



NDA 21-765/S-007

**CBE-30 SUPPLEMENT**

EMD Serono, Inc.  
Attention: Paul Lammers, M.D., M.Sc.  
Acting Head, Regulatory Affairs and Quality Assurance, US  
One Technology Place  
Rockland, MA 02370

Dear Dr. Lammers:

Please refer to your supplemental new drug application dated January 5, 2007, received January 8, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gonal-f<sup>®</sup> RFF (follitropin alfa for injection).

This "Changes Being Effectuated in 30 days" supplemental new drug application provides for a change from 27 gauge administration needles to 29 gauge administration needles.

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 enclosed labeling for the package insert submitted on January 5, 2007.

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 21-765/S-007.**" 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 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: Package Insert

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**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
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/s/

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Scott Monroe

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