

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: 020164/S010**

**CHEMISTRY REVIEW(S)**

*Over*

CHEMIST REVIEW #1		1. Organization: HFD-180	2. NDA Number: 20-164
3. Name and Address of Applicant (City & State): Rhone-Poulenc Rorer Pharmaceuticals, Inc. Coca-Cola Road, P.O. Box 1200 Pittsburgh, PA 19426-0107		4. AF Number:	5. Supplement(s)
		Number:	Dates:
6. Name of Drug: Lovenox® Injection	7. Nonproprietary Name: enoxaparin sodium	SE1-010	29 MAR 1996
8. Supplement Provides for: the following indication: "In addition, Lovenox® Injection is indicated after hospital discharge for long-term prevention of deep vein thrombosis following hip replacement surgery."		9. Amendments and Other (Reports, etc.) Dates: EER for SE1-008 and SE1-010 were noted as Acceptable dated September 27, 1996.	
10. Pharmacological Category: Anti-coagulant	11. How Dispensed: RX <u>XX</u> OTC <u>  </u>	12. Related IND/NDA/DMF(s): NDA 20-164/SE1-008 NDA 20-164/S-010 (CMC & Microbiology)	
13. Dosage Form: Injection (SVP)	14. Potency: 100 mg/mL		
15. Chemical Name and Structure: See Merck Index, Twelfth Edition, page 3627, Item 3626 Enoxaparin.		16. Records and Reports:	
		Current <u>      </u> Yes <u>      </u> No	
		Reviewed <u>      </u> Yes <u>      </u> No	

MAR 12 1997

Comments:

cc:  
Original NDA 20-164/S-010  
HFD-180/Div/File  
HFD-180/CSO/Koliver  
HFD-180/SFredd  
HFD-180/JSieczkowski

Drafted by: JSieczkowski/3-7-97/WP: c:\wpfiles\chem\S\20164010.1js  
Initialed by: EDuffy  
DRAFT dob 3-10-97  
final:

*ISI* 3/12/97

18. Conclusions and Recommendations: The adequacy of the CMC for this supplement is dependent upon the approval of Supplement SE1-008 which is currently under review. The environmental assessment for this supplement is adequate and a FONSI has been prepared for the environmental scientist's signature. From a chemistry viewpoint, the supplement is approvable upon the approval of supplement SE1-008 and the acceptance by the environmental scientist of the Environmental Assessment Review and FONSI.

19. Reviewer	Signature:	Date Completed:
Joseph Sieczkowski, Ph.D.	<i>ISI</i>	March 7, 1997

3-11-97