DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-273/S-003

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 (NDA) dated June 24, 2008, received June 25, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Follistim® AQ (follitropin beta) Injection.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of a professional sample presentation for the (approved) Follistim® AQ strength of 75 IU/0.5 mL.

We completed our review of this supplemental new drug application and it is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Catherine Tran-Zwanetz, Regulatory Health Project Manager, at (301) 796-3877.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

Eric Duffy

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