



NDA 10-402/S-050

NDA 20-216/S-055

Wyeth Pharmaceuticals Inc.
Attention: Jennifer D. Norman
Manager, Global Regulatory Affairs
500 Arcola Road
Collegeville, PA 19426

Dear Ms. Norman:

Please refer to your supplemental new drug applications dated January 25, 2006, received January 26, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Premarin® (conjugated estrogens, USP) for Injection and Premarin® (conjugated estrogens) Vaginal Cream.

We also acknowledge receipt of your submission dated June 1, 2006, and July 26, 2006 for NDA 20-216 and June 2, 2006 and July 26, 2006 for NDA 10-402.

These "Prior Approval" supplemental new drug applications provide for revised labeling based on the adjudicated data on coronary heart disease, deep vein thrombosis, stroke and breast cancer from the estrogen-alone substudy of the Women's Health Initiative (WHI) Study.

We have 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.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 10-402/S-050 and NDA 20-216/S-055.**" 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:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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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 George Lyght, R.Ph., Regulatory Health Project Manager, at (301) 796-2130.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Acting Director
Division of Reproductive and Urologic 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/

Scott Monroe

7/26/2006 04:35:29 PM