

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S22

MEDICAL REVIEW(S)

NDA 5-970/S-022

MEDICAL OFFICER'S REVIEW OF NDA 5-970/S-022

DATE COMPLETED: 9/22/76

COMPANY: Elkins-Sinn, Inc.

ORIGINAL APPROVAL DATE: 9/14/72
for safety and efficacy

NAME OF DRUG: Trade: Sotradecol

Generic: Sodium Tetradecyl Sulfate

DOSAGE FORM: Intravenous solution

ROUTE OF ADMINISTRATION: Intravenous

CATEGORY (USE) OF DRUG: Sclerosing agent

DATE OF SUBMISSION: 9/14/76

TYPE OF SUBMISSION: Labeling revision

REASON FOR SUBMISSION: Response to our letter of 9/3/76

CLINICAL EVALUATION:

In response to our letter of 9/3/76 which requested an additional statement in the Adverse Reactions section the applicant has submitted revised draft labeling adding this statement as requested. The draft labeling is now satisfactory.

RECOMMENDATION:

NDA 5-970/S-022 is approvable. Request submission of FPL.

Philip G. Walters, M.D.

cc:
LNDA 5-970/S-022
HFD-160, HFD-108
DocumentRoom/HFD-160
R/D P.G.Walters
R/D Init. M.Clark, M.D. 9/22/76
R/D Init. L.V.Pascual 9/22/76
ft pd 9/23/76

9/23/76