Mark J. Goldberger, M.D., M.P.H.
Director
Division of Special Pathogens and Immunologic Drug Products (DSPIDP)
HFD-590
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

/S/

Debra Bowen, M.D.
Director
Division of Over-the-Counter Drug Products (DOTCDP)
HFD-560
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Center for Drug Evaluation and Research