DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-071/S-017

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

Dear Ms. Rose:

Please refer to your supplemental new drug application dated March 31, 2006, received April 3**,** 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Desogen® (desogestrel/ethinyl estradiol) Tablets.

We also acknowledge receipt of your submission dated October 12 and December 6, 2006. Your December 6, 2006 submission constitutes a complete response to our October 3, 2006 action letter.

This "Changes Being Effected" supplemental new drug application provides for revisions to the physician and patient package inserts to reflect current 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 agreed-upon labeling text.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text/submitted labeling dated December 6, 2006. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert).

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-071/S-017**." Approval of this submission by FDA is not required before the labeling is used.

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 Kassandra Sherrod, R.Ph., Regulatory Project Manager, at (301) 796-0997.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Acting 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

6/7/2007 09:17:42 AM