

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S28

MEDICAL REVIEW(S)

MEDICAL OFFICER'S REVIEW

NDA 5-970
Supplement S-028 PD (Labeling)

Date submitted..... 2-13-1985
Date received (HFN 160)..... 2-19-1985
Date assigned..... 5 1985
Date completed..... 5-29-1985

APPLICANT: Elkins-Sinn, Inc.,
P. O. Box 5483
Cherry Hill, N.J. 08034

NAME OF DRUG:
Sotradecol injection.

ROUTE OF ADMINISTRATION:
Intravenous.- Treatment of small uncomplicated varicose veins of the lower extremities.

REASON FOR THIS SUBMISSION: Compliance with FDA's prescription Drug Labeling Format Revision Program. (FDR Notice 5-16-1980)

LABELING REVIEW.- Package insert.

DESCRIPTION: Satisfactory.

JUN 1 1985

CLINICAL PHARMACOLOGY: 1) To change the headline of this section in the package insert, from "ACTIONS" to "CLINICAL PHARMACOLOGY". This section should be expanded further to describe rationale of using the drug and mode of action. Include pharmacokinetic information.

INDICATIONS AND USAGE: To change the headline of this section in the package insert, from "INDICATIONS" to "INDICATIONS AND USAGE".

CONTRAINDICATIONS: Delete the sentence: "Do not use if precipitated".

WARNINGS: The statement regarding usage in pregnancy may be deleted, as its place is under Precautions section.

Include in this Warnings section the possibility of any serious

adverse reactions or potential safety hazards.

PRECAUTIONS: Specify under this section the following sub-heading:

- 1) General precautions.
- 2) Drug interactions (before the paragraph related to the concomitant use of antiovolatory agents.- 3) Nursing mothers.(if unknown, so state)

ADVERSE REACTIONS:

OVERDOSAGE: -----

DOSAGE AND ADMINISTRATION: Under this section to add "Do not use if precipitated or discolored"

HOW SUPPLIED: ---

RECOMMENDATIONS:

To request from sponsor to send a DRAFT COPY of a Package insert with the revisions in sections: Clinical Pharmacology, Indications and Usage, Contraindications, Warnings, Precautions and Dosage and Administration.

Chalon Rodriguez, M.D.

5/31/85

NDA 5-970

HFN-160

HFN-340

R/D CRodriguez 5/29/85

R/D Init. by PGWalters 5/31/85

Doc. Room 160