

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S18

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 NDE DSDDP HFD 160	2. NDA NUMBER 5-970
3. NAME AND ADDRESS OF APPLICANT (City and State) Elkins-Sinn, Incorporated Cherry Hill, N.J. 08002			4. DATE NDA APPROVED 8/13/46
6. NAME OF DRUG Sotradecol			5. IF PRIOR TO OCT. 10, 1962. DATE APPROVED FOR EFFICACY Sept. 14, 1972
7. NONPROPRIETARY NAME sodium tetradecyl sulfate			8. SUPPLEMENT NUMBER DATE S-018 2-3-75
9. PURPOSE OF SUPPLEMENT Labeling Revision			10. AMENDMENT DATE(s)
			11. OTHER DATE (Report, etc.)
12. PHARMACOLOGICAL CATEGORY Sclerosing agent			13. AF NUMBER 32-080
14. DOSAGE FORM solution for injection			15. HOW DISPENSED <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC
17. POTENCY (ies) 1% and 3% solutions			18. DRUG REQUIRES <input checked="" type="checkbox"/> NDA <input type="checkbox"/> ANDA
19. CHEMICAL NAME			20. RECORDS AND REPORTS CURRENT REVIEWED <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
21. CHEMICAL FORMULA cc: <u>NDA 5-970</u> orig. Final xerox pk 3/7/75 NYK-DO HFD-102/Dr. Kumkumian HFD-160 R/D CMonroe 3/4/75 R/D Init. by: RAJerussi 3/5/75			
22. REMARKS Applicant was issued an approval letter with a request for correction of a typographical error 'at the next printing'. This supplement provides the correction. However, I find in proofreading that the following changes have also been made: The redundant sentence starting has been removed. This statement appears in the heading. The word <u>extremities</u> is now spelled correctly in Indications. The ZIP code has been added to the Manufacturer's address.			
23. CONCLUSIONS The proprietary name (sodium tetradecyl sulfate) should appear in conjunction with the trade name (Sotradecol) on the second page of the insert. I recommend an 'ACKNOWLEDGEMENT' letter be sent recommending the change at the next printing.			
24. REVIEWER 0 3/5/75			
NAME		SIGNATURE	DATE COMPLETED 3/4/75
DISTRIBUTION	<input type="checkbox"/> ORIGINAL JACKET	<input type="checkbox"/> DUPLICATE JACKET	<input type="checkbox"/> REVIEWER