DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-164/S-063

Aventis Pharmaceuticals, Inc.
Attention: Dhiren N. Shah, Ph.D.
Director, Regulatory CMC
10236 Marion Park Drive
P.O. Box 9720
Kansas City, MO 64134-0720

Dear Dr. Shah:

Please refer to your supplemental new drug application dated October 26, 2004, received October 27, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lovenox® (enoxaparin sodium, injection).

This "Changes Being Effected" supplemental new drug application provides for the following changes: Revised carton and foil blister labeling for the Lovenox® 120 mg and 150 mg pre-filled syringes to be consistent with the labeling on the Lovenox® 120 mg and 150 mg pre-filled syringes.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on October 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 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}

Liang Zhou, Ph.D.
Chemistry Team Leader for the
Division of Gastrointestinal & Coagulation Drug Products
DNDC II, Office of New Drug Chemistry
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/

Liang Zhou

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