DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-472

APR 26 1996

Pharmacia Inc.
Attention: Ms. Betsy J. Waldheim
Manager, Regulatory Affairs
P.O. Box 16529
COLUMBUS OH 43216-6529

Dear Ms. Waldheim:

Please refer to your June 28, 1994, new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Estring (estradiol vaginal ring), 2 mg.

We acknowledge receipt of your amendments dated September 21, October 4, and November 3, 1995. We also acknowledge your telefacsimiles dated April 17, 19, 23, and 24, 1996.

This new drug application provides for the treatment of urogenital symptoms associated with post-menopausal atrophy of the vagina (such as dryness, burning, pruritus and dyspareunia) and/or the lower urinary tract (urinary urgency and dysuria).

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling submitted June 6, 1995, (pouch and carton) and April 23, 1996, (patient package insert and physician insert). Accordingly, this application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the drafts submitted April 23, 1996, (patient package insert and physician insert) and June 6, 1995, (carton and pouch). Marketing the product with FPL that is not identical to these draft labels may render the product misbranded as an unapproved new drug.

Please submit twenty copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount twelve of the copies on heavy weight paper or similar material. For administrative purposes this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-472. 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.

In addition, please submit three 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 in final print. Please submit one copy to this Division 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 one market package of the drug 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:

Ms. Christina Kish
Consumer Safety Officer
(301) 443-3520

Sincerely yours

Solomon Sobel

Solomon Sobel, M.D.
Director
Division of Metabolism and
Endocrine Drug Products (HFD-510)
Office of Drug Evaluation II
Center for Drug Evaluation and Research