NDA 20-378/S-006

Serono Laboratories, Inc.
Attention: Thomas A. Lang
Senior Vice President, Regulatory Affairs
100 Longwater Circle
Norwell, MA 02061

Dear Mr. Lang:

Please refer to your supplemental new drug application dated July 26, 1999, received July 27, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gonal-F® (follitropin alfa for injection).

We acknowledge receipt of your submissions dated August 30, September 1 and November 19, 1999, April 20, May 11 (facsimile), 15, 16 (2) (facsimile) 17, 18 and 23, 2000.

This supplemental new drug application provides for the use of Gonal-F® (follitropin alfa for injection) for induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon draft labeling text (package insert dated May 23, 2000). Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling (package insert dated May 23, 2000).

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-378/S-006." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Eufrecina DeGuia, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

Susan Allen, M.D., M.P.H.
Acting Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

.