DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 04-782/S-115 and S-130

Wyeth Pharmaceuticals
Attention: Jennifer D. Norman, R.Ph.
Associate Director
Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101

APPROVAL LETTER

Dear Ms. Norman:

Please refer to your supplemental new drug applications dated July 31, 2000, received July 31, 2000, (S-115) and February 11, 2003, received February 13, 2003, (S-130) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Premarin® (conjugated estrogens, USP) tablets.

We acknowledge receipt of your submissions dated October 15 and 28, 2002 and April 7 and 10, 2003 to S-115. Your October 15, 2002 submission constituted a complete response to our approvable letter of July 31, 2001.

We also acknowledge receipt of your submission dated February 20, 2003 (S-130).

These supplemental new drug applications provide for:

1. The use of Premarin® (0.45 mg) for the treatment of moderate to-severe vasomotor symptoms associated with the menopause and for the treatment of vulvar and vaginal atrophy associated with the menopause. When prescribing solely for the treatment of symptoms of vulvar and vaginal atrophy, topical vaginal products should be considered. (S-115).

2. Revisions in the text of the **CLINICAL PHARMACOLOGY, INDICATIONS AND USAGE, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, DOSAGE AND ADMINISTRATION AND HOW SUPPLIED** sections of the package insert**,** and the text of the patient package insert (S-115 and 130).

We completed our review of these supplemental applications, as amended. These supplemental applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert). 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 the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper 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 supplement NDA 04-782/S-115, S-130." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), 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 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kassandra Sherrod, R.Ph., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Daniel A. Shames

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