*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.*

Cipla USA Inc. is recalling the following batches of **Difluprednate Ophthalmic Emulsion 0.05%:**

| **LOT#** | **EXP DATE** |
|---|---|
| DEG1HC2 | 01/2023 |
| DEG2HC2 | 01/2023 |
| DEG3HC2 | 01/2023 |
| DEG4HC2 | 01/2023 |
| DEG5HC2 | 01/2023 |
| DEG6HC2 | 01/2023 |
| DEG1IC2 | 02/2023 |
| DEG2IC2 | 02/2023 |
| DEG3IC2 | 02/2023 |
| DEG4IC2 | 02/2023 |
| DEG1LC2 | 05/2023 |
| DEG2LC2 | 05/2023 |
| DEG1BD2 | 07/2023 |
| DEG2BO2 | 07/2023 |
| DEG3BO2 | 07/2023 |

The start date of distribution of subjected batches were September 15, 2021, respectively. The product is labeled for and marketed by **Cipla USA Inc.** bearing the NDC Numbers NDC- 69097-341-35.

The recall is due to market complaint received for security cap of the bottle is broken in 2 batches, Batch DEG4LC2 and DEG3LC2. Hence in the view of patient safety and as an abundant precaution, all the batches in market will be recalled.

Based on the Health Hazard Evaluation, although the current drug product contains 0.1% sorbic acid as a preservative, microbial contamination of the dispensing tips cannot be ruled out due to the breakage of the protective cap.