

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-138

20-164 S-075

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-138
NDA 20-164/S-075

Sanofi-Aventis U.S. Inc.
Attention: Eddie Li, Ph. D.
11 Great Valley Parkway
Malvern, PA 19355

Dear Dr. Li:

Please refer to your new drug application (NDA) dated November 17, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lovenox (enoxaparin sodium) Injection (NDA 22-138).

We acknowledge receipt of your submissions dated May 9 (two) and 11, 2007.

We also refer to your supplemental new drug application dated December 15, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lovenox (enoxaparin sodium) Injection (NDA 20-164/S-075).

We further acknowledge receipt of your submissions dated March 29, May 9, and May 16, 2007.

These new drug applications provide for the use of Lovenox (enoxaparin sodium) Injection for the treatment of acute ST-segment elevation myocardial infarction (STEMI).

We have completed our review of these applications, as amended. They are 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. Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions "SPL for approved NDA 22-138 and NDA 20-164/S-075."

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application (NDA 22-135).

In addition, submit four copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Medical Imaging and Hematology Products, one copy to the Division of Cardiovascular and Renal Products, and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81). All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA 20-164 for this drug product, not to NDA 22-138. In the future, do not make submissions to NDA 22-138 except for the final printed labeling requested above.

If you have any questions, please call:

Meg Pease-Fye, M.S.
Regulatory Health Project Manager
(301) 796 -1130

or

Diane Leaman
Regulatory Health Project Manager
(301) 796-1424

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

{See appended electronic signature page}

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

Enclosure: agreed upon labeling

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

/s/

Norman Stockbridge
5/16/2007 04:45:48 PM

Rafel Rieves
5/16/2007 05:10:07 PM