DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 10-402/S-048
NDA 20-216/S-054

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 September 22, 2004, received September 23, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Premarin® (conjugated estrogens) Vaginal Cream and Premarin® (conjugated estrogens, USP) for injection.

We acknowledge receipt of your submissions dated May 17, 2005 for NDA 20-216 and May 25, 2005 for NDA 10-402. These submissions were complete responses to our approvable letter dated March 23, 2005.

These "Changes Being Effected" supplemental new drug applications provide for changes to the text of the Premarin® (conjugated estrogens, USP) Intravenous and Premarin® (conjugated estrogens) Vaginal Cream labeling to include information from the conjugated estrogen arm of the Womens's Health Initiative (WHI) Study and the Women's Health Initiative Memory Study (WHIMS).

We completed our review of these applications, as amended. These applications are 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 -10-402/S-048 and 20-216/ S-054." 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, HFD-410
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 George Lyght, R.Ph., Regulatory Health Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Division 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/

Margaret Kober
8/30/2005 04:27:28 PM
signed for Dr. Shames