

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S22

CORRESPONDENCE

NDA 5970

JUL 22 1976

Elkins-Sinn, Inc.
Attention: Thelma C. Hilibrand
2 Esterbrook Lane
Cherry Hill, New Jersey 08002

Gentlemen:

We acknowledge receipt of your supplemental application for the following:

Name of drug: Sotradecol (Sodium Tetradecyl Sulfate)

NDA number: 5970

Supplement number: S-022

Date of supplement: July 19, 1976

Date of receipt: July 21, 1976

All communications concerning this NDA should be addressed as follows:

Bureau of Drugs HFD-160
Attention: DOCUMENT CONTROL ROOM #18B-03
5600 Fishers Lane
Rockville, Maryland 20852

Sincerely yours,

Clarence M. Nealey, Jr.
Supervisory Consumer Safety Officer
Division of Surgical-Dental
Drug Products
Bureau of Drugs

cc: NDA 5970 Orig.

HFD-160

HFD-160/Document Room

R/D by: DPaulsgrove 7/21/76

R/D Init. by: CMNealey Jr. 7/21/76 ^{0 7-22-76}

MClark MD 7/21/76

Final typed by: pk 7/22/76

SUPPLEMENT ACKNOWLEDGEMENT



ELKINS-SINN, INC. 2 Esterbrook Lane, Cherry Hill, N.J. 08002

NDA SUPPL FOR Labeling
N.J. | 609 424-3700
Phila. | 215 925-4559

mc 7/21/76
draft labeling
notice for tag
PLWalters 9/8/76

July 19, 1976

Margaret A. Clark, M.D., Director
Div. Surgical & Dental Products HFD-160
Document Control Rm. 18B-03
Food and Drug Administration
Bureau of Drugs
5600 Fishers Lane
Rockville, Maryland 20852

NDA 5-970 R
Sotradecol
(Sodium Tetradecyl Sulfate)

Supplement: Revised Labeling in accord with F.R.
Notice June 03, 1976

Dear Dr. Clark:

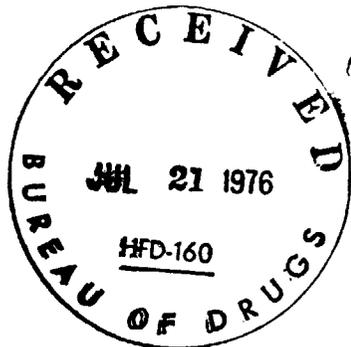
We are enclosing four draft copies of the Sotradecol^R insert revised to comply with the F.R. Notice listed above.

In response to our letter of July 1, 1976, I received a telephone call on July 16 from Mr. Frank Keurer of your division who informed me that the F.R. notice takes precedence over your March 16, 1976 approval letter for the insert. However, Mr. Keurer stated that we may exhaust our current supply of the inserts, provided that at the time of the next printing which will most likely be on or before 180 days from now, we will then revise the inserts as submitted in this supplement.

This supplement is being submitted in compliance with Paragraph 3(i) of the F.R. Notice of June 03, 1976 (Current container labeling was submitted in Periodic Report dated June 30, 1976.)

Sincerely,

Thelma C. Hilibrand
Mgr., Regulatory Affairs



TCH:ac
Enclosures



ELKINS-SINN, INC. 2 Esterbrook Lane, Cherry Hill, N.J. 08002

5-022
NDA SUPPL AMENDMENT

PHILA. 1 215 925-4559

September 14, 1976

Margaret A. Clark, M.D.
Director
Division Surgical-Dental Products
Bureau of Drugs HFD 160
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

NDA 5-970
Sotradecol^R
(Sodium Tetradecyl Sulfate)

Supplement: Revised Insert

Dear Dr. Clark:

The approvable letter which we received from Dr. Marion Finkel dated September 9, 1976 for S-022 directed us to submit final printed labeling. The next to the last sentence of that letter states that, "If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of that labeling may be required."

In view of the request in your letter dated September 3, 1976 for an additional sentence to be added to the Adverse Reactions section of the insert, and as a result of my phone conversations with Mr. Clarence Nealey, Jr., we consider this letter to supersede the September 9, 1976 approvable letter. Therefore, rather than submit final printed inserts at this time, we are submitting four copies of draft labeling which incorporates the recommended changes of both letters referred to above.

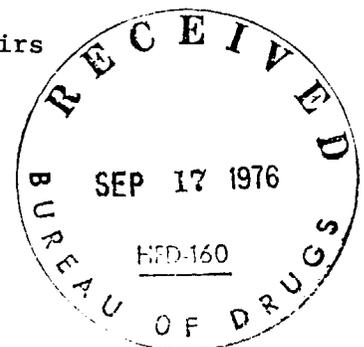
We believe this is the most efficient way to proceed.

If there are any questions, please contact me.

Sincerely,

Thelma C. Hilibrand
Manager, Regulatory Affairs

TCH:ac
Enclosures





ELKINS-SINN, INC. 2 Esterbrook Lane, Cherry Hill, N.J. 08002

Mc 4 17 4-5-77

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

NDA NO. 5970 REF. NO. S-022FP
NDA SUPPL FOR Labeling

March 29, 1977

Margaret A. Clark, M.D.
Director
Division Surgical Dental Products
Bureau of Drugs HFD 160
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

*FPC is acceptable -
perform the company
4/11/77* **FPL**

NDA 5-970/S-022
Sotradecol^R
(Sodium Tetradecyl Sulfate)

Supplement: Revised Insert - Final Printed Labeling

Dear Dr. Clark:

Enclosed are 12 copies of final printed inserts for Sotradecol^R identical in content to the draft labeling submitted September 14, 1976. In submitting this labeling we are following the instructions in your December 13, 1976 (NDA 5-970/S-022) letter to us.

Sincerely,

ELKINS-SINN, INC.

Thelma C. Hilibrand

Thelma C. Hilibrand
Manager, Regulatory Affairs

TCH:ac
Enclosures

