

Michael P. Swiatocha
Diagnostics Quality Control
and Regulatory Affairs Director



May 15, 1985

Dr. John Glenn
U.S. Nuclear Regulatory Commission
Region I
Nuclear Material Section B
631 Park Avenue
King of Prussia, Pennsylvania 19406

Dear Dr. Glenn:

Reference is made to our specific license no. 29-00139-04MD.

Squibb Diagnostics is proposing to change the design of the shield label for the products included in this license. As discussed in a telephone conversation on September 26, 1984 between yourself and Mr. L. Callan, we are submitting the proposed new label for one product, Sethotope, along with a copy of the current label. If this new design is acceptable, we plan to phase it in for all products. We will submit the additional labels when they become available.

Enclosed is a check for \$120.00 to cover the fee for this amendment.

We look forward to your prompt review and approval of this amendment.

Sincerely,

Lawrence Callan for
Michael P. Swiatocha

MPS:ks

Enclosure

RECEIVED BY LPMO
Date... 5/28/85
Log... May 14 I
Sy... Brown
Reg. To...
Relief Count 5/29/85

Applicant...
Check No. 668713
Amount/Fee Category \$120/3D
Type of Fee Amendment
Date Check Rec'd. 5/28/85
Received By... Brown

8507030664 850606
REG1 LIC30
29-00139-04MD PDR



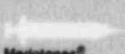
RECEIVED
MAY 20 1985

"OFFICIAL RECORD COPY"


03834

ML10

MAY 20 1985

 <p>Vial contains a sterile, nonpyrogenic, aqueous solution of L-selenomethionine ⁷⁵Se with not more than 3 mg L-methionine as a carrier and 1.5 mg L-selenomethionine hydrochloride as an antioxidant per mL sodium chloride for isotonicity, and 0.9% (w/v) benzyl alcohol as a preservative. pH adjusted to 3.5-6.0 with sodium hydroxide or hydrochloric acid.</p> <p>E. R. Squibb & Sons, Inc. Princeton, NJ 08540 Made in USA</p>	 <p><small>CAUTION RADIOACTIVE MATERIAL</small></p> <p><small>Must be handled only by qualified personnel in conformance with regulations of the U.S. Nuclear Regulatory Commission</small></p>	 <p>Medotope®</p> <p>Intravenous DIAGNOSTIC</p> <p>SETHOTOPE® Selenomethionine Se 75 Injection</p> <p><small>Usual dose for pancreas imaging: 1.8 to 3.5 microcuries per kg body weight (a total of 125 to 250 micro- curies). Do not administer more than 5 mL of the preparation. See insert.</small></p> <p><small>Caution: Federal (USA) law prohibits dispensing without prescription</small></p>	<p>List 06300</p> <p>STORE IN REFRIGERATOR</p> <p><small>Store vial in this container when not in use.</small></p> <p><small>If supplied in lead container, keep shielded.</small></p> <p>M7221E / 06300</p>
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Current Label

<p>List 06300</p> <p>Vial contains a sterile, nonpyrogenic, aqueous solution of L-selenomethionine ⁷⁵Se with not more than 3 mg L-methionine as a carrier and 1.5 mg L-selenomethionine hydrochloride as an antioxidant per mL sodium chloride for isotonicity, and 0.9% (w/v) benzyl alcohol as a preservative. pH adjusted to 3.5-6.0 with sodium hydroxide or hydrochloric acid.</p> <p>Squibb Diagnostics New Brunswick, NJ 08903 Made in USA</p>	 <p>SQUIBB® Diagnostics</p> <p><small>CAUTION RADIOACTIVE MATERIAL</small></p>	<p>Intravenous DIAGNOSTIC</p> <p>SETHOTOPE® Selenomethionine Se 75 Injection</p> <p><small>Do not administer more than 5 mL of the preparation. See insert for dosage information.</small></p> <p><small>Caution: Federal (USA) law prohibits dispensing without prescription</small></p>	<p><small>Must be handled only by qualified personnel in conformance with regulations of the U.S. Nuclear Regulatory Commission</small></p> <p>Store between 2° and 8° C</p> <p><small>Store vial in this container when not in use. If supplied in lead container, keep shielded.</small></p> <p>M7221G / 06300</p>
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Proposed Label

BETWEEN: William O. Miller, Chief
License Fee Management Branch
Office of Administration -

John E. Glenn, Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: E.R. Squibb + Sons, Inc.

Application Dated: 5/15/85

Control No.: 03834

License No.: 29-00139-04MD

2. FEE ATTACHED

Amount: \$ 120.00

Check No.: 668713

3. COMMENTS

Signed Brenda Platchek

Date 5/22/85

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 3D \$120

2. Correct Fee Paid. Application may be processed for:

Amendment ✓

Renewal _____

License _____

Signed Francis Brown

Date 5/28/85

"SECTION COPY"

E. R. Squibb & Sons, Inc.

FILE
REMITTANCE ADVICE

VENDOR NUMBER	INVOICE NO. OR DATE	CHECK TO	INVOICE AMOUNT	DISCOUNT	NET AMOUNT
918060	03005		120.00 120.00	.00 .00	120.00 120.00*

DETACH BEFORE DEPOSITING

CHECK NUMBER
668713

E. R. Squibb & Sons, Inc.

55-103
212

P

FIRST FIDELITY BANK, NA, NEW JERSEY

CHECK NO. 668713



DATE

03/08/85

AMOUNT

PAY → \$*****120.00*

TO THE
ORDER
OF

U.S. NUCLEAR REGULATORY
1717 H STREET N.W.
WASHINGTON DC20555

E. R. Squibb & Sons, Inc.

REGULAR ACCOUNT

Matthew P. Vane
A. Ruffalo
AUTHORIZED SIGNATURE

⑈668713⑈ ⑆021201037⑆ 163 000679 1⑈

L. Collins - NB