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APPLICATION NUMBER: NDA 5970/S28

ADMINISTRATIVE DOCUMENTS

JAN 29 1988

REVIEW OF FINAL PRINTED LABELING

DATE: 22 Jan 1988
FROM: James P. HANNAN, R.Ph.
TO: NDA 5-970/S-028 Sotradecol (sodium tetradecyl sulfate injection)
SUBJECT: Review of Final Printed Labeling (FPL) dated September 16, 1987

I have reviewed the Final Printed Labeling (FPL) dated September 16, 1987 against the draft labeling dated February 12, 1987 and I have found them to be identical except for the following changes requested in our approvable letter dated March 31, 1987 and found acceptable by the reviewing pharmacologist, Dr. Wilson:

1. the addition concerning no long term animal carcinogenicity studies to the "Carcinogenesis, Mutagenesis and Impairment of Fertility" subsection
2. the correction of the misspelling of microsis in the ADVERSE REACTION section

I recommend approval of this Final Printed Labeling.

James P. HANNAN, R.Ph.
Consumer Safety Officer

NDA 5-970
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OK for JCK
25 Jan 88