CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 16672/S47

APPROVAL LETTER

ORIGINAL

NDA 16-672/S-047
NDA 16-806/S-029

AUG 14 1997

AJ 8/27/97

Wyeth-Ayerst Laboratories
Attention: Ms. Joan E. Barton
Associate Director, Women's Healthcare Products
U.S. Drug Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Barton:

Please refer to your supplemental new drug applications dated April 17, 1997, received April 22, 1997, submitted under section 505(b) and for the Provisions of 21 CFR 314.70 (c) of the Federal Food, Drug, and Cosmetic Act for:

Ovral (norgestrel and ethinyl estradiol) Tablets	(NDA 16-672); and
Ovral-28 (norgestrel and ethinyl estradiol) Tablets	(NDA 16-806).

These supplemental applications provide for changes in the following sections in both the Prescribing Insert and the Patient Package Insert:

Prescribing Insert	Patient Package Insert

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drugs are safe and effective for use as recommended in the final printed labeling submitted on April 17, 1997. Accordingly, these supplemental applications are approved.

However, we request that at the time of the next printing you update the Trussell Table (Table 1 in the Prescribing Insert) to the 1998 version (a copy is enclosed for your reference). We also request that you return the contraceptive sponge to the appropriate tables in the Prescribing Insert and the Patient Package Insert.

Should a letter communicating important information about these drug products (i.e., a "Dear Doctor" letter) be issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20852-9787

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, please contact Christina Kish, Consumer Safety Officer, at (301) 827-4260.

Sincerely,

/S/

8/13/97

Lisa D. Rarick, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE
1998 Trussell Table

cc:
Orig. NDAs (2)
HFD-580
HFD-580/PPrice/HJolson/KSrinivasachar/MRhee
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFI-20/Press Office (with labeling)
HFD-580/CKish/7.28.97/n16672ap.s47
concurrence:LPauls 7.30.97/PPrice 7.31.97/KSrinivasachar 8.4.97/Mrhee 8.4.97/HJolson 8.11.97

SUPPLEMENT APPROVAL (S/AP)
DDR: PLEASE INCLUDE CSO REVIEW WITH LETTER TO THE LISTED CC'S

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 16672/S47

ADMINISTRATIVE DOCUMENTS

ORIGINAL

JUL 11 1997

CSO REVIEW OF FINAL PRINTED LABELING

Wyeth Laboratories

NDA 16-672/S-047 Ovral (norgestrel and ethinyl estradiol) Tablets
NDA 16-806/S-029 Ovral-28 (norgestrel and ethinyl estradiol) Tablets

SUBMISSION DATE: April 17, 1997

MATERIAL REVIEWED:
Physician Package Insert (PI)
Detailed Patient Package Insert (PPI)
Brief Summary Patient Package Insert

BACKGROUND:
This submission has been submitted as a SPECIAL SUPPLEMENT - CHANGES BEING EFFECTED (CBE) in response to our supplement request letter dated December 11, 1996, (see attached). The sponsor states that the changes are strictly those requested, however during the review of this CBE, it was noted that the sponsor has also taken this opportunity to update their label to reflect more precisely the Labeling Guidance Text for Combination Oral Contraceptives. The specific changes are outlined below:

REVIEW AND COMMENT:

RECOMMENDATION

Because all of these changes were either requested in our letter dated December 11, 1996, or are taken from our labeling guidance document the supplements should be approved. However, it has been the policy of this Division to request sponsors to return the vaginal sponge to the contraceptive tables in the Patient Package Insert because it has not been withdrawn, and may eventually return to the market.

The sponsor should also update the Trussell Table in the Physician Information section. These two changes can be made at the next printing without compromising the proper labeling of this product.

The reviewing chemist should be appraised of the additional storage statement in the DOSAGE AND ADMINISTRATION section.

/S/

Christina Kish, CSO 7/11/97

cc:
Org. NDA (2)
HFD-580 (2)
HFD-580/PPrice/HJolson/LRarick
HFD-580/KSrinivasachar
HFD-580/CKish/6.4.97/n16672rv.s47
concurrence:LPauls 6.5.97/PPrice 6.11.97/KSrinivasachar 6.12.97/HJolson 7.10.97

CSO LABELING REVIEW

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 16672/S47

CORRESPONDENCE

ORIGINAL

WYETH-AYERST RESEARCH

P.O. BOX 8299, PHILADELPHIA, PA 19101-8299 • (610) 902-3710
FAX: (610)964-5973

Division of American Home Products Corporation

U.S. REGULATORY AFFAIRS

NDA NO. 16-806 REF. NO. 039
NDA SUPPL FOR SLR 55

NDA No.16-672
NDA No.16-806

8/8/97

April 17, 1997

Lisa Rarick, M.D., Director
Division of Reproductive and Urologic Drug Products
Room 17B-20
Food and Drug Administration (HFD-580)
5600 Fishers Lane
Rockville, Maryland 20857

NA 4/22/97

CENTER FOR DRUG
RECD
APR 22 1997
HFD-580
EVALUATION AND

"SPECIAL SUPPLEMENT--Changes Being Effected"

Dear Dr. Rarick:

Reference is made to our approved New Drug Applications No. 16-672 and No. 16-806 for Ovral and Ovral-28, norgestrel and ethinyl estradiol Tablets, respectively.

Further reference is made to the Agency's correspondence of December 11, 1996 requesting that changes be made to the labeling for these products.

The purpose of this "Special Supplement--Changes Being Effected" is to provide final printed labeling incorporating these changes for Ovral and Ovral-28 Tablets as requested by the Agency. Revisions have not been made to the labeling for Ovral-28 (Femenal) and Ferrous Fumarate Tablets, NDA No. 16-786, because this product is not currently being marketed. Consequently, the labeling for Ovral and Ovral-28 do not reference Ovral 28 (Femenal) and Ferrous Fumarate in the revised text. However, should this product be re-introduced to the market, revised labeling will be submitted prior to the product's re-introduction.

In support of this "Special Supplement--Changes Being Effected" provided herewith are 16 copies of final printed labeling for both the physician and patient package inserts. One copy of each is highlighted for the reviewer's convenience showing the changes being made.

The changes are as follows:

We trust that you will find this labeling satisfactory and that this supplement may be approved at your earliest convenience. Should you have any questions concerning this information, please call the undersigned at (610) 902-3772 or Ms. Janice Barry at (610) 902-3784.

Sincerely yours,

WYETH-AYERST LABORATORIES

Joan E. Barton

Joan E. Barton, Associate Director
Women's Healthcare Products
U. S. Drug Regulatory Affairs

jkb/fb/rarick
encl