DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-287/S-029

Pharmacia & Upjohn Company
Attention: Anita Piergiovanni
Director, Global Regulatory Affairs
4901 Searle Parkway
Skokie, IL 60077

Dear Ms. Piergiovanni:

Please refer to your supplemental new drug application dated May 17, 2002, received May 20, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fragmin® (dalteparin sodium) Injection, 7500 IU.

This "Changes Being Effected" supplemental new drug application provides for the use of the UltraSafe Passive™ needle safety guards in conjunction with the approved 7500 IU (0.3 mL) single dose pre-filled syringes.

We 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 May 17, 2002.

Please note that the proposed color for the blister labeling for the 7500 IU syringe is acceptable, however, the previously approved color provides a stronger contrast that allows for easier letter and number discrimination and detail than the proposed color.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 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
11/19/02 05:02:26 PM
for Dr. Robert Justice