DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA21345/S-030

SUPPLEMENT APPROVAL

Glaxo Group Limited d/b/a GlaxoSmithKline
Attention: Linda Rebar
Director, Global Regulatory Affairs
2301 Renaissance Blvd.
P.O. Box 61540
King of Prussia, PA 19406-2772

Dear Ms. Rebar:

Please refer to your Supplemental New Drug Application (sNDA) dated February 20, 2013, received February 20, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Arixtra® (fondaparinux sodium) injection.

We acknowledge receipt of your amendment dated May 16, 2013.

This "Prior Approval" supplemental new drug application proposes the following changes: To revise the Contraindications and Adverse Reactions sections of the Arixtra® (fondaparinux sodium) injection Prescribing Information regarding the occurrence of serious allergic reactions (including angioedema and anaphylactoid/anaphylactic reactions) that have been reported with the use of Arixtra fondaparinux sodium).

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.

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, 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).

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 Janet G. Higgins, Regulatory Project Manager, at (240) 402-0330.

Sincerely,

{See appended electronic signature page}

Robert C. Kane, M.D.
Deputy Director for Safety
Division of Hematology Products
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/

JANET G HIGGINS
09/12/2013

ROBERT C KANE
09/12/2013