DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-351/SLR-018

GE Healthcare
Attention: Paula Clark, Associate Regulatory Affairs
101 Carnegie Center
Princeton, NJ 08540

Dear Ms. Clark:

Please refer to your supplemental new drug application dated June 30, 2004, received July 1, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Visipaque™ (iodixanol) Injection.

We acknowledge receipt of your submission dated June 30, 2004.

This "Changes Being Effected" supplemental new drug application, provides for an addition to the tradename "in +PlusPak (polymer bottle)" to the container label for the Visipaque polymer bottle presentations.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 30, 2004.

We remind you that you must comply with the requirements for an approved NDA set forth under 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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