



NDA 17-478\SCS-013

Prior Approval

Bristol-Myers Squibb Medical Imaging
Attention: Jeffrey P. Bourque, RA Manager
331 Treble Cove Road, Bldg. 500-2
North Billerica, MA 01862

Dear Mr. Bourque:

Please refer to your supplemental new drug application dated November 17, 2003, received November 18, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gallium Citrate Ga 67 Injection.

This supplemental application provides microbiology responses to the Agency's comments in the Approvable letter of October 28, 2003, for SCS-013 PA which proposed a manufacturing upgrade for Gallium Citrate Ga 67 Injection.

We have completed the review of this supplemental application, and it is approved.

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}

Eldon E. Leutzinger, Ph.D.
Chemistry Team Leader for the
Division of Medical Imaging and
Radiopharmaceutical Drug Products, HFD-160
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Eldon Leutzinger
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