CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S13

CORRESPONDENCE

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EPL

June 30, 1972

Division of Surgical-Dental Drug Products
Office of Scientific Evaluation
Bureau of Drugs
Food & Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

NDA 5-970/S-010 and S-013
SOTRADECOL (SODIUM TETRADECYL SULFATE)

Supplement for Ampul Dosage Form:
Final Printed Labeling

Gentlemen:

Enclosed are the final printed labeling for supplements S-010 and S-013. Labels (for S-010) included are:

1. Copy of ampul screen

2. Box label for ten ampuls

The package insert for S-010 and S-013 covers the latest FDA revisions (telephone changes to a draft submitted 5/10/72 as S-013) and the How Supplied section includes the ampul form. This package insert will be used with both the vials and ampuls. Four copies are enclosed.

S-010 was originally approved 8/14/70 except for final printed labelings. The formula is indentical to the approved formula for the vials. The enclosed labeling should permit rapid approval of this supplement. We plan to market the ampuls immediately on approval.

Respectively submitted,

EKLINS-SINN, INCORPORATED

DRReese cr

Davis R. Reese
Technical Director

DRR:cr
Enc.

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