



NDA 21-684/S-007

APPROVAL LETTER

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 June 18, 2007, received June 18, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gonal-f[®] RFF Pen (follitropin alfa injection).

We acknowledge receipt of your submission dated December 12, 2007, and your email correspondence on December 17, 2007.

This "Changes Being Effected in 30 days" supplemental new drug application provides for modifications to the pen injector device for Gonal-f[®] RFF Pen resulting in changes to the labeling.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed, agreed-upon labeling (text for the package insert and patient package insert in PLR format). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 21-684/S-007.**"

Submit final printed labeling for the enclosed package insert and patient package insert submitted on December 12, 2007, and container labels that were agreed upon on December 17, 2007, as soon as they are available, but no more than 30 days after they are printed. Submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. For administrative purposes, designate this submission "**Final Printed Labeling for approved supplement NDA 21-684/S-007.**" Approval of this submission by FDA is not required before the labeling is used.

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

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
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 John C. Kim, R.Ph., J.D., Regulatory Health Project Manager, at (301) 796-0932.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Agreed-upon labeling for PI and PPI

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

/s/

Scott Monroe
12/18/2007 06:43:32 PM