CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/28

PHARMACOLOGY REVIEW(S)
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.F. 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
APPLICANT:  Elkins-Sinn, Inc.

DRUG:  SOTRADECOL Injection

CHEMICAL NAME:  Sodium tetradecyl sulfate

CATEGORY:  Sclerosing agent

COMPOSITION:

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium tetradecyl sulfate</td>
<td></td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td></td>
</tr>
<tr>
<td>Sodium phosphate, dibasic</td>
<td></td>
</tr>
</tbody>
</table>

Per ML

mg

ml

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 carcinogenicity studies statement is included in the final printed labeling.

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, U3679P, 3/13/87

[Signature]
Wilson, Ph.D.
3/12/87