

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.

Teva Pharmaceuticals USA, Inc. (TEVA) is initiating a nationwide recall of the below 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.

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