DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 22-066

NDA APPROVAL

GE Healthcare
Michael Barbush
Senior Manager, Regulatory Affairs
101 Carnegie Center
Princeton, NJ 08540

Dear Mr. Barbush:

Please refer to your new drug application (NDA) dated July 6, 2006, received July 7, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OMNISCAN™ (gadodiamide) Injection - Pharmacy Bulk Package.

We acknowledge receipt of your submissions dated July 3 and August 27, 2007.

The July 3, 2007, submission constituted a complete response to our May 1, 2007, action letter.

This new drug application provides for the use of OMNISCAN™ (gadodiamide) Injection-Pharmacy Bulk Package for (1) intravenous use in MRI to visualize lesions with abnormal vascularity (or those thought to cause abnormalities in the blood-brain barrier) in the brain (intracranial lesions), spine, and associated tissues; (2) intravenous administration to facilitate the visualization of lesions with abnormal vascularity within the thoracic (noncardiac), abdominal, pelvic arteries, and the retroperitoneal space.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling text for the package insert. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 22-066."

Submit final printed carton and container labels that are identical to the submitted carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22-066.**" Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 should 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
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 Tiffany Brown, Regulatory Health 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

Enclosure: NDA 22-066 Draft 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

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