DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-123/S-035

GE Healthcare
Attention: Jennifer Jones
Manager, Regulatory Affairs
101 Carnegie Center
Princeton, New Jersey 08540

Dear Ms. Jones:

Please refer to your supplemental new drug application dated September 14, 2007, received September 17, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Omniscan™ (gadodiamide) Injection.

This supplemental new drug application provides for the Omniscan labeling in the Physician Labeling Rule (PLR) format to be consistent with the labeling for NDA 22-066 Omniscan™ (gadodiamide) Injection-Pharmacy Bulk Package, which was approved on September 5, 2007.

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 enclosed labeling text for the package insert.

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/these submission(s) "**FPL for approved supplement NDA 20-123/S-035**." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division/ the Division of Medical Imaging and Hematology Products and two copies of both the promotional materials and the package insert(s) directly 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

We refer to our September 5, 2007 letter that described your post-marketing commitment to submit a final protocol by October 31, 2007 for a study that will assess the magnitude of risk for the development of Nephrogenic Systemic Fibrosis (NSF) with Omniscan among patients with moderate to severe renal failure. We have not received a copy of your protocol. We are concerned about your failure to comply with the commitment time line and encourage you to expeditiously submit the study protocol.

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

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 Tiffany Brown, Regulatory Health Project Manager, at (301) 796-1972.

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

Enclosure: PLR Labeling

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

12/14/2007 08:16:06 AM