DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-287/S-027

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

Dear Mr. Brier:

Please refer to your supplemental new drug application dated January 29, 2002, received January 30, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fragmin® (dalteparin sodium injection) 2500 IU, 5000 IU.

We acknowledge receipt of your submissions dated July 31 and August 27, 2002.

The August 27, 2002 submission constituted a complete response to our July 29, 2002 action letter.

This supplemental new drug application proposes to add the use of the UltraSafe Passive™ needle safety guards in conjunction with the approved Fragmin® (dalteparin sodium injection) 2500 IU (0.2 mL) and 5000 IU (0.2 mL) single-dose pre-filled syringes.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) for the patient package insert submitted on August 27, 2002, immediate container and carton labels (2500 IU per 0.2 mL immediate container sticker labeling, 2500 IU syringe blister labeling and 2500 IU syringe carton labeling submitted February 5, 2002 and 5000 IU immediate container sticker labeling per 0.2 mL, 5000 IU syringe blister labeling and 5000 IU syringe carton labeling dated March 14, 2002). Marketing the products with FPL that is not identical to the approved labeling text may render the products misbranded and unapproved new drugs.

Please submit one market package of the drug product when it is available.

If you have any questions, call Diane Moore, Regulatory Project Manager, at (301) 827-7476.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H..
Deputy 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

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