DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-090/S-003

Organon Inc.
Attention: Giselle Rose
Director, Regulatory Affairs
375 Mt. Pleasant Avenue
West Orange, NJ 07052

Dear Ms. Rose:

Please refer to your supplemental new drug application dated November 5, 2003, received November 6, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cyclessa® (desogestrel/ethinyl estradiol) Tablets.

This supplemental new drug application provides for labeling changes requested in an approvable letter dated October 1, 2003.

We have completed the review of this supplemental application 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 5, 2003.

If you have any questions, please call Karen Anderson, N.P., 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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