DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-351/SCP-011

Amersham Health
Attention: Paula Clark
Associate, Regulatory Affairs
101 Carneige Center
Princeton, NJ 08540

Dear Mrs. Clark:

Please refer to your supplemental new drug application dated December 16, 2002, received December 17, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Visipaque (iodixonal) Injection 270 mg L/mL and 320 mg L/mL.

We acknowledge receipt of your submissions dated January 28, March 5, April 15, and May 6, 2003.

Your submission of May 6, 2003 constituted a complete response to our April 17, 2003 action letter.

These supplemental new drug applications provide(s) chemistry, manufacturing and controls documentation to support the addition of an alternate container closure system.

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 labeling text and with the minor editorial revisions listed below:

> (b)(4)----------
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> and plastic bottle immediate container labels to include the statement "Do not freeze." on all labels.

The final printed labeling (FPL) must be identical, to the submitted labeling (package insert submitted May 6, 2003, and immediate container and carton labels submitted May 6, 2003) and include the minor editorial revisions indicated to the immediate container labeling submitted May 6, 2003. These revisions are terms of the approval of this application.

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/SCP-011." 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) 827-7498.

Sincerely,

{See appended electronic signature page}

Eldon E. Leutzinger, Ph.D.
Chemistry Team Leader
Division of Medical Imaging and
Radiopharmaceutical Drug Products
HFD-160
DNDC II, Office of New Drug Chemistry
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/

Eldon Leutzinger
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