DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021187/S-025

SUPPLEMENT APPROVAL

Organon USA, Inc.
Attention: Ripal Shah, Pharm.D.
Regulatory Liaison, Worldwide Regulatory Affairs
P.O. Box 2000, RY33-208
Rahway, NJ 07065-0900

Dear Dr. Shah:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 13, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NuvaRing (etonogestrel/ethinyl estradiol vaginal ring).

We acknowledge receipt of your amendment dated October 24, 2014.

This "Changes Being Effected" supplemental new drug application proposes to update the Patient Package Insert, Instructions for Use Leaflet, to be in alignment with the Package Insert. Specifically, under the section entitled, "**What should I do if my NuvaRing comes out of my vagina?" T**he following revision is proposed (underlined for inserted text and strikethrough for deleted text):

- If the expelled NuvaRing has been out of your vagina for more than 3 continuous hours: ~~insert a new NuvaRing as soon as you remember (See Step 1 thru Step 4).~~
  - **During Weeks 1 and** 2 ~~after you have inserted your new NuvaRing~~**,** you may not be protected from pregnancy. Reinsert the ring as soon as you remember **(See Steps 1 through 4)**. ~~You should~~ Use another birth control method, such as male condoms with spermicide, until the ring has been in place for 7 days in a row.
  - ~~At the end of~~**During Week 3,** do not reinsert the NuvaRing that has been out of your vagina; but ~~you should remove the NuvaRing and~~ throw it away in your household trash away from children and pets~~.~~ ~~and~~ Use another birth control method, such as male condoms with spermicide, until the new NuvaRing has been used for 7 days in a row, following one of the two options below:

- **Option 1.** Insert a new ring right away to start your next 21 Day NuvaRing use cycle. You may not have your regular period but you may have spotting or vaginal bleeding.
- **Option 2.** Insert a new ring no later than 7 days from the time the previous ring was removed or expelled. During this time, you may have your period.

Note: You should only choose to do option 2 if you used NuvaRing for 7 days in a row, prior to the day that your previous NuvaRing was accidently removed or expelled.

~~With either option 1 or 2, you should use another birth control method such as male condoms with spermicides until the new NuvaRing has been used for 7 days in a row.~~

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below.

- Option 2. Insert a new ring no later than 7 days from the time the previous ring was removed or expelled. During this time, you may have your period.

There was a comma in your submission after the word "days" in the above paragraph that has been subsequently removed.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the Instructions for Use leaflet, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf."

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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

Sincerely,

{See appended electronic signature page}

Audrey Gassman, M.D.
Deputy Director
Division of Bone, Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

AUDREY L GASSMAN
10/31/2014