DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-216/S-060

Wyeth Pharmaceuticals Inc.
Attention: Donald Lewis, Manager
Global Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19102-8299

Dear Mr. Lewis:

Please refer to your supplemental new drug application dated September 25, 2007, 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 September 4, November 4, 5, and 6, 2008.

Your submission of September 4, 2008, received on September 5, 2008, constituted a complete response to our July 25, 2008 action letter.

This supplemental new drug application provides for the use of Premarin® (conjugated estrogens) Vaginal Cream for (1) a new indication, the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause and (2) a new dosing regimen for this indication, 0.5 g Premarin® (conjugated estrogens) Vaginal Cream intravaginally twice weekly.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling and to the immediate container and carton labels submitted on November 4 and 5, 2008.

We are waiving the requirement of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed, agreed-upon labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 20-216/S-060**."

PEDIATRIC RESEARCH EQUITY ACT (PREA)

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause because studies are impossible given the lack of pediatric patients with this condition.

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

11/7/2008 03:46:14 PM