DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 04-782/S-138, S-139

Wyeth Pharmaceuticals Inc.
Attention: Jennifer D. Norman
Manager, Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101

Dear Ms. Norman:

Please refer to your supplemental new drug applications dated August 6, 2004, received August 9, 2004 (S-138), and August 27, 2004, received August 30, 2004 (S-139) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Premarin® (conjugated estrogens tablets, USP).

We acknowledge receipt of your submissions dated October 22, 2004 (S-138) and January 11 and March 24, 2005.

These supplemental new drug applications provide for revisions to the Premarin labeling based on information from the conjugated estrogens sub study of the Women's Health Initiative Study and the Women's Health Initiative Memory Study published in JAMA in April and June, 2004 and the approved labeling for Premarin 1.25 mg reformulation.

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

The final printed labeling (FPL) must be identical to the attached package insert and patient package insert.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format-NDA (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 supplements NDA 04-782/S-138, S-139." Approval of these submissions 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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