CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S13

ADMINISTRATIVE DOCUMENTS

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER: 5-970

DATE APPROVAL LETTER ISSUED: SEP 14 1972

TO: Press Relations Staff *(CE-300)*

FROM:
- [X] Bureau of ~~Medicine~~ Drugs
- [ ] Bureau of Veterinary Medicine

ATTENTION

Forward original of this form for publication only after approval letter has been issued and the date of approval has been entered above.

TYPE OF APPLICATION
- [ ] ORIGINAL NDA
- [X] SUPPLEMENT TO NDA

CATEGORY
- [X] HUMAN
- [ ] VETERINARY

TRADE NAME *(or other designated name)* AND ESTABLISHED OR NONPROPRIETARY NAME *(if any)* OF DRUG

Sotradecol (Sodium tetrodecyl sulfate)

DOSAGE FORM: Solution

HOW DISPENSED
- [X] RX
- [ ] OTC

ACTIVE INGREDIENT(S) *(as declared on label. List by established or nonproprietary name(s) and include amount(s), if amount is declared on label.)*

Sodium tetrodecyl sulfate 1% and 3%

NAME OF APPLICANT *(Include City and State)*

Elkins-Sinn Incorporated
Cherry Hill, New Jersey 08002

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

Revised labeling to conform with the provisions of Federal Register Notice dated July 30, 1970, and for a new 2 ml ampul dosage form.

FORM PREPARED BY

NAME: Charles Monroe

DATE: Aug. 28, 1972

FORM APPROVED BY

NAME: Leon J. DeMerre

DATE: Aug. 2[illegible]

FD FORM 1642 (12/67)

NDA 5-970 June 13, 1972

MEMORANDUM FROM SUPERVISORY MEDICAL OFFICER

I have reviewed the Medical Officer's Review of supplement dated May 4, 1972, as well as the additional comments made by Dr. Tom Wong. Although the suggestions made by Dr. Wong concerning technic in sclerotherapy are good ones, I feel that the submitted package insert covers adequately any question of technique by the statement under PRECAUTIONS - "The drug should be administered by physicians who are familiar with an acceptable injection technique."

The other suggestions of Dr. Wong, although all of significant importance, I also believe are adequately covered under the submitted package insert. These include his statement of maximum dose not to exceed 10 ml per treatment (covered under dosage and administration, 3rd line, 1st paragraph), his definition of lower extremity is adequately taken care of under-indications and his suggestion concerning the mentioning of the advantage of compression-sclerotherapy appears to be well covered under the second paragraph of Precautions, described above.

RECOMMENDATIONS:

In view of previously agreed upon labeling, I feel that the submitted package insert adequately covers the questions raised in the review of the Medical Officer's Review by Dr. Wong.

This was discussed with Dr. Grigsby and he concurs.

Samuel J. Sunnenblick, M.D.

cc: NDA 5-970 Orig., Dup.
BD-100
BD-160
R/D SJSunnenblick (BD-160) 6/13/73
R/D Init. by FJGrigsby 6/13/73
Typed Final jaf 6/14/72