DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-367/S-005

Warner Chilcott
Attention: Ileana Brown
Director, Regulatory Affairs
Rockaway 80 Corporation Center
100 Enterprise Drive, Suite 280
Rockaway, NJ 07866

Dear Ms Brown:

Please refer to your supplemental new drug application dated March 18, 2005, received March 21, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Femring® (estradiol acetate vaginal ring).

This supplemental new drug application provides for a change to update the labeling in accordance with the Agency's draft Guidance for Industry entitled "Labeling Guidance for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms - Prescribing Information for Health Care Providers and Patient Labeling" to reflect discontinuation of the estrogen alone arm of the Women's Health Initiative Memory Study (WHIMS).

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

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 21-367/S-005. Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
FDA
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 George Lyght, R.Ph., Regulatory Health Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Division Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Approved PI

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

/s/

Daniel A. Shames
8/16/2005 12:38:56 PM