DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-287/S-034

Pharmacia & Upjohn Company
Attention: Robert Clark
Vice President, Regulatory Affairs
235 E. 42nd Street
New York, NY 10017

Dear Mr. Clark:

Please refer to your supplemental new drug application dated September 8, 2003, received September 9, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fragmin® (dalteparin sodium, injection).

We acknowledge receipt of your submission dated March 26, 2004.

Your submission of March 26, 2004, constituted a complete response to our March 9, 2004 action letter.

This "Changes Being Effected" supplemental new drug application provides for revisions to the DOSAGE AND ADMINISTRATION section of the package insert to add instructions to expel the air bubble prior to using the 10,000 IU single-dose graduated prefilled syringe.

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) submitted on March 26, 2004.

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 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 and Coagulation Drug Products (HFD-180)
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
4/21/04 01:19:24 PM
for Dr. Robert Justice