DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-164/S-058

Aventis Pharmaceuticals
Attention: Christine Chansky, M.D., J.D.
Director, Regulatory Liaison
Global Drug Regulatory Affairs
200 Crossing Blvd.
Bridgewater, NJ 08807

Dear Dr. Chansky:

Please refer to your supplemental new drug application dated November 14, 2003, received November 17, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lovenox® (enoxaparin sodium, injection).

This supplemental new drug application provides for deletion of the one point ampule from the **DESCRIPTION**, **DOSAGE AND ADMINISTRATION** and **HOW SUPPLIED** sections of the package insert.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the revisions listed below.

1. Incorporate the revisions made in S-048 (submitted August 9, 2002, received August 12, 2002, approved on draft December 18, 2003).

2. Incorporate the revisions made in S-056 (submitted October 10, 2003, received October 14, 2003, approved on draft April 13, 2004.

3. In the **PRECAUTIONS** section, Laboratory Tests subsection, in the first paragraph, fourth sentence that begins, "If during Lovenox Injection therapy . . ." the term "Pharmacodynamics" should be revised to "Pharmacokinetics" so that the sentence reads "If during Lovenox Injection therapy abnormal coagulation parameters or bleeding should occur, anti-factor Xa levels may be used to monitor the anticoagulant effects of Lovenox Injection (see **CLINICAL PHARMACOLOGY: Pharmacokinetics**)."

The final printed labeling (FPL) must be identical, except for the revisions indicated above, to the submitted labeling (package insert submitted November 14, 2003) and must be formatted in accordance with the requirements of 21 CFR 201.66. 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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-164/S-058." 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, 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

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 01:17:54 PM
for Dr. Robert Justice