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:

"This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function."

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Sally Loewke
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Signing for P. Love