DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-663

Ferring Pharmaceuticals
Attention: James H. Conover, Ph.D.
Executive Director, Regulatory Affairs
400 Rella Boulevard, Suite 300
Suffern, NY 10901

Dear Dr. Conover:

Please refer to your new drug application (NDA) dated December 19, 2003, received December 29, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Menopur® (menotropins for injection, USP).

We acknowledge receipt of your submissions dated January 13, 23, and 27, February 12(3), 13, 18(2), 20, and 26, March 4, April 8, 27, and 29, May 10, June 10(2), July 2(2), 19, and 29, August 3, 5(2), 10, 13, and 17, September 1, 2, 10, 16, and 23, October 4, 22, 25(2), 2004.

This new drug application provides for the use of Menopur® (menotropins for injection, USP) by subcutaneous injection for the indication of the development of multiple follicules and pregnancy in patients participating in Assisted Reproductive Technologies.

We completed our review of this application, as amended. 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 (text for the package insert) and the carton and container labeling submitted May 10, 2004. Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-663**." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 Martin Kaufman, D.P.M., M.B.A., Regulatory Health Project Manager, at (301) 827-4234.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products (HFD-580)
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 this page is the manifestation of the electronic signature.

/s/

Daniel A. Shames

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