



Food and Drug Administration  
1401 Rockville Pike  
Rockville MD 20852-1448

Our Reference: BN 19862/12

APR 24 2003

Medi-Physics, Incorporated d.b.a. Amersham Health  
Attention: David Risley  
Director, Marketed Products  
Regulatory Affairs  
101 Carnegie Center  
Princeton, NJ 08540

Dear Mr. Risley:

Your request to supplement your new drug application for Indium-In-111 Chloride Sterile Solution with the addition of a "Geriatric Use" subsection in the package insert has been approved.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

We remind you that you must comply with the requirements of an approved NDA set forth under 21 CFR 314.80 and 314.81, including submission of annual reports.

If you have any questions, contact Dr. Craig Doty, Regulatory Project Manager, at (301) 827-5101.

Sincerely yours,

Patricia Keegan, M.D.  
Acting Director  
Division of Clinical Trials Design  
and Analysis  
Office of Therapeutics  
Research and Review  
Center for Biologics  
Evaluation and Research

Enclosure: Final Draft Labeling