DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 04-782/S-146

Wyeth Pharmaceuticals
Attention: Jennifer D. Norman
Associate Director, Worldwide Regulatory Affairs, CMC
Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Norman:

Please refer to your supplemental new drug applications dated October 21, 2005, received October 24, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Premarin® (conjugated estrogens tablets, USP).

This "Prior Approval" Supplemental new drug application provides for changes to the text of the Premarin® (conjugated estrogens tablets, USP) labeling to include information from the conjugated estrogens sub-study of the Womens's Health Initiative (WHI) Study and the Women's Health Initiative Memory Study (WHIMS) published in JAMA in April and June, 2004.

We acknowledge receipt of your submission dated January 18, 2006.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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 15 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-146." 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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Health Project Manager, at (301) 796-0997.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Package insert
Patient Package insert

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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