

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 one lot of Testosterone Gel, 1.62% 1.25 grams, CIII, for topical use, 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 assay are above the specification limit for lot 100042386. The clinical concern is a risk for patients experiencing adverse events associated with testosterone replacement therapy. Nonetheless, patients are expected to be monitored by their treating physician to ensure proper dosing through the entire treatment period, including monitoring of testosterone levels thus allowing for dose adjustments according to the patient's needs. TEVA has not received any product quality complaints related to this lot. Teva's health hazard assessment concluded that use of the recalled lot could result in moderate adverse events while the likelihood of the harm is remote and overall risk of harm in patient population is low.

PRODUCT: Testosterone Gel, 1.62% 1.25 grams, CIII, for topical use

CARTON NDC: 0591-2925-30

PACKET NDC: 0591-2925-32

LOT NUMBER: 100042386

EXPIRATION DATE: 06/2025