

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.

Imprimis RX has initiated a recall for **MYDRIATIC-4: Tropicamide - Proparacaine - Phenylephrine - Ketorolac Sterile Ophthalmic Solution Drops 1% - 0.5% - 2.5% - 0.5%** from their 503B facility, Imprimis NJOF, situated at 1705 US-46, Suite 6B, Ledgewood, NJ 07852. Imprimis has determined that current stability data for Mydriatic-4 may not support the assigned expiration date for lot 24OCT041. Potency specifications for Mydriatic-4 should be between 90.0-110.0%, and we recently identified stability batches that had subpotent Proparacaine assay levels of 88.9%. The subpotent Proparacaine may result in reduced effectiveness when used on patients. As a result, we have identified 1 (one) unexpired batch of Mydriatic-4 eyedrops that were impacted by this failed stability lot.

PRODUCT: MYDRIATIC-4: Tropicamide - Proparacaine - Phenylephrine - Ketorolac Sterile Ophthalmic Solution Drops 1% - 0.5% - 2.5% - 0.5%

LOT NUMBER: 24OCT041

DATE COMPOUNDED: 10/29/2024

EXPIRATION DATE: 4/26/2025