



NDA 17-692/S-018

Organon USA Inc.  
Attention: Shrinivas (Cheenu) K. Murti, Ph.D., M.B.A.  
Director, Regulatory Affairs  
56 Livingston Avenue  
Roseland, NJ 07068

Dear Dr. Murti:

Please refer to your supplemental new drug application dated June 29, 2006, received June 30, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pregnyl® (chorionic gonadotropin for Injection, USP).

This supplemental new drug application provides for a revised package insert in Structured Product Labeling (SPL) format and revised container/carton labeling. These revisions to the labeling reflect a change in manufacturing site from Organon USA Inc. to Baxter Pharmaceutical Solutions LLC.

We completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert, immediate container, and carton labels submitted June 29, 2006).

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 17-692/S-018.**" 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 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.  
Acting Director  
Division of Reproductive and Urologic Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

Enclosure: Submitted package insert

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/s/

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Scott Monroe  
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