CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-044 / S-005

Trade Name: Indium In-111 Oxyquinoline

Generic Name:

Sponsor: GE Healthcare

Approval Date: April 11, 1989

Indications: For a revised package insert to include changes int the Pregnancy Category C and the Nursing Mothers sections.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-044 / S-005

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-044 / S-005

APPROVAL LETTER

NDA 19-044/S-005

APR 11 1989

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

Attention: Jack Waterman
Manager, Scientific and Regulatory Affairs

Dear Mr. Waterman:

Reference is made to your supplemental new drug application dated February 14, 1989 submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for the diagnostic radiopharmaceutical indium In 111 oxyquinoline.

This supplement provides for a revised package insert to include changes in the Pregnancy Category C and the Nursing Mothers sections. Specifically, the changes are the following.

1. The Pregnancy Category C has been revised to state:

   "Animal reproduction studies have not been conducted with Indium In 111 oxyquinoline labeled leukocytes. It is also not known whether indium In 111 labeled leukocytes can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Indium In 111 oxyquinoline labeled leukocytes should be given to a pregnant woman only if clearly needed."

2. The Nursing Mothers section has been revised to state:

   "It is reported that indium In 111 is secreted in human milk following administration of indium In 111 labeled leukocytes. Therefore, formula feedings should be substituted for breast feedings."

Reference is made to your March 29, 1989 telephone conversation with Susan Lange of this Administration in which you agreed to include the following sentence as an addition to the Pregnancy Category C statement.

"However, indium nitrate, a closely related compound, was teratogenic and embryopathic in hamsters."

We have completed our review of this supplemental new drug application including the submitted draft labeling as amended in the March 29, 1989 telephone conversation and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling submitted on February 14, 1989.

Accordingly, the application is approved, effective as of the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on February 14, 1989 as amended March 29, 1989. Marketing of the product with FPL that is not identical to the draft labeling may render the product misbranded and an unapproved new drug. Please individually mount seven copies of the final printed version of the revised labeling on heavy weight paper or similar material and submit a total of twelve copies to FDA as soon as available. This submission should be designated for administrative purposes as "FPL for the Approved Supplemental Application 19-044/S-005." Approval of this submission by FDA is not required before the labeling may be used.

Should additional information relating to the safety and effectiveness of this drug product become available prior to our receipt of the final printed labeling, revision of that labeling may be required.

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,

JPalmer 4-11-89

John F. Palmer, M.D.
Director
Division of Oncology and
Radiopharmaceutical Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
√NDA 19-044/S-005
HFD-150/DIVISION FILE
HFD-151/CSO/Lange
HFD-150/D. Lee Ham, Ph.D.
HFD-80/DDIS
HFD-730/DDBPE
HFD-232/DGD
HFD-101/P.Botstein, M.D.
HFD-244/DDAL/B. Purvis
R/D Endorsed by:
S. Lange 3.31.89
D. Lee Ham,Ph.D. 3.31.89
D. Richman,Ph.D. 3.31.89
A.E. Jones,M.D. 4.03.89
R. Scully,SCSO 4.05.89
drafted by: S. Lange: 3.31.89 Wang 0769C
To printing 4.6.89
F/T by: SDavis/4-6-89

APPROVAL OF SUPPLEMENT

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-044 / S-005

PHARMACOLOGY REVIEW(S)

0

Supplemental Review and Evaluation of Pharmacology and Toxicology Data

NDA: 19-044 February 23, 1989

Applicant: Amersham Corporation
Arlington Heights, Illinois 60005

Name of Drug: Indium In-111 Oxyquinoline

Category: Radiolabeling atuologous leukocytes

Material Reviewed: NDA 19-044/005 SLR

We accept the submitted draft labeling with this NDA application, under Pregnancy Category C that "Animal reproduction studies have not been conducted with Indium In-111 Oxyquinoline labeled leukocytes. It is also not known whether Indium In-111 Oxyquinoline labeled leukocytes can cause fetal harm when administered to a pregnant woman."

We recommend to add the following statement after the above statement that "However, Indium nitrate, a closely related compound, was teratogenic and embryopathic in hamsters."

We have no objections to the statement in regarding the Nursing Mothers that "It is reported that Induim 111 is secreted in human milk following administration of Indium In-111 labeled leukocytes. Therefore, formula feedings should be substituted for breast feedings."

Doo Y. Lee Ham, Ph.D 3/29/89

cc:
Orig. NDA 19-044
HFD-150/Division File
HFD-150/Doo Y. Lee Ham, Ph.D.
HFD-151/West
HFD-340
R/D Init. by: Dave Richman/2/23/89
F/T by: LMR/3/29/89/
Wang 16060

4-11-89

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-044 / S-005

OTHER REVIEW(S)

JUL 1 1 1989

DIVISION OF RADIOPHARMACEUTICAL, SURGICAL AND DENTAL DRUG PRODUCTS

RADIOPHARMACEUTICAL DRUG GROUP

REVIEW OF A FINAL PRINTED PACKAGE INSERT

NDA/SUPPLEMENT: 19-044/S-005 **APPLICANT:** Amersham Corporation

DRUG: Indium In 111 oxyquinoline

DATE OF SUBMISSION: June 5, 1989

DATE REC'D: June 6, 1989

DATE REC'D BY REVIEWER: June 10, 1989

REVIEWER: Susan Lange, Consumer Safety Officer
Radiopharmaceutical Drug Products

BACKGROUND:

FDA issued an approval letter on April 11, 1989 to Amersham Corporation to provide for a revised package insert to include changes in the Pregnancy Category C and Nursing Mothers sections. The changes requested by the company corrected an existing error in the Pregnancy Category C section and updated the Nursing Mothers section to reflect current medical literature information. After a pharmacology review, FDA requested the company to add another sentence to the Pregnancy Category C section. This request was conveyed to the company in a March 29, 1989 telephone conversation with Susan Lange of this Administration and was also included in the supplement approval letter dated April 11, 1989. The letter also requested Amersham Corporation to submit final printed package inserts incorporating the revisions.

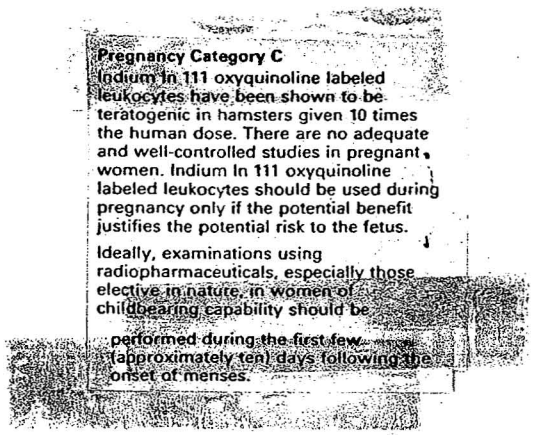
REVIEW OF FINAL PRINTED LABELING (PACKAGE INSERT):

I have reviewed the final printed package insert (designated Code IN.15PA and Printed 5/89) as submitted on June 5, 1989 and have compared it to (1) the currently approved package insert (designated Code IN.15PA and Printed 4/86) and to (2) the supplement approval letter dated April 11, 1989. The revisions to the PREGNANCY CATEGORY C and NURSING MOTHERS sections of the package insert have been made exactly as requested in our letter and are acceptable. No other changes in content or format are noted. These changes are presented in detail below.

I. PREGNANCY CATEGORY C

The applicant has revised this section as approved in our April 11, 1989 letter.

PREGNANCY CATEGORY C as it appears in current labeling (4/86):

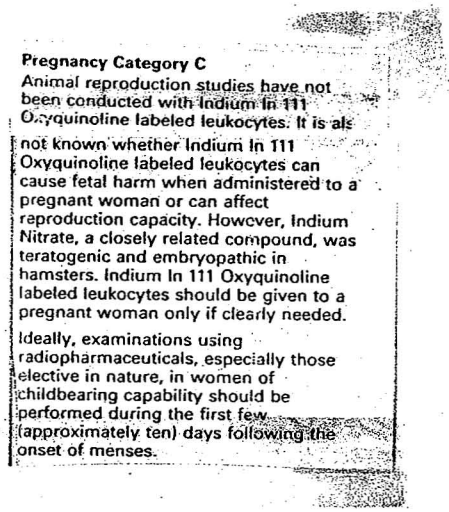


Pregnancy Category C

Iodium In 111 oxyquinoline labeled leukocytes have been shown to be teratogenic in hamsters given 10 times the human dose. There are no adequate and well-controlled studies in pregnant women. Indium In 111 oxyquinoline labeled leukocytes should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, in women of childbearing capability should be performed during the first few (approximately ten) days following the onset of menses.

PREGNANCY CATEGORY C as it appears in revised labeling (5/89):



Pregnancy Category C

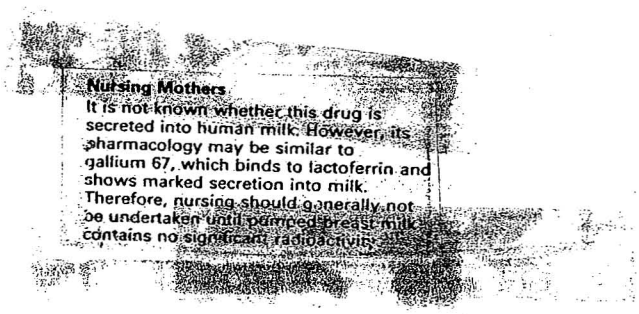
Animal reproduction studies have not been conducted with Indium In 111 Oxyquinoline labeled leukocytes. It is als not known whether Indium In 111 Oxyquinoline labeled leukocytes can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. However, Indium Nitrate, a closely related compound, was teratogenic and embryopathic in hamsters. Indium In 111 Oxyquinoline labeled leukocytes should be given to a pregnant woman only if clearly needed.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, in women of childbearing capability should be performed during the first few (approximately ten) days following the onset of menses.

II. NURSING MOTHERS

The applicant has revised this section as approved in our April 11, 1989 letter.

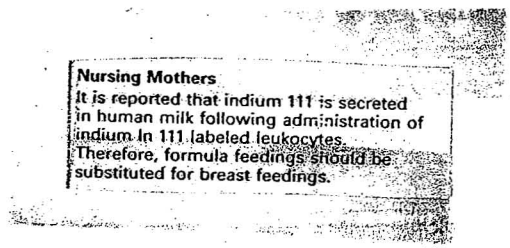
NURSING MOTHERS as it appears in current labeling (4/86):



Nursing Mothers

It is not known whether this drug is secreted into human milk. However, its pharmacology may be similar to gallium 67, which binds to lactoferrin and shows marked secretion into milk. Therefore, nursing should generally not be undertaken until pumped breast milk contains no significant radioactivity.

NURSING MOTHERS as it appears in revised labeling (5/89):



Nursing Mothers

It is reported that indium 111 is secreted in human milk following administration of indium In 111 labeled leukocytes. Therefore, formula feedings should be substituted for breast feedings.

CONCLUSION:

The final printed package insert submitted by Amersham Corporation on June 5, 1989 contains the revisions approved in the FDA supplement approval letter of April 11, 1989. No other changes in content or format are noted.

RECOMMENDATION:

Approve supplement S-005 providing a revised final printed package insert (5/89) to include revisions in the PREGNANCY CATEGORY C and NURSING MOTHERS sections.

ATTACHMENTS:

(1) April 11, 1989 supplement approval letter.

Susan Lange 7-7-89

Susan Lange 7.07.89

A. Eric Jones M.D. 7/11/89

Concur: A. Eric Jones, M.D.
Group Leader

CC:
See distribution on Acknowledge and Accept letter

Noted
J Palmer
7-14-89

LABELING REVIEW

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-044 / S-005

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

JUL 17 1989

NDA 19-044/S-005

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

Attention: John H. Waterman
Manager, Scientific and Regulatory Affairs

Dear Mr. Waterman:

We acknowledge the receipt of your final printed labeling (FPL) dated June 5, 1989 for your approved supplemental new drug application (S-005) for diagnostic radiopharmaceutical indium In 111 oxyquinoline.

We have reviewed the FPL that you have submitted in accordance with our approval letter dated April 11, 1989 and we find it acceptable.

Sincerely yours,

J Palmer 7-14-89

John F. Palmer, M.D.
Acting Director
Division of Radiopharmaceutical,
Surgical and Dental Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

CC:
Original NDA 19-044/S-005
HFD-160/DIVISION FILE
HFD-161/CSO:Lange
HFD-161/F.Stone
HFD-80/DDIS (3 FPL)
HFD-730/DES (1 FPL)
HFD-231/DGD (1 FPL)
HFD-101/P.Botstein (1 FPL)
R/D Endorsed by:
S.Lange 7.07.89
A.Eric Jones, M.D. 7.11.89
G.Boyer,SCSO 7.12.89
drafted:Lange:7.07.89 Wang 0242B
To printing 7.14.89

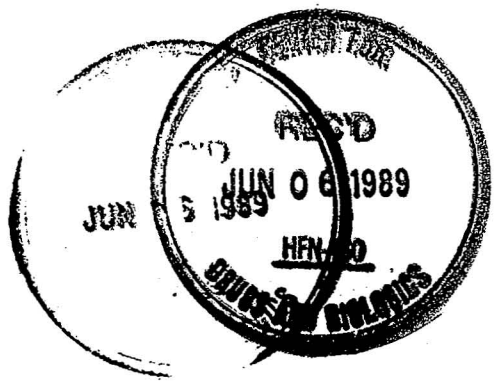
ACKNOWLEDGE AND ACCEPT

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

SUP-005
SPA

Amersham

June 5, 1989



Division of Radiopharmaceutical and
Surgical-Dental Drug Products (HFD-160)
Document Control Room 18B-03
5600 Fishers Lane
Rockville, MD 20857

Attention: Ms Susan Lange
Consumer Safety Officer

Re: NDA 19-044/S-005
Indium-111 Oxyquinoline
FPL for Approved SNDA

Dear Ms. Lange:

Please refer to our approved Supplement, identified above. Please refer also to Doctor Palmer's letter dated April 17, 1989, approving the Supplement and requesting submission of Final Printed Labeling (revised package insert).

Accompanying this letter are twelve copies of the package insert for Indium-111 Oxyquinoline. We appreciate your continued interest in our Application.

Yours truly,

Jack Waterman

John H. Waterman
Manager, Scientific & Regulatory Affairs

mc
2761P

NDA 19-044/S-005
Indium-111 Oxyquinoline
Amersham Corporation

FINAL PRINTED LABELING

ORIGINAL

Labeling:
NDA No: 19-044 Rc'd. 6-6-89
Reviewed by:
7-7-8

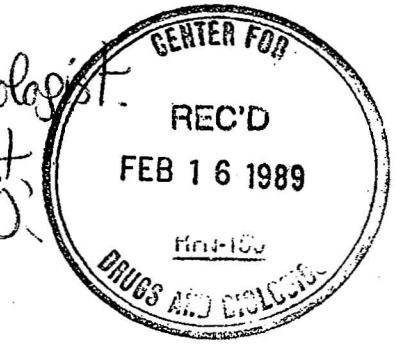
4 Pages of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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

NDA NO. 19-044 REF. NO. 005
NDA SUPPL FOR SLR

Amersham

2/22/89
Noted, To
reviewing pharmacologist.
Robert Lisi
CSO



February 14, 1989

Division of Oncology &
Radiopharm. Drug Products (HFN-150)
Office of Drug Evaluation I
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: NDA #19-044, Indium In 111 Oxyquinoline
Supplemental New Drug Application
EXPEDITED REVIEW REQUESTED

Gentlemen:

Please refer to our approved New Drug Application, identified above. The purpose of this Supplement, for which expedited review is requested, is to correct an existing error in the Pregnancy Category C section, and to update the Nursing Mothers section, of the prescribing information.

In Item 10 of the original Application, submitted December 12, 1983, Amersham Corporation discussed the embryotoxicity of indium administered intravenously to pregnant hamsters. The publication which was reviewed described a study with indium nitrate, not with indium oxyquinoline labeled leukocytes. It was noted that the level of indium reaching patients receiving indium In 111 oxyquinoline labeled leukocytes would be "on the order of 10^4 times less" than the indium nitrate intravenous dose resulting in embryotoxicity. This was a very conservative estimate. A copy of this page from the original Application accompanies this letter as Attachment 1.

Based upon these findings, Amersham Corporation submitted draft labeling with this Application, which properly noted, under Pregnancy Category C, that "Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus." A copy of this page of the original Application accompanies this letter as Attachment 2.

The Division's Approvable letter for this Application, dated October 17, 1985, provided a draft package insert including the following text under Pregnancy Category C: "Indium In 111 Oxyquinoline labeled leukocytes have been shown to be teratogenic in hamsters given 10 times the human dose." A copy of the Approvable letter and page 6 of the draft package insert accompany this letter as Attachments 3 and 4 respectively. Unfortunately, the text of the Division's draft package insert was incorporated into the final printed labeling for indium In 111 oxyquinoline without further critical review.

It is evident that two significant errors were incorporated in the draft labeling. Indium nitrate, and not indium In 111 oxyquinoline labeled leukocytes, was reported to be teratogenic in hamsters. In addition, the direct intravenous dose of indium nitrate administered was at least 10^4 times the equivalent human dose of indium which results from the administration of indium In 111 oxyquinoline labeled leukocytes.

This Supplemental New Drug Application provides for revising the statement to read: "Pregnancy Category C. Animal reproduction studies have not been conducted with Indium In 111 Oxyquinoline labeled leukocytes. It is also not known whether Indium In 111 Oxyquinoline labeled leukocytes can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Indium In 111 Oxyquinoline labeled leukocytes should be given to a pregnant woman only if clearly needed." This statement complies with the requirements of 21 CFR 201.57. Four copies of this draft paragraph accompany this letter as Attachment 5.

During our regular, ongoing review of the medical literature related to the product, we located a letter to the editor of The Journal of Nuclear Medicine detailing a study of the appearance of In 111 in breast milk following administration of indium 111 labeled leukocytes. A copy of this publication accompanies this letter as attachment 6. Based upon this information, we propose revising the Nursing Mothers statement to read: "It is reported that indium 111 is secreted in human milk following administration of indium In 111 labeled leukocytes. Therefore, formula feedings should be substituted for breast feedings." This statement closely follows that recently approved for Ceretec™. Four copies of this draft paragraph accompany this letter as Attachment 7.

No other revisions are proposed at this time. The commodity code number and revision date will be changed when final printed labeling is prepared.

Please contact me if you should have any questions about this Supplement or our request for expedited review. We appreciate your prompt attention this submission.

Sincerely,

Jack Waterman

John H. Waterman
Manager, Scientific & Regulatory Affairs

mc
attachments
2602P

2 Pages have been Withheld as b4 (CCI/TS) immediately following this page

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314)

Form Approved: OMB No. 0910-0001
Expiration Date; August 31,1989.

FOR FDA USE ONLY	
DATE RECEIVED	DATE FILED
DIVISION ASSIGNED	NDA/ANDA NO. ASS.

NOTE: No application may be filed unless a completed application form has been received *(21 C.F.R. Part 314).*

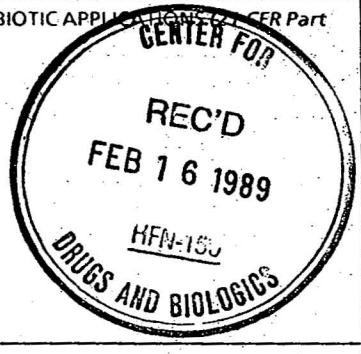
NAME OF APPLICANT: Amersham Corporation	DATE OF SUBMISSION: Feb. 14, 1989
ADDRESS *(Number, Street, City, State and Zip Code)*: 2636 S. Clearbrook Dr. Arlington Hts., IL 60005	TELEPHONE NO. *(Include Area Code)*: (312) 593-6300
	NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER (If previously issued): NDA 19-044

DRUG PRODUCT

ESTABLISHED NAME *(e.g., USP/USAN)*	PROPRIETARY NAME *(If any)*	
Indium In 111 Oxyquinoline		
CODE NAME *(If any)*	**CHEMICAL NAME**	
IN.15PA		
DOSAGE FORM	**ROUTE OF ADMINISTRATION**	**STRENGTH(S)**
Injection	intravenous injection	1 mCi/mL

PROPOSED INDICATIONS FOR USE
For radiolabeling autologous leukocytes

LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS *(21 CFR Part 312)*, NEW DRUG OR ANTIBIOTIC APPLICATIONS *(21 CFR Part 314)*, AND DRUG MASTER FILES *(21CFR 314.420)* REFERRED TO IN THIS APPLICATION:



INFORMATION ON APPLICATION

TYPE OF APPLICATION *(Check one)*

☒ THIS SUBMISSION IS A FULL APPLICATION *(21 CFR 314.50)* ☐ THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)

IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

NAME OF DRUG	HOLDER OF APPROVED APPLICATION

STATUS OF APPLICATION *(Check one)*

☐ PRESUBMISSION ☐ ORIGINAL APPLICATION ☐ AN AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION ☒ SUPPLEMENTAL APPLICATION

PROPOSED MARKETING STATUS *(Check one)*

☒ APPLICATION FOR A PRESCRIPTION DRUG PRODUCT *(Rx)* ☐ APPLICATION FOR AN OVER - THE - COUNTER PRODUCT *(OTC)*

FORM FDA 356h (3/87)

CONTENTS OF APPLICATION	
This application contains the following items: *(Check all that apply)*	
1. Index	
2. Summary (21 CFR 314.50 (c))	
3. Chemistry, manufacturing, and control section (21 CFR 314.50 (d) (1))	
4. a. Samples (21 CFR 314.50 (e) (1)) (Submit only upon FDA's request)	
b. Methods Validation Package (21 CFR 314.50 (e) (2) (i))	
c. Labeling (21 CFR 314.50 (e) (2) (ii))	
i. draft labeling *(4 copies)*	X
ii. final printed labeling (12 copies)	
5. Nonclinical pharmacology and toxicology section (21 CFR 314.50 (d) (2))	
6. Human pharmacokinetics and bioavailability section (21 CFR 314.50 (d) (3))	
7. Microbiology section (21 CFR 314.50 (d) (4))	
8. Clinical data section (21 CFR 314.50 (d) (5))	
9. Safety update report (21 CFR 314.50 (d) (5) (vi) (b))	
10. Statistical section (21 CFR 314.50 (d) (6))	
11. Case report tabulations (21 CFR 314.50 (f) (1))	
12. Case reports forms (21 CFR 314.50 (f) (1))	
13. Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))	
14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b) (2) or (j) (2) (A))	
15. OTHER *(Specify)*	

I agree to update this application with new safety information about the drug that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit these safety update reports as follows: (1) 4 months after the initial submission, (2) following receipt of an approvable letter and (3) at other times as requested by FDA. If this application is approved, I agree to comply with all laws and regulations that apply to approved applications, including the following:

1. Good manufacturing practice regulations in 21 CFR 210 and 211.
2. Labeling regulations in 21 CFR 201.
3. In the case of a prescription drug product, prescription drug advertising regulations in 21 CFR 202.
4. Regulations on making changes in application in 21 CFR 314.70, 314.71, and 314.72.
5. Regulations on reports in 21 CFR 314.80 and 314.81.
6. Local, state and Federal environmental impact laws.

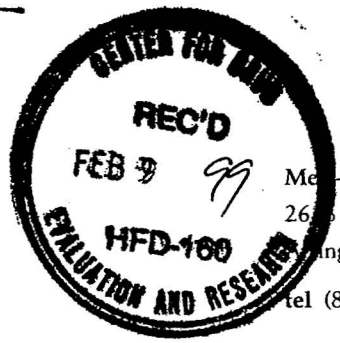
If this application applies to a drug product that FDA has proposed for scheduling under the controlled substances Act I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

NAME OF RESPONSIBLE OFFICIAL OR AGENT	SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	DATE
John H. Waterman, Mgr. Scientific & Reg. Affairs	John H Waterman	2-14-89
ADDRESS *(Street, City, State, Zip Code)* 2636 S. Clearbrook Dr. Arlington Hts., IL 60005		TELEPHONE NO. *(Include Area Code)* (312)593-6300, x214

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

☆ U.S GOVERNMENT PRINTING OFFICE:1987-181-338/55255

NDA NO. 19.044 REF. NO. SCS016
NDA SUPPL FOR Control Rev



February 1, 1999

Medi-Physics, Inc.
2636 S. Clearbrook Drive
Arlington Heights, IL 60005
tel (847) 593-6300

Amersham HEALTHCARE

Dr. Eldon Leutzinger
Division of Medical Imaging and Radiopharmaceutical
Drug Products [HFD-160]
Central Document Room 18B-03
5600 Fishers Lane
Rockville, MD 20857

Re: NDA 19-044
Indium In-111 Oxine

Dear Dr. Leutzinger,

Please refer to our Application, identified above. Please also refer to our telephone discussion of January 20, 1999, during which we discussed the NDA (b) (4) (b) (4).

(b) (4)

Inadvertently, NDA 19-044 for Indium Oxine did not get supplemented at the same time as NDA (b) (4). Medi-Physics is, therefore, submitting the Supplement. This Supplement proposes to (b) (4). Attachment 1 includes the justification for this change. Medi-Physics proposes (b) (4) for the drug product. There is no change to the manufacturing process.

Should you have any questions or require further information, please contact me at (610) 225-4107.

Yours Truly,

Susan K. Olinger
Director
Drug Regulatory Affairs
Encl.

REVIEWS COMPLETED
CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO
CSO INITIALS DATE