



TRANSMITTED BY FACSIMILE

Daisy Chhatwal, Pharm.D. SC3-735A
Senior Regulatory Analyst
US Drug Regulatory Affairs & Compliance
Aventis Pharmaceuticals
300 Somerset Corporate Boulevard
Bridgewater, NJ 08807-2854

RE: NDA # 20-164
Lovenox (enoxaparin sodium) Injection
MACMIS # 10148

Dear Dr. Chhatwal:

This letter concerns Aventis Pharmaceuticals' (Aventis) dissemination of promotional materials for Lovenox. As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed promotional materials for Lovenox submitted by Aventis under cover of Forms FDA 2253 dated June 6 and June 8, 2001. The materials included a convention panel (item number 21092601/011711E1) and a sales aid (item number 50058941/21077901/011472E1). These materials promote Lovenox in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Specifically, we have the following objections:

The convention panel and sales aid lack fair balance because they provide information relating to the effectiveness of Lovenox but fail to provide any information regarding side effects and contraindications (including warnings and precautions). For example, each provides the seven indications of Lovenox, but fails to include important risk information such as the boxed warning regarding spinal/epidural hematomas.

Neither the established name nor the dosage form appears in the header of the sales aid. Both are required to appear prominently.

You should immediately stop using these and all other promotional materials with the same or similar presentations. You should respond to this letter on or before July 10, 2001. Your response should include your intent to comply with this request and a list of all similarly violative materials that will be discontinued as a result of this letter. It should be directed to me by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-42, Rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

In all future correspondence regarding this particular matter, please refer to MACMIS ID # 10148 in addition to the NDA number. DDMAC reminds you that only written communications are considered official.

Sincerely,

{See appended electronic signature page}

Margaret M. Kober, R.Ph.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications

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

/s/

Margaret Kober

6/25/01 11:31:40 AM

LOVENOX[®] (enoxaparin sodium) INJECTION... THE ONLY LMWH WITH SEVEN INDICATIONS!

PROOF OF PERFORMANCE IN MORE INDICATIONS THAN ANY OTHER LMWH

Prophylaxis of DVT, which may lead to PE

In medical patients who are at risk for thromboembolic complications due to severely* restricted mobility during acute illness

In patients undergoing hip-replacement surgery

In patients undergoing extended prophylaxis in hip replacement

In patients undergoing knee-replacement surgery

In patients undergoing abdominal surgery who are at risk for thromboembolic complications

Inpatient treatment of acute DVT with or without PE and outpatient treatment of DVT without PE, when administered in conjunction with warfarin sodium therapy

Prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction, when concurrently administered with aspirin



MORE THAN 82 MILLION PATIENTS TREATED WORLDWIDE¹

* Defined as walking distance of <10 meters for ≤ 3 days.
Reference: 1. Data on file, Aventis Pharmaceuticals.

Please see full prescribing information, including boxed WARNING, available at this booth.
Visit our website, www.LOVENOX.com, for professional and patient information.

Aventis Pharmaceuticals
Bridgewater, NJ 08807

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2007/07/15

LOVENOX . . .

More indications than any other low-molecular-weight heparin (LMWH)*

LOVENOX® (enoxaparin sodium) Injection	Innohep® (enoxaparin sodium) Injection	Innohep® (enoxaparin sodium) Injection
✓	✓	
✓	✓	
✓	✓	
✓		
✓		✓ ‡
✓		‡
✓	✓	

*From LOVENOX® and Innohep® package inserts and Physicians' Desk Reference, 54th ed. Montvale, NJ: Medical Economics Co; 2000;2448-2451.

†Defined as walking distance of <10 meters for ≤3 days.

‡Innohep is indicated for the treatment of acute symptomatic deep vein thrombosis with or without pulmonary embolism when administered in conjunction with warfarin sodium. The safety and effectiveness of Innohep were established in hospitalized patients.

Fragmin® is a registered trademark of Pharmacia Corporation. Innohep® is a registered trademark of Leo Pharmaceutical Products Ltd.

Please see enclosed full prescribing information, including boxed warning.

SPECIMEN

