DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-372/SCM_011

Amersham Health
Attention: Stefan Ochalski, MBA
Senior Manager, Regulatory Affairs
101 Carnegie Center
Princeton, NJ 08540

Dear Mr. Ochalski:

Please refer to your supplemental new drug application dated January 21, 2002, received January 22, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Myoview (Kit for the Preparation of Technetium Tc99m Tetrofosmin).

We acknowledge receipt of your submissions dated March 8 and May 15, 2002.

This supplemental new drug application provides for an alternate manufacturing site for Myoview and all other changes proposed, including the following:

1. Batch size for drug product from (b)(4)-vials per batch to ((b)(4)--als per batch.
2. ----------
3. ((b)(4)----------
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4. ----------
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5. ----------

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6. ((b)(4)----------

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 labeling text and with the minor editorial revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

However, the following information should be submitted as soon as it is available under a new correspondence communication:

1. Provide the findings of the current and future work related to the analysis and

confirmation on the origin of the b)(4)-------impurity((b)(4)---------found in Myoview Injection accelera(b)(4)----------ort ----------n, if any, ----------ken to avoid this potential leach of----------into the product.

2. Provide information on the presence and levels of the potential leachable(b)(4)---(b)(4)----------impurity into the reconstituted product stored at 25 °C for at least 12 hours, which its ---------- shelf life. Data should be presented for both inverted and upright storage positions.

The following labeling revisions should be implemented in the next printing cycle and reported to the NDA in the corresponding annual report.

3. While we acknowledge the package insert includes a statement regarding the shelf life of the reconstituted Myoview Injection in the section of "Instructions for Preparation of Technetium Tc99m Tetrafosmin Injection", we recommend you revise the STORAGE section of your package insert for more clarity and to include a statement on the shelf life of the product after reconstitution. For example,

STORAGE
Store the kit in the refrigerator at 2-8 °C , 36 – 46 °F. (b)(4) d (b)(4)
Store the reconstituted product at 2-25 °C , 36 –77 °F (b)(4)), using appropriate radiation shielding.

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nt kit is approved for use …etc. (same).

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (package insert submitted January 21, 2002, immediate container and carton labels submitted January 21, 2002). These revisions are terms of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten 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/SCM_011." Approval of this submission by FDA is not required before the labeling is used.

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) 827-7510.

Sincerely,

{See appended electronic signature page}

Eldon E. Leutzinger, Ph.D.
Chemistry Team Leader for the
Division of Medical Imaging and Radiopharmaceutical Drug Products, (HFD-160)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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

/s/

Eldon Leutzinger
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