

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 5970/S22**

**ADMINISTRATIVE DOCUMENTS**

September 14, 1976

Elkins-Sinn, Inc.  
Cherry Hill, N.J. 08002

MEMORANDUM OF TELEPHONE CONVERSATION

Between: Thelma C. Hilibrand, Manager  
Regulatory Affairs

and: Clarence M. Nealey, jr., SCSO  
HFD-160

Additional Revisions package insert  
(Our Letter September 3, 1976)

Dr. Walters brought to my attention the subject letter called for additional revisions under adverse reactions due to a death report which he reviewed 8/23/76. That the approvable letter on September 9, 1976 signed out by Dr. Finkel on S-022 has labeling that should include the adverse reaction change.

Ms. Hilibrand was returning my call of the 13th and when I explained fully what has happened, she stated she would amend S-022 with revised draft to amend the labeling to include the revision in our September 3, 1976 letter. The conversation ended with the usual amenities.

Clarence M. Nealey, jr, SCSO

CC:

NDA 5-970

HFD-160(2)

HFD-108

DocumentRoom/HFD-160

R/D C.M.Nealey/HFD-160

R/D Init. M.Clark,M.D. 9/17/76

R/D Init. P.G.Walters 9/17/76

ft pd 9/22/76

NOTICE OF APPROVAL  
NEW DRUG APPLICATION OR SUPPLEMENT

DATE APPROVAL LETTER ISSUED

MAY 03 1977

TO:

Press Relations Staff (PA-40)

FROM:

Bureau of 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

SUPPLEMENT  
TO NDA

ABBREVIATED  
ORIGINAL NDA

SUPPLEMENT  
TO ANDA

CATEGORY

HUMAN

VETERINARY

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

Sotradecol (Sodium tetradecyl sulfate)

DOSAGE FORM

Injection

HOW DISPENSED

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.)

As above

NAME OF APPLICANT (include City and State)

Elkins-Sinn, Inc.  
Cherry Hill, NJ 08002

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY

A sclerosing agent

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

Labeling revision

FORM PREPARED BY

NAME

F. Kuerer

DATE

4/12/77

FORM APPROVED BY

NAME

P. G. Walters M.D.

DATE