

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.

This is to notify you that Viona Pharmaceuticals Inc. ("Viona"), is reclassifying this recall from the WHOLESale to the RETAIL LEVEL for Tavaborole Topical Solution 5%. This recall has been initiated due to an Out of specification in stability analysis reported in Description test for Tavaborole Topical Solution 5%, batch no. T401968, at 9-month, 25°C/60%RH Long term condition. Out of specification reported in description as "Light Yellowish alcohol based-solution, free from particulate matter, filled in amber glass bottle with a screw cap" against the description as per specification i.e. "Clear colorless alcohol based-solution, free from particulate matter, filled in amber glass bottle with a screw cap".

This product was shipped to our customers from November 2024 to January 2025.

Detailed investigation is under progress for the below mentioned product lot. Further root cause will be finalized based on the final investigation. But as a precautionary measure, Viona initiating recall of below mentioned lot.

PRODUCT: Tavaborole Topical Solution 5%

NDC NUMBER: 72578-102-04

LOT NUMBER: T401968

EXPIRATION DATE: 09/2026

DISTRIBUTION DATE: 11/21/2024 - 01/03/2025