NDA 21-149

Serono Laboratories
Attention: Pamela Williamson-Joyce
Vice President, Regulatory Affairs
100 Longwater Circle
Norwell, MA 02061

APPROVAL LETTER

Dear Ms. Williamson-Joyce:

Please refer to your new drug application (NDA) dated November 23, 1999, received November 24, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ovidrel® (choriogonadotropin alfa for injection), 250 mcg.

We acknowledge receipt of your submissions dated January 7 (facsimile), 13, and 31, February 16, April 7, June 16 (3), 26, 27 and 28, July 5, 13, 20 and 24 (facsimile), August 2 (2 - facsimiles), 3, 4 (facsimile), 7, 9 (facsimile), 14, 14 (facsimile), 16 (facsimile), 17 (facsimile), 18 (facsimile), 28, 28 (facsimile), 28, 29 (2), 31, 31 (facsimile), and September 5 (facsimile), 6, 11, 12, 13, 15 (facsimile) and 20, 2000.

We also acknowledge receipt of your submission dated September 30, 1999 which provided a CMC (Chemistry, Manufacturing and Controls) preview of the planned NDA as requested by Dr. Duu Gong Wu, Chemistry Team Leader for the Division of Metabolic and Endocrine Drug Products.

This new drug application provides for the use of Ovidrel® (choriogonadotropin alfa for injection) 250 mcg for induction of final follicular maturation and early luteinization in infertile women who have undergone pituitary desensitization and who have been appropriately pretreated with follicle stimulating hormones as part of an Assisted Reproductive Technology (ART) program. Ovidrel® (choriogonadotropin alfa for injection) is also indicated for the induction of ovulation (OI) and pregnancy in anovulatory infertile patients in whom the cause of infertility is functional and not due to primary ovarian failure.

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 September 20, 2000 and the carton and container label submitted September 12, 2000). 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 paper 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. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 21-149." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not

to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.
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 action on this application.

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-42
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, please call Eufrecina DeGuia, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

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