



NDA 21-211/S-002

Organon, Inc.
Attention: Lawrence C. Starke, Ph.D.
Director, Regulatory Affairs
375 Mount Pleasant Avenue
West Orange, NJ 07052

Dear Dr. Starke:

Please refer to your supplemental new drug application dated October 8, 2004, received October 12, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Follistim[®] AQ Cartridge (follitropin beta injection).

We acknowledge receipt of your submissions dated: January 25, February 2 and 9, 2005.

This supplemental new drug application provides for the following changes:

- Two new strengths of drug product (150 IU and 900 IU per cartridge)
- A change in the immediate container for the drug product for the 300 IU and 600 IU cartridges
- A change in the extractable volume specification for the drug product
- A change in the secondary packaging of the drug product
- For the proposed 150 IU and 900 IU (trade) presentations, three and nine needles will be included in the carton, respectively
- Minor changes to the analytical methods used to analyze the drug product
- Revised labeling reflecting both these new strengths, as well as the extractable volume specification for the 300 IU and 600 IU cartridges

We 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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, immediate container and carton labels). These revisions are terms of the approval of this application.

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 21-211/S-002.**" 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) 827-3003.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug
Products, HFD-580
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Agreed-upon PI, PPI and carton/container labels

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/s/

Daniel A. Shames
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