DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 10-402/S-046

Wyeth Pharmaceuticals Inc.
Attn.: Colleen D. Murray
Senior Regulatory Specialist
P.O. Box 8299
Philadelphia, PA 19101

Dear Ms. Murray:

Please refer to your supplemental new drug application dated December 4, 2003, received December 5, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Premarin® Intravenous (conjugated estrogens, USP for injection).

We acknowledge receipt of your submissions dated March 19 and 29, 2004.

This supplemental new drug application provides for changes in the labeling to the following sections: BOXED WARNINGS, DESCRIPTION, CLINICAL PHARMACOLOGY, INDICATIONS AND USAGE, WARNINGS, PRECAUTIONS DOSAGE AND ADMINISTRATION, HOW SUPPLIED, and PATIENT INFORMATION. These changes were to update the labeling regarding the Women's Health Initiative Memory Study (WHIMS) and the Million Women Study.

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

The final printed labeling (FPL) must be identical to the package insert and patient package insert submitted on March 29, 2004.

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 supplements NDA 10-402/S-046." 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: agreed-upon labeling text

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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