

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.

The Harvard Drug Group, LLC d/b/a Major® Pharmaceuticals and Rugby® Laboratories has initiated a recall for ChlorproMAZINE Hydrochloride Tablets, USP, 10 mg. We began shipping this product on November 19, 2024.

This recall has been initiated by Zydus Pharmaceuticals (USA) Inc. due to an observed OOS (Out of Specification) of Nitrosamine Drug Substance-Related Impurities (NDSRIs) in the drug product. Consumption of the affected product may carry a potential risk of carcinogenicity, which is considered a general characteristic of Nitrosamine compounds. However, due to limited research and literature on this molecule, conducting an assessment is challenging.

This recall should be carried out to the retail level.

PRODUCT: ChlorproMAZINE Hydrochloride Tablets, USP, 10 mg, 100 Unit Doses (10 x 10 blister packs)

NDC NUMBER: 0904-7129-61

LOT NUMBER: N02114

EXPIRATION DATE: 12/2025