



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 10-402/S-051

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

Dear Mr. Le:

Please refer to your supplemental new drug application dated January 31, 2006, received February 1, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Premarin (conjugated estrogens, USP) Injection, 25 mg.

This prior approval supplemental new drug application provides for removing the 2% benzyl alcohol diluent from the Premarin Intravenous (IV) for Injection package.

We 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 submitted labeling text.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 10-402/S-051.**" 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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Susan Jenney, Regulatory Health Project Manager, at (301) 796-0062.

Sincerely,

{See appended electronic signature page}

Eric Duffy, Ph.D.
Director
Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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

/s/

Eric Duffy
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