

URGENT Drug Recall

Pulmolite[®]

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

Pharmalucence Part #	Date of Manufacture	NDC #:	Expiration	Lot #'s:	Action
Pul05 Pul30	April 1, 2009 April 1, 2009	45567-0415-1 45567-0415-2	October 31, 2010 October 31, 2010	160034	Immediately return to Pharmalucence for replacement

July 21, 2010

Dear Customers and Distributors:

Recent lot stability testing of Pulmolite[®] (Kit for the Preparation of Technetium Tc99m Albumin Aggregated for Injection), Lot 160034, indicates that lower than expected particle numbers may be present. Recent testing does not confirm that the average particle count reflects the expected value of 4.3 million particles per vial for this lot. A testing value as low as 2.4 million particles per vial was measured for Lot 160034 during routine monitoring. Monitoring data demonstrates that this lot does meet all other established specifications.

Pharmalucence Medical Affairs has reviewed Pulmolite[®] Lot 160034 testing data and concluded that the low number of particles in this lot may not provide a sufficient number of particles in each prepared dose to assure diagnostic efficacy. Therefore, Pharmalucence is initiating a voluntary recall of this lot from the field. Pharmalucence has notified FDA of this action.

See reverse side for Recall Processing Instructions

Pulmolite® Lot 160034 Recall Instructions

- Please examine your inventory for the affected lot; **Pulmolite® Lot 160034**.
- If any vials of this lot remain in your inventory, please cease use of this lot and proceed with instructions below outlining how to return these vials for replacement.
- If you are a Radiopharmacy or other Distributor of this product, please contact your Customers to ensure all affected Customers are notified of this recall.
- For immediate needs, including orders and medical / clinical inquiries contact:

Pharmalucence Customer Service Phone
800-221-7554

- Upon receipt of this notice, please fill out the attached Product Return Form with information concerning your inventory of Pulmolite® (Kit for the Preparation of Technetium Tc99m Albumin Aggregated for Injection), **Lot 160034** and your contact information. This form should be completed even if you no longer have any remaining inventory. Fax the completed form to Pharmalucence. Retain the original for inclusion in your return shipment.

Pharmalucence Customer Service Fax Number: 781-275-2634

Ship any product to be returned via Federal Express, Standard Overnight, Bill Recipient to:

Pharmalucence, Inc., 54 Loomis Street, Bedford, MA 01730

- Pharmalucence will provide replacement inventory within 5 business days to address the recalled product lot.
- Upon receipt of your fax, Pharmalucence will arrange replacement of the lot affected in this recall using your contact information provided on the faxed Product Return Form.

Pharmalucence is conducting this recall with the knowledge of the Food and Drug Administration. We appreciate your cooperation with this recall program and regret any inconvenience that it may cause. Any updates will be posted on the Pharmalucence website at www.pharmalucence.com.

Thank you for your continued support of Pharmalucence.

Sincerely,



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

**URGENT DRUG RECALL
PRODUCT RETURN FORM**

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

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**Ship returns via Federal Express, Standard Overnight, Bill Recipient to:
Pharmalucence, Inc., 54 Loomis Street, Bedford MA 01730**

Product Return Authorization #: PRA-2010-015

Customer Name: _____

Customer Address: _____

Telephone Number: _____

Email Address: _____

Lot Number	5 vial kits returned	30 vial packs returned	Partial Kits Returned (# of vials)
160034			

Check this box if you have no inventory from the lot referenced above to return.

I hereby certify return to Pharmalucence Inc., all inventory in the possession of this organization from lot referenced in this recall action, if applicable.

Customer Signature _____

Date: _____

Fax this form to Pharmalucence Customer Service at (781) 275-2634