



NDA 17-944/S-018

Amersham Health  
Attn: Susan Elliott  
101 Carnegie Center  
Princeton, NJ 08540

Dear Ms. Elliott:

Please refer to your supplemental new drug application dated March 18, 2003, received March 18, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DMSA™ (Kit for the preparation of Tc99m Succimer for Injection).

We acknowledge receipt of your submissions dated August 5, and November 10, 2003.

Your submission of November 10, 2003 constituted a complete response to our August 25, 2003, action letter.

This supplemental new drug application provides for "Geriatric Use" under subsection in the PRECAUTIONS section of the package in compliance with 21 CFR 201.57(f)(10)(ii)(A). Please include the following agreed upon verbiage:

"Clinical studies of DMSA™ did not include sufficient numbers of subjects age 65 and over to determine whether they respond differently from younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and the concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function."

We have completed the review of this supplemental application, as amended, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling (package insert submitted November 10, 2003).

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 17-944/SLR-018." Approval of this submission by FDA is not required before the labeling is used.

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 Diane C. Smith, Regulatory Project Manager, at (301) 827-7510.

Sincerely,

*{See appended electronic signature page}*

Sally Loewke, M.D.  
Acting Division Director for the  
Division of Medical Imaging and  
Radiopharmaceutical Drug Products, HFD-160  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

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/s/

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Patricia Stewart  
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