

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 for **Ciprofloxacin Ophthalmic Solution USP 0.3% 5 mL**, batch number **083L111 and 084A032** (ANDA 077568) manufactured at FDC Limited located in Maharashtra, India and marketed by Leading Pharma, LLC (A sole distributor for this product in USA).

This recall is based on complaints received from patients 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 has performed 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.

Product Name	NDC(s)	Lot(s) /	Exp. Date	Consignee	Quantity Shipped to Distributor	Shipping dates
Ciprofloxacin Ophthalmic Solution	69315-308-05	083L111	11/2025	Leading Pharma, LLC	67656 Units	02/08/2024
USP 0.3%, 5 mL						
Ciprofloxacin Ophthalmic Solution	69315-308-05	084A032	12/2025	Leading Pharma, LLC	68616 Units	02/08/2024
USP 0.3%, 5 mL						