CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-044 / S-003

Trade Name: Indium In-111 Oxyquinoline

Generic Name:

Sponsor: GE Healthcare

Approval Date: June 8, 1987

Indications: For a change in Indium In-111 Oxyquinoline

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APPLICATION NUMBER:

19-044 / S-003

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	**X**
Other Action Letters	
Labeling	
Summary Review	
Officer/Employee List	
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	
Chemistry Review(s)	**X**
Environmental Assessment	
Pharmacology Review(s)	**X**
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	
Other Reviews	
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	
Administrative/Correspondence Document(s)	**X**

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APPLICATION NUMBER:

19-044 / S-003

APPROVAL LETTER

NDA 19-044/S-003

Amersham Corporation
2636 South Clearbrook Drive
Arlington Heights, Illinois 60005-4692

JUN 8 1987

Attention: Donald E. Baker, Manager
Medical Regulatory Affairs

Dear Mr. Baker:

Please refer to your supplemental new drug application of December 23, 1986, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Indium In 111 Oxyquinoline Solution.

The supplemental application provides for a change in (b) (4) strength for (b) (4) of Indium (b) (4) In 111.

We have completed the review of this supplemental application and it is approved. We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

Sincerely yours,

Robert A. Jerussi 6/5/87

Robert A. Jerussi, Ph.D.
Deputy Director
Division of Oncology and
Radiopharmaceutical Drug Products
Office of Drug Research and Review
Center for Drugs and Biologics

cc:
Orig. NDA 19-044
HFN-150/Division File
HFN-150/Leak/1-12-87 for 6/1/87
HFN-150/West
R/D init. by: RHWood/3-27-87
F/T by: tag/5-28-87
revised by RHWood/6-1-87
F/T by tag/6-1-87
Wang # 09850
Approved

H. J. Kerly
Acting Supervising Chemist
6-1-87

Robert Lyckot
6/3/87

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APPLICATION NUMBER:

19-044 / S-003

CHEMISTRY REVIEW(S)

FINISHED REVIEW
R.A. Jenni 6/5/87

CHEMIST'S REVIEW
(If necessary, continue any item on 8" x 10½" paper. Key continuation to item by number.)

1. ORGANIZATION	2. NDA NUMBER
DORDP	19-044

3. NAME AND ADDRESS OF APPLICANT *(City and State)*
Amersham Corporation
Arlington Heights, IL 60005

4. AF NUMBER

5. SUPPLEMENT (S)

NUMBER(S)	DATE(S)
S003	12/23/86

6. NAME OF DRUG
Indium In 111 Oxyquinoline Solution

7. NONPROPRIETARY NAME

8. SUPPLEMENT(S) PROVIDES FOR:
a change in (b) (4) strength for (b) (4) of (b) (4)

9. AMENDMENTS AND OTHER *(Reports, etc.)* DATES

10. PHARMACOLOGICAL CATEGORY
Radiopharmaceutical

11. HOW DISPENSED
☒ RX ☐ OTC

12. RELATED IND/NDA/DMF(S)

13. DOSAGE FORM (S)
Inj

14. POTENCY *(Ies)*

15. CHEMICAL NAME AND STRUCTURE

16. RECORDS AND REPORTS
CURRENT ☐ YES ☐ NO
REVIEWED ☐ YES ☐ NO

17. COMMENTS
This is a special supplement - Changes being effected before approval under 21CFR 314.70 (c) (1) with an effective date of 1/5/87. The concentration of the (b) (4) used for the (b) (4) of the Indium 111 (b) (4) was changed (b) (4). Data would indicate that the (b) (4) is more consistant using the more (b) (4). The effect on the (b) (4) impurity level does not seem to be effected.
In addition, the level of (b) (4) in this component used in the manufacture of the drug will be specified as less than (b) (4) µg/ml, lower than previously specified.

18. CONCLUSIONS AND RECOMMENDATIONS
An approval letter should be sent to the applicant. A draft of the letter is attached.

RHwood 3/27/87

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
John C Leak, PhD	John C Leak	3/23/87

DISTRIBUTION ☐ ORIGINAL JACKET ☒ REVIEWER ☐ DIVISION FILE

FORM FDH 2266 (7/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED. 1

IA 19-044/S003

NDA-S- (b) (4)

(1) (b) (4)

(2) Indium In 111 Oxyquinoline Solution

NDA-S-8

(1) a change in (b) (4) strength for (b) (4) of (b) (4)

NDA-S- (b) (4)

(1) (b) (4)

RAS

Jack 3/23/87

RAtwood
3/27/87

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APPLICATION NUMBER:

19-044 / S-003

PHARMACOLOGY REVIEW(S)

PHARMACEUTICAL DIVISION

QUALITY ASSURANCE

BASIS FOR PHARMACEUTICAL LOT RELEASE

CODE:INS1P/INS1PA

STOCK SOLUTION		Sample of INS1 submitted by Production	
CRITERIA:	1	Radioactive Concentration	(b) (4) mCi/ml
	2	Chemical Purity*	ug/ml, In (b) (4) ug/ml ug/ml Any other detectable cation (b) (4) ug/ml Total detectable cations (b) (4) ug/ml
	3	Indium-111 identity:	Confirmed
	4	Radionuclidic Purity:	** (i)In-114m (b) (4) % at reference ** (ii)Other (b) (4). None detectable
	5	(b) (4):	(i) (b) (4) identity test (ii) (b) (4)
	6	(b) (4):	(b) (4) ug (b) (4)/ml
METHODS:		See QA Procedures	

COMMENTS:
* This spec applies to material with an RAC of (b) (4) mCi/ml and must be raised pro rata for higher RAC's.
** Measured on corresponding IN15PA final pack. In-114m specification corresponds to (b) (4) % at INS1P ref. date. If no IN15PA is produced then full RNP analysis must be done on INS1

DILUTION
CRITERIA : Not analysed by QA

FINAL PACK — Final Packs submitted by the Dispensary

CRITERIA:	1		Approval of INS1 stock
	2		Total activity: label value (b) (4) %
	3		Radioactive concentration: label value (b) (4) %
	4	*	Radiochemical purity: (b) (4) %
	5		Radionuclidic purity: No (b) (4) detected
	6		Chemical Purity: (b) (4) ug/ml any detectable cation (b) (4) ug/ml total detectable cations
	7		(b) (4): (b) (4) M HCl
	8		Wipe Test: (b) (4) uCi
	9		Pyrogen test (Limulus) Pass

(b) (4) only)

J1

1 Page has been Withheld as b4 (CCI/TS) immediately following this page

APPROVED BY QUALITY ASSURANCE 16 DEC 1986

Rev. 12/86
*120

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-044 / S-003

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

To JL 1/12/87

Amersham Corporation
2636 South Clearbrook Drive
Arlington Heights, Illinois 60005-4692
(312) 593-6300

NDA NO 19-044 REF. NO. 5003
NDA SUPPL FOR SCM

Amersham

December 23, 1986

Department of Health, Education and Welfare
Food and Drug Administration
HFN-150
Attention: Document Control Room #17B-34
5600 Fishers Lane
Rockville, MD 20857

Re: NDA #19-044
Indium In 111 Oxyquinoline Solution
SPECIAL SUPPLEMENT - CHANGES BEING EFFECTED

Gentlemen:

Reference is made to Indium In 111 Oxyquinoline Solution, NDA #19-044, approved on December 24, 1985.

In accordance with 21 CFR Subpart B Section 314.70(c)(1), Amersham wishes to supplement the application for modifications to processing controls, to provide increased assurance that the drug product Indium In 111 Oxyquinoline Solution has the chemical purity it is represented to possess.

1. Description of change:

In the preparation of the radioactive raw material, Indium (In-111) (b) (4), the (b) (4) strength of the (b) (4) (b) (4) used in the (b) (4) of the target material, (b) (4), from the radioactive Indium (In-111), is reduced from (b) (4)% (concentrated (b) (4)) to (b) (4)% (an (b) (4)% aqueous solution of concentrated (b) (4)).

2. Reason for change:

(b) (4)

(b) (4)

3. Section of NDA #19-044 to be revised:

The section of NDA #19-044 affected by the process control modifications is Part 8(h) on pages 8.118-8.119; 8.125; 8.126. Revised pages with the correct page number are attached for substitution.

Attached for your information are two new pages containing the revised chemical purity specifications for Indium (In-111) (b) (4). These pages originally appeared in Part 4 of the Indium (In-111) (b) (4) DMF # (b) (4) as raw material tests. In the near future, these pages will be incorporated in NDA #19-044, (annual report) as additional reference information for Raw Material Indium (In-111) (b) (4).

4. Justification for change - supporting information:

(b) (4)