

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-490

APPROVAL LETTER(S)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-490

Warner Chilcott, Inc.
Attention: Mr. Alvin Howard
Vice President, Regulatory Affairs
Rockaway 80 Corporate Center
100 Enterprise Drive, Suite 280
Rockaway, New Jersey 07866

Dear Mr. Howard:

Please refer to your new drug application (NDA) dated March 29, 2002, received April 2, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ovcon[®] 35 (norethindrone and ethinyl estradiol tablets, chewable) 0.4 mg and 0.035 mg.

We acknowledge receipt of your submissions dated February 6, May 13, June 30, August 1, August 20, September 29, September 30, October 17, and November 14, 2003.

The May 13, 2003 submission constituted a complete response to our January 31, 2003 action letter.

This new drug application provides for the use of Ovcon[®] 35 (norethindrone and ethinyl estradiol tablets, chewable) 0.4 mg and 0.035 mg for oral contraception.

We completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package inserts) and submitted labeling (immediate container and carton labels submitted October 17, 2003). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-490.**" Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to

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the Division of Urologic and Reproductive Drug Products and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
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 Anderson, N.P., Regulatory Project Manager at (301) 827-4259.

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

Enclosure

**CENTER FOR DRUG EVALUATION AND
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Attention: Mr. Alvin Howard
Vice President, Regulatory Affairs
Rockaway 80 Corporate Center
100 Enterprise Drive, Suite 280
Rockaway, New Jersey 07866

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Please refer to your new drug application (NDA) dated March 29, 2002 received April 2, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Oycon[®] 35 (norethindrone and ethinyl estradiol tablets, chewable).

We have completed our review of this application as submitted with the draft labeling and it is approvable. Before the application may be approved, it will be necessary for you to address the following issues:

1. During a recent inspection of the Bristol-Myers Squibb manufacturing facility in Mayaguez, Puerto Rico, our field investigator conveyed deficiencies to the facility's representative. Satisfactory resolution to these deficiencies is required before this application may be approved.
2. Based on the available stability data, the proposed _____ shelf life for the drug product is not acceptable.
3. _____ Therefore, we recommend that you:
 - a) tighten the acceptance criterion for total _____ substances to not more than _____ during the shelf life.
 - b) adopt the following _____ assay specification for ethinyl estradiol:
 - _____
 - _____

In addition, you must submit final printed labeling (FPL) for the drug. The labeling should be identical in content to the enclosed labeling (text for the package insert, text for the patient package insert).

Please submit the final printed labeling (FPL) electronically 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.

If additional information relating to the safety or effectiveness of the drug becomes available, revision of the labeling may be required.

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request an informal meeting or telephone conference with the Division of Reproductive and Urologic Drug Products to discuss what steps need to be taken before the application may be approved.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, call Karen Anderson, N.P.- Regulatory Project Manager, at (301)827-4260.

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

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Draft Labeling Page(s) Withheld

**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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