DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-287/S-031

Pharmacia & Upjohn
Attention: Gregory A. Brier
Senior Regulatory Manager
7000 Portage Road
Kalamazoo, MI 49001

Dear Mr. Brier:

Please refer to your supplemental new drug application dated January 14, 2003, received January 15, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fragmin (dalteparin sodium injection) 10,000 IU.

We acknowledge receipt of your submission dated June 4, 2003.

This "Changes Being Effected" supplemental new drug application provides for the use of UltraSafe Passive™ needle safety guards in conjunction with the approved Fragmin® (dalteparin sodium injection) 10,000 IU (1.0 mL) graduated pre-filled syringes.

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.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted June 4, 2003, immediate container and carton labels submitted January 14, 2003).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-287/S-031." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
FDA
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 Moore, Regulatory Project Manager, at (301) 827-7476.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal & Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

/s/

Joyce Korvick
6/30/03 05:42:00 PM
for Dr. Robert Justice