

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020287/S010

CHEMISTRY REVIEW(S)

CSO/Oliver

CHEMIST'S REVIEW #1		1. Organization: HFD-180	2. NDA Number: 20-287
3. Name and Address of Applicant (City & State): Pharmacia & Upjohn 7000 Portage Road alamazoo, Michigan 49001-0199		AUG - 4 1998	4. AF Number:
6. Name of Drug: FRAGMIN® Injection		7. Nonproprietary Name: dalteparin sodium	Supplement(s) Number(s) Date(s) SE1-010 29 MAY 1998
8. Supplement Provides for: the treatment of unstable angina and non-Q-wave myocardial infarction for the prevention of ischemic complications in patients on concomitant aspirin therapy.		9. Amendments and Other (Reports, etc.) Dates:	
10. Pharmacological Category: anti-thrombotic	11. Dispensed Rx <u>XX</u> OTC <u> </u>		12. Related IND/NDA/DMF(s):
13. Dosage Form: Injection: 0.2 mL Single dose syringe 9.5 mL multidose vial	14. Potency: 12,500 & 25,000 IU (anti-factor Xa/mL); 10,000 IU/mL (vial)		6. Records and Reports: Current Yes No Reviewed Yes No
15. Chemical Name and Structure: See Merck Index, Twelfth Edition, 2870 Dalteparin.			
17. Comments: The chemistry review pertains to Item 4, Chemistry, Environmental Assessment (Claim for Exclusion), Vol. 1.1, Item 4, page 4-1-2. Claim for exclusion was found acceptable			
cc: NDA 20-287 HFD-180/Div File HFD-181/CSO/K.Oliver HFD-180/L.Talarico HFD-180/J.Sieczkowski <i>JSI</i> [REDACTED] <i>8/4/98</i> R/D init by: E.Duffy JS/dob DRAFT 7-24-98\F\T 7-28-98\ WORD: c/wpfiles\chem\S\20287010.1JS			
18. Conclusions and Recommendations: Based on the information submitted to the Supplement under 21 CFR 25.15(d), the supplement should be approved with respect to environmental considerations. (Approvable - chemistry.)			
19. Reviewer			
Name: Joseph Sieczkowski, Ph.D.		Signature: <i>JSI</i> [REDACTED]	Date Completed: July 16, 1998