



NDA 20-164/S-053

Aventis Pharmaceuticals Products Inc.
Attention: Dhiren N. Shah, Ph.D.
Director, Regulatory CMC
10236 Marion Park Drive
P.O. Box 9720
Kansas City, MO 64134-0720

Dear Dr. Shah:

Please refer to your supplemental new drug application dated April 11, 2003, received April 14, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lovenox[®] (enoxaparin sodium, injection) 10 mg/0.1 mL.

We acknowledge receipt of your submissions dated April 17, 2003, and April 19 and October 15, 2004. Your submission of April 19, 2004, constituted a complete response to our October 17, 2003, action letter.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an additional manufacturing site for the multi-dose vial presentation (300 mg per mL) of Lovenox Injection. The additional manufacturing site will be Aventis Pharma, Frankfurt, Germany. The supplement further proposes to revise the labeling in the **CONTRAINDICATION** section of the package insert (PI) regarding the contraindication for benzyl alcohol and to revise the "Manufactured By" address in the **HOW SUPPLIED** section. Lastly, the supplement provides for the deletion of the "do not freeze" statement on the 300 mg per mL multi-dose vial carton.

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 revisions listed below.

Please include all revisions made to the package insert in Supplements S-055, S-056 and S-057.

The final printed labeling (FPL) must be identical, and include the revisions indicated, to the submitted labeling (package insert submitted April 19, 2004, immediate container and carton labels submitted April 11, 2003). These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20164/S-053." 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, HFD-410
FDA
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 Diane Moore, Regulatory Project Manager, at (301)827-7476.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Acting Director
Division of Gastrointestinal and Coagulation Drug
Products, (HFD-180)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Joyce Korvick
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