

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**22-057**

**APPROVAL LETTER**



NDA 22-057

**NDA APPROVAL**

Ferring Pharmaceuticals, Inc.  
Attention: James H. Conover, Ph.D.  
Executive Director, Regulatory Affairs  
4 Gatehall Drive, 3<sup>rd</sup> Floor  
Parsippany, NJ 07054

Dear Dr. Conover:

Please refer to your new drug application (NDA) dated August 21, 2006, received August 21, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Endometrin<sup>®</sup> (progesterone) Vaginal Insert, 100 mg.

We acknowledge receipt of your submissions dated October 4, December 22, 2006; January 26, March 1, 23, April 25, May 9, 18, 23, 24, and June 8, 20, 2007.

This new drug application provides for the use of Endometrin<sup>®</sup> (progesterone) Vaginal Insert to support embryo implantation and early pregnancy by supplementation of corpus luteal function as part of an Assisted Reproductive Technology (ART) treatment program for infertile women.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

#### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed, agreed-upon labeling (text for the package insert and patient package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 22-057."

#### **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and container labels that were agreed upon on June 15, 2007, as soon as they are available, but no more than 30 days after they are printed. Submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22-057.**" Approval of this submission by FDA is not required before the labeling is used.

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.

**PEDIATRIC RESEARCH EQUITY ACT (PREA)**

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. We are waiving the pediatric study requirement for this application.

**PROMOTIONAL MATERIALS**

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 the Division of Reproductive and Urologic Products and two copies of both the promotional materials and the approved labeling directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

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}*

Scott Monroe, M.D.  
Acting Director  
Division of Reproductive and Urologic Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

Enclosure: Agreed-upon package insert.