DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020527/S-045 **SUPPLEMENT APPROVAL**

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 and received May 20, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PREMPRO® and PREMPHASE® (conjugated estrogens/medroxyprogesterone acetate tablets).

We acknowledge receipt of your amendments dated March 17, 2009 and December 10, 18, and 24, 2009.

This supplemental new drug application updates labeling for PREMPRO® and PREMPHASE® to conform to the Physician Labeling Rule (PLR).

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

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)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. For administrative purposes, please designate this submission, "SPL for approved NDA 020527/S-045."

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

We are waiving the requirements 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.

Within 14 days from the date of this letter, please amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements for which FDA

has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format that includes the changes approved in this supplemental application.

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, contact 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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20527	SUPPL-45	WYETH PHARMACEUTICALS INC	PREMPRO/PREMPHASE

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SCOTT E MONROE
12/30/2009