DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-608/S-018 PRIOR APPROVAL SUPPLEMENT

GE HealthCare
Attention: Paula Clark
Manager, Regulatory Affairs
101 Carnegie Center
Princeton, NJ 08540

Dear Ms. Clark:

Please refer to your supplemental new drug application dated May 31, 2007, received June 1, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Omnipaque™ (Iohexol) Injection Pharmacy Bulk Pack.

This supplemental new drug application provides for the addition of the following statement in the Omnipaque™ Injection Pharmacy Bulk Pack package insert, under the **Storage** section: "Omnipaque™ Injection in all presentations may be stored in a contrast media warmer for up to one month at 37°C (98.6°F)". This supplement also contains documentation to support the following statement for the Omnipaque™ Injection Pharmacy Bulk Pack under the **Directions for Proper Use** of Omnipaque™ Pharmacy Bulk Pack: "The temperature of the container should not exceed 37°C after the closure has been entered."

We completed our review of this supplemental new drug application, as amended. This supplement is approved.

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

If you have any questions, call Valerie Jimenez, MS, Senior Regulatory Project Manager, at (301) 796-1345.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

Hasmukh Patel

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