DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-284\SLR-009

Bristol-Meyers Squibb Medical Imaging, Inc.
Attention: Sherrill L. Wagner
331 Treble Cove Road, Bldg. 500-2
North Billerica, MA 01862

Dear Ms. Wagner:

Please refer to your supplemental new drug application dated October 18, 2002, received October 21, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Xenon X-133 Gas.

We also acknowledge receipt of your submission dated February 12, 1999, and our Approvable action letter of September 30, 2002.

This supplemental new drug application provides for a waiver regarding inclusion of the following additional language under 21 CFR 201.57(F)(10)(iii)(B) to the current GERIATRIC USE section of the package insert:

> "This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions this drug may be greater in patients with renal function. Because elderly patients are more likely to 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 and have concluded that adequate information has been presented to support your waiver request. Accordingly, the supplemental application is approved effective on the date of this letter.

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 17-284\SLR-009." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division (HFD-160) and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5600 Fishers Lane, HFD-42
Rockville, Maryland 20857

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 M. Nguyen, M.P.H., Regulatory Health Project Manager, at (301) 827-7510.

Sincerely,

{See appended electronic signature page}

Sally Loewke, M.D.
Acting Division Director
Division of Medical Imaging and
Radiopharmaceutical Drug Products, HFD-160
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 Stewart
10/27/03 03:43:30 PM
Signing for Dr. Sally Loewke