

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.

FDC Limited, is initiating a recall on Timolol Maleate Ophthalmic Solution USP, 0.5%, 10 mL (ANDA 077259) batch numbers 083I091 and Timolol Maleate Ophthalmic Solution USP, 0.5%, 5 mL (ANDA 077259) 083K063 manufactured at FDC Limited located in Maharashtra, India and marketed by Rising Pharma Holdings, Inc. USA.

This recall is based on complaints received from patients by FDC Limited wherein it is reported that the patients are unable to get the product solution out of the bottle as the spike of the cap was lodged in the nozzle of product bottle.

FDC Limited has conducted preliminary investigation and health hazard assessment. This assessment concluded that it is unlikely that this issue can cause any adverse health consequences to the patients and no long-term risk can be stipulated.

These batches were distributed between December 2023 to August 2024.

Product Name	NDC(s)	Lot(s) /	Exp. date	Distributed Quantity	Distribution dates
Timolol maleate ophthalmic solution USP, 0.5%, 10 mL	64980-514-01	083I091	08/2025	53520 units	12/05/2023 – 08/02/2024
Timolol maleate ophthalmic solution USP, 0.5%, 5 mL	64980-514-05	083K063	10/2025	116568 units	04/24/2024 – 05/17/2024