CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-044 / S-018

Trade Name: Indium In-111 Oxyquinoline

Generic Name:

Sponsor: GE Healthcare

Approval Date: September 19, 2002

Indications: For the addition of a Geriatrics Use subsection to the PRECAUTIONS section.

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APPLICATION NUMBER:

19-044 / S-018

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APPLICATION NUMBER:

19-044 / S-01

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-044/S-018

Amersham Health.
Attention: Mr. David Risley
Director, Marketed Products
Regulatory Affairs
101 Carnegie Center
Princeton, NJ 08540

Dear Mr. Risley:

Please refer to your supplemental new drug application dated March 28, 2002 received April 4, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for INDIUM In 111 Oxyquinoline Solution.

This "Changes Being Effected" supplemental new drug application provides for the addition of a **'Geriatrics Use'** subsection to the **PRECAUTIONS** section of the package insert to comply with the final rule 21 CFR 201.57(f)(10)(ii)(A), to read as follows:

> "Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy."

We also acknowledge your submission dated September 17, 2002, to comply with the final rule, 21 CFR 201.57(f)(10)(iii)(B), to read as follows:

(b) (4)

We have completed the review of this supplemental application, as amended, 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 agreed upon labeling text. The supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted March 28, 2002).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissons in Electronic Format*-NDA(January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material .For administrative purposes, this submission should be designated " FPL for approved supplement NDA 17-858/S-024." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional "letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MED WATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Diane C. Smith, Project Manager, at (301) 827-7510.

Sincerely,

{See appended electronic signature page}

Patricia Y. Love, M.D., M.B.A.
Director
Division of Medical Imaging and
Radiopharmaceutical Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Sally Loewke
9/19/02 03:53:37 PM
Signing for P. Love

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APPLICATION NUMBER:

19-044 / S-018

OTHER REVIEW(S)

DIVISION OF MEDICAL IMAGING AND RADIOPHARMACEUTICAL DRUG PRODUCTS

LABELING REVIEW

NDA **19-044**

SPONSOR: Amersham Health

DRUG: INDIUM In 111 Oxyquinoline Solution

BACKGROUND: This supplement provides a comparison between the most recently approved labeling for NDA 19-044/S/015 and the proposed labeling for S-018 was completed. Any differences between the labelings are noted below:

1. **SECTION I,** under **PRECAUTIONS**:

   Proposed labeling S-015 reads:

   Geriatric Use
   Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflection the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

   PM note: The sponsor has committed, on September 12, 2002, to include in compliance with the final rule, 21 CFR 201.57 (f)(10)(iii)(B), the following verbiage:

   (b) (4)

ACCEPTABLE **UNACCEPTABLE** _____Patricia Y. Love, M.D.

2. SECTION II, under **HOW SUPPLIED**

Proposed labeling S-018 reads:

NDC 17156-021-01 added

ACCEPTABLE **UNACCEPTABLE** _____ Eldon Leutzinger, Ph.D.

Recommendation: Pending that all changes to the labeling are found acceptable, the Supplement and the proposed labeling can be approved. If the proposed changes are not found acceptable, the supplement can be approved on marked-up draft labeling.

Diane C. Smith, R.Ph.
Project Manager

Concur:
Eldon Leutzinger, Ph.D.
Chemistry Team Leader, DNDC II

Concur:
Patricia Y. Love, M.D., M.B.A.
Director, Division of Medical Imaging and
Radiopharmaceutical Drug Products

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/s/

Sally Loewke
9/18/02 10:08:30 AM
Signing for P. Love

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APPLICATION NUMBER:

19-044 / S-018

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-044/S018

PRIOR APPROVAL SUPPLEMENT

Amersham Health
Attention: Mr. David Risley
Director, Marketed Products
Regulatory Affairs
101 Carnegie Center
Princeton, NJ 08540

Dear Mr. Risley:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product:	Indium 111 Oxyquinoline Solution
NDA Number:	19-044
Supplement number:	S-018
Date of supplement:	March 28, 2002
Date of receipt:	April 4, 2002

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on May 28, 2002, sixty days from date of receipt of application in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Center for Drug Evaluation and Research
Division of Medical Imaging &Radiopharmaceutical Drug Products, HFD-160
Attention: Division Document Room, 18B-06
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Medical Imaging & Radiopharmaceutical Drug Products, HFD-160
Attention: Document Room 18B-06
5600 Fishers Lane Mail Stop (HFD-160)18B-06
Rockville, Maryland 20857

If you have any question, call Tia Harper-Velazquez, Pharm.D., Regulatory Health Project Manager, at (301) 827-7510.

Sincerely yours,

Kyong Cho, Pharm.D.
Supervisory Consumer Safety Officer
Division of Medical Imaging & Radiopharmaceutical
Drug Products HFD-160
Office of Drug Evaluation III
Center of Drug Evaluation & Research

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/s/

Kyong Cho
4/23/02 04:38:23 PM