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{Part of Complete Approval Document 5202438A} Lovenox Injection (Aventis) 11/27/2000 Supplemental Approval [New Indication - Prevention of Deep Vein Thrombosis in Patients with Acute Illness]: S36 Approval Letter; Approvable Letter; Final Labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-164/S-036

Aventis Pharmaceuticals Products Inc.
C/O Quintiles Inc.
Attention: Ms. Michelle Kliewer
Mail Stio F3-3026
P.O. Box 9708
Kansas City, MO 64123-0708

Dear Ms. Kliewer:

Please refer to your supplemental new drug application dated December 10, 1999, received December 10, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for

We acknowledge receipt of your submissions dated February 24, March 6, April 26, May 1 and 24, July 13, September 15, and October 12, 2000. Your submission of July 13, 2000 constituted a complete response to our June 8, 2000 action letter.

This supplemental new drug application provides for the use of Lovenox® (enoxaparin sodium) Injection for the thromboprophylaxis of deep vein thrombosis, which may lead to pulmonary embolism, in medical patients who are at risk for thromboembolic complications due to severely restricted mobility during acute illness.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please 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. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-164/S-036." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, 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 (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Karen Oliver, Regulatory Project Manager, at (301) 827-7457.

Sincerely,

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Package Insert Text

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-164/S-036

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 20-164/S-036

JUN - 8 2000

Aventis Pharmaceuticals Products Inc.
Attention: Edmond Roland, M.D.
P.O. Box 5096
500 Arcola Road, H-10
Collegeville, PA 19426-5299

Dear Dr. Roland:

Please refer to your supplemental new drug application dated December 10, 1999, received December 10, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lovenox® (enoxparin sodium) Injection.

We acknowledge receipt of your submissions dated February 24, March 6, April 26, and May 1 and 24, 2000.

This supplemental new drug application proposes for the use of Lovenox® Injection for a new indication, stated as follows:

> Lovenox Injection is indicated for the thromboprophylaxis of deep vein thrombosis, which may lead to pulmonary embolism, in medical patients who are at risk for thromboembolic complications due to severely restricted mobility during acute illness.

We have completed the review of this application, as amended, and it is approvable. Before this application may be approved, however, it will be necessary for you to submit final printed labeling (FPL) for the drug. The labeling should be identical in content to the enclosed labeling (text for package insert). In addition, all previous revisions as reflected in the most recently approved labeling 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.

Please submit 20 copies of the final printed labeling ten of which are individually mounted on heavy weight paper or similar material. The submission should include the appropriate number of copies of the package insert from both the Maison-Alfort and the Dagenham printing sites.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

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