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Application Number: NDA 5970/S35

APPROVAL LETTER

NDA 5-970/S-035

SEP 18 1991

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

Attention: Steven R. Eby
Regulatory Affairs Associate

Dear Mr. Eby:

Please refer to your supplemental new drug application dated August 23, 1990, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sotradecol (sodium tetradecyl sulfate injection)

This supplement provides for a conversion from screen to paper labeling on the immediate container for Sotradecol 1% and 3%.

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

Sincerely yours,

9/17/91

Wiley A Chambers, M.D.
Acting Director
Division of Medical Imaging,
Surgical and Dental Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation
and Research

cc:NDA 5-970

HFD-160 with copy of labeling

HFD-160/Stewart/Sheinin/Kenealy/DeWitt

HFD-160/Rhee *JR 5/31/91*

HFC-35/JAllen

HFD-80

HFD-100 with copy of labeling

HFD-230 " " " "

HFD-735 " " " "

R/D: JRhee 5/28/91 (3278M)

R/D init by:

F/T by:

9-16/91

Approval

5/31/91 // 9/16/91