



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-216/S-052

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® (conjugated estrogens) Vaginal Cream.

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 Vaginal Cream® as recommended in the agreed-upon labeling text and with a commitment to revise the Premarin Vaginal Cream storage statement as you proposed in your March 29, 2004 submission, no later than December 31, 2004 and the revision will be in the annual report 010 to NDA 20-216 due in January 2005.

The final printed labeling (FPL) must be identical to the package insert, patient package insert and patient leaflet 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 20-216/S-052." 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

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Daniel A. Shames  
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