



HFI-35 FOI [initials]

SSO

August 21, 1997

TRANSMITTED VIA FACSIMILE

Guy Marlow
President
Amersham Healthcare, Inc.
2636 S. Clearbrook Drive
Arlington Heights, IL 60005

RE: NDA 20-372
Myoview (kit for the preparation of Technetium
Tc99m Tetrofosmin Injection)
MACMIS ID # 5243

WARNING LETTER

Dear Mr. Marlow:

This Warning letter concerns Amersham Healthcare, Inc.'s (Amersham) promotion of Myoview (kit for the preparation of Technetium Tc99m Tetrofosmin Injection). Based on information the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed as part of its monitoring and surveillance program, we have concluded that Amersham is promoting Myoview in violation of 21 USC §§ 355(a), 352(a), 352(f), 352(n), 331(a), and 331(d) of the Federal Food, Drug, and Cosmetic Act and applicable regulations.

Myoview

Myoview is a diagnostic radiopharmaceutical agent. It is marketed as a kit for the preparation of technetium Tc99m tetrofosmin for injection. Myoview is indicated for

Scintigraphic imaging of the myocardium following separate administrations under exercise and resting conditions. It is useful in the delineation of regions of reversible myocardial ischemia in the presence or absence of infarcted myocardium.

Amersham has not submitted evidence to demonstrated that Myoview is safe and effective for other diagnostic procedures such as in conjunction with the use of a pharmacologic stress agent in patients who are unable to exercise adequately, or for the assessment of ventricular function.

Promotion of Unapproved Use - Pharmacologic Stress Testing

In its promotional materials including, but not limited to, sales brochure identified as MPI 95016 entitled "Introducing a view from the heart,"¹ Amersham claims that "Myoview can be used with pharmacologic stressors."² However, Myoview was studied and is indicated for use only in procedures that involve imaging under actual exercise or resting conditions. It is not indicated for use in conjunction with pharmacologic stress agents in patients who are unable to exercise.

Promotion of Unapproved Use - Assessment of Heart Function

In the same brochure as well as other promotional materials, Amersham claims that Myoview is useful in SPECT imaging for "first-pass and gated wall motion" studies, and that Myoview is practical because "Myocardial perfusion and ventricular function [can be] assessed with a single injection." However, Amersham has not submitted evidence that Myoview is safe and effective for use in procedures to assess ventricular function.

Conclusion and Requested Actions

The materials and promotional messages Amersham disseminated contain false and/or misleading information about the safety and effectiveness of Myoview and promote the product for unapproved uses. Accordingly, Amersham should propose an action plan, including the mailing and publication of a "Dear Health Care Professional" letter to disseminate corrective messages about the issues

¹ This brochure is specifically cited in this Warning Letter as an example of Amersham's promotion of unapproved uses. Amersham has also promoted these unapproved uses in other labeling pieces such as brochures MPI 95026, 95027; in advertisements appearing in journals such as the Journal of Nuclear Medicine; and in exhibit halls of professional meetings such as the Society of Nuclear Medicine.

² Pharmacologic stress agents are products used in myocardial perfusion scintigraphy in patients unable to exercise adequately.

discussed in this letter to all health care providers, institutions, and organizations who received the violative messages.

This corrective action plan should also include:

- A. Immediately ceasing the dissemination of all materials that state, suggest, or imply that Myoview is safe and effective for unapproved uses and that contain false, or misleading claims of the type discussed in this letter.
- B. A written statement of Amersham's intent to comply with "A" above.
- C. A complete listing of all advertising and promotional materials that will remain in use and those that will be discontinued. Also, provide two copies of all promotional materials for Myoview that Amersham intends to continue to distribute.
- D. Within 15 days of the date of this letter, disseminating a message to all Amersham sales representatives and marketing personnel involved in the marketing and sales of Myoview, instructing them to immediately cease dissemination of all promotional materials and messages discussed in this letter and providing each person a copy of this letter.

The "Dear Health Care Professional" letter and Amersham's action plan should be submitted to DDMAC for approval. After such approval, the letter should be disseminated by both direct mail and through a paid advertisement in all journals that contained advertisements for Myoview during the 12 months before the date of this letter.

The violations discussed in this letter do not necessarily constitute an exhaustive list. We are continuing to evaluate other aspects of Amersham's promotional campaign for Myoview and we may determine that additional remedial measures will be necessary to fully correct the false and/or misleading messages resulting from Amersham's violative conduct.

Amersham's response should be received no later than September 5, 1997. If Amersham has any questions or comments, please contact Warren Rumble, Thomas Abrams, or Norman A. Drezin, Esq. by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and

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Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857.
DDMAC reminds Amersham that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 5243 and NDA 20-372.

Failure to respond to this letter may result in regulatory action, including seizure or injunction, without further notice.

Sincerely,



Minnie Baylor-Henry, R.Ph., JD
Director
Division of Drug Marketing,
Advertising and Communications