

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 notice is to inform you of a product recall involving, **Tretinoin 0.05% Cream, 20 g and 45 g**; see enclosed product label for ease in identifying the product at the retail level. (This is a marketed product under the Taro Pharmaceutical label and NorthStar label).

This recall has been initiated in response to Out of Specification, (OOS), result for impurity, (Impurity-2), during analysis at the 18-month long term stability station, at (25°C, 60%RH).

The Health Hazard Evaluation concluded "the impurity is considered as non-mutagenic. All other critical quality parameters are within specification limit including assay at the 18-month time point. Therefore, it can be concluded that the out of specification result observed for the known impurity, (Impurity 2), against the specification limit of NMT 2.5%, is unlikely to pose any serious safety concern in patients other than the known safety profile of the drug. "

The lots complied with all of the established product quality specifications at the time the product was released for distribution.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on 9/2/2025.

Product Name	Package Description	NDC#	Lot#	Expiration Date
Tretinoin 0.05% Cream	45G tube	51672-1394-9	AD96184	12/31/2026
Tretinoin 0.05% Cream	45G tube	16714-249-02	AD96183	12/31/2026
Tretinoin 0.05% Cream	20 G tube	51672-1394-0	AD96196	12/31/2026