DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-057/S-002

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

Dear Dr. Conover:

Please refer to your supplemental new drug application dated December 1, 2008, received December 3, 2008, submitted under the Federal Food, Drug, and Cosmetic Act for ENDOMETRIN® (Progesterone) Vaginal Insert, 100 mg.

This supplemental new drug application provides for the addition of a professional sample package, to include 6 progesterone vaginal tablets, packaged together with 6 disposable applicators, and a Package Insert.

We also refer to your letter dated March 10, 2009, in which you confirm that you will not apply NDC codes on the professional sample box.

We have completed our review of this supplemental new drug application. This supplement is approved, effective on the date of this letter.

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, call Celia Peacock, MPH, RD, Regulatory Project Manager, at (301) 796-4154.

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

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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