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 one (1) lot of Octreotide Acetate Injectable Suspension, 30 mg/day to the RETAIL LEVEL. The product in this recall is distributed under the Teva Pharmaceuticals Inc. label. The reason for the recall is due to quality system deficiencies identified during a routine U.S Food and Drug Administration (FDA) inspection of the Pharmathen International SA Sapes facility which manufactures Octreotide for Teva. Observations by FDA included deficiencies implicating microbiological contamination, contamination with foreign matter or particles, potential out of specification due to poor laboratory controls, and data integrity.

Teva's health hazard assessment concluded that the likelihood of harm is remote/unlikely and the overall risk of harm in the patient population is considered to be medium.

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

PRODUCT: Octreotide Acetate Injection 30 mg/vial (1 kit)

NDC NUMBERS
Carton Kit: 0480-9262-08 Diluent Label: 0480-9263-21 Vial Label: 0480-9260-01 Tray Label: 0480-9262-08

LOT NUMBER: 4501102

EXPIRATION DATE: 03/2027