DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-065/S-012

Warner Chilcott Company, Inc.
Attention: Alvin Howard
Rockaway 80 Corporate Center
100 Enterprise Drive, Suite 280
Rockaway, NJ 07866

Dear Mr. Howard:

Please refer to your supplemental new drug application dated March 12, 2004, received March 15, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for femhrt® 0.5 mg/2.5 mcg (norethindrone acetate/ethinyl estradiol tablets).

We acknowledge receipt of your submissions dated March 22 and 29, September 2 and 16, November 18, December 7 and 15 (2), 2004; January 4 and 6, 2005.

This supplemental new drug application provides for the use of femhrt® 0.5 mg/2.5 mcg (norethindrone acetate/ethinyl estradiol tablets) in women with an intact uterus for the:

1. Treatment of moderate to severe vasomotor symptoms associated with the menopause.
2. Prevention of postmenopausal osteoporosis.

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

We continue to be extremely concerned that your product's tradename is misleading for two reasons. The first, the name implies that it is a medication for heart disease (or prevention) in women. Secondly, the name implies it is replacement therapy for women, much as thyroid hormone is for patients who are hypothyroid. In fact, estradiol is approved for treatment of symptoms of menopause and for prevention of osteoporosis, not physiologic replacement of estrogens.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert and patient package insert) and the immediate container and carton labels submitted January 4, 2005. 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 the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-065/S-012." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

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 this division and two copies of both the promotional materials and the package insert 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 Kassandra Sherrod, R.Ph., 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
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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