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Application Number 020527/S-006

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-527/S-006

JAN 09 1998

Wyeth-Ayerst Laboratories
Attention: Ms. Joan E. Barton
Associate Director
Women's Health Care Products
U.S. Drug Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Barton:

Please refer to your supplemental new drug application dated January 8, 1997, received January 9, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prempro™ (conjugated estrogens/medroxyprogesterone acetate) Tablets.

We acknowledge receipt of your submissions dated April 2, June 2, December 19 and 31, 1997; January 5, and 6(2), 7(2), 8(3) and 9, 1998. The User Fee goal date for this application is January 9, 1998.

This supplemental application provides for the continuous combined dosing regimen of 0.625 mg conjugated estrogens (CE)/5 mg medroxyprogesterone acetate (MPA) for PREMPRO Tablets for use in women with an intact uterus, for the following indications:

1. Treatment of moderate to severe vasomotor symptoms associated with the menopause.

2. Treatment of vulvar and vaginal atrophy.

3. Prevention of osteoporosis.

We have completed the review of this supplemental 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 in the submission dated January 9, 1998. Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on January 9, 1998.

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 supplemental NDA 20-527/S-006. 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 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

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20852-9787

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 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