CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 5970/S13

APPROVAL LETTER

SEP 14 1972

NDA 5-970/S-010, S-013

AF 52-080

Elkins-Sinn, Incorporated
Attention: Mr. Davis R. Reese
2 Esterbrook Lane
Cherry Hill, New Jersey 08002

Gentlemen:

We acknowledge the receipt on July 5, 1972 of your communication dated June 30, 1972 enclosing printed labeling pursuant to your supplemental new drug application dated May 10, 1972 and June 5, 1970 for Sotradecol (sodium tetradecyl sulfate) 1% and 3%.

The supplemental application provides for revised labeling to conform with the provisions of the Federal Register Notice dated July 30, 1970 (S-013) and also provides for a new 2 ml Ampul dosage form (S-010). We recommend that the zip code be added to the address at the next printing.

We have completed the review of this supplemental application, and it is approved. This action approves your application, as supplemented, on the basis of effectiveness of the drug as well as safety. The enclosure summarize the conditions relating to the approval of this application.

This action also approves those supplemental applications which were permitted under the provisions of regulation 130.9(f) and (g) and have not been superseded.

cc:
NWK-DO
OSE (BD-100)
DSDDP (BD-160) 9/8/72
Med (BD-106)
IAS (BD-242)
CMonroe 8/28/72:abc/9/6/72
R/D init. by: LJDeMerre 8/28/72

APPROVAL

Enclosure:

Sincerely yours,

Frederick J. Grigsby, M.D.
Deputy Director
Division of Surgical-Dental
Drug Products
Office of Scientific Evaluation
Bureau of Drugs

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S13

APPROVABLE LETTER

NDA 5-970/S-013

JUL 12 1972

AF 32-080

Elkins-Sinn, Incorporated
Attention: Mr. Davis R. Reese
2 Esterbrook Lane
Cherry Hill, New Jersey 08002

Gentlemen:

Reference is made to your supplemental new drug application of May 10, 1972 submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sotradecol (sodium tetradecyl sulfate) 1% and 3%.

The supplemental application provides for revised labeling to comply with Federal Register Notice dated July 30, 1970 and as discussed by telephone May 8, 1972 between your representative Mr. Davis R. Reese and Dr. A. H. Pate of this Administration.

We have completed the review of this supplemental application as submitted with draft labeling. However, before the supplement may be approved, it will be necessary for you to submit final printed labeling. The labeling should be identical in content to the draft copy. 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,

7/10/72

Marion J. Finkel, M.D.
Director
Office of Scientific Evaluation
Bureau of Drugs

cc:
NWK-DO
OSE (BD-100)
DSDDP (BD-160) 7/5/72 7/5/72
Med (BD-106)
IAS (BD-242)
APate/CMonroe 6/15/72:mcs 6/19/72
R/D init. by LDeMerre 6/16/72

APPROVABLE