DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-372/SLR-015

Amersham Health
Attention: Stefan J. Ochalski, M.B.A.
Senior Manager, Regulatory Development
101 Carnegie Center
Princeton, NJ 08540-6231

Dear Mr. Ochalski:

Please refer to your supplemental new drug application dated September 4, 2002, received September 5, 2002, 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 also acknowledge receipt of your submissions dated May 12, and November 6 and 13, 2003. Your submission of May 12, 2003 constituted a complete response to our March 5, 2003 action letter.

This supplemental new drug application provides for the addition of a "**Geriatric Use**" subsection to the **PRECAUTIONS** section of the package insert, containing the following verbiage:

> *"Of 2300 patients in clinical studies of MYOVIEW™ (Kit for the Preparation of Technetium Tc99m Tetrofosmin for Injection), 1053 (46%) patients were 65 or older and 270 (12%) were 75 or older. No overall differences in safety were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out."*

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please 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/SLR-015." 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 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, MD 20857

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Lynn Panholzer, Pharm.D., Regulatory Project Manager, at (301) 827-3132.

Sincerely,

{See appended electronic signature page}

Sally Loewke, M.D.
Acting Director
Division of Medical Imaging and
Radiopharmaceutical Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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

/s/

Sally Loewke

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