**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-345/S-018

GlaxoSmithKline
Attention: Linda Rebar
Director, U.S. Regulatory Affairs
One Franklin Plaza
200 N. 16th St., FP-1005
Philadelphia, PA 19102

Dear Ms. Rebar:

Please refer to your supplemental new drug application dated April 25, 2008, received April 25, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Arixtra® (fondaparinux sodium) Solution for Injection, 2.5mg, 5.0mg, 7.5mg, 10.0mg.

We also acknowledge receipt of your submissions dated October 8, 13 and 17, 2008.

This "Changes Being Effected" supplemental new drug application provides for revisions to the **ADVERSE REACTIONS** and **WARNINGS** sections of the Package Insert.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the 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 labeling (text for the package insert and text for carton container labeling and/or submitted labeling (package insert submitted October 17, 2008 and carton container labeling submitted April 25, 2008). 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 21-345/S-018**."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Medical Imaging and Hematology Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Diane Leaman, Safety Regulatory Project Manager, at (301) 796-1424.

Sincerely,

*{See appended electronic signature page}*

Rafel Dwaine Rives, MD
Division Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure; package insert and carton labeling

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

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/s/

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Rafel Rieves

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