DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-187/S-008

Organon Inc.
Attention: Edwina L. Muir
Group Director, Regulatory Affairs
375 Mt. Pleasant Avenue
West Orange, New Jersey 07052

Dear Ms. Muir:

Please refer to your supplemental new drug application dated November 11, 2003, received November 12, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NuvaRing® (etonogestrel/ethinyl estradiol vaginal ring).

We also acknowledge receipt of your correspondence dated November 11, 2003 and February 17, 2004 amending this supplemental application. This supplemental new drug application provides for revisions of labeling components.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling dated November 11, 2003, with the NDC number repositioned, as indicated in your February 17, 2004 amendment.

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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-187/S-008." 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, HF-2
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, please call Charlene Williamson, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

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

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

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