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.

Eugia US LLC (f/k/a AuroMedics Pharma LLC) has initiated a recall to the Retailer level for the product **EPTIFIBATIDE INJECTION 20mg/10mL (2mg/mL) & 10ml vial-USA Market** from the US market due to OOS (Out of specification results) for commercial stability at long term condition stability (2°C-8°C), invert condition study, 21 Month(s) sample analysis of **"EPTIFIBATIDE INJECTION 20mg/10mL (2mg/mL) & 10ml vial-USA]"** having batch no: 3EF22003 for the test related substance (By HPLC), for 'Eptifibatide dimer' impurity is not complying with specification (NMT 0.2%) (Reference OOS: E3OOS240069).

Eptifibatide is a cyclic heptapeptide containing 6 amino acids and 1 mercaptopropionyl (des-amino cysteinyl) residue. An interchain disulfide bridge is formed between the cysteine amide and the mercaptopropiony1 moieties. Chemically it is N^6-(aminoiminomethy1)-N^2-(3-mercapto-1-oxopropy1)-L lysylglycyl-L-a-asparty1-L-tryptophyl-L-proly1-L-cysteinamide, cyclic (1 à 6) disulfide. Eptifibatide binds to the platelet receptor glycoprotein (GP) lib/Illa of human platelets and inhibits platelet aggregation.

Eptifibatide injection is a clear, colorless, sterile, non-pyrogenic solution free from visible particles for intravenous (I.V.) use with a molecular formula of $C_{35}H_{49}N_{11}O_9S_2$ and a molecular weight of 831.96. Each 10 mL vial contains 2 mg/mL of eptifibatide, and each I 00 mL vial contains either 0.75 mg/mL of eptifibatide or 2 mg/ mL of eptifibatide. Each vial of either size also contains 5.25 mg/mL citric acid and sodium hydroxide to adjust the pH to 5.35. Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Eugia US LLC (f/k/a AuroMedics Pharma LLC) began shipping this batch to customers nationwide 29Aug2022.

PRODUCT DESCRIPTION: EPTIFIBATIDE INJECTION 20mg/10mL (2mg/mL) & 10 ml vial

NDC NUMBER: 55150-219-10

BATCH NUMBER: 3EF22003

EXPIRATION DATE: JUNE 2025