CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 017024

Trade Name: STROTOPE

Generic Name: STRONTIUM NITRATE Sr 85 INJECTION

Sponsor: E. R. SQUIBB AND SONS, INC.

Approval Date: 07/09/73

INDICATION(s): RADIOPHARMACEUTICAL DRUG

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APPLICATION: 017024

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative Approval Letter				X
Approvable Letter				X
Printed Labeling			X	
Medical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI				X
Pharmacology Review(s)	X			
Statistical Review(s)				X
Microbiology Review(s)				X
Clinical Pharmacology Biopharmaceutics Review(s)				X
Bioequivalence Review(s)				X
Administrative/ Correspondence Document(s)	X			

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Application Number: 017024

APPROVAL LETTER

JUL 10 1973

NDA 17-024

AF 9-561

E. R. Squibb & Sons, Inc.
Attention: Norman W. Lavy, M.D.
Georges Road
New Brunswick, New Jersey 08903

Gentlemen:

Reference is made to your new drug application dated April 2, 1971 submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for the preparation Strotope (Strontium Nitrate Sr 85 Injection).

We also acknowledge receipt of your additional communication dated June 22, 1973, providing final printed labeling as requested in our letter dated April 24, 1973.

We have completed the review of this application as amended and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved.

The enclosures summarize the conditions relating to the approval of this application.

Sincerely yours,

J. Richard Crout, M.D.
Acting Director
Bureau of Drugs

Enclosures

cc:
NDA 17-024 Orig., Dup., Trip.(NYK-DO)
BD-100, BD-150, BD-106, BD-242
BD-150/EKagan:6-28-73
R/D endorsed by CFBruening:6-28-73; MHein for DJRichman:6-29-73
                BLJones, M.D., MIChacalos, M.D.:6-29-73
Final typed 7-3-73:jd

APPROVAL