**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-287/S-011

Pharmacia & Upjohn Company
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 August 28, 1998, received August 25, 1998, 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 September 12, 2002 and January 16, 2003.

Your submission of September 12, 2002, constituted a complete response to our July 19, 2002, action letter.

This supplemental new drug application provides for revisions to the **PRECAUTIONS** section, **Geriatric Use** subsection of the package insert (PI) in response to the Final rule entitled "Specific Requirements on Content and format of labeling for human Prescription Drugs: Addition of 'Geriatric Use' Subsection in the Labeling," published in the August 27, 1997 Federal Register (62 FR 45313-45326).

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 revisions listed below.

Package Insert:

> In the **PRECAUTIONS** section, **Geriatric Use** subsection, in the sixth sentence that begins "(see also **CLINICAL PHARMACOLOGY** . . ." bold the terms "**CLINICAL PHARMACOLOGY**," "**General**," "**Drug Interactions**" and "**PRECAUTIONS**."

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling (package insert submitted January 16, 2003). These revisions are terms of the approval of this application.

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 ten 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-011." 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, HF-2
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

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

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/s/
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Joyce Korvick
2/27/03 03:52:32 PM
for Dr. Robert Justice