**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-367/S-009

Warner Chilcott
Attention: Deepa B. Desai
Sr. Manager, Regulatory Affairs
100 Enterprise Drive
Rockaway, NJ 07866

Dear Ms. Desai:

Please refer to your supplemental new drug application dated April 15, 2008, received April 16, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Femring® (estradiol acetate vaginal ring).

We also acknowledge receipt of your submission dated April 17, 2009.

This "Changes Being Effected" supplemental new drug application provides for revisions to the:

(1) **ADVERSE REACTIONS** section, creating a **Postmarketing Experience** subsection of the Package Insert to include cases of:
   (a) toxic shock syndrome
   (b) ring adhesion to the vaginal wall making ring removal difficult
   (c) bowel obstruction

(2) "**What are the possible side effects of vaginal rings?**" and "**What can I do to lower my chances of getting a serious side effect with Femring**?" sections of the Patient Package Insert

(3) Package Insert and Patient Package Insert to conform with current estrogen class labeling

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text which includes the minor editorial revisions discussed during our teleconference on May 14, 2009.

As soon as possible, but no later than 14 days from the date of this letter, please submit the 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 to the enclosed, agreed-upon labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 21-367/S-009**."

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 George Lyght, R.Ph., Sr. Regulatory Health Project Manager, at (301) 796-0948.

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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Scott Monroe

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