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.

Macleods Pharmaceuticals Limited is initiating a Retail/ Pharmacy level Recall of Olanzapine tablets USP 5 mg. This recall is being conducted with the knowledge of the United States Food and Drug Administration.

This recall is based upon an Out-of-Specification (OOS) result identified during 37-month long-term stability testing of the subject batch under long-term storage conditions (25°C/60% RH). Organic impurities testing by HPLC identified results exceeding the applicable specification for Olanzapine Related Compound-B (0.530% observed vs. Not More Than (NMT) 0.50% specification limit) and an individual unspecified impurity at RT 13.63 min/RRT 0.616 (0.213% observed vs. NMT 0.20% specification limit). Total impurities (0.843%) remained within the NMT 1.50% specification limit.

Macleods Pharmaceuticals Limited conducted a Health Hazard Assessment evaluating the observed impurity concentrations, maximum patient exposure, available impurity characterization, and toxicological/genotoxicity data. The assessment concluded that the observed impurity levels are not expected to pose a risk to consumer safety under the labeled conditions of use. Accordingly, as a precautionary measure, Macleods Pharmaceuticals Limited is recalling the subject batch at the retail/pharmacy level (Class II recall) from the market.

The batch was distributed during the period of 20th November 2023 & 22nd November 2023.

PRODUCT: Olanzapine Tablets USP 5 mg

NDC NUMBER: 33342-068-07

LOT NUMBER: BOB22321A

EXPIRATION DATE: 07/2027