



NDA 20-287/S-032

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 February 7, 2003, received February 10, 2003, 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 May 2, June 6 and December 5 and 10 (2 telefacsimilies), 2003.

This supplemental new drug application provides for the use of Fragmin[®] (dalteparin sodium) injection for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in medical patients who are at risk for thromboembolic complications due to severely restricted mobility during acute illness.

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 enclosed labeling (text for the package insert) and submitted labeling (package insert submitted December 10, 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 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-032." Approval of this submission by FDA is not required before the labeling is used.

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 Gastrointestinal and Coagulation Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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

Enclosure

**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
12/10/03 06:35:49 PM
for Dr. Robert Justice