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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020287/S010

CHEMISTRY REVIEW(S)

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CSO/Oliver

CHEMIST'S REVIEW #1 1. Organiz		<u>Carpina</u>
Name and Address 15 7. Organiz	zation: HFD-180	2. NDA Number: 20-287
3. Name and Address of Applicant Pharmacia & Upjohn	(City & State):	4. AF Number:
7000 Portage Road		
alamazoo, Michigan 49001-0199	AUG - 1 1998	
	1000	
6. Name of Drug: 7. Nonprop		Supplement(s)
FRAGMIN® Injection dalteparin	rietary Name:	Number(s) Date(s)
8 Supplement Provides 6	sodium	SE1-010 29 MAY 1998
8. Supplement Provides for: the t	treatment of	9. Amendments and Other
unstable angina and non-Q-wave myoinfarction for the prevention of	ocardial	(Reports, etc.)
complications in patients on conce	iscnemic	Dates:
therapy.	omitant aspirin	
10. Pharmacological Category:	12.2	
anti-thrombotic	11.Dispensed	12. <u>Related</u>
		IND/NDA/DMF(s):
13.Dosage Form:	1.4	
Injection:	14. <u>Potency:</u>	
0.2 mL Single dose syringe	12,500 &	
9.5 mL multidose vial	25,000 IU (anti-factor	
	Xa/mL);	에 대한 경험 등 보는 경험하는 것이 되었다. 그는 경험 전에 되었다.
	10,000 IU/mL	
	TO OOO TO WIT	기계를 하고 되었다. 이번 하고 있다는 것이 보고 있는 것은 것은 것이다.
<u>보고 있는 이 이 문문 항상 하고 있다. 그 등은 반대는 하나 하는 일 만든 것이라고 있다. 하다 하다.</u>	1/17:511	나는 살이 얼마나 하는 것이 없는 사람들이 되었다. 그 살아 없는 것이 없는 것이 없었다.
15.Chemical Name and Structure: S	(vial) See Merck	
15.Chemical Name and Structure: S Index, Twelfth Edition, 2870 Dalte	oo Mozal-	6. Records and Reports:
15.Chemical Name and Structure: S Index, Twelfth Edition, 2870 Dalte	oo Mozal-	
15.Chemical Name and Structure: S Index, Twelfth Edition, 2870 Dalte	oo Mozal-	Current
15.Chemical Name and Structure: S Index, Twelfth Edition, 2870 Dalte	oo Mozal-	Current Yes No
Index, Twelfth Edition, 2870 Dalte	ee Merck parin.	Current Yes No Reviewed
.7. Comments: The Chemistry revio	ee Merck parin.	Current Yes No Reviewed Yes No
7. Comments: The chemistry revie	w pertains to I	Current Yes No Reviewed Yes No tem 4, Chemistry,
1ndex, Twelfth Edition, 2870 Dalte 17. Comments: The chemistry revie Environmental Assessment (Claim	w pertains to I	Current Yes No Reviewed Yes No tem 4, Chemistry,
17. Comments: The chemistry revie Environmental Assessment (Claim 4-1-2. Claim for exclusion was	w pertains to I	Current Yes No Reviewed Yes No tem 4, Chemistry,
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