**United States Food and Drug Administration**

**Consumer Complaint / Injury Report**

This is an accurate reproduction of the original electronic record as of 04/17/2023

**COMPLAINT # 179177**

| Complaint Date | Receiving Organization | Accomplishing District | How Received | Complaint Source | Complaint Received By | Complaint Status |
|---|---|---|---|---|---|---|
| 02/16/2023 | CIN-DO | CIN-DO | Email | Other, identify in Remarks | Boone-Hall,Carla M | (b) (5) |

**Complainant Identification**

| Name | Address |
|---|---|
| (b) (7)(C), (b) (6) | (b) (7)(C), (b) (6) |

| Phone (W) | Phone (H) | Source POC Name | Source Phone |
|---|---|---|---|
| | (b) (7)(C), (b) (6) | FAERS Case ID (b) (7)(C), (b) (6) | |

**Complaint/Injury**

| Complaint Description | Adverse Event Result | Adverse Event Date | Injury / Illness |
|---|---|---|---|
| CCC CIN-DO received via email from NCCC. Report states,"I purchased the two pack of Ezri artificial tears from (b) (6) and received them on September 10, 2022. I had them on (b) (4) It was my third shipment, and I didn't use the drops right away, because I didn't particularly like them. The bottles had a bad habit of leaking, and most of the solution usually ended up wasted. So, I did not use the Ezri drops until January 2023. The first bottle of the two pack leaked all over my pants pocket, and only about four or five drops actually ended up in my eyes before I threw it away. The second bottle was in my car. I have advanced Sjogren's syndrome, and my eyes are exceptionally dry. Given that it was the first week of January, my eyes were even worse than usual. I have a habit of keeping eyedrops everywhere, using drops, ointments and gels all the time for my dryness. I have probably tried every brand of eyedrops on the market. I noticed serious pain in my eye and my sinuses by Wednesday the first week in January. I thought it was just extreme dryness, because I was recovering from Covid. By Friday afternoon, January 6th at 5:00, I knew I was dead wrong. It was an extremely bad eye infection, along with a sinus infection. It had me crying and rocking in pain. I am (b) (7)(C), (b) (6) . I can be hardheaded, and yes, I did not want to be in the emergency room on a Friday night with flu patients, SRV and Covid. I was in so much pain, the last thing I could tolerate was the idea of being in a waiting room, clutching my eyes.I did not want to be admitted to the hospital I just wanted to go home. I knew at home I had oral doxycycline from a prior infection, eye ointment antibiotics from a prior infection, and painkillers. I went home, took a doxycycline, took a painkiller and put the ointment in my eye | Non-Life Threatening Injury/Illness - No Adverse Event Reporting | 01/06/2023 | Other - identify in Remarks |

| Notify OEO? | Notification Date | Attended Health Professional? | Required Hospitalization? | Emergency Room / Outpatient Visit? | Reported Complaint To? | Need addnl. FDA Contact? |
|---|---|---|---|---|---|---|
| Yes | 02/16/2023 | | | | | |

**Remarks**

FAERS Case ID (b) (7)(C), (b) (6)

Continued from Complaint Description:I promised my daughter if I wasn't better by midnight, I would go to the hospital. The pain marginally subsided, and I continued the treatment. I messaged my family doctor and he said to continue what I was doing. I also saw my ophthalmologist a few days later. The eye infection was not clearing up, so he prescribed another antibiotic eye drop. I was unable to drive because of the condition of my eyes. I have spent a lot of time in the dark because the light hurts so much. The first round of doxycycline and neo-poly-dex antibiotic drops did not clear up the infection. I had to take another course of Bactrim and Polymycin B drops. I saw my ophthalmologist today, and he is still not convinced it is cleared up. My vision has definitely not cleared up.I am seeing the pulmonologist tomorrow because my lungs seem to have also be affected. When I received both the alert from (b) (6) and a blurb from the CDC that the drops had been recalled, I immediately found the bottle of eyedrops still in my car.They are a number lot match for the recalled eyedrops. Unfortunately, the bottle is almost empty. It was resting on its side and most of the eyedrops have leaked out. My ophthalmologist says we can send the bottle to pathology, but he is uncertain that will have any results because it was an opened bottle. The bottle is now in a sealed plastic bag. I have collected as much material as I thought could be helpful. I have a few pictures taken of my eye. I have all the correspondence back-and-forth with my doctors, and copies of all prescriptions and other paperwork."

**Complaint Symptoms**

| Sympton | System Affected | Onset Time | Duration | Remarks |
|---|---|---|---|---|

**Health Care Professional**

| Provider Name | Address | Phone | Occupation |
|---|---|---|---|

**Hospital Information**

| Hospital Name | Address | Phone | Dates of Stay |
|---|---|---|---|

**Emergency Room/Outpatient Visit**

| Hospital Name | Address | Phone | ER Date |
|---|---|---|---|

**Product and Labeling**

| Brand Name | Product Name | Product Code | Product Description | PAC | UPC Code |
|---|---|---|---|---|---|
| EzriCare | Artificial Tears | 64DBY01 | Carboxymethylcellulose Sodium, Emollient,Lubricant;Human - Non/Rx Combination Ingredient;NEC | 56R801 | |

| Qty / Unit / Package | Lot/ Serial # | Exp/Use by Date | Purchase Date | Product Used | Amount Consumed/Used |
|---|---|---|---|---|---|
| | PCMJ013 | 20 Mar 2025 | 9/10/2022 | Yes | UNK |

| Date Used | Date Discontinued | Amount Remained | Imported Product? | Country of Origin | Label Remarks |
|---|---|---|---|---|---|
| 01/01/2023 | 01/06/2023 | | No | India | NDC 79503-0101-15 |

**Retail**

**Problem Ingredient Group**

| Name | Address |
|---|---|
| (b) (6) | |

**Manufacturer/Distributor**

| FEI | Name & Address | Home District | Firm Type |
|---|---|---|---|
| 3012323885 | Global Pharma Healthcare Private Limited A - 9 Sidco Pharmaceutical Complex Thiruporur Chennai India 603110 | ORAHQ | Manufacturer |
| (b) (4) | (b) (4) | NYK-DO | Importer |
| 3022210898 | EzriCare, LLC. 1525 Prospect St Ste 204 Lakewood New Jersey United States 08701-4662 | NWJ-DO | Distributor |

**Initial Evaluation/Initial Disposition**

**Problem Keyword** **Problem Keyword Details**

**Initial Evaluation** **Initial Disposition** **Disposition Made By** **Disposition Date**

**Initial Disposition Remarks**

Manufacturer Verified via NCCC, The Importer (b) (4) is OOB. The phone number listed on the box is for EzriRx
02/16/2023 1st attempt to contact consumer for further information
02/23/2023 2nd attempt

**Referrals**

**Org Name** **HHS Mail Code**

**There are no Cosmetics details for this Complaint.**

**There are no Adverse Event details for this Complaint.**

**Related Complaints**

## COMPLAINTS FOLLOW - UP

### Grouped Follow - Up Operations

| Operation Id | Operation Code | Assignment Number | Accomplishing Organization | Performing Organization | Sample Number | PAF | Status | Status Date |
|---|---|---|---|---|---|---|---|---|
| 11859504 | 13 | 12271954 | PHRM1 | PHRM1-2-G3 | | | Completed | 02/23/2023 |

### Disposition Summary

**Is Consumer Responsible?** **Responsible FEI** **Address** **Name** **Firm Type**

**Follow-Up Disposition** **Disposition Made By** **Disposition Date**

**Disposition Remarks**

### Follow-Up Sent To

**Organization Name** **HHS Mail Code**