

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 2 lots (Lot# PH0072404A, PH0082404A) of Phytonadione injectable emulsion USP 10 mg/ml. The product is labeled for and marketed by Cipla USA, Inc. bearing the NDC Numbers# 69097-708-96.

The extrapolated stability data for Batch PH0082404A up to its intended shelf life of 18 months indicates an out-of-specification (OOS) result in the color index when tested at the 9-month time point. Currently there are 2 live batches in the market (i.e., batch PH0072404A and PH0082404A) which is under scope of recall.

Based on Health Hazard Evaluation, it is concluded that the exposure to the product with observed OOS results is not likely to cause adverse health consequences.

Sr. No.	Product Name	FG Batch No.	Dates distributed
1.	Phytonadione injectable emulsion USP 10mg/ml	PH0072404A	December 05, 2024, to March 18, 2025
2.	Phytonadione injectable emulsion USP 10mg/ml	PH0082404A	January 14, 2025 to March 21, 2025