DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-490/S-005

Warner Chilcott Company, Inc.
Attention: Ileana Brown
Director, Regulatory Affairs
100 Enterprise Drive
Rockaway, NJ 07866

Dear Ms. Brown:

Please refer to your supplemental new drug application dated July 28, 2006, received July 31, 2006, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ovcon® 35 (norethindrone/ethinyl estradiol) Chewable Tablet, 0.4 mg NE / 0.035 mg EE.

We also acknowledge receipt of your submission dated October 30, 2006

This "Changes Being Effected" supplemental new drug application provides for substituting seven green inert tablets ("reminder pill") found in the drug product with seven inert brown placebo tablets each containing 75 mg of ferrous fumarate.

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the content of labeling submitted on October 30, 2006.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Susan Jenney, Regulatory Health Project Manager, at (301) 796-0062.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
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/

Hasmukh Patel

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