

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020164, S015

CHEMISTRY REVIEW(S)

BEST POSSIBLE

ore
oliver

CHEMIST REVIEW #2 1. Organization: HFD-180 2. NDA Number: 20-164

3. Name and Address of Applicant (City & State): Rhone-Poulenc Rorer Pharmaceuticals Inc. 4. AF Number: FEB 13 1998

Box 5096
Cola Road
geville, Pennsylvania 19426-0800 5. Supplement(s)

6. Name of Drug: Lovenox® Injection 7. Nonproprietary Name: enoxaparin sodium
Number: SE1-015, BC, BS, BC, BC
Dates: 28 FEB 1997, 26 MAR 1997, 17 JUN 1997, 18 JUN 1997, 10 JUL 1997

8. Supplement Provides for: a treatment of deep vein thrombosis and for new 1 mL graduated syringes filled with either 60, 80, or 100 mg of enoxaparin sodium as the previously approved 100 mg/mL formulation, manufactured on line 4 at the site.
9. Amendments and Other (Reports, etc.) Dates: 1. See the Chemistry Review for SE1-016 for the complete chemistry Review of this supplement

10. Pharmacological Category: antithrombotic 11. How Dispensed: RX XX OTC
12. Related IND/NDA/DMF(s): SE1-016 18 MAR 1997

13. Dosage Form: Injection (SVP) 14. Potency: 100 mg/mL in glass prefilled syringe; 0.3 and 0.4 mL/0.5 mL syringe; 0.6, 0.8, and 1 mL/1.0 mL syringes

15. Chemical Name and Structure: See package insert labeling in 1, page 51. 16. Records and Reports: Current Yes No Reviewed Yes No

17. Comments:
cc: Original NDA 20-164
HFD-180/Div/File
HFD-180/CSO/KOliver
HFD-180/JSieczkowski
HFD-180/Chemist
Drafted by: Joseph Sieczkowski/2/11/98/WP: c:\wpfiles\chem\S\20164015.2JS
Initaled by: EDuffy
Draft dob/2-11-98/F/T 2-11-98
final: 2/13/98

18. Conclusions and Recommendations: Based on the adequacy of the CMC for the drug product in Supplement S-016, the acceptability of the EA and FONSI by the Environmental Scientist, Ms. Nancy Sager (HFD-357), and the Biopharmaceutics Review conclusion of "satisfactory", it is concluded by this reviewer that the chemistry section of this supplement is adequate. Deficiencies in the drug product labeling may be made after supplement approval and coordinated with the comments submitted by the RHPM, Karen Oliver.

19. Reviewer
Name: Joseph Sieczkowski, Ph.D. Signature: [Signature] Date Completed: February 11, 1998