DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-287/S-021, S-022, S-023

Pharmacia & Upjohn Company
Attention: Anita Piergiovanni
4901 Searle Parkway
Skokie, Illinois 60077

Dear Ms. Piergiovanni:

Please refer to your supplemental new drug applications dated September 15, 2000, received September 19, 2000, 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 March 8, March 18, March 19,March 22, and March 29, 2002.

For S-021, your submission of October 5, 2001 constituted a complete response to our September 4, 2001 action letter.

For S-022, your submission of October 18, 2001 constituted a complete response to our September 4, 2001 action letter.

For S-023, your submission of October 18, 2001 constituted a complete response to our September 4, 2001 action letter.

These supplemental new drug applications provide for:

S-021: a 3.8 mL multi-dose vial (25,000 IU/mL) presentation; revised labeling to differentiate vial presentations [9.5 mL (10,000 IU/mL) and 3.8 mL (25,000 IU/mL)]; and revised labeling to reflect current corporate logo and tradedress.

S-22: (1) a 7500 IU/0.75 mL single dose syringe presentation and a 10,000 IU/1.0 mL single dose syringe presentation manufactured at Vetter Pharma-Fertigung; (2) revised labeling to differentiate single dose syringe presentations; and (3) revised labeling to reflect current corporate logo and tradedress.

S-023: (1) a 7500 IU/0.3 mL single dose syringe presentation manufactured at Vetter Pharma-Fertigung; (2) revised labeling to differentiate single dose syringe presentations; and (3) revised labeling to reflect current corporate logo and tradedress.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted March 29, 2002 (Example 2, where the product title is immediately above the black box), immediate container labels (submitted March 29, 2002), and carton labels submitted March 18, 2002).

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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, these submissions should be designated "FPL for approved supplement NDA 20-287/S-021, S-022, S-023." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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

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

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 Alice Kacuba, R.N., MSN, RAC, Regulatory Health Project Manager, at (301) 827-1602.

Sincerely,

{See appended electronic signature page}

Victor F. C. Raczkowski, M.D., M.Sc.
Acting Director
Division of Gastrointestinal and 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
4/4/02 03:11:20 PM
for Victor Raczkowski