

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

On January 10, 2025, you were notified that Teva Pharmaceuticals USA, Inc. (TEVA) initiated a nationwide recall of three lots of Granix® (tbo-filgrastim) Injection 300 mcg/0.5 mL to the RETAIL LEVEL. **This UPDATE is issued to provide clarification of the package configuration for one of the recalled products, Lot 137149, which has an outer carton AND ten (10) inner cartons.** This lot has an outer carton labeled with NDC 63459-910-15, and ten (10) inner cartons each labeled with NDC 63459-910-11, that each contain one syringe in blister packaging having NDC 63459-910-12. Any inner cartons from Lot 137149 should be returned and will be considered a “partial” quantity from the original 10-pack.

The reason for the recall is the 12-month stability test result for one of the known peptides is below the specification limit for the subject lots. 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.

Granix® (tbo-filgrastim) Injection 300 mcg/0.5 mL

Outer 10- Pack NDC	Single 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- 910-11	63459- 910-12	137149	09/2025	10 syringes in 1 CARTON	10 x 1 Single- dose prefilled syringes each with a safety

63459-910-17	No Blister	137148	09/2025	1 syringe in 1 CARTON	needle guard in blisters 1 Single-dose prefilled syringe without a safety needle guard
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