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.*

Recall of these batches has been initiated due to a market complaint that was received from Customer Service Representative of Amerisource Bergen on behalf of Westwood Pharmacy Staff for the product Indomethacin Capsules USP 25mg, Batch# 19231903 (PQC no. CH-2023015651- 00), stating that "The product was labelled as Naproxen Tablets USP 250 mg, but it actually contained Indomethacin Capsules USP 25 mg, and it was placed in an original manufacturer's bottle".

On review of complaint sample photograph it was observed complaint bottle was labeled with "Naproxen Tablets, USP 250mg" and product inside the bottle pack was "Indomethacin Capsule 25mg". The batch details and 2D code details were of Indomethacin Capsule 25mg.

The preliminary investigation reveals that the batch was manufactured as per the instructions mentioned in the batch production record without any deviation(s). Currently, no evidence has been observed that could lead to a label mix up at the drug product manufacturing site.

The reported complaint is believed to be an isolated event and as of now only one complaint for one bottle pack has been received. The investigation was extended to the label supplier, Barcom Industries Limited. Based on the initial assessment of the processes followed by the vendor, Glenmark have confidence in that the presence of the "Naproxen Tablet" stray label originated at the vendor's facility and the extent of such mix up within a roll is very limited.

The lot number of label used in the impacted batch was also used in four (4) other batches of Indomethacin Capsules 25 mg (Batch# 19231858, 19231881, 19233484 and 19233490).

Reserve samples of complaint batch# 19231903 and other four (04) batches (Batch# 19231858, 19231881, 19233484 and 19233490) of product Indomethacin Capsules USP 25mg were inspected for any label of different product present on the bottle and no anomaly was observed. All the bottles were found to be with correct product label of Indomethacin Capsules USP 25mg.

Following is the risk assessment,

1. So far only one complaint is received from pharmacy. All the reserve samples and sample labels in the batch records are with correct product label.
2. The extent of label mix-up is limited and an isolated
3. Both the drugs Indomethacin and Naproxen are NSAIDs and are indicated for the treatment of As per Health Hazard Assessment report, there is low impact on the patient safety.Detectability of the label mix up is high, the mix up can be identified by the pharmacist before dispensing the product to patient since Indomethacin Capsules 25mg is in Capsules dosage form and Naproxen Tablets is in Tablets dosage Hence the possibility of wrong product dispensing is remote. Also, 2D code and printing details on the bottle label are of Indomethacin Capsules 25 mg.

   As an immediate action, implemented procedure for review of Bar Code on each label in a roll before dispensing on packaging line.

   In view of reported complaint as stated above and as an abundance of caution, Glenmark proposes a voluntary recall of Indomethacin Capsules USP 25mg Batch# 19231903, 19231858, 19231881, 19233484 and 19233490. Glenmark Pharmaceuticals, Inc. initiated shipment of this product in June 28, 2023.

lndomethacin Capsules USP 25mg

S.No.	NDC	Batch#	Pack Size	Expiry
1.	68462-406-0 **l**	19231903	100s Count	April 2025
2.	68462-406-01	19231858	100s Count	April 2025
3.	68462-406-01	19231881	100s Count	April 2025
4.	68462-406-01	19233484	100s Count	August 2025
5.	68462-406-01	19233490	100s Count	August 2025

Naproxen Tablets USP 250mg

S.No.	NDC	Batch#	Pack Size	Expiry
1.	68462-188-01	19231903	100s Count	April 2025
2.	68462-188-01	19231858	100s Count	April 2025
3.	68462-188-01	19231881	100s Count	April 2025
4.	68462-188-01	19233484	100s Count	August 2025
5.	68462-188-01	19233490	100s Count	August 2025