DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-663/S-001
NDA 21-663/S-002

Ferring Pharmaceuticals, Inc.
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 supplemental new drug applications dated: December 16, 2004, received December 16, 2004, for S-001; and March 11, 2005, received March 14, 2005, for S-002. These were 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 August 29 and September 16, 2005.

Your submission of September 16, 2005, constituted a complete response to our June 16 and September 14, 2005, action letters for S-001 and S-002, respectively.

S-001 supplemental new drug application provides for the following:

- Final Printed Label for the approved container and carton label.
- New patient package insert.

S-002 "Changes Being Effected in 30 days" supplemental new drug application provides for the following:

- The copackaging of the approved drug product with needle free vial adapters, Q-Cap™.
- New outer carton label.
- Addition of the statement, "NDC 55566-7501-2: Box of 5 vials + 5 vials diluent + 5 Q-Caps™ vial adapters," under the **HOW SUPPLIED** section of the package insert.
- Revised patient package insert containing directions on how to use the needle free adapter.

We have completed our review of these applications; and as amended, these applications are 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 patient package insert) and submitted labeling (package insert submitted March 11, 2005, and revised outer carton label submitted August 29, 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 these submissions "**FPL for approved supplement NDA 21-663/S-001, S-002**." Approval of these submissions 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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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}

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: Agreed-upon PPI

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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