DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-287/S-035

Pharmacia & Upjohn
Attention: Robert B. Clark
Vice President, U.S. Regulatory Strategy
Agent for Pharmacia & Upjohn Company
235 East 42nd Street
New York, NY 10017

Dear Mr. Clark:

We acknowledge receipt on March 1, 2007 of your February 28, 2007 resubmission to your supplemental new drug application for Fragmin® (dalteparin sodium injection).

Please refer to your supplemental new drug application dated March 16, 2004, received March 17, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fragmin® (dalteparin sodium injection).

We acknowledge receipt of your submissions dated February 28, April 26, 27 (2) and April 30, 2007 (4).

Your submission of February 28, 2007 constituted a complete response to our March 14, 2006 action letter.

This supplemental new drug application provides for the use of Fragmin® (dalteparin sodium injection) for extended treatment of symptomatic venous thromboembolism (VTE) [proximal deep vein thrombosis (DVT) and/or pulmonary embolism (PE)] to reduce the recurrence of VTE in patients with cancer.

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 and with the minor editorial revision listed below.

Include the revisions to the blister labeling and carton container labeling in the respective colors at your next printing.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the package insert, immediate container and carton labels) and submitted labeling (package insert submitted April 30, 2007, immediate container labels submitted April 27, 2007, blister labeling submitted April 30, 2007, and carton labels submitted April 30, 2007).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-287/S-035**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies until May 1, 2010.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. These commitments are listed below.

We remind you of your postmarketing study commitments in your submission dated April 27, 2007. These commitments are listed below.

1. To evaluate efficacy and safety of dalteparin in pediatric cancer patients. Studies using dalteparin for venous thromboembolism (VTE) treatment in all age ranges of the pediatric population should be performed.

Protocol Submission:	Within 6 months of the date of this letter.
Study Start:	Within 18 months of the date of this letter.
Final Report Submission:	Within 36 months of the date of this letter.

   Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment(s) must be clearly designated "**Required Pediatric Study Commitments.**"

2. To conduct a study to evaluate the safety and efficacy of dalteparin in cancer patients (both metastatic and non-metastatic) receiving extended treatment with dalteparin (>6 months) for prevention of new or recurrent symptomatic venous thromboembolism (VTEs), including subjects with renal impairment (including severe renal impairment).

Protocol Submission:	Within 6 months of the date of this letter.
Study Start:	Within 18 months of the date of this letter.
Final Report Submission:	Within 60 months of the date of this letter.

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

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
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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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

Sincerely,

{See appended electronic signature page}

Rafel Dwaine Rieves, M.D.
Acting Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure
Fragmin®
dalteparin sodium injection

For *Subcutaneous* Use Only

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

/s/

Rafel Rieves

5/1/2007 04:11:48 PM