

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S30

CORRESPONDENCE

OCT 16 1986

NDA 5-970/S-030

Elkins-Sinn Inc.
2 Esterbrook Lane
P.O. Box 5483
Cherry Hill, NJ 08034

Attention: Thelma C. Hilibrand
Associate Director, Regulatory Affairs

Gentlemen:

Please refer to your supplemental new drug application dated August 22, 1986 submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sotradecol (sodium tetradecyl sulfate injection) and the amendment dated August 25, 1986.

The supplemental application provides for raising the upper limit of the pH specification for Sotradecol gel (purified raw material) from (S-030).

We have completed our review and find that the information presented is inadequate and that the supplemental application is not approvable. The deficiencies are as follows:

1. Please present data to demonstrate that the increase in pH reading of Sotradecol gel is not also associated with chemical and physical changes in the new drug substance.
2. It is noted that you have failed to make the necessary labeling revisions which were indicated in FDA letters dated June 19, 1984 (NDA 5-970/S-027 and August 24, 1985 (NDA 5-970/S-028 PD).

Within 10 days after the date of this letter, you are required to amend the application, or notify us of your intent to file an amendment, or follow one of the other actions under 21 CFR 314.120. In the absence of such action the FDA may take action to withdraw the application.

Sincerely yours,

Patricia H. Russell, M.D.
Director
Division of Surgical-Dental
Drug Products
Office of Drug Research and Review
Center for Drugs and Biologics

NDA 5-970

HFN-160, Doc Rm 160

HFN-160/Poochikian

R/D JPHannan 10/2/86 JPH 10/15/86

R/D init by JJGibbs/Hoiberg 10/3/86; TFolinsz/GBoyer 10/3/86;

GPoochikian 10/3/86; PHRussell 10/3/86

Ft/MPatterson (w4290x) 10/6/86

NOT APPROVABLE



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA No. 5-976/S030 & S031

Date August 28, 1975

Elkins-Sinn, Inc.
2 Esterbrook Lane
Cherry Hill, N.J. 08034

Attention: Thelma C. Wilibrand

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Sotradecol(R) (Sodium Tetradecyl Sulfate Injection)

NDA Number: 5-976

Supplement Number: S-030 Controls S-031 Controls

Date of Supplement: August 28, 1975

Date of Receipt: August 28, 1975

All communications concerning this NDA should be addressed as follows:

Center for Drugs and Biologics, HFN-160
Attention: Document Control Room 18B-03
5600 Fishers Lane
Rockville, MD 20857

Sincerely Yours,

Thelma C. Wilibrand
Supervisory Consumer Safety Officer
Division of Surgical-Dental Drug Products
Center for Drugs and Biologics



JPH 11/5/86
ELKINS-SINN, INC.
A subsidiary of A. H. Robins Company

2 Esterbrook Lane, Cherry Hill, NJ 08003-4099

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

October 24, 1986

NDA SUPPL AMENDMENT

*S-030 AEX
S-031 AEX*

Patricia H. Russell, M.D.
Director, Division of Surgical-
Dental Drug Products
HFN-160 Room 18B-08
Center for Drugs and Biologics
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

NDA 5-970
Sotradecol
(Sodium Tetradecyl Sulfate Injection)

Dear Dr. Russell:

In response to your letter of October 16, 1986 re: S-030 and S-031, we wish to inform you that we intend to amend the supplements referenced above. The labeling will be revised as indicated and draft copy will be submitted for your review. Please note that we did respond to your 6/18/84 letter (see letter 2/13/85).

We plan to respond to all issues listed in the two supplements within 60 days.

Sincerely,
ELKINS-SINN, INC.

Thelma C. Hilibrand

Thelma C. Hilibrand
Associate Director,
Regulatory Affairs

TCH:hg

cc: L. Hayko/AHR
D. Reese
J. Plaza



CM 11/11/86
9/29/86

NDA SUPPL AMENDMENT

S-030 BC N.J. / 609 424-3700
Phila. / 215 925-4559



ELKINS-SINN, INC.
A Subsidiary of A. H. Robins Company

2 Esterbrook Lane, Post Office Box 5483 Cherry Hill, N.J. 08034

August 25, 1986

Patricia H. Russell, M.D.
Director, Division of Surgical-
Dental Drug Products
HFN-160 Room 18B-08
Center for Drugs and Biologics
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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

Supplement: Change in pH Specification (REPLACEMENT FOR
ORIGINAL DATED AUGUST 22, 1986)

Dear Dr. Russell:

Our NDA lists the pH for Sotradecol gel) as
after dilution to % solutions. We have observed variations in pH results
depending on the extent of exposure of the sample to carbon dioxide in the
atmosphere. As a result, we have modified the pH testing to obtain consistency
in our pH measurements (see T.P. 133 enclosed).

Protection of the sample from carbon dioxide in the atmosphere occasionally
results in slightly higher pH readings than those observed with unprotected
samples. Therefore, we are raising the upper limit of the pH specification
from to account for the minimal upward shift.

The slightly higher pH is of no consequence since the 7% intermediate made from
the gel and the finished product formulations made from the 7% intermediate are
all buffered to a lower pH Stability data on the gel
having a pH of 10.4 at the 3% level is comparable to that of the ESI gel with a
pH of 9.5. We are enclosing a revised SAT (5066) with the change in pH limit.

Sincerely,
ELKINS-SINN, INC.

Thelma C. Hilibrand

Thelma C. Hilibrand
Associate Director,
Regulatory Affairs

TCH:hg
Encs.
cc: L. Hayko/AHR
D. Reese
J. Plaza
D. Sacks
T. Ingallinera





ELKINS-SINN, INC. 2 Esterbrook Lane, Post Office Box 5483 Cherry Hill, N.J. 08034
 A Subsidiary of A. H. Robins Company

*CAH/HHI
8/29/86*

NDA NO. 5470 IND. NO. S-030
 NDA SUPPL FOR CONTROLS

N.J. | 609 424-3700
 Phila. | 215 925-4559

August 22, 1986

Patricia H. Russell, M.D.
 Director, Division of Surgical-
 Dental Drug Products
 HFN-160 Room 18B-08
 Center for Drugs and Biologics
 Food and Drug Administration
 5600 Fishers Lane
 Rockville, MD 20857

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

Supplement: Change in pH Specification

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Sincerely,
 ELKINS-SINN, INC.

Thelma C. Hilibrand
 Thelma C. Hilibrand
 Associate Director,
 Regulatory Affairs



TCH:hg
 Encs.
 cc: L. Hayko/AHR
 D. Reese
 J. Plaza
 D. Sacks