DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-956/SCM-065

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

Dear Ms. Clark:

Please refer to your supplemental new drug application dated November 24, 2004, received November 26, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Omnipaque (iohexol) Injection.

We acknowledge receipt of your submissions dated November 24, 2004 and March 3, 2005.

This supplemental new drug application provides for the addition of a new container closure system 200 ml prefilled, (b)(4) for Omnipaque Injection that will be manufactured at (b)(4)

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 submitted labeling (November 24, 2004) and with the minor editorial revisions:

In the labeling (package insert), in the **How Supplied** section:

1. The statement: "Omnipaque 350 (100 mL) (NDC 0407-1414-31)", is listed twice. Please delete one of the statements.
2. Please add the following statement: "Omnipaque 350 (150 mL) (NDC 0407-1414-33)".

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling (package insert, immediate container and carton labels submitted November 24, 2004). These revisions are terms of the approval of this application.

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 18-956\SCM-065**". Approval of this submission by FDA is not required before the labeling is used.

Please submit one market package of the drug product when it is available.

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 Health 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
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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