DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-527/S-046

Wyeth Pharmaceuticals Inc.
Attention: Christian D. Le
Sr. Regulatory Specialist, Global Regulatory Affairs, CMC
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Mr. Le:

Please refer to your supplemental new drug application (sNDA) dated and received June 25, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prempro® 0.3 mg/1.5 mg and 0.45 mg/1.5 mg (conjugated estrogens/medroxyprogesterone acetate tablets).

We also acknowledge receipt of your submissions dated September 12, October 20, December 23, 2008, April 22 (2), and May 18, 2009.

Your submission of December 23, 2008, constituted a complete response to our December 15, 2008, action letter.

This supplemental new drug application provides for:

1. Reformulation of Prempro® 0.3 mg/1.5 mg and 0.45 mg/1.5 mg (conjugated estrogens/medroxyprogesterone acetate tablets).
2. Revisions to the **DESCRIPTION, Pharmacokinetics** subsection (Table 2) of **CLINICAL PHARMACOLOGY**, and **HOW SUPPLIED** sections of the Physician Package Insert to incorporate information on reformulated Prempro® 0.3 mg/1.5 mg and 0.45 mg/1.5 mg tablets.
3. Revisions to the Patient Information Insert under **"What are the ingredients in Prempro and Premphase?"** to incorporate information on the reformulated Prempro® 0.3 mg/1.5 mg and 0.45 mg/1.5 mg tablets.
4. A new 28-day Blister card, revisions to the Carton and Bottle labels, and new NDC numbers for Prempro® 0.3 mg/1.5 mg and 0.45 mg/1.5 mg tablets.
5. Change of the ™ symbol after Prempro to a ® symbol in all occurrences.

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 enclosed, 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(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 20-527/S-046**."

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 Health 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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