CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20-843

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-843

DEC 16 1998

Schering Corporation
Attention: Joseph F. Lamendola, Ph.D.
Vice President, U.S. Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Dr. Lamendola:

Please refer to your new drug application (NDA) dated March 10, 1997, received March 11, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prometrium (Progesterone, USP) Capsules.

We acknowledge receipt of your submissions dated March 14 and July 17, 1997; January 19, February 9, August 26, September 24, October 14, November 11, December 2, 9, 10, 14 and 15, 1998 submitted in response to our approvable letter dated March 11, 1998.

This new drug application provides for the use of Prometrium (progesterone, USP) Capsules for use in the prevention of endometrial hyperplasia in nonhysterectomized post-menopausal women who are receiving conjugated estrogens tablets.

We have completed the review of this application, as amended, 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 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 submitted draft labeling (package insert submitted December 15, 1998, patient package insert submitted December 15, 1998, immediate container and carton labels submitted August 26, 1998). 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 20-843." Approval of this submission by FDA is not required before the labeling is used.

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, contact Diane Moore, Project Manager, at (301) 827-4260.

Sincerely,

/S/

Lisa D. Rarick, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research