NOV 24 1998

NDA 20-574

Schering-Plough HealthCare Products
Attention: Ronald J. Garutti, M.D.
Vice President, Clinical Research/Regulatory Affairs
Schering-Plough Corporation
110 Allen Road
Liberty Corner, New Jersey 07938-0276

Dear Dr. Garutti:

Please refer to your November 25, 1997, new drug application (NDA) for Gyne-Lotrimin 3® Vaginal Cream (clotrimazole), 2%, NDA 20-574, received November 25, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act. This new drug application provides for an over-the-counter, 3-day clotrimazole vaginal cream for the treatment of vulvovaginal candidiasis. The User Fee goal date for this application is November 25, 1998.

We acknowledge receipt of your submissions and amendments dated December 15, 16, and 18, 1997, January 8, 15, 23, 28, and 30, February 24, March 17, and 24, April 14, May 19, June 11, July 30, August 3, 7, 11, 17, and 26, September 24, October 1, 16 (2), 23, and 28, and November 6 (2), 10 (2), 17, and 20 (2), 1998.

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 enclosed labeling text. Accordingly, the application is approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling as follows:

1. The approved labeling text for the **carton** and **educational brochure** is specified in Attachment A.

2. The approved labeling text for the **tube**, to be used at the time of the product launch up to 6 months following approval of this application, is specified in Attachment B.

3. The approved labeling text for the **carton and educational brochure**, to be used after 6 months following approval of this application or at the next printing of the product labeling, whichever comes first, is specified in Attachment C, with the exception of the toll-free number which may be implemented within 12 months of approval date.

4. The approved labeling text for the **tube,** to be used after 6 months following approval of this application or at the next printing of the product labeling, whichever comes first, is specified in Attachment D.

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 be advised that no promotional materials should be attached to any part of the labeling for this drug product.

Please submit 20 copies of the FPL as soon as they are available, in no case more than 30 days after they are 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 20-574." 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 commitments specified in your submissions dated November 6 and 20, 1998. These commitments, along with any completion dates agreed upon, are as follows:

Protocols, data, and final reports should be submitted to this NDA with a copy of the cover letter to the Investigational New Drug Application (IND) for this product. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the 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 post-approval commitments must be clearly designated "Phase 4 commitments."

In addition, please submit four 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 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 materials 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

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.

In line with Center for Drug Evaluation and Research policy, oversight of this application is being transferred to the Division of Over-the-Counter Drug Products.

If you have any questions regarding this application, please contact:

Sakineh Walther, R.N.,
Project Manager,
Phone: (301) 827-2222.

Sincerely yours,

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

Debra L. Bowen, M.D. 11/24/96
Acting Director
Division of Over-the-Counter Drug
Products (DOTCDP)
HFD-560
Office of Drug Evaluation V
Center for Drug Evaluation and Research