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 USA) is initiating a nationwide recall of Isotretinoin Capsules, USP 40 mg to the **RETAIL LEVEL.** The product in this recall was distributed to TEVA USA direct customers under the Teva Pharmaceuticals USA, Inc. label**.** The reason for the recall is because the 3-month stability result for assay was found to be above specification limit for some capsules of the specified lot. A Teva USA Health Hazard Assessment determined that Isotretinoin overdose can exacerbate the common Isotretinoin side effects and could lead to moderate adverse events, which may require minimal medical intervention. Nonetheless, Isotretinoin is available only through a restricted prescription program under REMS (Risk Evaluation Mitigation Strategy). Therefore, patients are routinely monitored by a treating physician.

PRODUCT NAME: Isotretinoin Capsules, USP 40 mg - 30 Capsules (3 x 10 Blister Packs)

NDC NUMBER: (Carton) 0591-2436-15 (Blister Pack) 0591-2436-45

LOT NUMBER: 100044259

EXPIRATION DATE: 07/2025