DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-064\SLR-002

Prior Approval Supplement

Bristol-Myers Squibb Medical Imaging, Inc.
Attention: William J. Regan
331 Treble Cove Rd.
North Billerica, MA 01862

Dear Mr. Regan:

Please refer to your supplemental new drug application dated February 14, 2002, received February 14, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension.

This supplemental new drug application provides for a change in the **PRECAUTIONS** section; **General** subsection of the current package insert:

Electrocardiographic (EGG) Changes:

TO

Electrocardiographic (ECG) Changes:

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 submitted final printed labeling (package insert submitted February 14, 2002, immediate carton and vial labels submitted February 14, 2002). Accordingly, the supplemental application is approved effective on the date of this letter.

In addition, 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. 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}

Patricia Y. Love, M.D., M.B.A.
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 Love

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