DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022201/S-003

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Ferring Pharmaceuticals, Inc.
Attention: Erik Thygesen, M.Sc. Pharm.
Director, Regulatory Affairs
4 Gatehall Drive
Parsippany, NJ 07054

Dear Mr. Thygesen:

Please refer to your Supplemental New Drug Application (sNDA) dated February 21, 2013, received February 21, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Firmagon® (degarelix for injection) Lyophilized Powder for Injection, 80 mg and 120 mg.

We acknowledge receipt of your amendments dated March 15, July 2, and July 12, 2013.

This "Prior Approval" supplemental new drug application provides for the addition of data from the extension study FE200486 CS21A to the Adverse Reactions section of the labeling. This is in response to PMR 1273-1 from the December 24, 2008 AP letter. The data was submitted in the Postmarketing Final Report submitted on June 7, 2012.

We have completed our review of this supplemental 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, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and text for the patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria applies to your application, you are exempt from this requirement.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We have received your submission dated June 7, 2012, containing the final report for the following postmarketing requirement listed in the December 24, 2008, approval letter.

1273-1 To complete the ongoing extension study FE200486 CS21A entitled "An Open-Label, Multi-Center, Extension Study, Evaluating the Long-Term Safety and Tolerability of Degarelix One Month Dosing Regimen in Patients with Prostate Cancer Requiring Androgen Ablation Therapy"

Protocol Submission:	January 2007
Trial Start Date:	March 2007
First Annual Report Submission:	March 2009
Second Annual Report Submission:	March 2010
Third Annual Report Submission:	March 2011
Final Report and Dataset Submission:	June 2012

We have reviewed your submission and conclude that the above requirement fulfilled.

This completes all of your postmarketing requirements acknowledged in our December 24, 2008, letter.

REPORTING REQUIREMENTS

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 Rajesh Venugopal, Regulatory Project Manager, at (301) 796-4730.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, MD
Deputy Division Director
Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

AMNA IBRAHIM
08/16/2013