

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%, 5 mL (ANDA 077259) 083J033 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. This batch was distributed between April 2024 to August 2024. This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

PRODUCT: Timolol maleate ophthalmic solution USP0.5%, 5 mL

NDC NUMBER: 64980-514-05

LOT NUMBER: 083J033

EXPIRATION DATE: 09/2025

DISTRIBUTION DATES: 04/04/2024 – 08/19/2024