CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/28

PHARMACOLOGY REVIEW(S)

Date: 8/6/85

NDA 5-970

REVIEW AND EVALUATION OF PHARMACOLOGY AND TOXICOLOGY DATA

Supplement S-028 Dated 2/13/85

APPLICANT: Elkins-Sinn, Inc.

DRUG: SOTRADECOL Injection

CHEMICAL NAME: Sodium tetradecyl sulfate

CATEGORY: Sclerosing agent

COMPOSITION:

	Per Ml
Sodium tetradecyl sulfate	mg
Benzyl alcohol	ml
Sodium phosphate, dibasic	mg

PURPOSE OF SUPPLEMENT:

The firm has presented draft labeling in accordance with the Labeling Format Revision Program.

DOSAGE: 0.5 to 2.0 ml for each injection and the maximum single treatment should not exceed 10 ml.

COMMENTS ON LABELING:

(5)	Carcinogenesis, mutagenesis, impairment of fertility	See draft of letter to applicant
(6)	Pregnancy-teratogenic effects	Labeling adequate
(8)	Nursing mothers	See draft of letter to applicant

AUG - 7 1985

CONCLUSION:

Labeling is incomplete in that two subsections are missing from the "Precautions" section of the package insert.

J.E. Wilson,. Ph.D.
8/6/85

cc: NDA 16-366 etal
HFN 160, HFN 340
Doc Room 160
R/D JEWilson,8/6/85
R/D init. JKInscoe,8/6/85
FT/jb,W4029P,D3601P,8/6/85

Date: 3/12/87

NDA 5-970
REVIEW AND EVALUATION OF PHARMACOLOGY AND TOXICOLOGY DATA
Amendment Dated 2/12/87 to S-028

APPLICANT: Elkins-Sinn, INc.

DRUG: SOTRADECOL Injection

CHEMICAL NAME: Sodium tetradecyl sulfate

CATEGORY: Sclerosing agent

COMPOSITION:

	Per Ml
Sodium tetradecyl sulfate	mg
Benzyl alcohol	ml
Sodium phosphate, dibasic	mg

PURPOSE OF SUPPLEMENT:

The firm has presented draft labeling in accordance with the Labeling Format Revision Program.

DOSAGE: 0.5 to 2.0 ml for each injection and the maximum single treatment should not exceed 10 ml.

COMMENTS ON LABELING:

Our not approvable letter of August 24, 1985, requested the addition of

subsections to the Precautions Section of the package insert. Resubmitted draft labeling now contains the foregoing subsections, but subsection still remains incomplete. A statement is needed that long-term animal carcinogenicity studies have not been performed.

CONCLUSION:

Supplement is approvable from the standpoint of pharmacology provided a no carcinogeniicity studies statement is included in the final printed labeling.

J.E. Wilson, Ph.D.
3/12/87

cc: NDA 5-970
HFN 160, HFN 340
Doc Room 160
R/D JEWilson,3/12/87
R/D init. JKInscoe,3/13/87
FT/jb,W5815P,D3679P,3/13/87