



NDA 21-765/S-004

CBE-30 SUPPLEMENT

Serono, Inc.
Attention: Pamela Williamson Joyce, RAC
Vice President, Regulatory Affairs and Quality Assurance
One Technology Place
Rockland, MA 02370

Dear Ms. Williamson Joyce:

Please refer to your supplemental new drug application dated June 20, 2005, received, June 21, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gonal-f[®] RFF (follitropin alfa for injection).

This "Changes Being Effectuated in 30 days" supplemental new drug application provides for changes to the closure system of the pre-filled reconstitution syringe containing Sterile Water for Injection, USP supplied with Gonal-f[®] RFF.

We completed our review of this application, and it is approved.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted June 20, 2005).

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-004.**" 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 Kim, R.Ph., J.D., Regulatory Health Project Manager, at (301) 796-0932.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D., F.A.C.S.
Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

**This is a representation of an electronic record that was signed electronically and
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/s/

Daniel A. Shames
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