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 *the below two (2) lots* of **Claravis™ (Isotretinoin Capsules USP), 10mg** to the **RETAIL LEVEL.** The products in this recall were distributed under the Teva Pharmaceuticals USA Inc. label**.** The reason the two (2) lots listed in the table below are being recalled is due to out of specification result for the specified impurity Tretinoin. The specification limit (not more than [NMT]) for the specified impurity Tretinoin is an NMT of 3.5% and the reported result was 3.8%. Teva's health hazard assessment concluded that the above-mentioned incident is clinically irrelevant, therefore the exposure to the product of concern is not expected to lead to any adverse health consequences beyond the known safety profile of Claravis™ Capsules. Consequently, the overall risk of harm in patient population is considered to be not applicable.

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

Claravis™ (Isotretinoin Capsules USP), 10 mg

NDC Carton (Outer)	NDC Wallet (Inner)	Lot	Exp. Date	Size
0555-1054-56	0555-1054-60	100067507	07/2026	100 Capsules (10 x 10 Blister Packs)
0555-1054-86	0555-1054-60	100067508	07/2026	30 Capsules (3 x 10 Blister Packs)