DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-864/S-002

Wyeth Pharmaceuticals, Inc.
Attention: Robert DiGregorio, D.O.
Director, Global Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Dr. DiGregorio:

Please refer to your supplemental new drug application dated and received March 6, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lybrel™ (levonorgestrel/ethinyl estradiol) Tablets.

We acknowledge receipt of your submission dated September 4, 2008.

This "Changes Being Effected in 30 days" supplemental new drug application provides for (1) the additional of "Focal nodular hyperplasia" to the ADVERSE REACTIONS section the Package Insert and (2) revision of the BEFORE YOU START TAKING LYBREL sections of the Brief and Detailed Patient Labeling.

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 enclosed labeling text.

Within 14 days of the date of this letter, submit 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 in content to the enclosed labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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 21-864/S-002**." Approval of this submission by FDA is not required before the labeling is used.

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 Pam Lucarelli, Regulatory Project Manager, at (301) 796-3961.

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

9/15/2008 10:56:50 AM