



Food and Drug  
Administration  
Rockville MD 20857

NDA 04-782/S-125

Wyeth-Ayerst Laboratories  
Attention: Jennifer Norman, R. Ph.  
Associate Director, Worldwide Regulatory Affairs  
PO Box 8299  
Philadelphia, PA 19101-8299

Dear Ms. Norman:

Please refer to your supplemental new drug application dated April 30, 2002, received May 1, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Premarin® (conjugated estrogens tablets, USP) 0.45 mg and 0.3 mg.

We acknowledge receipt of your submissions dated April 7, 21 and 30, May 29, June 13 and 27, 2003.

This supplemental new drug application provides for:

Labeling which incorporates changes for the prevention of postmenopausal osteoporosis indication (NDA 21-417), for Premarin 0.45 mg and 0.3 mg.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert).

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-125." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

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 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

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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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Margaret Kober  
7/16/03 05:49:45 PM  
signed for Daniel Shames