DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-899/S-010

GE Healthcare
Attention: David Risley
Director, Marketed Products
101 Carnegie Center
Princeton, New Jersey 08540

Dear Mr. Risley:

Please refer to your supplemental new drug application(s) dated October 16, 2007, received October 17, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OPTISON™ (Perflutren Protein-Type A Microspheres for Injection, USP).

This "Changes Being Effected" supplemental new drug application contained a revised product label that consisted of all the modifications that we requested in our letter of October 2, 2007. However, the submitted label revision also included a section within PRECAUTIONS that was identified as "Information for Patients." This information was intended to improve safe use of the product and a form of this information is reasonable for inclusion within the label. The current text is acceptable but could be improved. Please be aware that the product label information is primarily for the prescriber, not the patient. Hence, we request that you modify the text at the printing of your next product label to contain a modified "Information for Patients" section that states the following:

"Patients receiving OPTISON™ should be instructed to inform their healthcare provider if they:

1. have a congenital heart defect. or recent worsening of heart or lung conditions;
2. have had reactions to blood, blood products, albumin or a prior

   OPTISON™ administration (see CONTRAINDICATIONS AND WARNINGS);
3. may be pregnant or are nursing an infant."

Submit the revised label that incorporates this text change as a component of your annual report. Highlight the altered label within the cover letter to that annual report and cite this specific letter's request. Include a copy of this letter.

The format you chose to use for the "Information for Patients" section suggests that you were not fully aware of the expectations for product labeling. We request that, in the future, you contact FDA prior to instituting any modifications to your product label.

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 and with the minor editorial revisions referenced above.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling package insert. 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 20-899/S-010**." 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 November 1, 2007 to:

1. Provide clinical data that assesses the occurrence of serious adverse reactions among patients who receive Optison in routine medical practice.

Protocol Submission:	by December 31, 2007
Study Start:	by March 31, 2008
Final Report Submission:	by January 1, 2010

Submit clinical protocols to your IND for this product. Submit non-clinical 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, 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 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 acknowledge your plans to issue a Dear Healthcare 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 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: 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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