DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-088/S-018

Wyeth Pharmaceuticals, Inc.
Attention: Nanette Holston, Director
Worldwide Regulatory Affairs
P.O. Box 8299
Phildelphia, PA 19101-8299

Dear Ms. Holston:

Please refer to your supplemental new drug application dated August 25, 2003, received August 27, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norplant System® (levonorgestrel implants).

This supplemental new drug application provides for the inclusion of "visual disturbances" in the Adverse Reaction section and minor editorial changes.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

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, please call Karen Anderson, N.P., 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

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

/s/

Margaret Kober
1/6/04 05:33:16 PM
signed for Dr. Shames