

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S13

MEDICAL REVIEW(S)

7/19/72

MEDICAL OFFICER'S REVIEW OF REPORT NDA 5-970

NAME OF COMPANY: Elkins-Sinn, Inc.
Cherry Hill, New Jersey 08034

NAME OF DRUG: Trade: Sotradecol
Generic: Sodium Tetradecyl Sulfate
Chemical: Sodium tetradecyl sulfate

ORIGINAL DATE OF APPROVAL: August 13, 1946
DATE OF REPORT: 6/6/72
DATE RECEIVED BY BUREAU: 6/8/72
DATE RECEIVED BY DSDDP: 6/20/72
DATE RECEIVED BY MEDICAL OFFICER: 7/10/72
TYPE OF REPORT: Annual

CATEGORY OF DRUG: Sclerosing Agent

COMPOSITION OF DRUG: Sodium Tetradecyl Sulfate % or %
Benzyl Alcohol %
Disodium Phosphate or Sodium Hydroxide to adjust pH q.s.

DOSAGE FORM: Liquid: 10 cc multiple dose vial.

DOSAGE AND ADMINISTRATION: The product is a sclerosing agent for intravenous injection in the treatment of varicose veins. The usual dose is 1/2 to 1 cc not to exceed 1 cc per injection, and the maximum single treatment should not exceed 10 cc.

PHARMACOLOGY REVIEW: Pending
CHEMIST'S REVIEW: Pending

CLINICAL EVALUATION: No clinical data, adverse reactions, animal data, chemical or physical drug properties, or manufacturing or control changes were reported. The submission consists of the current labeling and quantity distributed.

Quantity Distributed: Sotradecol 1/2 -
Sotradecol 1/2 -

Labeling: The labeling is in the process of revision. See Supplement dated 5/10/72 and Medical Officer's Review of Supplement dated May 31, 1972.

CONCLUSIONS: No adverse comments.

RECOMMENDATIONS: No regulatory action indicated on the basis of this report.

A. H. Pate, M.D. - 8-4-72

cc: NYK-DO

NDA 5-970 Orig. Dup.

BD-100

BD-160

R/D AHPate (BD-160) 7/19/72

R/D Init. by SJSunnenblick 7/19/72

Typed Final jaf 8/3/72 *8/5/72*