

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S28

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW <small>(If necessary, continue any item on 8" x 10 1/2" paper. Key continuation to item by number.)</small>		1. ORGANIZATION HFN-160	2. NDA NUMBER 5-970
3. NAME AND ADDRESS OF APPLICANT (City and State) Elkins-Sinn, Inc. Cherry Hill, NJ 08034		4. AF NUMBER	
		5. SUPPLEMENT (S)	
		NUMBER(S)	DATE(S)
6. NAME OF DRUG Sotradecol Injection	7. NONPROPRIETARY NAME Sodium Tetradecyl Sulfate Injection	S-028 S-030 S-031	2/13/85 8/22/86 8/22/86
8. SUPPLEMENT(S) PROVIDES FOR: S-028 Labeling Revision S-030 Raising pH upper limit S-031 as alternate manufacturer		9. AMENDMENTS AND OTHER (Reports, etc.) DATES S-028 AL S-030 AC 12/30/86 S-031 AC	
10. PHARMACOLOGICAL CATEGORY Sclerosing Agent	11. HOW DISPENSED <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC	12. RELATED IND/NDA/DMF(S)	
13. DOSAGE FORM(S) Intravenous Injection	14. POTENCY (ies) 1% and 3%		
15. CHEMICAL NAME AND STRUCTURE $\begin{array}{c} \text{CH}_3 \quad \text{OSO}_3\text{Na} \quad \text{C}_2\text{H}_5 \\ \quad \quad \\ \text{CH}_3-\text{CH}-\text{CH}_2-\text{CH}-(\text{CH}_2)_2-\text{CH}-(\text{CH}_2)_3-\text{CH}_3 \\ \text{7-ethyl-2-methyl-4-hendecanol sulfate sodium salt} \end{array}$		16. RECORDS AND REPORTS CURRENT <input type="checkbox"/> YES <input type="checkbox"/> NO REVIEWED <input type="checkbox"/> YES <input type="checkbox"/> NO	
17. COMMENTS See page 2. cc: NDA 5-970 HFN-160, Doc Room 160 R/D PStewart, 2/11/87 R/D init. GPoochikian, 2/19/87			
18. CONCLUSIONS AND RECOMMENDATIONS The application is approvable pending receipt of revised label. Initialed per GPoochikian, 2/19/87			
19. REVIEWER			
NAME Patricia Stewart	SIGNATURE	DATE COMPLETED 2/11/87	
DISTRIBUTION <input type="checkbox"/> ORIGINAL JACKET <input type="checkbox"/> REVIEWER <input type="checkbox"/> DIVISION FILE			

CHEMIST'S REVIEW <small>(If necessary, continue any item on 8" x 10 1/2" paper. Key continuation to item by number.)</small>		1. ORGANIZATION FDA/HFN-160	2. NDA NUMBER 5970
3. NAME AND ADDRESS OF APPLICANT (City and State) Elkins - Sinn Inc. Cherry Hill, New Jersey 08034		4. AF NUMBER	
		5. SUPPLEMENT (S) NUMBER(S) DATE(S)	
6. NAME OF DRUG Sotradecol Injection	7. NONPROPRIETARY NAME Sodium Tetradecyl Sulfate Injection		S-027RC S-028PD 2/13/85 2/13/85
8. SUPPLEMENT(S) PROVIDES FOR: Responses to FDA letter dated 6/18/84 concerning S-027 and PR-021.			9. AMENDMENTS AND OTHER (Reports, etc.) DATES
10. PHARMACOLOGICAL CATEGORY Sclerosing Agent	11. HOW DISPENSED <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC		12. RELATED IND/NDA/DMF(S)
13. DOSAGE FORM (S) Injection (intravenously)	14. POTENCY (ies) 1% and 3%		
15. CHEMICAL NAME AND STRUCTURE $\text{CH}_3-\overset{\text{CH}_3}{\text{CH}}-\overset{\text{OSO}_3\text{Na}}{\text{CH}_2}-\overset{\text{C}_2\text{H}_5}{\text{CH}}-(\text{CH}_2)_2-\text{CH}-(\text{CH}_2)_3-\text{CH}_3$ 7-Ethyl-2-methyl-4-hendecanol sulfate sodium salt.			16. RECORDS AND REPORTS
			CURRENT <input type="checkbox"/> YES <input type="checkbox"/> NO REVIEWED <input type="checkbox"/> YES <input type="checkbox"/> NO
17. COMMENTS S-027 RC responds to FDA letter dated 6/18/84. S-028 PD responds to FDA letter dated 6/18/84 concerning PR-021. cc: / NDA 5970 HFN-160, Doc Room 160 R/D GPoochikian, 5/28/85 R/D init. CPhoiberg, 5/30/85			
18. CONCLUSIONS AND RECOMMENDATIONS Approval letter is recommended. However, it is recommended that the word be part of the product name to comply with the USP format. <p style="text-align: right;">JUN 10 1985</p> Initialed per CPhoiberg, 5/30/85			
19. REVIEWER			
NAME G. Poochikian, Ph.D.	SIGNATURE		DATE COMPLETED 5/28/85
DISTRIBUTION <input type="checkbox"/> ORIGINAL JACKET <input type="checkbox"/> REVIEWER <input type="checkbox"/> DIVISION FILE			

CHEMIST'S REVIEW <i>(If necessary, continue any item on 8" x 10 1/4" paper. Key continuation to item by number.)</i>		1. ORGANIZATION HFN-160	2. NDA NUMBER 5-970
3. NAME AND ADDRESS OF APPLICANT-(City and State) Elkins-Sinn, Inc. Cherry Hill, NJ 08034		4. AF NUMBER	
6. NAME OF DRUG Sotradecol Injection		7. NONPROPRIETARY NAME Sodium tetradecyl sulfate injection.	
8. SUPPLEMENT(S) PROVIDES FOR: S-028 Labeling Revision S-030 Raising pH upper limit S-031 as alternate manufacturer		5. SUPPLEMENT(S) NUMBER(S) DATE(S) S-028 2/13/85 S-030 8/22/86 S-031 8/22/86	
10. PHARMACOLOGICAL CATEGORY Sclerosing Agent		11. HOW DISPENSED <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC	
13. DOSAGE FORM(S) Intravenous Injection		14. POTENCY (ies) 1% and 3%	
15. CHEMICAL NAME AND STRUCTURE $ \begin{array}{c} \text{CH}_3 \quad \text{OSO}_3\text{Na} \quad \text{C}_2\text{H}_5 \\ \quad \quad \quad \quad \\ \text{CH}_3-\text{CH}-\text{CH}_2-\text{CH}-(\text{CH}_2)_2-\text{CH}-(\text{CH}_2)_3-\text{CH}_3 \\ \text{7-ethyl-2-methyl-4-tetradecyl sulfate sodium salt} \end{array} $		9. AMENDMENTS AND OTHER (Reports, etc.) DATES S-028 BL S-030 BC 2/12/87 S-031 BC	
17. COMMENTS As requested, the label has been revised to add the word _____ to the generic name. cc: NDA 5-970 HFN-160, Doc Room 160 R/D PStewart, 2/19/87 R/D init. GPoochikian, 2/19/87		12. RELATED IND/NDA/DMF(S)	
18. CONCLUSIONS AND RECOMMENDATIONS These supplements can be approved from a chemistry standpoint. The CSO should check the FPL to see that it agrees with the revised draft label. FEB 26 1987 Initialed per GPoochikian, 2/19/87		16. RECORDS AND REPORTS CURRENT <input type="checkbox"/> YES <input type="checkbox"/> NO REVIEWED <input type="checkbox"/> YES <input type="checkbox"/> NO	
19. REVIEWER NAME Patricia Stewart		SIGNATURE	
DISTRIBUTION <input type="checkbox"/> ORIGINAL JACKET <input type="checkbox"/> REVIEWER <input type="checkbox"/> DIVISION FILE		DATE COMPLETED 2/19/87	