DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-031/S-034

Wyeth Pharmaceutical Inc.
Attention: Lester Gibbs, Ph.D.
Associate Director, Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Dr. Gibbs:

Please refer to your supplemental new drug application dated February 25, 2004, received February 27, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Overette® (norgestrel) Tablets.

This supplemental new drug application provides for revisions to wording on the back of the blister pack for product distributed outside the United States by the United States Agency for International Development (USAID) under NDA 17-031. The change proposed is under contractual obligation with USAID.

We completed our review of the supplemental new drug application and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted changes to the blister package.

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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-031/S-034." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

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, HFD-410
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 Karen Kirchberg, N.P. - Regulatory Project Manager, at (301) 827-4254.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Deputy Director
Division of Reproductive and Urologic Drug Products, HFD-580
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/

Donna Griebel

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