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 one (1) lot of Cephalexin For Oral Suspension, USP 125mg/5mL 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) assay result associated with this specific lot. Teva's health hazard assessment concluded the main consequence of a lower assay could be reduced efficacy derived from a lower delivered dose, possibly causing a slower clinical response or treatment failure. In addition, sub-optimal drug exposure may favor antimicrobial resistance, a concern stated specifically in the product labelling. Therefore, the severity of the hazard could lead to moderate adverse events, due to delayed resolution of the infection and/or the need for medical intervention in the form of treatment prolongation, dose adjustments or replacement with another antibacterial product, and the likelihood of the harm occurrence is remote. Consequently, the overall risk of harm in patient population is considered to be low.

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

PRODUCT: Cephalexin For Oral Suspension, USP 125mg/5mL, 100mL bottle

NDC NUMBER: 0093-4175-73

LOT NUMBER: 100076716

EXPIRATION DATE: 09/2027