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, Sumatriptan and Naproxen Sodium Tablets, 85mg/500 mg. (This is a marketed product under the Sun Pharmaceutical label and NorthStar label).

This recall has been initiated in response to Out of Specification, (00S), result for dissolution, during analysis at the 12- month long term stability station at, (25°C, 60%RH.

The Health Hazard Evaluation concluded *"considering that the product is indicated for the acute treatment of migraine and is not intended for the management of conditions with severe outcomes, any subtherapeutic clinical response can generally be managed by the treating physician through appropriate dose adjustment. Furthermore, all other critical quality attributes were found to be within their respective specification limits. Therefore, the use of impacted tablets with low dissolution values is expected to pose a minor risk to 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 and with dissolution requirements at the initial, 3-month, 6-month, and 9-month stability intervals.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on 9/3/2025.

Product Name	**Package Description**	**NDC#**	**Lot#**	**Expiration Date**
Sumatriptan and Naproxen Sodium Tablets	85mg/500 mg; 9 in 1 bottle	16714-891-01	DNG0559A	5/31/2027
Sumatriptan and Naproxen Sodium Tablets	85mg/500 mg; 9 in 1 Bottle	47335-410-22	DNG0559B	5/31/2027