DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-057/S-001

APPROVAL LETTER

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

Dear Dr. Conover:

Please refer to your supplemental new drug application dated August 16, 2007, received August 20, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Endometrin® (progesterone) Vaginal Insert.

We acknowledge receipt of your submission dated February 25, 2008.

This supplemental new drug application provides for editorial changes to the Highlights and Full Prescribing Information of the package insert. These changes include the following:

- Minor revision to the DOSAGE AND ADMINISTRATION section
- Addition of missing items (initial FDA approval date, strength of product in Highlights)
- Revision to the storage information
- Updated NDC number
- Update of the revision date
- Corrections of typographical errors

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.

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 in Physician Labeling Rule format). 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/S-001**."

The final printed labeling (FPL) must be identical to the enclosed package insert and patient package insert.

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 22-057/S-001.**" Approval of this submission by FDA is not required before the labeling is used.

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.
Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Agreed-upon labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Scott Monroe

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