CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S22

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW
(If necessary, continue any item on 8" x 10½" paper. Key continuation to item by number.)

1. ORGANIZATION: WDE DSDDP HFD160

2. NDA NUMBER: 5-970

3. NAME AND ADDRESS OF APPLICANT (City and State): Elkins Sinn, Inc. Cherry Hill, N.J. 08002

4. AF NUMBER: 32-080

5. SUPPLEMENT (S)

NUMBER(S)	DATE(S)
S-022	7/19/76

6. NAME OF DRUG: Sotradecal

7. NONPROPRIETARY NAME: sodium tetradecyl sulfate

8. SUPPLEMENT(S) PROVIDES FOR: S-022 - Draft labeling revision per FR 6/3/76

9. AMENDMENTS AND OTHER (Reports, etc.) DATES: 6/30/76 R14

10. PHARMACOLOGICAL CATEGORY: sclerosing agent

11. HOW DISPENSED: [X] RX [ ] OTC

12. RELATED IND/NDA/DMF(S)

13. DOSAGE FORM (S): solution - 2 mg ampules - 10 mg for export

14. POTENCY (ies): 1% + 3%

15. CHEMICAL NAME AND STRUCTURE

16. RECORDS AND REPORTS
CURRENT: [X] YES [ ] NO
REVIEWED: [X] YES [ ] NO

17. COMMENTS

Draft labeling represents only revisions in the Indications section as per FR 6/3/76. The Description and How Supplied sections are satisfactory.

The Package Insert displayed in the Annual Report are different in content between the one used for Export and that for domestic use. However, the differences are in pharmacology and in the How Supplied section, so that no action is required. (Provided for 10 mg multiple dose vial)

The updating information is adequate for an abbreviated supplement.

18. CONCLUSIONS AND RECOMMENDATIONS

Re Reply the Annual report R14 "approvable" letter is indicated

NYK-DO
cc: NDA 5-970
HFD-160
Doc.Rm./HFD-160
R/D C.Monroe 8/9/76
R/D Init.R.A.Jerussi 8/17/76
fx pd 8/18/76

8/17/76

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
		Aug 9, 1976

DISTRIBUTION: [ ] ORIGINAL JACKET [ ] REVIEWER [ ] DIVISION FILE

FORM FDH 2266 (7/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.