**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-372/SCF-019

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 September 30, 2004 received October 1, 2004 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Myoview™ (Kit for the Preparation of Technetium Tc99m Tetrofosmin for Injection).

We acknowledge receipt of your submission dated April 29, 2005, which constituted a complete response to our February 4, 2005, action letter.

This supplemental new drug application provides for a new formulation of MYOVIEW™ with the trade name MYOVIEW30ml.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed draft package insert and the immediate container and carton labels submitted April 29, 2005.

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, this submission should be designated "FPL for approved supplement NDA 20-372/SCF-019." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42

Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Patricia A. Stewart, Regulatory Project Manager, at (301) 827-7496.

Sincerely,

*{See appended electronic signature page}*

Eldon E. Leutzinger, Ph.D.
Chemistry Team Leader for the
Division of Medical Imaging and
Radiopharmaceutical Drug Products
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Eldon Leutzinger
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