DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-351/SCM-020

GE Healthcare, Inc.
Attention: Paula Clark, Manager, Regulatory Affairs
101 Carnegie Center
Princeton, NJ 08540

Dear Mrs. Clark:

Please refer to your supplemental new drug application dated December 17, 2004, received December 20, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Visipaque™ (iodixanol) Injection 270 mgI/mL and 320 mgI/mL.

We acknowledge receipt of your submission dated December17, 2004 and February 2, 2005.

This supplemental new drug application provides for a new container closure system, 50 mL prefilled syringe for Visipaque Injection in 270 mgI/mL and 320 mgI/mL. The new prefilled disposable syringe will be manufactured at Amersham Health AS, Oslo, Norway.

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.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted December 17, 2004, and the immediate container and carton labels submitted December 17, 2004.

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/SCM-020**." 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}

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

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/s/

Eldon Leutzinger
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