NDA 16-672/S-046
NDA 16-806/S-028

Wyeth-Ayerst Laboratories
Attention: Jennifer W. Phillips, Pharm.D.
Director, Women's Health Care Products
World Wide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

23 MAR 2001

Dear Dr. Phillips:

Please refer to your supplemental new drug applications dated December 12, 1996, received December 17, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ovral® (norgestrel and ethinyl estradiol), Ovral®-28 (norgestrel and ethinyl estradiol).

These "Changes Being Effected" supplemental new drug applications provided for a revision of the EFFECTIVENESS OF ORAL CONTRACEPTIVES SECTION of the Package Insert.

We acknowledge receipt of your submission dated March 21, 2000. Your submission of March 21, 2000 constituted a complete response to our July 31, 1997 action letter requested additional label revisions as follows:

1. Revision of the Trussell Table in the Prescribing Information to be updated to the 1998 Table.

2. Reinstatement of references to the contraceptive sponge that were deleted.

In addition, the Division sent a supplement request letter dated March 4, 1998, requesting the addition of a Pediatric Use subsection to all oral contraceptive labeling:

> "Safety and efficacy of **Tradename** have been established in women of reproductive age. Safety and efficacy are expected to be the same for postpubertal adolescents under the age of 16 and for users 16 years and older. Use of this product before menarche is not indicated."

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, these supplemental applications are approved effective on the date of this letter.

The contraceptive sponge is no longer available, so a reference to the use of the contraceptive sponge as a back-up method of contraception in the patient labeling is not required at this time. Instead, the Division requests that the following revision be made:

Detailed Patient Labeling

IMPORTANT POINTS TO REMEMBER

Before You Start Taking Your Pills:

> "5. IF YOU HAVE VOMITING OR DIARRHEA, ~~for any reason,~~ or IF YOU TAKE SOME MEDICINES, including some antibiotics, your pills may not work as well. Use a back-up method (such as condoms or ~~foam~~ spermicides) until you check with your doctor or clinic."

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (package insert submitted March 21, 2000, patient package insert submitted March 21, 2000). These revisions are terms of the approval of these applications.

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 16-672/S-046, 16-806/S-028." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jennifer Mercier, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

Susan Allen, M.D., M.P.H.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research