CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S28

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 5-970/S-028

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

OCT 2 1987

Attention: Thelma C. Hilibrand

Gentlemen:

Reference is made to your supplemental new drug application dated February 13, 1985 submitted pursuant to section 505(b) of the Federal Food, Drug and Cosmetic Act for the preparation

Sotradecol Injection.

We also acknowledge receipt on September 21, 1987 of your supplemental amendment dated September 16, 1987.

The Division Director has determined that your supplemental amendment is a major amendment in accordance with 21 CFR 314.60 and therefore the review process may take up to 45 days. The review clock will be extended accordingly.

Sincerely yours,

Gary H. Boyer
Supervisory Consumer Safety Officer
Division of Surgical-Dental
Drug Products
Office of Drug Research and Review
Center for Drugs and Biologics

NDA 5-970/S-028 PD

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

AUG 24 1985

Attention: Thelma C. Hilibrand

Gentlemen:

Please refer to your supplemental new drug application dated February 13, 1985, submitted pursuant to section 505(b)(1) of the Federal Food, Drug and Cosmetic Act for Sotradecol (sodium tetradecyl sulfate) Injection.

The supplement provides for labeling revised in accordance to 21 CFR 201.56 and 201.57, the Labeling Format Revision Program (S-028).

We have completed our review and find that the information presented is inadequate and the application is not approvable under section 505(b)(1)(F) in that specimens of the proposed labeling are not complete. Specific deficiencies are as follows:

1. It is recommended that the word be part of the product name on all labels and labeling to comply with the USP format.

2. Clinical Pharmacology section - The section now labeled Actions should be entitled, Clinical Pharmacology. This section should be expanded to include rationale for use, mode of action and pharmacokinetic information.

3. Indications and Usage section - The section now labeled Indications should be entitled Indications and Usage.

4. Contraindications section - Delete the sentence,

5. Warnings section - deleted and should be included here.

6. Precautions section - The following subsections should be added:

7. Dosage and Administration section - Add the statement,

Within 10 days after the date of this letter, you are required to take one of the following actions as described under 21 CFR 314.120:

(a) Amend the application or notify us of an intent to file an amendment.

(b) Withdraw the application without prejudice to future filing.

(c) Request an opportunity for a hearing. Such a request should be submitted to the Division of Regulatory Affairs (HFN-360), Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(d) Notify us that you agree to an extension of the review period under section 505(c) of the Act, so that you can determine whether to respond further under paragraph (a), (b), or (c) above. Your are required to state the length of such an extension.

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

cc: NDA 5-970
HFN-160
HFN-83
HFN-160/Rodriguez/Poochikian/Wilson
Doc. Room 160
R/D: JPHannan 8/13/85 8-23-85
R/D init by PHRussell 8/21/85, CPHoiberg 8/20/85, JCKenealy 8/21/85, JKInscoe 8/19/85, GBoyer 8/19/85
FT td W2004Y 8/22/85

NOT APPROVABLE

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

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

ORIGINAL

September 16, 1987 NDA SUPPL AMENDMENT

Package insert contains warning requested in our letter of 3/31/87. Supplement remains approvable.
J Edelson 1/22/88

Philip G. Walters, M.D.
Acting 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/S-028
Sotradecol®

Response to March 31, 1987 Letter

Dear Dr. Walters:

In response to your letter noted above, we are submitting 12 copies of final printed inserts revised in accordance with 21 CFR 201.56 and 201.57. The labeling incorporates the revisions indicated in your March 31, 1987 letter.

If there are any questions or comments, please call.

Sincerely,

ELKINS-SINN, INC.

Thelma C. Hilibrand

Thelma C. Hilibrand
Associate Director,
Regulatory Affairs

TCH:hg

Encs.

cc: L. Hayko/AHR
D. Reese

CENTER FOR
REC'D
SEP 2 1
HFN-160
DRUGS AND BIOLOGICS

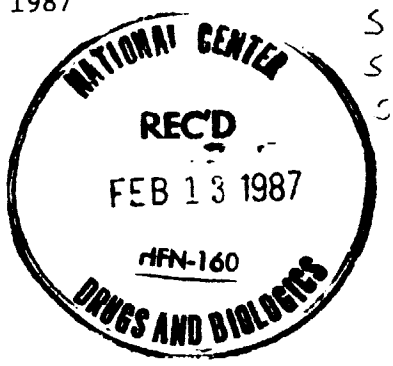
PHARMACEUTICALS

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

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

February 12, 1987

S-028 G
S-030 G
S-031 G



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 (S-028, S-030, S-031)
Sotradecol®
Sodium Tetradecyl Sulfate Injection

Supplemental Amendment: Label Copy

Dear Dr. Russell:

In response to a phone call today from Ms. Pat Stewart of your division, we are submitting revised draft labels, immediate and boxes, for Sotradecol® 1% and 3%. We were requested to add the word to the generic name, which we have done.

Ms. Stewart indicated that this was the only data outstanding for the approval of the Supplements currently pending (028-030-031). The approvals, especially for the alternate processing site and pH change, are needed as rapidly as possible in order to prevent a back order situation for a product for which we are the sole source.

If there are any questions or comments, please do not hesitate to call.

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

Desk Copy: Ms. P. Stewart/FDA

20-970/S-028

ELKINS-SINN, INC. 2 Esterbrook Lane, Post Office Box 5483 Cherry Hill, N.J. 08034
PHARMACEUTICALS A Subsidiary of A. H. Robins Company
N.J. 609 424-3700
Phila. 215 925-4559

September 4, 1985

SUPPL NEW CORRES
S-028

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

DOTOD: JPH 10/17/85

NDA 5-970/S-028 PD
Sotradecol Injection

Dear Dr. Russell:

In response to your letter of August 24, 1985, we wish to inform you that we intend to amend the supplement referenced above. The labeling will be revised as necessary, and draft copy of this labeling will be provided for your review as soon as it is available.

With the provision of this notification of the intent to file an amendment to the supplement referenced above, we are in compliance with 21 CFR 314.120.

Sincerely,

ELKINS-SINN, INC.

Thomas L. Pituk

Thomas L. Pituk
Regulatory Affairs Associate

TLP:hg

cc: L. Kayko
D. Reese
J. Plaza

NATIONAL CENTER
REC'D
SEP 05 1985
HFN-160