**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-057/S-007

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 December 26, 2007, received December 27, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ganirelix Acetate Injection.

We acknowledge receipt of your submission dated May 28, 2008.

This supplemental new drug application provides for changes to the Package Insert (PI) requested in our June 6, 2007, Supplemental Labeling Request letter.

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 enclosed agreed-upon labeling text.

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

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 Karl Stiller, Regulatory Project Manager, at (301) 796-1993.

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

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

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/s/

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Scott Monroe

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