DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-351/SLR-013

Amersham Health
Attention: Paula Clark, Associate
Regulatory Affairs
101 Carnegie Center
Princeton, NJ 08540-6231

Dear Mrs. Clark:

Please refer to your supplemental new drug application dated June 18, 2003, received June 19, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Visipaque (iodixonal) Injection 270mgI/mL and 320mgI/mL.

We acknowledge receipt of your submission dated June 18, 2003.

This supplemental new drug application proposes the product package insert be revised to include the addition of a 'Geriatric Use' Subsection. The proposed text reads as follows:

> *"Of the total number of patients in the clinical studies of VISIPAQUE in the U.S., 254/757 (34%) were 65 and over. No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in response between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. 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. 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 completed our review of this application as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon draft labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert submitted June 18, 2003).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-351/SLR-013." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Renee C. Tyson, Regulatory Project Manager, at (301) 827-7510.

Sincerely,

{See appended electronic signature page}

Sally Loewke, M.D.
Acting Director
Division of Medical Imaging and
Radiopharmaceutical Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Package Insert

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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