



NDA 21-684/S-008

EMD Serono, Inc.
Attention: Robert M. Kirsch, RAC
Director, Regulatory Affairs
One Technology Place
Rockland, MA 02370

Dear Mr. Kirsch:

Please refer to your supplemental new drug application dated August 6, 2007, received August 6, 2007, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gonal-f[®] RFF Pen (follitropin alfa) Injection.

This supplemental new drug application provides for an extension of the room temperature storage conditions for the Gonal-f[®] RFF Pen from one month to three months before the first injection.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 6, 2007, for the immediate carton labels.

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

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 Susan Jenney, Regulatory Health Project Manager, at (301) 796-0062.

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/

Hasmukh Patel
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