CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 5970/S28

APPROVAL LETTER

NDA 5-970/S-028

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

JAN 29

Attention: Thelma C. Hilibrand
Associate Director
Regulatory Affairs

Gentlemen:

Please refer 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 Sotradecol (sodium tetradecyl sulfate injection).

We also acknowledge your additional communications dated September 16, 1987, providing final printed labeling.

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

We have completed our review of this supplemental application and it is approved. Please be advised that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

Sincerely yours,

Philip G. Walters, M.D.
Acting Director
Division of Surgical-Dental
Drug Products
Office of Drug Research and Review
Center for Drug Evaluation and Research

cc: NDA 5-970
HFN-160
HFN-83 w/ labeling
HFN-231 w/ labeling
Doc Rm 160
R/D JPHannan 0899z 01/22/88 SPH 1/27/88
R/D Init. by: GBoyer 1/25/88 JKInsoe 1/25/88
DHaggerty for JCKenealy 1/25/88 CPHoiberg for PGWalters 1/25/88
F/T MJO 1/26/88

APPROVAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S28

APPROVABLE LETTER

MAR 31 1987

NDA 5-970/S-028

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

Attention: Thelma C. Hilibrand
Associate Director
Regulatory Affairs

Gentlemen:

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

We also acknowledge your additional communications dated December 30, 1986 and February 12, 1987, amending the application.

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

We have completed the review of this supplemental application. However, before this supplemental application may be approved, it will be necessary for you to submit final printed labeling. The labeling should be identical in content to the draft labeling included in the February 12, 1987, submission except for the following changes:

1. A statement is needed in the "Carcinogenesis, mutagenesis, impairment of fertility" subsection of the package insert that no long term animal carcinogenicity studies with sodium tetradecyl sulfate have been performed.

2. There is a misspelling in the ADVERSE REACTION section on line 3. In the sentence, "Sloughing and microsis of tissue...", the word microsis should be changed to necrosis.

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.

Please submit twelve copies of the printed labeling.

Sincerely yours,

Philip G. Walters, M.D.
Acting 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-160/Rodriguez/Stewart/Wilson
Doc Rm 160
R/D JPHannan 2482k 03/24/87 JPH 3/31/87
R/D init by GPoochikian 3/25/87; GBoyer 3/25/87; JKInscoe 3/25/87;
JCKenealy 3/27/87; CPHoiberg/PHRussell 3/27/87;
Ft/MPatterson 3/30/87

APPROVABLE