DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-345/S-019 **APPROVAL LETTER**

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 February 25, 2009, received February 25, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Arixtra® (fondaparinux sodium) Injection.

We acknowledge receipt of your submission dated August 12, 2009.

Your submission of February 25, 2009, constituted a complete response to our January 9, 2009, action letter.

This supplemental new drug application provides for: (1) the addition of pharmacokinetic data (and corresponding dosing recommendations) for patients with liver impairment and (2) conversion of the package insert to the format prescribed by the Physician Labeling rule (PLR).

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 12, 2009.

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 submitted labeling (package insert submitted August 12, 2009). 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-019."**

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 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
Beltsville, MD 20705-1266

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 questions, contact Marcus Cato, Regulatory Project Manager, at (301) 796-3903.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Package Insert

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

/s/

RAFEL D RIEVES
08/14/2009