

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020287/S008

CHEMISTRY REVIEW(S)

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CHEMIST REVIEW #1		1. <u>Organization:</u> HFD-180	2. <u>NDA Number:</u> 20-287
3. <u>Name and Address of Applicant (City & State):</u> Pharmacia & Upjohn 7000 Portage Road Kalamazoo, Michigan 49001-0199		4. <u>AF Number:</u>	
		JUL 22 1997. <u>Supplement(s)</u>	
		Number:	Dates:
6. <u>Name of Drug:</u> Fragmin ® Injection	7. <u>Nonproprietary Name:</u> dalteparin sodium	SE1-008 BC	16 APR 1997 12 JUN 1997
8. <u>Supplement Provides for:</u> a new indication, thromboprophylaxis in patient's undergoing hip replacement surgery.		9. <u>Amendments and Other (Reports, etc.) D.</u>	
10. <u>Pharmacological Category:</u> anti-coagulant	11. <u>How Dispensed:</u> RX <u>XX</u> OTC <u> </u>	12. <u>Related IND/NDA/DMF(s):</u> DMF [REDACTED] DMF [REDACTED] DMF [REDACTED] DMF [REDACTED]	
13. <u>Dosage Form:</u> Injection (SVP)	14. <u>Potency:</u> 2500 IU and 5000 IU (anti-Factor Xa) per 0.2 mL PFS		
15. <u>Chemical Name and Structure:</u> See NDA 20-287, Chemistry Review #1.		16. <u>Records and Reports:</u>	
		Current <u> </u> Yes <u> </u> No	
		Reviewed <u> </u> Yes <u> </u> No	
17. <u>Comments:</u> S [REDACTED]			
<p>cc: Original NDA 20-287 (S-008) HFD-180/Div/File HFD-180/CSO/KOliver HFD-180/LTalarico HFD-180/JSieczkowski</p> <p>Drafted by: Joseph Sieczkowski/7-15-97/WP; c:\wpfiles\chem\S\20287008.1JS Initaled by: E Duffy/ [REDACTED] JS dob DRAFT 7-15-97/FT 7-17-97 final: [Signature]</p>			
18. <u>Conclusions and Recommendations:</u> From a chemistry viewpoint, it is recommended that the supplement be approved. The R.H. Project Manager should convey to the applicant the acceptability of this application from a chemistry viewpoint.			
19. <u>Reviewer</u>			
Name:		Signature:	Date Completed:
Joseph Sieczkowski, Ph.D.		[REDACTED] JS	7-18-97 July 11, 1997