*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 Budesonide Extended-Release Tablets to the **RETAIL LEVEL.** The product in this recall is distributed to TEVA USA direct customers under the Actavis Pharma, Inc. label**.** The reason for the recall is test results for dissolution were above approved product specifications for the subject lot. The main health consequences arising from this is a potential overdose due to a higher amount of active substance being released. For systemic glucocorticosteroid effects of excessive doses for prolonged periods, the medical consequences could be hypercorticism and adrenal suppression. The review of the Teva Global Safety Database did not identify any cases potentially related to the incident (i.e., none of the case reports described symptoms of overdose). TEVA's health hazard assessment concluded that no adverse health consequences (outside the known safety profile of the product) are expected for the recalled lot. TEVA's records indicate that the specified lot was commercially distributed/shipped to its direct customers from 9/5/2023 through 11/20/2023.

PRODUCT NAME: Budesonide Extended-Release Tablets, 9 mg (30 count)

NDC NUMBER: 0591-2510-30

LOT NUMBER: 100047273

EXPIRATION DATE: 07/2025