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 # 179209

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
02/13/2023	SEA-DO	NWJ-DO	Email	Other, identify in Remarks	Volkman,Kelsey A	(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)	FAERS (b) (7)(C), (b) (6)	(b) (7)(C), (b) (6)

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
On 2/13/2023 (b) (7)(C), (b) (6), Medical Epidemiologist, (b) (7)(C), (b) (6) reported a probable case of P. aeruginosa (VIM CRPA infection) associated with EzriCare Lubricant Eye Drops Artificial Tears. A nationwide recall of this product (RES 91621) was initiated on 2/02/2023:	Non-Life Threatening Injury/Illness - No Adverse Event Reporting	01/30/2023	Other - identify in Remarks

https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/global-pharma-healthcare-issues-voluntary-nationwide-recall-artificial-tears-lubricant-eye-drops-due

The identified case and his wife had been using the product for at least a year and multiple times a day. (b) (7)(C), (b) (6) added that CDC conducted whole genome sequencing (WGS) and on 2/22/2023, and confirmed the isolate was a match for the ongoing recall/ outbreak. She explained the product was purchased from (b) (6) by the case's daughter (screen snip of (b) (6) sales attached). The product is packaged in a 15-ml plastic bottle with a tamper-evident twist-off cap, placed inside paper box and sold as a 2-pack. Photos of product bottles were provided by (b) (7)(C), (b) (6) (photographs & email correspondence attached).

On 2/17/2023, I contacted (b) (7)(C), (b) (6), who reported that the case is an older gentleman, residing in the (b) (7)(C), (b) (6), and was suffering from a UTI. He previously resided with his wife in their daughter's home; but was taken to (b) (7)(C), (b) (6) because he contracted COVID-19 in (b) (7)(C), (b) (6) On or about (b) (7)(C), (b) (6) he was transferred from the hospital to the (b) (7)(C), (b) (6), because of weakness and fragility. He continues to reside there.

CONTINUED IN REMARKS:

Notify OEO?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	02/17/2023	No	Yes	No	Not Report to Other Source	Yes

Remarks

4On or about 1/23/2022 (approximately 1-year ago), the case and his wife began using the EzriCare Eye Drops for their dry eyes. Both have glaucoma and macular degeneration. On (b) (7)(C), (b) (6), he developed a UTI, experiencing an increased urge to urinate and cloudy urine. A urine isolate was cultured by third-party lab, (b) (6), and determined to be pan-resistant. The isolate was forwarded to the (b) (6) and tested positive for Pseudomonas. WGS was conducted by CDC. (b) (6)) was notified of the case and contacted the case's daughter to obtain information.

(b) (7)(C), (b) (6) explained the case's eye drop samples are in her custody. There are 5 bottles remaining, 3 opened, 2 intact. One of the bottles has a sticker affixed to it by the nursing care facility the case resides in and was covering the lot number. I asked if she could slit the label from it and she said she did try to; however, the bottle label became affixed to the sticker because of the glue. I was unable to verify that lot number during our interview. Specific lot details are discussed in Initial Disposition Remarks of this report.

CONTINUED IN INITIAL DISPOSITION REMARKS:

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks
Other Urogenital	RENAL/URINARY	Weeks	Weeks	cloudy urine and urge to urinate
Eye irritation	NERVOUS	Months	Months	eye dryness

Health Care Professional

Provider Name	Address	Phone	Occupation

Hospital Information

Hospital Name	Address	Phone	Dates of Stay
(b) (7)(C), (b) (6)	(b) (7)(C), (b) (6)	(b) (7)(C), (b) (6)	(b) (7)(C), (b) (6)

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, Lubricant Eye Drops	64DBY99	Emollient, Lubricant, N.E.C.;Human - Non/Rx Combination Ingredient;NEC	56R801	3 79503 10115 7

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
15 Milliliters Bottle	Multiple lots (See Remarks)	See Remarks	est. 1 year ago	Yes	unk

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
01/2023	01/30/2023	See Initial Disp. Remarks	Yes	India	Other packaging codes: NDC: 79503-0101-15 Manufacturing Lic. No.: TN 0002176

Retail

Problem Ingredient Group

Name	Address
Amazon.com	

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	UTI, cloudy urine, increased urge to urinate, eye irritation & dryness
Other, identify in Details	Recall 91621

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	(b) (5)	Bennett Hoffman,Camille	02/23/2023

Initial Disposition Remarks

On 2/23/2023, I contacted (b) (7)(C), (b) (6), who followed up with the case and determined he had been using the EzriCare Eye Drops. Nurse (b) (7)(C), (b) (6) obtained copies of the case's daughter's (b) (6) purchase receipts ang health information. Nurse (b) (7)(C), (b) (6) explained the case's eye dryness and irritation had increased during the use of the EzriCare Eye Drops. The daughter, a nurse, also observed her father's eye irritation increased after he started using the EzriCare Eye Drops. And he developed red rings of irritation in the skin surrounding his orbitals. Once the eye drops were implicated in his UTI, he stopped using them and these rings abated. The cases' wife did not experience any illness symptoms after using the eyedrops. Nurse Richardson said any medical records or additional case health information could be obtained for FDA if necessary.

Lot codes and expiration dates are as follows:
1. Lot and expiration unknown, hidden by patient label (open) - facility
2. Lot: PCMJ 011, Exp: MAR 2025 (closed) - facility
3. Lot: PCMJ 014, Exp: MAR 2025 (opened) - home
4. Lot: PCMJ 014, Exp: MAR 2025 (closed) - home
5. Lot: PCMI 001, Exp: AUG 2024 (opened) - home
The Importer (b) (4)., FEI# (b) (4), is OOB

4/4/2023 NWJ-DO - This complaint was shared with CDC and OCI on March 31, 2023. A nationwide recall of this product was initiated on 2/02/2023 (RES #91621) Per Sheila VanTwuyver, NCCC, this is a FAERS complaint ID#(b) (6), (b) (7)(C). I corrected source on page 1. Linda Price, CCC.

Referrals

Org Name	HHS Mail Code

There are no Cosmetics details for this Complaint.

Related Complaints

Complaint #

ADVERSE EVENT DETAILS	Product Name	Artificial Tears, Lubricant Eye Drops	Product Code	64DBY99

Birth Date	Age	Gender	Race	Previous Adv Effects of Product?
		(b) (7)(C), (b	Question Not Asked	Unknown

Consumption Site	Recommended Dosage/Serving Size	Label Indications for Use
Nursing Home	PRN	yes

Recommended Duration of Use	Product Label Available?	Sample Available?
unk	No	No

Product Ingredients

Lubricant Eye Drops, Artificial Tears

Duration of Product Used	Frequency of Product Used	How was Product Taken?
Months	Other	dropped into eyes

Remarks

none

Symptoms Occurence

Did event abate after stopping use of product?	Did symptoms recur after product reintroduction?	Did symptoms recur after using products with same ingredients?
Yes	Yes	No

Did adverse event result in Congenital Anomaly?	Did adverse event require intervention to prevent permanent impairment / damage?
No	No

Medications / Other Products Used

Medical Test Performed	Results
urinalysis	UTI

Medical History

Preexisting Conditions	Treatment	Remarks
Glaucoma	eyedrops	also has macular degeneration

Medical Diagnosis	Medical Treatment
UTI, Pseudamonas	antibiotics

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date
11867360	31	12270847	PHRM4	PHRM4-GRP4	1152477		Completed	03/09/2023
11867360	31	12270847	PHRM4	PHRM4-GRP4	1152477		Completed	03/09/2023
11868297	31	12270847	PHRM4	PHRM4-GRP4	1152480		Completed	03/09/2023
11868298	31	12270847	PHRM4		1152478		Completed	03/09/2023
11868299	31	12270847	PHRM4	PHRM4-GRP4	1152479		Completed	03/09/2023
11865093	31	12270847	PHRM4	PHRM4-GRP1			Canceled	03/01/2023
11867360	31	12270847	PHRM4	PHRM4-GRP4	1152477		Completed	03/09/2023

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type
No	3022210898	1525 Prospect St Ste 204 Lakewood New Jersey United States 08701-4662	EzriCare, LLC.	Importer

Follow-Up Disposition	Disposition Made By	Disposition Date
(b) (5)	Bennett Hoffman,Camille	04/04/2023

Disposition Remarks

closed. referred to NWJ-DO

Follow-Up Sent To

Organization Name	HHS Mail Code
NWJ-DO	HFR-MA300