

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S35

CORRESPONDENCE

NDA 5-970/S-035

SEP 7 1990

Elkins-Sinn, Inc.
2 Esterbrook Lane
Cherry Hill, New Jersey 08003-4099

Attention: Steven R. Eby
Regulatory Affairs Associate

Gentlemen:

We acknowledge receipt of your supplemental application(s) for the following:

Name of Drug: Sotradecol (Sodium Tetradecyle Sulfate Injection)

NDA Number: 5-970

Supplement Number: S-035 Labeling

Date of Supplement: August 23, 1990

Date of Receipt: August 29, 1990

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research, HFD-160
Attention: Document Room 18B-03
5600 Fishers Lane
Rockville, Maryland 20857

Sincerely yours,

9/7/90

Warren F. Rumble
Supervisory Consumer Safety Officer
Division of Medical Imaging,
Surgical and Dental Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

CC:
Orig. NDA 5-970/S-035
HFD-160/Division File
HFD-161 CSO/Joyce/Stone
R/D by: P. Abner 9/4/90
R/D init by: W. Rumble 9/04/90
F/T by: RCannon 9/05/90
Wang 4833X

ACKNOWLEDGEMENT OF NDA SUPPLEMENT



ELKINS-SINN, INC. 2 Esterbrook Lane, Cherry Hill, NJ 08003-4099
A subsidiary of T. H. Robins Company

NJ 609 424-3700
Phila. 215 925-4559
FAX 609 424-8747
TWX 710-896-0804

*Proposed change in packaging
concern. No medical response
required. J. H. Eby 8/30/90
9/14/90*

ORIGINAL

August 23, 1990

John F. Palmer, M.D., Acting Director
Division of Medical Imaging, Surgical
and Dental Drug Products
Center for Drug Evaluation and Research
Food and Drug Administration (HFD-160)
5600 Fishers Lane
Rockville, MD 20857

NDA NO. 5-970 REF. NO. SLR-035
NDA SUPPL FOR Labeling

NDA 5-970
Sotradecol® (Sodium Tetradecyl
Sulfate Injection)

Supplement: Change Being Effected - Conversion from
Screen to Paper Labels

Dear Dr. Palmer:

We are in the process of converting from screen (immediate container) labeling to paper labeling for Sotradecol® 1% and 3%. There has been no change in text between the currently approved screen labeling and the new paper labeling. The bars on the left side of the paper label are for an internal control system (Pharmacode). During the phase-in period both screen and paper labeling will be used.

Enclosed are twelve (12) copies of final printed labeling.

If you have any questions, please do not hesitate to call.

Sincerely,

ELKINS-SINN, INC

Steven R. Eby

Steven R. Eby
Regulatory Affairs Associate

/SRE

Encs.

cc: L. Hayko
D. Reese

