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 NJOF would like to inform you of a product recall involving Tropicamide-Proparacaine-Phenylephrine-Ketorolac (1%, 0.5%, 2.5%, 0.5%) Sterile Ophthalmic Solution (Mydriatic-4).

Although lot 25JUN027 achieved Proparacaine potency results within specification (98.1%) at time of release, Imprimis is recalling this specific batch of Mydriatic-4 due to stability data indicating that the product may not meet the assigned 120-day expiration date. The stability data for lot 25JUN027 showed a potency of 93.0% for Proparacaine at day 60 timepoint. Based on the regression analysis this batch (25JUN027) for Mydriatic-4 may not meet the assigned 120-day expiration date.

While the primary agents for pupil dilation (Tropicamide and Phenylephrine) remain unaffected, the role of Proparacaine—used to reduce discomfort—is secondary to this effect. Although Proparacaine's reduced potency may result in a minor decrease in patient comfort, it does not significantly impact pupil dilation.
This recall will be carried out to a physician/healthcare provider (retail) level.

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

DESCRIPTION: 5 mL Sterile Ophthalmic Solution Drops Multi-use bottles

NDC NUMBER: 71384-733-05

DATE COMPOUNDED: 7/8/2025

EXPIRY DATE: 11/4/2025

DISTRIBUTION DATE RANGES: 07/31/2025 to 8/29/2025