

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 above referenced drug products to the **RETAIL LEVEL**. The products in this recall were distributed to TEVA USA direct customers under the Teva Pharmaceuticals USA, Inc. label. The reason for the recall is out-of-specification (OOS) assay results for the clavulanate potassium, associated with a portion of the specified lots. The addition of clavulanic acid to amoxicillin increases the susceptibility of amoxicillin-resistant bacterial strains to amoxicillin. A reduced amount of clavulanic acid in the product, due to the OOS, could result in reduced effectiveness in certain situations, potentially causing an infection to worsen. Nonetheless, scientific literature suggests that because of the variability in absorption of clavulanic acid, a reduced amount of clavulanic acid is not likely to have a significant consequence in the efficacy of the drug combination. According to the Health Hazard Assessment by Teva USA, exposure to the product of concern could potentially lead to severe adverse health consequences, but the likelihood of harm was assessed as remote.

Amoxicillin and Clavulanate Potassium Tablets USP, (Chewable) 400mg/57mg

NDC	Lot	Exp. Date	Size
0093-2272-34	35449379A	07 2024	20 Count bottle
0093-2272-34	100047634	04 2025	20 Count bottle