

pharmalucence  
  
**URGENT Drug Recall**

**Pulmolite®  
Kit for the Preparation of Technetium Tc99m Albumin Aggregated for Injection  
Lot 160034**

August 19, 2010

Dear Healthcare Professional:

Pharmalucence, Inc. has initiated a voluntary nationwide recall of Pulmolite®, (Kit for the Preparation of Technetium Tc99m Albumin Aggregated for Injection) Lot 160034.

Recent testing associated with routine product monitoring of Pulmolite® Lot 160034 found the average particle count to be lower than listed on the carton label (average of 4.3 million particles per vial). A test value as low as 2.4 million particles per vial was measured for Lot 160034. This value is below established specifications. Lot 160034 meets all other established specifications.

Pulmolite® Lot 160034 may not provide a sufficient number of particles in each vial to assure the recommended quantity of particles per radioactive dose. A dose with insufficient particles could affect diagnostic efficacy.

Please examine your inventory for the affected lot; Pulmolite® Lot 160034. You will find the lot number printed on the white label affixed to each five-vial or thirty-vial Pulmolite® carton and printed on each Pulmolite® vial label. Contact Pharmalucence at: 800-221-7554 if you have experienced uninterpretable or non-diagnostic images in association with Lot 160034.

If any vials of this lot remain in your inventory, please cease use of this lot and proceed with instructions on how to return these vials. If you are a Radiopharmacy or other Distributor of this product, you already received instructions for returning the vials and to notify your Customers of this recall. For immediate needs, including instructions for returning vials and medical / clinical inquiries contact: Pharmalucence Customer Service: **800-221-7554**.

To report suspected Adverse Events, non-diagnostic or altered biodistribution results from the use of Pulmolite® product, contact the FDA's Med Watch Adverse Event Reporting Program online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm), by phone at 1-800-FDA-1088, or by returning the postage-paid FDA form 3500 which may be downloaded from [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) by mail to FDA Med Watch, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787 or fax to 1-800-FDA-0178.

Pharmalucence is conducting this recall with the knowledge of the U.S. Food and Drug Administration.

Sincerely,



John J. Felock  
Director of Marketing and Sales  
Pharmalucence, Inc.