

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S18

CORRESPONDENCE

NDA 5-970

FEB 21 1975

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

Gentlemen:

We acknowledge receipt of your supplemental application for the following:

Name of drug: Sotradecol

NDA number: 5-970

Supplement number: S-018

Date of supplement: February 4, 1975

Date of receipt: February 6, 1975

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,

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Margaret A. Clark, M.D.
Acting Director
Division of Surgical-Dental
Drug Products
Bureau of Drugs

cc:

NDA 5-970 Orig.

HFD-160

R/D by: MVBrown 2/7/75

R/D init. by: GBoyer 2/10/75

Final typed by: jw:2/20/75

SUPPLEMENT ACKNOWLEDGEMENT



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

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

Orig.

NDA 5-970 Supplement

Date: February 4, 1975

NDA NO. 5970 REF. NO. 5418 **FPL**

NDA SUPPL FOR Labeling Revision

Att: Document Control Room #18B-03
Bureau of Drugs (HFD-160)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Product: **Sotradecol**
Re: Final Printed Labeling

Gentlemen:

We are submitting 12 copies of inserts for the following reason:

- New Label - Labeling Agreement Attached
- Deficiency letter dated 11/29/73
- Labeling revised:

- Format change
- NDC # added or completed
- Route of Administration IV IM SC
 Deleted Added
- Usual dose statement added
- Deletion of indications
- Zip code change
- Storage directions added or expanded
- Other Word added to first sentence of Precautions.

Sincerely yours,

Thelma C. Hilibrand

Thelma C. Hilibrand
Assistant Manager, Regulatory Affairs

TCH:mf

