CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-066

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 22-066

GE Healthcare
Attn: Michael Barbush
Senior Manager, Regulatory Affairs
101 Carnegie Center
Princeton, New Jersey 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 20 and 21, August 30, September 7, October 12 and 18, November 14 and 29, December 15, 2006; February 28, March 30, April 19 and 20, 2007.

We completed our review of this application, as amended, and it is approvable. Before the application may be approved, however, it will be necessary for you to:

1. Submit a revised product label that is consistent with the draft text attached to this letter. Please be aware of our on-going review of safety considerations related to nephrogenic systemic fibrosis. As discussed in the telephone conversation with you on April 26, 2007, we anticipate finalizing this review within the near future and may request a revision to your product labels for gadolinium-based contrast agents. Hence, this ongoing review may impact the product labeling for Omniscan™ (gadodiamide) Injection-Pharmacy Bulk Package.

2. Submit a product labeling supplement for NDA 20-123 (the NDA for your currently approved presentation of Omniscan™ gadodiamide Injection) that maintains consistency, as applicable, with the product label for Omniscan™ (gadodiamide) Injection-Pharmacy Bulk Package. In this regard, the two labels should differ only in the text directly applicable to the product presentation (pharmacy bulk package or currently approved presentation).

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 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

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file (an) amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with this division to discuss what steps need to be taken before the application may be approved.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, call Tiffany Brown, 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

[Enclosed: Draft Labeling]

25 Page(s) Withheld

_____ Trade Secret / Confidential

✓ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Approvable Letter- 1

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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