CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-372/S-013

Approval Letter(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-372/SE-013

Amersham Health
Attention: Stefan Ochalski, MBA
Senior Manager, Regulatory Affairs
101 Carnegie Center
Princeton, NJ 08540-6231

Dear Mr. Ochalski:

Please refer to your supplemental new drug application dated April 29, 2002, received April 29, 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 acknowledge receipt of your submissions dated June 14 and 24, August 23, September 3, 17, and 20,
December 19, 2002, and February 28, 2003.

This supplemental new drug application proposes to expand the indication for Myoview™ (Kit for the Preparation of Technetium Tc99m Tetrofosmin for Injection) to include the assessment of ventricular function in subjects being evaluated for heart disease and/or ventricular function.

We have completed the review of this supplemental application 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 for the following expanded indication:

"Myoview™ is indicated in the scintigraphic imaging of the myocardium following separate administrations under exercise and/or resting conditions. It is useful in the delineation of regions of reversible myocardial ischemia in the presence or absence of infarcted myocardium.

Myoview™ is also indicated for scintigraphic imaging of the myocardium to identify changes in perfusion induced by pharmacologic stress in patients with known or suspected coronary artery disease.

Myoview is also indicated for the assessment of left ventricular function (left ventricular ejection fraction and wall motion) in subjects being evaluated for heart disease."

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

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/SE-013." Approval of this submission by FDA is not required before the labeling is used.

We also refer to your submission dated December 12, 2001, notifying the Agency that (b)(4)----------will not be marketed and remind you of your commitment to submit a labeling supplement prior to marketing in the future.

We acknowledge receipt of your July 17, 2001, submission requesting a waiver for the postmarketing study commitments in your submission dated February 9, 1996. The waiver request will be responded to under separate cover. Unless the waiver request is granted, the commitments listed below will remain in effect.

1. Perform a human study to define tetrofosmin's pharmacokinetic and metabolic profile.

2. Perform pharmacokinetic studies to determine if dose adjustment is needed in the pediatric population on the basis of age, weight, body size, renal function and liver function.

We also acknowledge completion of the following postmarketing agreements:

1. Information regarding the MYOVIEW stoppers, correcting the discrepancy in SOP 10-03-04, and including a concomitant determination of a reference standard each time the (b)(4)---------- for(b)(4)----- is performed.
   Commitment Date: February 9, 1996
   Submission Date: September 4, 1996.

2. Reconstitute one(b)(4)---------- at the maximum radioactivity level (b)(4)--------- and follow the (b)(4over the course of 24 hour expiration dating period.
   Commitment Date: August 4, 2001
   Submission Date: September 28, 2001

If the post-marketing waiver is not granted, submit clinical protocols to your IND for this product. Submit nonclinical 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 Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

We acknowledge your submission dated September 17, 2002, requesting a waiver of pediatric studies. FDA's Pediatric Rule [at 21 CFR 314.55/21 CFR 601.27] was challenged in court. On October 17, 2002, the court ruled that FDA did not have the authority to issue the Pediatric Rule and has barred FDA from enforcing it. Although the government decided not to pursue an appeal in the courts, it will work with Congress in an effort to enact legislation requiring pharmaceutical manufacturers to conduct appropriate pediatric clinical trials. In addition, third party interveners have decided to appeal the court's decision striking down the rule. Please be aware that whether or not subsequent submission of pediatric data will be required depends upon passage of legislation or the success of the third party appeal.

The pediatric exclusivity provisions of FDAMA as reauthorized by the Best Pharmaceuticals for Children Act are not affected by the court's ruling. Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products. You should refer to the Guidance for Industry on Qualifying for Pediatric Exclusivity (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request". FDA generally does not consider studies submitted to an NDA before issuance of a Written Request as responsive to the Written Request. Applicants should obtain a Written Request before submitting pediatric studies to an NDA.

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}

/S/

Sally Loewke, M.D.
Deputy 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
2/28/03 05:10:58 PM