DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022201/S-009

SUPPLEMENT APPROVAL

Ferring Pharmaceuticals, Inc.
Attention: Erik Thygesen, M.Sc. Pharm.
Director, Regulatory Affairs
100 Interpace Parkway
Parsippany, NJ 07054

Dear Mr. Thygesen:

Please refer to your Supplemental New Drug Application (sNDA) dated August 29, 2014, received August 29, 2014, 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 October 1, 2014, January 28 and February 6, 2015.

This "Prior Approval" supplemental new drug application proposes the following change(s):

1. Revisions to the Warnings and Precautions section of the label that were requested in the Agency's Prior Approval Supplement Request letter dated May 23, 2014.

2. Other minor editorial revisions throughout the package insert.

APPROVAL & LABELING

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 which incorporates the minor editorial revision listed below.

1. In the Recent Major Changes section of Highlights, the subsection number (5.3) was added.

2. The subsection number 17.2 and title "FDA – approved Patient Labeling", was deleted from the Table of Contents section.

3. The subsection number 17.2, was deleted from the Patient Labeling section.

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 apply to your application, you are exempt from this requirement.

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
Acting 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
02/26/2015