URGENT DRUG RECALL
Neomycin Sulfate Tablets, USP 500 mg, 100 count
August 23, 2022

Teva Pharmaceuticals USA, Inc.

Neomycin Sulfate Tablets, USP 500 mg			
NDC	Lot #	Exp. Date	Bottle Size
0093-1177-01	3007830	10/2024	100 count
0093-1177-01	3007746	10/2024	100 count
0093-1177-01	3007829	10/2024	100 count

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (Teva USA) is initiating a voluntary recall of the above drug product lots to the Retail Level. Please take the following actions given below. The subject product lots were distributed under label of Teva Pharmaceuticals and were distributed nationwide from 11/24/2021 through 06/28/2022.

This recall is being initiated because foreign matter was found in the Active Pharmaceutical Ingredient (API) used in the manufacture of the three drug product lots in this recall after the product's release to the US market.

The main safety concern is the foreign matter, acrylate adhesives. Even though the amount of the foreign material found within API is most likely clinically insignificant, given that the typical consumption of 12 grams per day or 24 tablets, over a period of five to six days (as indicated for hepatic coma), possible accumulation of the acrylate adhesives and exposure to high amounts, cannot be fully excluded. Exposure to the product of concern could lead to severe health consequences and the likelihood of the harm occurrence is remote. Consequently, the overall risk of harm in patient population is considered to be medium.

This recall is being made with the knowledge of the Food and Drug Administration.

ACTIONS: Please *promptly* perform the following actions that are necessary for this recall:

- Examine your inventory for the above drug product NDCs and Lot numbers.
- Quarantine and cease distribution of the product lots indicated for this recall.
- Promptly complete the enclosed Recall Stock Response Form (SRF), *even if you have **no** product to return*.
- Promptly return your completed SRF by any one of these means to Inmar, Attn: Recall Coordinator:

  MAIL: Inmar, 635 Vine Street, Winston Salem, NC 27101
  EMAIL: **rxrecalls@inmar.com**
  FAX: 817-868-5362.

- **If you have further distributed product lot affected by this recall, please perform a SUB-RECALL to your accounts using this Recall Notification and Stock Response Form as a basis of your recall notification.**

After receipt of your completed SRF, if you have recorded product to return, Inmar will send labels for Return Goods Authorization (RGA) and the return shipping labels. Appropriate credit for your product returns, plus handling and shipping expenses, will be issued after receipt of said product and your RGA. All recalled product returned without a RGA may delay the issuance of a credit. Products returned that are not the subject of the recall will not be credited and will be destroyed.

CONTACT INFORMATION
Product Returns and Stock Response Forms: Contact Inmar at: 855-898-9828 (Hours of Operation: 9 am to 5 pm Eastern Time) or acquire forms from clsnetlink.com.
Medical-related Questions or to report an Adverse Event: Contact Medical Information at: 888-838-2872, option 3, then, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week Or Email druginfo@tevapharm.com
Product Quality Complaint-related Questions: Contact Quality Assurance Services: 888-838-2872, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 3 then, option 2 Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
FDA contact information for reporting adverse events/quality complaints: Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088

Sincerely,

Regulatory Compliance, Teva Pharmaceuticals USA, Inc.

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RECALL STOCK RESPONSE FORM

Enter the information of the recalled product to be returned in the table below. If additional space is needed, please make copies of this form.

Please fill out completely **Date:** _____

DIRECT CUSTOMERS ONLY: Does this response include **all** your DC locations? ☐ YES ☐ NO	
Customer/Store Name:	
*DEA #: ***DEA # is required; in order to process your form.***	*Debit Memo #
Address:	City/State/Zip
Contact Name (please print):	Telephone #:

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.

Neomycin Sulfate Tablets, USP 500 mg				
NDC	Lot #	Exp. Date	Bottle Size	**Number of Bottles to Return** (Count Partial Bottles as 1)
0093-1177-01	3007830	10/2024	100 count	
0093-1177-01	3007746	10/2024	100 count	
0093-1177-01	3007829	10/2024	100 count	

Please send me _____ shipping box labels

NON DIRECT CUSTOMERS ONLY: Please complete the following:	
City / State	DEA #: ***DEA # is required; in order to process your form.***
Purchased From (Wholesaler name):	

Promptly return your completed SRF by any one of these means to Inmar, Attn: Recall Coordinator
MAIL: Inmar, 635 Vine Street, Winston Salem, NC 27101
EMAIL: rxrecalls@inmar.com
FAX: 817-868-5362

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