DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-692/S-020

APPROVAL LETTER

Organon USA Inc.
Attention: Lawrence C. Starke, Ph.D.
Senior Director, Regulatory Affairs
56 Livingston Avenue
Roseland, NJ 07068

Dear Dr. Starke:

Please refer to your supplemental new drug application dated May 31, 2007, received June 4, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pregnyl® (chorionic gonadotropin for injection, USP).

This "Changes Being Effected" supplemental new drug application provides for a new professional sample presentation.

We have completed our review of this supplemental new drug application, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 31, 2007.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call John C. Kim, R.Ph., J.D., Regulatory Health Project Manager, at (301) 796-0932.

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

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

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