



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-576/S-051

Warner Chilcott
Attention: Geoffrey Millington
Director, Regulatory Affairs
100 Enterprise Drive, Suite 280
Rockaway, NJ 07866

Dear Mr. Millington:

Please refer to your supplemental new drug application dated January 18, 2008, received January 22, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OVCON® 50 (norethindrone/ethinyl estradiol) Tablets.

This "Changes Being Effected" supplemental new drug application provides for the removal of the term "week" from the blister card of product packaging and from the patient portion of the Package Insert.

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

Within 14 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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 Jennifer Mercier, Chief, Project Management Staff, at (301) 796-0957.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Director
Division of Reproductive and Urologic Products
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/

Scott Monroe
7/22/2008 11:15:06 AM