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 *two lots* of **Testosterone Gel, 1.62% 2.5 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 out of specification (OOS) viscosity test results for lot 100029472 and OOS assay results for some packets of lot 100032183 that were above approved product specifications, which could result in reducing or increasing the amount of testosterone absorbed. The safety concern for lower absorption is insufficient management of the underlying disease, leading to testosterone deficiency related adverse events. The clinical concern for increased testosterone absorption is undesirable adverse events, mostly 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). TEVA's health hazard assessments for the OOS viscosity and assay results for the respective lots have determined that the risk of harm to the patient population is unlikely/remote and adverse health consequences are not expected.

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

Testosterone Gel, 1.62% 2.5 grams, CIII, for topical use

Carton NDC	Packet NDC	Lot #	Exp. Date	Size
0591-2926-30	0591-2926-25	100029472	02/2024	30 packets/carton
0591-2926-30	0591-2926-25	100032183	06/2024	30 packets/carton