URGENT DRUG RECALL

Multiple Products

INITIATED 04/26/2021

Teva Pharmaceuticals USA, Inc.

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling specific lots of multiple products, to the RETAIL LEVEL. The list of products and lots being recalled are found in the Attachment I of this letter. These lots were distributed under the labels for Teva Pharmaceuticals USA, Inc. and novaplus™.

This recall is being initiated because some manufacturing areas for the recall lots exceeded acceptance levels for microbial recovery. The trends were discovered during a standard review process for Environmental Monitoring of both, manufacturing facilities and personnel. It is important to note that at the time of commercial release, the lots in this recall met all test specification, including sterility. Based on available data, there is no indication of product quality and sterility failure. As such, the Health Hazard Assessment concluded that the likelihood of an adverse event is remote. However, if by a remote chance of exposure to a product with compromised sterility, severe adverse events could occur in susceptible individuals.

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

Please perform the following activities that are necessary for this recall:

- Immediately examine your inventory for the products and lots specified in Attachment I**.**
- Immediately discontinue distribution of the specified product lots affected by this recall.
- Refer Attachment I for shipping dates of these specified lots.
- **If you have further distributed these lots, please perform a SUB-RECALL to your accounts. Use this Recall Notification and Stock Response Form (SRF) as a basis for your SUB-RECALL letter.**
- Even if you have **no** product to return, promptly complete the attached recall SRF and return by mail, email, or FAX to Inmar, Attn: Recall Coordinator:

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

Inmar will send labels for Return Goods Authorization (RGA) and shipping after receipt of your SRF. Appropriate credit for product returns, plus handling and shipping expenses, will be issued after receipt of said product with 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 AND CREDIT
Product Returns: Contact Inmar at: 855-722-0171 (dedicated phone line). Hours of Operation: M – F, 9.00 AM to 5.00 PM Eastern Time Recall Stock Response Forms - Contact Inmar at 855-722-0171 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
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.

Teva Pharmaceuticals USA, Inc.

Attachment I – Recall Product Lots

Table 1				
Product Description Leucovorin Calcium for Injection, USP			Ship Dates: 12/15/2018 - 03/01/2019	
Vial/Carton NDC	Lot#	Exp. Date	Strength	Size
0703-5145-01	31325332B	08/2021	350 mg/vial	1 x 30 mL Single-Dose Vial / CARTON
0703-5145-01	31325756B	09/2021	350 mg/vial	1 x 30 mL Single-Dose Vial / CARTON

Table 2				
Product Description: Leucovorin Calcium For Injection novaplus™			Ship Dates: 01/16/2019 - 07/17/2019	
Vial/Carton NDC	Lot#	Exp. Date	Strength	Size
0703-5145-91	31325685B	09/2021	350 mg/vial	1 x 30 mL Single-Dose Vial / CARTON

Table 3				
Product Description: MethylPREDNISolone Acetate Injectable Suspension USP			Ship Dates: 11/21/ 2019 - 12/04/2019	
Vial/Carton NDC	Lot#	Exp. Date	Strength	Size
0703-0045-01	31327989B	04/2021	40 mg/mL	1 x 10 mL Multiple Dose Vial / CARTON

Table 4					
Product Description: Metoclopramide Injection USP				Ship Dates: 08/27/2020 - 12/16/2020	
Tray NDC	Vial/Carton NDC	Lot#	Exp. Date	Strength	Size
0703-4502-04	0703-4502-01	31325459B	08/2021	5 mg /mL	25 x 2 mL Single-Use Vials / TRAY

Table 5					
Product Description: Haloperidol Decanoate Injection				Ship Dates: 07/09/2019 - 12/28/2020	
Tray NDC	Vial/Carton NDC	Lot#	Exp. Date	Strength	Size
0703-7121-03	0703-7121-01	31325793C	09/2021	50 mg/mL	10 x 1 mL Single Dose Vials/TRAY
0703-7131-03	0703-7131-01	31325394C	09/2021	100 mg/mL	10 x 1 mL Single Dose Vials/ TRAY
0703-7131-03	0703-7131-01	31327161B	04/2022	100 mg/mL	10 x 1 mL Single Dose Vials/ TRAY

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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** DC locations? ☐ YES ☐ NO

Customer/Store Name: _____ DEA #: _____

**DEA # is required; in order to process your form.*

Address: _____

City: _____ State: _____ Zip: _____

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

Refer to Attachment I of the recall letter for the list of products and lots being recalled

Tray NDC	Vial/Carton NDC	Product Description	Lot #	Quantity to Return (Full Trays)	Quantity to Return (Vials)

Additional Stock Response Forms included: Yes ☐ *No* ☐

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: _____

Please return this form by FAX to: 817-868-5362 or by E-mail at: rxrecalls@inmar.com or Mail to:
Inmar, Attn: Recall Coordinator, Inmar, 635 Vine Street, Winston Salem, NC 27101.

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