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 # 179249

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
02/21/2023	SEA-DO	NWJ-DO	Telephone	Consumer	Bennett Hoffman,Camille	(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
n/a	(b) (7)(C), (b) (6)	n/a	

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
On 2/21/2023, a complainant reported eye pain and burning after using EzriCare Artificial Tears, Lubricant Eye Drops. Medical attention was sought. The product is packaged in a 15-ml plastic bottle with a tamper-evident twist-off cap, placed inside paper box. A nationwide recall of this product was initiated on 2/02/2023: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/global-pharma-healthcare-issues-voluntary-nationwide-recall-artificial-tears-lubricant-eye-drops-due The complainant reported she began experiencing dry eyes in 01/2022 and had been using Systane Hydration Preservative-Free Eye Drops in single-use vials. When she ran out, she purchased the EzriCare drops from (b) (6) in 05/2022. She opened and began using them twice daily on 1/30/2023. She gradually began experiencing burning and pain and stopped using them when she heard of the recall on the news on 2/06/2023. She attained an eyecare professional, who dilated examined her eyes and said he didn't think she had Pseudomonas. He prescribed erythromycin 5-mg ointment to use at bedtime, which improved her condition. On 2/19/2023, she tested positive for COVID-19 and began coughing up phlegm. Her eyes began burning and felt painful. She also noticed her urine smelled sweet. She took her temperature with an infrared device and in aiming for her forehead, she missed and inadvertently aimed it into her eye. The device read 101.8 degrees F; however, her forehead measured 97.8-degrees F. She began considering she might have Pseudomonas as well as COVID and wondered is her use of the EzriCare drops may have affected her eyes and caused them to be warmer. She sought no further healthcare or lab testing.	Non-Life Threatening Injury/Illness	02/04/2023	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	02/21/2023	Yes	No	No	Not Report to Other Source	No

Remarks
Consumer experienced eye pain and burning after using product

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks
Localized pain and tenderness	MUSCULO-SKELETAL	6 Days	Persists	eye pain and burning

Health Care Professional

Provider Name	Address	Phone	Occupation
(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	optometrist

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	Lubricant Eye Drops, Artificial Tears	64DBY01	Carboxymethylcellulose Sodium, Emollient,Lubricant;Human - Non/Rx Combination Ingredient;NEC	56R801	0 30700 15930 2

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
15 Milliliters Bottle	LOT: PCMI 002 EXP: AUG 2024	08/2024	05/2022	Yes	12 applications

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
01/30/2023	02/06/2023	1 intact, 1 open	Yes	India	The product is a 2-pack, packaged in a 15-ml plastic bottle with a tamper-evident twist-off cap, placed inside paper box. 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
3018035065	Delsam Pharma LLC 55 E Gun Hill Rd Bronx New York United States 10467-2103	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
Reaction	eye pain and burning, sweet-smelling urine and chest phlegm

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	(b) (5)	Price,Linda L	03/02/2023

Initial Disposition Remarks

Manufacturer address identified in recall notification.

The Importer (b) (4), FEI# (b) (4), is OOB.

Referred to NWJ-DO.

NWJ-DO Received from SAN-DO. This lot number is included in RES 91621. Dispositioning (b) (5) per Sheila Vantwuyver, NCCC. Current inspection assignment in India. Emailing Nerizza Guerin, DIB Pharm1, William Muszynski, ERC, and Sheila.

Referrals

Org Name	HHS Mail Code
NWJ-DO	HFR-MA300

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

There are no Follow Up Operations related to this complaint.

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