CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number:NDA 21047

APPROVAL LETTER

NDA 21-047 August 27, 1999

Ferring Pharmaceuticals, Inc.
Attention: Ronald V. Nardi, Ph.D.
President, Regulatory & Scientific Affairs
120 White Plains Road, Suite 400
Tarrytown, NY 10591

Dear Dr. Nardi:

Please refer to your new drug application (NDA) dated October 27, 1998, received October 28, 1998, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Repronex (menotropins for injection, USP) 75 or 150 IU.

We acknowledge receipt of your submissions dated March 24, May 11, June 17, 18, July 12, 22 (3), August 3, 6, 9, 12, 13, 18, 19, 23 and 26, 1999.

This new drug application provides for the use of Repronex (menotropins for injection, USP) 75 or 150 IU, in conjunction with hCG for multiple follicular development (controlled ovarian stimulation) and ovulation induction in patients who have previously received pituitary suppression.

We have completed the review of this 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 labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling [package insert submitted August 26, 1999, immediate container and carton labels submitted August 12 (75 IU) and August 19 (150 IU), 1999]. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-047." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this application at this time.

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:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 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, contact Diane Moore, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

/S/ 8/27/98

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