DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 04-782/S-155

Wyeth Pharmaceuticals Inc.
Attention: Jennifer Norman, Manager
Global Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Norman:

Please refer to your supplemental new drug application submitted August 22, 2007, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Premarin® (conjugated estrogen tablets, USP).

We also acknowledge receipt of your submission dated February 28, 2008.

This "Changes Being Effected" supplemental new drug application, as amended, provides for revision to the **ADVERSE REACTION** section of the Package Insert and updating of the estrogen class labeling of the Package Insert and Patient Package Insert.

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.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. 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., Sr. Regulatory Project Manager, at (301) 796-0948.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
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

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