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

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

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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