DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-472/S-007

Pharmacia & Upjohn Company
Attention: Clara Arrocain, Associate Director
235 East 42nd Street
New York, NY 10010

Dear Ms. Arrocain:

Please refer to your supplemental new drug application dated April 5, 2007, received April 6, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ESTRING® (estradiol vaginal ring).

We also refer to your submissions dated October 11, 2007, January 11, and February 15, 2008.

Your submission of February 15, 2008 constituted a complete response to our October 4, 2007, action letter.

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

(1) ADVERSE REACTIONS section, creating a Post-Marketing 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 ESTRING?" and "What can I do to lower my chances of getting a serious side effect with ESTRING?" 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 labeling text.

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

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

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