URGENT DRUG RECALL

Multiple Products

INITIATED 07/29/2021

Teva Pharmaceuticals USA, Inc.

CORRECTION Issued 08/06/2021

*** *This letter is to advise you of a correction to the subject Recall Notification as Initiated on 07/29/2021. This correction supersedes the previous Recall Notification. The correction is for an Expiration Date for* MethylPREDNISolone Acetate Injectable Suspension USP lot # 31329340B that is being corrected to 12/2021.***

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 of potential risks related to microbial recoveries found during historical assessments of Environmental Monitoring results in aseptic areas of manufacturing. It is important to note that at the time of commercial release, the lots in this recall met all test specification, including both sterility and endotoxin. Based on available data to date, there is no indication of product quality and sterility failure of the products in this recall. As such, the Health Hazard Assessment concluded that the likelihood of an adverse event is remote. However, if by a remote chance a patient is exposed to a product with compromised sterility, the potential for adverse health consequences cannot be excluded for immunocompromised patients, those with serious co-morbidities, and those with an indwelling medical device. To date, Teva has not received any product quality complaints or adverse event reports related to sterility of these products.

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 recalled products.
- **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 and Stock Response Forms: Contact Inmar at: (855) 767-5756 (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) 767-5756 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.

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Attachment I – Recall Product Lots

Adenosine Injection, USP

Carton NDC	Vial NDC	Lot#	Exp. Date	Strength	Size	Ship Dates
N/A	0703-8776-01	100022400	04/2023	3 mg/mL	1 IN 1 CARTON 20 ML SINGLE-DOSE VIAL	06/02/2021 - 6/25/2021

Alprostadil Injection USP

Carton NDC	Vial NDC	Lot#	Exp. Date	Strength	Size	Ship Dates
0703-1501-02	0703-1501-01	31329295B	01/2022	500 mcg/mL	5 in 1 CARTON 1 mL in 1 VIAL, SINGLE-USE	9/24/2020 - 2/22/2021

Amikacin Sulfate Injection USP

Carton NDC	Vial NDC	Lot#	Exp. Date	Strength	Size	Ship Dates
0703-9040-03	0703-9040-01	31329243B	05/2022	250mg/mL	10 in 1 CARTON 4 mL in 1 VIAL, SINGLE-DOSE	7/29/2020 - 5/21/2021

DAUNORUBICIN Hydrochloride Injection

Carton NDC	Vial NDC	Lot#	Exp. Date	Strength	Size	Ship Dates
0703-5233-13	0703-5233-11	31329250B	08/2022	5mg/mL	10 in 1 CARTON 4 mL in 1 VIAL, SINGLE-DOSE	01/05/2021 - 07/06/2021

Epoprostenol Sodium for Injection

Tray NDC	Vial/Carton NDC	Lot#	Exp. Date	Strength	Size	Ship Dates
N/A	0703-1995-01	31329113B	05/2022	1.5 mg	1 in 1 CARTON 1 X 10mL VIAL/ CARTON	07/01/2020 - 09/02/2020

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Haloperidol Decanoate Injection

Carton NDC	Vial NDC	Lot#	Exp. Date	Strength	Size	Ship Dates
0703-7131-03	0703-7131-01	31327056B	03/2022	100 mg/mL	10 in 1 CARTON 1 mL in 1 VIAL, SINGLE-DOSE	10/08/2019 - 04/23/2021
		31328547B	01/2023			
N/A	0703-7133-01	31327066B	03/2022	100 mg/mL	1 in 1 CARTON 5 mL in 1 VIAL, MULTI-DOSE	10/17/2019 – 5/11/2020

IDArubicin Hydrochloride Injection

Tray NDC	Vial/Carton NDC	Lot#	Exp. Date	Strength	Size	Ship Dates
N/A	0703-4156-11	31328668B	04/2023	1 mg/mL	1 in 1 CARTON 20 mL in 1 VIAL, SINGLE-DOSE	05/28/2020 - 05/14/2021

Leucovorin Calcium for Injection, USP

Tray NDC	Vial/Carton NDC	Lot#	Exp. Date	Strength	Size	Ship Dates
N/A	0703-5140-01	31325596B	08/2021	100 mg/vial	1 IN 1 CARTON 10 ML IN 1 VIAL, SINGLE-USE	12/26/2018 - 07/06/2021
		31328129B	11/2022			
		31328356B	01/2023			
		31329297B	06/2023			
		31329569B	08/2023			
		31329821B	09/2023			
N/A	0703-5145-01	31325852B	10/2021	350 mg/vial	1 in 1 CARTON 17.5 mL in 1 VIAL, SINGLE-USE	02/13/2019 - 01/14/2021
		31325985B	10/2021			
		31326349B	01/2022			
		31326873B	03/2022			
		31326995B	05/2022			
		31327158B	06/2022			
		31328946B	05/2023			
		31329180B	05/2023			

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Leucovorin Calcium For Injection novaplus™

Tray NDC	Vial/Carton NDC	Lot#	Exp. Date	Strength	Size	Ship Dates
N/A	0703-5145-91	31328285B	11/2022	350 mg/vial	1 in 1 CARTON 17.5 mL in 1 VIAL, SINGLE-USE	02/28/2020 - 11/16/2020

MethylPREDNISolone Acetate Injectable Suspension USP

Tray NDC	Vial NDC	Lot#	Exp. Date	Strength	Size	Ship Dates
0703-0031-04	0703-0031-01	31328455B	09/2021	40 mg/mL	25 in 1 TRAY 1 mL in 1 VIAL, SINGLE-DOSE	07/24/2020 - 6/11/2021
		31329340B	***12/2021***			
		31329439B	01/2022			
N/A	0703-0031-01	31328347B	07/2021	40 mg/mL	1 in 1 CARTON 1 mL in 1 VIAL, SINGLE-DOSE	05/07/2020 - 09/09/2020
N/A	0703-0043-01	31328321B	07/2021	40 mg/mL	5 mL in 1 VIAL, MULTI-DOSE	6/26/2020 - 10/13/2020
N/A	0703-0045-01	31328368B	07/2021	40 mg/mL	1 in 1 CARTON 1 x 10 mL MULTIPLE DOSE	03/06/2020 - 06/04/2021
		31328394B	07/2021			
		31328699B	09/2021			
		31328834B	10/2021			
		31329286B	12/2021			
0703-0051-04	0703-0051-01	31329363B	01/2022	80 mg/mL	25 in 1 TRAY 1 mL in 1 VIAL, SINGLE DOSE	05/06/2021 - 07/06/2021
		31329484B	03/2022			
N/A	0703-0063-01	31328367B	07/2021	80 mg/mL	1 in 1 CARTON 5 mL in 1 VIAL, MULTI-DOSE	7/31/2020 - 4/30/2021
		31328431B	07/2021			
		31329014B	11/2021			

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Metoclopramide Injection USP

Tray NDC	Vial/Carton NDC	Lot#	Exp. Date	Strength	Size	Ship Dates
0703-4502-04	0703-4502-01	31326043B	10/2021	5 mg /mL	25 in 1 TRAY 2 mL in 1 VIAL, SINGLE-USE	09/03/2020 - 07/06/2021
		31326138B	11/2021			
		31329399B	08/2023			
		31329539B	08/2023			
		31329599B	09/2023			

Norepinephrine Bitartrate Injection USP

Tray NDC	Vial NDC	Lot#	Exp. Date	Strength	Size	Ship Dates
0703-1153-03	0703-1153-01	31329045B	07/2021	1 mg/mL	10 in 1 CARTON 4 mL in 1 VIAL, SINGLE-USE	06/08/2020 - 01/20/2021
0703-1153-03	0703-1153-01	31329077B	08/2021			
0703-1153-03	0703-1153-01	31329312B	09/2021			

Octreotide Acetate Injection

Tray NDC	Vial NDC	Lot#	Exp. Date	Strength	Size	Ship Dates
N/A	0703-3333-01	31329150B	06/2022	200 mcg/mL	1 in 1 CARTON 5 mL in 1 VIAL, MULTI-DOSE	07/14/2020 - 10/05/2020
0703-3311-04	0703-3311-01	31327466B	08/2021	100 mcg/mL	25 in 1 TRAY 1 mL in 1 VIAL, SINGLE-USE	09/09/2019 - 10/24/2019
0703-3301-04	0703-3301-01	31329169B	06/2022	50 mcg/mL	25 in 1 TRAY 1 mL in 1 VIAL, SINGLE-USE	07/14/2020 - 10/13/2020
0703-3301-04	0703-3301-01	31329231B	06/2022			

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Vecuronium Bromide for Injection						
Carton NDC	Vial NDC	Lot#	Exp. Date	Strength	Size	Ship Dates
0703-2914-03	0703-2914-01	31325960B	12/2021	10 mg/vial	10 in 1 CARTON 10 mL in 1 VIAL, SINGLE-USE	02/26/2019 - 01/19/2021
		31326111B	01/2022			
		31326875B	03/2022			
		31326915B	03/2022			
		31326916B	04/2022			
		31326917B	04/2022			
		31329079B	04/2023			
		31329085B	05/2023			

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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.

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