



NDA 20-123/S-018

Nycomed Amersham Imaging  
Attention: Fred Longenecker  
Director, Regulatory Affairs  
101 Carnegie Center  
Princeton, NJ 08540-6231

Dear Mr. Longenecker:

Please refer to your supplemental new drug application dated December 28, 2000, received December 29, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OMNISCAN (gadodiamide) Injection.

We also acknowledge your fax dated July 8, 2002, stating your agreement of the following geriatric language to be incorporated into the '**Geriatrics Use**' subsection to the **PRECAUTIONS** section of the package insert to be compliant with 21 CFR 201.57(f)(10)(ii)(A) and 21 CFR 201.57(f)(10)(iii)(B):

Of the total number of patients in clinical studies of OMNISCAN, 19.3 percent were 65 to 80, while 1.2 percent were over 80. No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in response between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. 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 of 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 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. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling.

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 20-123/S-018." 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

Please submit one market package of the drug product when it is available.

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 Thuy Nguyen, Project Manager, at (301) 827-7510.

Sincerely,

*{See appended electronic signature page}*

Patricia Y. Love, M.D., M.B.A.  
Director  
Division of Medical Imaging and Radiopharmaceutical  
Drug Products  
Office of Drug Evaluation III  
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/

-----  
Patricia Love

7/8/02 01:05:24 PM