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.

Sun Pharmaceutical Industries, Inc., would like to inform you of a recall involving Diclofenac Sodium Gel, 3%.

This recall has been initiated in response to Out of Specification (OOS) [slightly lower than the limit] result in viscosity for Diclofenac Sodium Gel, 3%**,** for Batch AD92721, during analysis at the 6- month long term stability station, at (25°C, 60%RH).

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

Based on the Health Hazard Evaluation, *"As this is a topical formulation, and the lot remained visually acceptable with its description, homogeneity, container uniformity, assay, and degradation products, all within specification, the observed OOS is unlikely to affect the gel's spreadability, usage, or therapeutic efficacy. Therefore, it is not expected to pose any additional safety concerns to the patient beyond the established safety profile of the drug".*

Sun Pharmaceutical Industries, Inc. initiated shipment of this product between September 5, 2025, and October 1, 2025.

PRODUCT: Diclofenac Sodium Gel, 3%, 100g

NDC NUMBER: 51672-1363-7

LOT NUMBER: AD92721

EXPIRATION DATE: 3/31/2027