CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 017024

CHEMISTRY REVIEW(S)

CHEMIST REVIEW OF NDA 17-024

Division of Oncology and Radiopharmaceutical Drug Products

I. NDA: 17-024 June 30, 1971

NON-PROTRIETARY NAME:
Strontium Nitrate (Sr-85)

SPONSOR: E. R. Squibb & Sons, Inc
New Brunswick, New Jersey

PROPRIETARY NAME: Strotope[R]

DOSAGE FORM: Parenteral (I.V.)
Rx

II. ACTIVE INGREDIENT: Radioactive Strontium 85

CHEMICAL NAME: Strontium Nitrate

SUPPORTING DMF's: [redacted]

III. ORIGINAL SUBMISSION AND DATES: Dated April 2, 1971 to provide for use of Strotope in detection of localized skeletal lesions.

IV. a) REMARKS: Information is needed for (1) raw material obtained from General Electric, (2) meaning of "prime container label" and (3) meaning of "assay" on label.

b) CONCLUSIONS: Request applicant to provide adequate immediate container labels and answers to deficiencies noted above.

Benjamin Kagan, Chemist

cc:
Orig.
Dup.
Trip. (NYK-DO)
BD-100
BD-150
BD-150/BKagan:6/30/71
R/D Endorsed by CFBruening:6/30/71
Final typed by slt:7/1/71

[redacted] APPEARS THIS WAY ON ORIGINAL

Division of Oncology and Radiopharmaceutical Drug Products

Chemist's Review #3

October 30, 1972

A. 1. NDA 17-024

APPLICANT: E. R. Squibb & Sons, Inc.

ADDRESS: New Brunswick, New Jersey

AF # 9-561

2. PRODUCT NAME: Proprietary: Strotope

3. DOSAGE FORM: Rx, Parenteral

B. 2. AMENDMENTS: 6/6, 9/15/72.

C. REMARKS: Previous chemist's review (B. Kagan, 2/29/72), NDA not approvable.

An amendment dated 6/6/72, applicant states that laboratory personnel consider radiochemical purity test to be unnecessary. However, the 9/15 amendment provides just such a test.

[redacted]

Newark District advised us [redacted] dated 2/1/72 that there is no objection to approval, based on establishment inspection, even though there was a problem concerning quarantine for sterility testing. A re-inspection was requested by our [redacted] dated 7/7/72.

A monograph for Strontium Nitrate Sr 85 has been proposed for inclusion in the U.S.P. When this monograph is published, our method validation procedure will be unnecessary.

D. CONCLUSIONS: NDA is essentially approvable, but will require acceptable inspection report and either USP Monograph or methods validation report to complete the file for approval.

Benjamin Kagan, Chemist

cc: NDA 17-024 Orig. Dup., Trip.(NYK-DO)
BD-100, BD-150, BD-54, CA-226
BD-150/BKagan:10/30/72
R/D Endorsed by CFBruening:10/30/72
Final typed deg:1/16/73

APPEARS THIS WAY ON ORIGINAL

DORDP (BD-150) June 28, 1973

CHEMIST'S REVIEW #5

A.1. NDA 17-024

Applicant: E. R. Squibb & Sons, Inc.

Address: New Brunswick, N. J.

2. Product Name:

Proprietary Name: Strotope

3. Dosage Form and Route of Administration: Rx, Parenteral

B.2. Amendments: June 22, 1973

C. Remarks: Previous chemist's review (B. Kagan, 4/4/73); NDA approvable, request final printed labeling.

Amendment dated 6/22/73 provides FPL as requested.

D. Conclusions: Final printed labeling is identical to approved draft labeling.

NDA should be approved.

Benjamin Kagan, Chemist

cc:
NDA 17-024 Orig., Dup., Trip.(HYK-DO)
BD-100, BD-150, BD-54
BD-150/BKagan:6-28-73
R/D endorsed by CFBruening:6-28-73; EHChacalos:6-29-73
Final typed 7-3-73:jd

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Division of Oncology and Radiopharmaceutical Drug Products

Chemists Review # 4

April 4, 1973

A. 1. NDA: 17-024

Applicant: E. R. Squibb & Sons, Inc.

Address: New Brunswick, New Jersey

AF 9-561

2. Product Name:

Proprietary Name: Strotope.

3. Dosage Form: Rx, Parenteral

B. 2. Amendments: 11/15/72, 12/19/72, 1/26/73, 3/23/73.

C. REMARKS: Previous chemist's review (B.Kagan, 10/30/72); NDA will be approvable after methods are validated and receipt of acceptable FIR.

Amendment dated 11/15/provides additional information for assay procedures as requested by our laboratories. Information sent to laboratories on 1/16/73. Major portion of methods had been sent on 11/24/72.

Amendments dated 12/19/72 and 3/23/73 provide revised package inserts.

Amendment dated 1/26/73 notes that samples for methods validation are being forwarded as requested.

[redacted]

[redacted] dated 9/27/72, Newark DO informs us that recent EI shows Squibb to be in compliance with provisions of NDA and GMP.

D. Conclusions: All manufacturing and controls requirements have been satisfied. NDA is approvable.

Benjamin Kagan, Chemist

cc:
BDA100, OBO-050g.BDu54, TBBp150YKKB0an:4/4/73
R/D Endorsed by CFBruening:4/4/73 deg:4/9/73

BD 150

APPEARS THIS WAY ON ORIGINAL

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