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.

Product recalled: Testosterone Gel 1% CIII 25 mg/2.5 g per unit dose

Carton NDC **(30 packets in 1 carton)**	**Packet NDC**	**Lot Number**	**Expiration Date**
0591-3216-30	0591-3216-17	1403180	10/2022

Teva Pharmaceuticals USA, Inc. is recalling the one lot of Testosterone Gel 1% CIII 25 mg/2.5 g per unit dose, for topical use, to the RETAIL LEVEL, which was distributed nationwide under the Actavis Pharma Inc. label.

This recall is being initiated because an out of specification assay result was obtained during stability testing. Specifically, the product may have slightly higher concentrations of testosterone. The main safety concern that may arise from a slightly higher assay limit for testosterone is a higher risk of experiencing adverse events associated with testosterone replacement therapy. Teva's health hazard assessment concluded that use of product of concern might lead to moderate adverse events. Common adverse events associated with testosterone replacement therapy include application site reactions (e.g. skin irritation), acne, lab tests changes (e.g., elevated hemoglobin or hematocrit, elevated triglycerides, hyperlipidemia, etc.), and elevated prostate specific antigen (PSA). Patients with benign prostatic hyperplasia (BPH) treated with androgens immediately examine your inventory for lot # 1403180 of Testosterone Gel 1% CIII and discontinue distribution.

Teva USA shipped lot # 1403180 to its direct customers from 02/17/2021 through 04/07/2021.