URGENT DRUG RECALL
Granix® (tbo-filgrastim) Injection 300 mcg/0.5 mL
January 10, 2025

Teva Pharmaceuticals USA, Inc.

Granix® (tbo-filgrastim) Injection 300 mcg/0.5 mL					
Carton NDC	Blister (Inner) NDC	Lot #	Exp. Date	Package Size	Syringe Description
63459-910-11	63459-910-12	135738	09/2025	1 syringe in 1 CARTON	1 Single-dose prefilled syringe with a safety needle guard in blister
63459-910-15	63459-910-12	137149	09/2025	10 syringes in 1 CARTON	1 x 10 Single-dose prefilled syringes each with a safety needle guard in blisters
63459-910-17	No Blister	137148	09/2025	1 syringe in 1 CARTON	1 Single-dose prefilled syringe without a safety needle guard

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (TEVA) is initiating a voluntary nationwide recall of *the above three lots* of Granix® (tbo-filgrastim) Injection 300 mcg/0.5 mL to the RETAIL LEVEL. The product in this recall is distributed under the Teva Pharmaceuticals USA, Inc. label. The reason for the recall is the 12-month stability test result for one of the known peptides is below the specification limit for lot # 137149. Because the three lots in this recall were produced from a common bulk batch, the other two lot #'s 135738 and 137148 are potentially impacted. The clinical concern of the product problem is drug ineffectiveness. However, TEVA has not received any complaints related to drug ineffectiveness, lack of effect or lack of efficacy. Teva's health hazard assessment concluded that use of the subject product lots of concern is unlikely to lead to adverse health consequences outside the known safety profile of the product.

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

Please take the following actions upon receipt of this letter:

- Immediately examine your inventory for the above recall lot numbers.
- Immediately discontinue distribution of and quarantine the above recall lot numbers being recalled.
- TEVA's records indicate that the recalled lots were commercially distributed/shipped to its direct customers from 09/07/2023 through 05/01/2024.
- **If you have further distributed the recall lots, please perform a SUB-RECALL to your sub-accounts using this Recall Notification and Business Reply Form (BRF) as a basis for your recall notification.**
- Promptly complete the attached Recall BRF, even if you have **no** product to return, and return the completed Recall BRF to Inmar, Attn: Recall Coordinator by any one of these means:

  MAIL: Inmar, One West Fourth Street, Suite 500, Winston Salem, NC 27101
  EMAIL: **rxrecalls@inmar.com**.
  FAX: 817-868-5362.

After receipt of your Recall BRF, Inmar will send labels for your Return Goods Authorization (RGA) and shipping of your product return. Appropriate credit for your product returns, plus expenses for handling and shipping, will be issued after receipt of said product with your RGA. All recalled product returned without a RGA will 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 877-560-8455 (Hours of Operation: M – F, 9.00 am to 5.00 pm Eastern Time) for Recall Stock Response forms or acquire from clsnetlink.com
Medical-related Questions or to report an Adverse Event: Contact Teva Medical Information at: 888-483-8279 Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week or by email at druginfo@tevapharm.com
Product Quality Complaint-related Questions: Contact Teva 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 or by email at QAS@tevapharm.com
Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 3, then option 2 Live calls received: M - F, 9:00 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 BUSINESS REPLY FORM

Date Form Completed _____

Promptly return your completed Business Reply Form (BRF) by any one of these means to Inmar, Attn: Recall Coordinator
MAIL: Inmar, 1 W 4th St., Winston Salem, NC 27101 EMAIL: rxrecalls@inmar.com FAX: 817-868-5362

Section 1 – Customer Information

This Stock Response is for (Check One):

☐ **Teva Direct Account** ☐ **Non-Direct Customer**

Customer/Store Name:	Address (Street/City/State/Zip)
*DEA #: ***DEA # is required; in order to process your form.***	*Debit Memo #
Contact Name (please print):	Telephone #:

Please mark your answer - I have checked my stock and:

☐ I ***do*** have stock of the recalled item(s) **(complete section 2)** **OR** ☐ I **do not** have stock of the recalled item(s).

Teva Direct Accounts

Does your response include **all** your DC locations? ☐ YES ☐ NO

Did you communicate the recalls to your direct accounts ☐ YES ☐ NO

Non-Direct Customer

The product(s) in this recall were purchased from: _____
Name of Your Wholesaler/Distributor and Location

Section 2 – Quantity of Product to Return

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

Carton NDC	Blister (Inner) NDC	Lot #	Package Size	# of Cartons to Return *(Count Partials as 1)*
63459-910-11	63459-910-12	135738	1 syringe in 1 CARTON	
63459-910-15	63459-910-12	137149	10 syringes in 1 CARTON	
63459-910-17	No Blister	137148	1 syringe in 1 CARTON	

See Attachment 1 for the Carton Label Images

Please indicate the number of shipping labels that you need to return the recalled product(s): _____

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

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RECALL BUSINESS REPLY FORM

Attachment 1 – Carton (Label Images are Not to Scale)

NDC 63459-910-11 contains 1 Single-dose prefilled syringe with a safety needle guard in blister

NDC 63459-910-11
Granix®
(tbo-filgrastim)
Injection
300 mcg/0.5 mL
For Subcutaneous Use Only
For Healthcare Professional Use Only
Rx only
300 mcg/ 0.5 mL
teva

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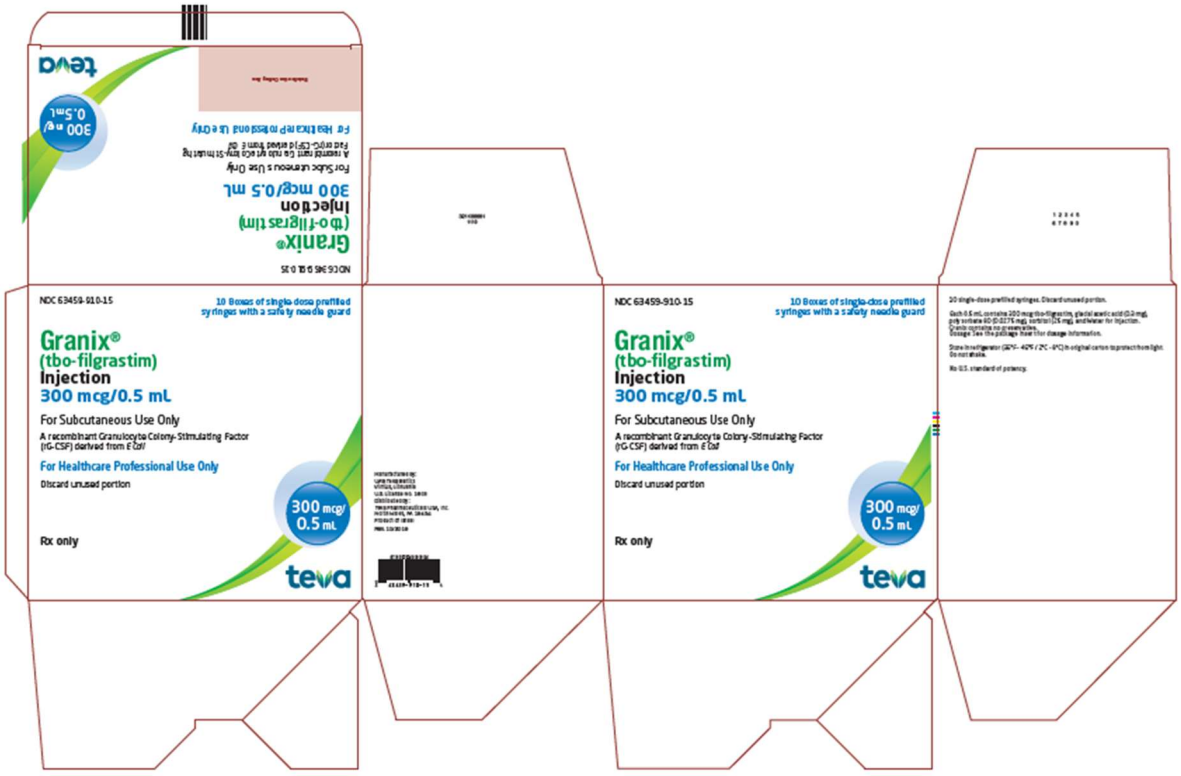
RECALL BUSINESS REPLY FORM

Attachment 1 – Carton (Label Images are Not to Scale)

NDC 63459-910-15 contains 1 x 10 Single-dose prefilled syringes each with a safety needle guard in blisters



NDC 63459-910-17 contains 1 Single-dose prefilled syringe without a safety needle guard