Teva Pharmaceuticals, USA Inc.

URGENT DRUG RECALL – USER LEVEL - INITIATED 3/9/16

Amikacin Sulfate Injection USP 1 gram/4 mL (250 mg/mL)

RECALLED BY:
Teva Pharmaceuticals USA, Inc.
Horsham, PA 19044

Lot #	Exp. Date	Vial Size	NDC# individual vials	NDC# carton of 10 vials
4750915	9/2017	4 mL	0703-9040-01	0703-9040-03

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lot of **Amikacin Sulfate Injection USP 1 gram/4 mL (250 mg/mL)** distributed under the **Teva Pharmaceuticals label.** This recall is being carried out to the USER LEVEL (both human and veterinary) due to the presence of glass particulate matter observed in a retention sample of Lot 4750915. Teva has not received any complaints or adverse events for glass particles for Lot 4750915. The administration of a glass particulate, if present in an intravenous drug, may result in local irritation or swelling in response to the foreign material. More serious potential outcomes would include blockage and clotting in blood vessels, which may be life-threatening if a critical organ is affected.

Wholesalers / Distributors / Retailers - Please perform the following activities:

- Examine your inventory immediately for the specified lot of **Amikacin Sulfate Injection USP 1 gram/4 mL (250 mg/mL).**
- Our records indicate we shipped this product between December 23, 2015 and January 21, 2016.
- Immediately discontinue distribution of the specific lot being recalled.
- **Please perform a SUB-RECALL to your retail/physician level accounts using this Recall Notification and Stock Response Form.**
- Promptly complete the attached recall stock response and reply via fax number 817-868-5362 or mail, even if you have **no** product to return.

Completed Recall Stock Response forms can be mailed, emailed, or sent via FAX to Inmar Attn: Recall Coordinator, 4332 Empire Road Suite 200, Fort Worth, TX 76155. Inmar Email address: recallnotice@inmar.com. Inmar FAX: 817-868-5362. Inmar will send a Return Goods Authorization label and shipping label. Appropriate credit for product returns, plus handling and shipping expenses, will be issued upon receipt of said product with the Return Goods Authorization form. All recalled product returned without a Return Goods Authorization label may delay the issuance of your credit.

This recall is being made with the knowledge of the Food & Drug Administration. Your cooperation and prompt response to this notice is appreciated. If you have Customer Service related questions, please contact Teva Customer Service at 800-545-8800. For medical-related questions please contact Medical Information at 888-838-2872, option 3, then, option 4. For product complaint-related questions please contact Quality Assurance Services at 888-838-2872, option 3, then, option 3. If you need a Recall Stock Response form, contact Inmar at 800-967-5952 or acquire it from clsnetlink.com.

Sincerely,

James S. Young
Director, Quality Systems & Regulatory Compliance
Teva Pharmaceuticals USA, Inc.

Teva Pharmaceuticals, USA Inc.

URGENT DRUG RECALL – USER LEVEL - INITIATED 3/9/16

Amikacin Sulfate Injection USP 1 gram/4 mL (250 mg/mL)

STOCK RESPONSE FORM

Please fill out completely **Date:** _____

DIRECT CUSTOMERS ONLY: Does this response include **all** DC locations? ☐ YES ☐ NO

Customer/Store Name: _____ DEA #: _____

**DEA # is required; if not provided the processing of your form will be delayed*

Address: _____

City: _____ State: _____ Zip: _____

Contact Name (please print): _____ Telephone #: _____

Lot #	Exp. Date	Vial Size	Quantity to Return # of single vials NDC# 0703-9040-01	Quantity to Return # of cartons of 10 vials NDC# 0703-9040-03
4750915	9/2017	4 mL		

I have checked my stock and:

____ I **do not** have stock of the recalled item(s) **OR** ____ I **do** have stock of the recalled item(s) listed above.

Please send me _____ shipping box labels

NON DIRECT CUSTOMERS ONLY: Please complete the following:

Purchased From (Wholesaler name): _____ DEA #: _____

City: _____ State: _____

Inquiries regarding this recall are to be directed to the following:

Recall Stock Response forms - If your return kit is not received between 7-10 business days contact Inmar at 800-967-5952, Option 1 then Option 3. Please **do not resubmit** response form.

Customer service related questions - contact Teva Customer Service at 800-545-8800
Medical-related questions - contact Medical Information 888-838-2872, option 3, then, option 4.
Product complaint-related questions please contact Quality Assurance Services at 888-838-2872, option 3, then, option 3.
Please fax this form to: 817-868-5362 or E-mail at: recallnotice@inmar.com

Inmar/MedTurn Use Only:				
Scan	Labels	Store	Kit	D.B