

*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 inform you of a product recall by Cipla USA, Inc. for one lot of Lanthanum Carbonate Chewable Tablets, 1000mg. The product is labeled for and marketed by Cipla USA, Inc. bearing the NDC Numbers 69097-0936-98.

The recall is due to an OOS for hardness test during stability testing.

Based on Health Hazard Evaluation, The observed product nonconformance may impact other critical quality parameters i.e. dissolution, related substance, assay and water content test. However, results of all these tests were found within the specification limit. Hence, observed product nonconformance had no impact on these critical quality attributes of a tablet. Additionally, no broken or chip off tablets were observed in stability as well as reserve samples.

Based on these observations, it is concluded that the exposure of the product with observed nonconformance is not likely to cause adverse health consequences.

PRODUCT: Lanthanum Carbonate Chewable Tablets, 1000mg

NDC NUMBER: 69097-0936-98

BATCH NUMBER: NB240315

EXPIRY DATE: 12/25

DISTRIBUTION DATE: 03/21/2024- 04/30/2024