DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-187/S-018

Organon USA, Inc.
Attention: Giselle Rose
Director, Regulatory Affairs
56 Livingston Avenue
Roseland, NJ 07068

Dear Ms. Rose:

Please refer to your supplemental new drug application dated November 1, 2007, received November 2, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NuvaRing® (etonogestrel/ethinyl estradiol vaginal ring).

We acknowledge receipt of your submission dated February 26, 2008.

This "Changes Being Effected" supplemental new drug application provides for changes to the Patient Information section of labeling relating to the insertion and removal of NuvaRing, particularly regarding inability to locate the product or to remove the product from the vagina.

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

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(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed 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 21-187/S018."

The final printed labeling (FPL) must be identical to the enclosed labeling.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Charlene Williamson, Regulatory Project Manager, at (301) 796-1025.

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

4/29/2008 05:34:28 PM