DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 20-372/S-022

GE Healthcare
Attention: Michael Barbush
Senior Manager, Regulatory Affairs
101 Carnegie Center
Princeton, NJ 08540- 6231

Dear Mr. Barbush:

Please refer to your supplemental new drug application dated December 19, 2007 received December 20, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Myoview™ (Kit for Preparation of Technetium ^{99m} Tc Tetrofosmin for Injection).

We acknowledge receipt of your submission dated May 16, 2008, which constitutes a complete response to observations cited in the FDA Form 483 issued on April 18, 2008.

This supplemental new drug application provides for a new formulation for Myoview 30™ mL. The new formulation contains the same ingredients as in the currently approved Myoview 30™ mL product with the following changes:

1. The amount of tetrofosmin has been increased from 0.69 mg/vial to 1.38 mg/vial
2. The amount of disodium sulphosalicylate has been increased from 0.96 mg/vial to 1.92 mg/vial
3. The amount of ascorbic acid has been decreased from 5 mg/vial to 3 mg/vial

We completed our review of this supplemental 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. In addition, all previous revisions as reflected in the most recently approved package insert must be included. To facilitate review of your submission, please provide a highlighted or marked-up copy that shows the changes that are being made.

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 20-372/S-022 SCF." 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 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

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Frank Lutterodt, Regulatory Project Manager, at (301) 796-4251.

Sincerely,

{See appended electronic signature page}

Rafel Dwaine Rieves, M.D.
Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure: Package Insert