DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-164/S-051

Aventis Pharmaceuticals, Inc.
Attention: Shaler G. Smith, III, Ph.D.
Global Drug Regulatory Director and Liaison
200 Crossing Boulevard
P.O. Box 6890
Bridgewater, NJ 08807-0890

Dear Dr. Shaler:

Please refer to your supplemental new drug application dated December 19, 2002, received December 20, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lovenox® (enoxaparin sodium injection).

We acknowledge receipt of your submissions dated April 16 and 18, May 9 and June 5, 2003.

This "Changes Being Effected" supplemental new drug application provides for the addition of an automatic safety device to all presentations of Lovenox® pre-filled syringes.

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 minor editorial revisions listed below.

Include the manufacturing information on the Lovenox multiple-dose vial in the **HOW SUPPLIED** section at your next printing of the package insert.

All previous revisions as reflected in the most recently approved labeling, specifically Supplement S-043 approved January 23, 2003, must be included. To facilitate review of your submission, please provide a highlighted or marked-up copy that shows the changes that are being made.

The final printed labeling (FPL) must be identical, and include the minor editorial revision indicated, to the text for the package insert submitted December 19, 2002, carton labels submitted December 19, 2002, immediate container labels for the 30 mg, 80 mg, 100 mg, 120 mg and 150 mg strength prefilled syringes submitted December 19, 2002, and immediate container labeling for the 40 mg and 60 mg strength prefilled syringes submitted June 5, 2003. This revision is 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 20-164/S-051." 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
6/20/03 02:21:13 PM
for Dr. Robert Justice