DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-164/S-070

Sanofi-Aventis
Attention: Shivani Poirier, Ph.D.
Manager, U.S. Regulatory Affairs Marketed Products
300 Somerset Corporation Boulevard
P.O. Box 6977
Bridgewater, NJ 08807-0977

Dear Dr. Poirier:

Please refer to your supplemental new drug application dated January 18, 2006, received January 19, 2006, 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 September 8, 2006 and January 10, 2007.

Your submission of September 8, 2006 constituted a complete response to our May 26, 2006 action letter.

This supplemental new drug application provides for a change in multiple dose vial labeling supported by chemistry, manufacturing and controls (CMC) information. The proposed change to the label and packaging components is to incorporate the statement "Do not store the multiple dose vials for more than 28 days after the first use" following the storage conditions.

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 the minor editorial revisions listed below and indicated in the enclosed labeling.

1. In the **DESCRIPTION** section, in the sixth paragraph, in the second sentence that begins "The multiple-dose vial contains . . ." remove the trailing zero in the number "1.0" to read "1" and revise the wording so that the sentence reads "The multiple-dose vial contains 15 mg benzyl alcohol per 1 mL as a preservative."

2. In the **CLINICAL PHARMACOLOGY** section, **Pharmacokinetics** subsection, *Hemodialysis* sub-subsection, in the first sentence that begins "In a single study, . . ." delete the trailing zero in the number "0.50" after the word "or" so that the sentence reads "In a single study, elimination rate appeared similar but AUC was two-fold higher than control population, after a single 0.25 or 0.5 mg/kg intravenous dose."

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the package insert, immediate container and carton labels) and/or

submitted labeling (package insert submitted September 8, 2006, immediate container labels submitted January 18, 2006, and carton labels submitted September 8, 2006). These revisions are terms of the approval of this application.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-164/S-070**." 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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Leaman, Regulatory Project Manager, at (301) 796-1424.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch 8, Division of Postmarketing Evaluation
Office of New Drug Quality Assessment
Center of Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Hasmukh Patel

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