DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-351/SCP-021

GE Healthcare/Amersham Health
Attention: Paula Clark
Manager, Regulatory Affairs
101 Carneige Center
Princeton, NJ 08540

Dear Ms. Clark:

Please refer to your supplemental new drug application dated April 26, 2005, received April 27, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Visipaque™ (iodixanol) Injection.

We acknowledge receipt of your submissions dated April 26 and May 23, 2005.

This supplemental new drug application provides for the addition of a new container closure system, 200 ml prefilled disposable cartridge in 270 and 320 mgI/mL for Visipaque injection manufactured at Amersham Health AS, Oslo, Norway.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted April 26, 2005, and the immediate container and carton labels submitted April 26, 2005).

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-351/SCP-021**." 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, HF-2
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}

Eldon E. Leutzinger, Ph. D.
Chemistry Team Leader for the
Division of Medical Imaging and
Hematology 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

8/25/2005 03:53:27 PM