NDA 20-164

MAR 29 1993

Rhone-Poulenc Rorer
Attention: Ms. Judith Plon
500 Arcola Road
Collegeville, Pennsylvania 19426

Dear Ms. Plon:

Please refer to your December 30, 1991 new drug application resubmitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Lovenox (enoxaparin injection).

We also acknowledge receipt of your amendments dated January 30, February 24, March 26, April 8, May 1 and 12, June 19 and 29, August 11 and 13, November 24, and December 8, 17 and 24, 1992; January 8 and 29, and February 3, 18, and 23, 1993.

We have completed the review of this 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 enclosed revised draft labeling. Accordingly, the application, with these labeling revisions, is approved effective on the date of this letter.

These revisions are terms of the NDA approval. Marketing the product before making the revisions, exactly as requested, in the product's final printed labeling (FPL) may render the product misbranded and an unapproved new drug.

Please submit 12 copies of the FPL as soon as it is available. Seven of the copies should be individually mounted on heavy-weight paper or similar material. The submission should be designated for administrative purposes as "FPL for approved NDA 20-164." Approval of the submission by FDA is not required before the labeling may be used.

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, please contact:

Bronwyn Collier
Consumer Safety Officer
(301) 443-0487

Sincerely yours,

Robert Temple 3/29/93

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure