



NDA 20-527/S-036

Wyeth Pharmaceuticals Inc.
Attn.: Jennifer D. Norman
Manager
Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101

Dear Ms. Norman:

Please refer to your supplemental new drug application dated September 22, 2004 received September 23, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PREMPRO™/PREMPHASE® (conjugated estrogens/medroxyprogesterone acetate) tablets.

We acknowledge receipt of your submission dated May 31, 2005.

This "Changes Being Effected" supplemental new drug application provides for revisions to the PREMPRO™/PREMPHASE® labeling based on information from the conjugated estrogens sub study of the Women's Health Initiative Study and the Women's Health Initiative Memory Study published in JAMA in April and June, 2004.

We have completed our review of this application, as amended. This application is approved, effective on date of this letter, for use of PREMPRO™/PREMPHASE® as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the package insert and patient package insert submitted on May 31, 2005.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-527/S-036." Approval of this submission by FDA is not required before the labeling is used.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Cassandra Sherrod, R.Ph., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: agreed-upon labeling text

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

/s/

Daniel A. Shames
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