

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. is initiating a nationwide recall of one lot of Montelukast Sodium Oral Granules USP, 4 mg to the RETAIL LEVEL. The product in this recall is distributed under the Teva Pharmaceuticals USA, Inc. label. The reason for the recall is test results for known Organic Impurities were above approved product specifications for the subject lot. Teva's toxicological and health hazard assessments determined that the level of the organic impurities pose a low risk to patient health.

Product: Montelukast Sodium Oral Granules USP, 4 mg

Lot Number: 3007556A

Expiration Date: 05/2023

Carton NDC: 0093-7487-56

Packet NDC: 0093-7487-19

Strength: 4 mg

Size: 30 (individual foil) packets/carton