



NDA 20-164/S-080

Sanofi-aventis US, LLC
Attention: Virginia Foley
Senior Manager, U.S. Regulatory Affairs Marketed Products
55 Corporate Drive
P.O. Box 5925
Bridgewater, NJ 08807-0977

Dear Ms. Foley:

Please refer to your supplemental new drug application dated January 15, 2008, received January 16, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lovenox[®] (enoxaparin sodium) Injection.

We acknowledge receipt of your submission dated July 14, 2008.

This "Changes Being Effected" supplemental new drug application provides for Revisions to the package insert, **ADVERSE REACTIONS** section, subsection **6.2, Post-Marketing Experience** and Section **4, CONTRAINDICATIONS**.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, and/or submitted labeling (package insert submitted July 14, 2008).

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-080.**" 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
Suite 12B05
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 Mrs. Diane Leaman, Regulatory Project Manager, at (301) 796-1424.

Sincerely,

{See appended electronic signature page}

Rafel Dwaine Rieves, M.D.
Director
Division of Medical Imaging and Hematology
Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure: Package Insert

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

/s/

Libero Marzella
7/16/2008 05:25:58 PM
Signing for Dr. Rieves