DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-123/S-034

GE HealthCare
Attention: Fred Longenecker
Director, Regulatory Development
101 Carnegie Center
Princeton, NJ 08540

Dear Mr. Longenecker:

Please refer to your supplemental new drug application dated June 21, 2007, received June 22, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Omniscan™ Injection.

We acknowledge receipt of your submissions dated July 24, August 17, 2007 and September 5, 2007.

This "Changes Being Effected"supplemental new drug application provides for the addition of a boxed warning that describes the increased risk for NSF associated with GBCAs in patients with acute or chronic severe renal insufficiency or acute renal insufficiency of any severity due to the hepato-renal syndrome or in the perioperative liver transplantation period and a Warning subsection that contains additional information about the risk of NSF associated with GBCAs and a recommendation to screen patients for renal dysfunction prior to administering GBCAs.

We completed our review of this application. This application is approved, as amended, 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 package insert submitted on September 5, 2007.

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 20-123/S-034". Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment in your submission dated June 20, 2007.

1. To conduct a post-marketing study to collect clinical data sufficient to assess the magnitude of risk for the development of NSF with your product among patients with moderate (GFR<60ml/min/1.73m2) to severe renal insufficiency.

   Final Protocol: October 31, 2007
   First patient in (start of study accrual): January 31, 2008
   Last patient out: January 31, 2011
   Data Analysis: February 28, 2011
   Completion of study report for FDA submission: April 30, 2011

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

In addition, the Division of Drug Marketing, Advertising, and Communications (DDMAC) have reviewed the revised product labeling and have determined that it contains significant new risk information relating to your drug product. We are hereby requesting that all promotional materials for your drug product that include representations about your drug product be revised to include the new risk information immediately. These revisions should include prominent disclosure of the important new information described in the BOXED WARNING and WARNINGS sections that appear in the revised package labeling. Please submit a written response to this request within 14 days, following receipt of this letter, stating whether you intend to comply with this request to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 James Moore, Regulatory Project Manager, at (301) 796-2050.

Sincerely,

{See appended electronic signature page}

Rafel Dwaine Rieves, M.D.
Acting Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
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/

Rafel Rieves

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