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 # 179044

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
02/08/2023	SEA-DO	NWJ-DO	Email	Local	Bennett Hoffman,Camille	(b) (5)

Complainant Identification

Name	Address
Anonymous	WA

Phone (W)	Phone (H)	Source POC Name	Source Phone
		(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
On 2/03/23, local Seattle news sources reported a WA death following the use of EzriCare Artificial Tears, Lubricant Eye Drops. HAFW6 CCC and SEA-DO ERC held a call with WA Department of Health (WA DOH) (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C) to gather information. 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 (RES #91621): https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/global-pharma-healthcare-issues-voluntary-nationwide-recall-artificial-tears-lubricant-eye-drops-due During the call, HAFW6 was informed the use of EzriCare Artificial Tears was not confirmed and no product information was available, because the family had not been interviewed regarding eye drops used prior to hospitalization. (b) (4), (b) (7)(C) contacted the patient's daughter for more information. On 2/08/23, WA/DOH provided an update from (b) (4), (b) (7)(C) confirming the patient did use EzriCare Artificial Tears 1-2 times per day since a cataract surgery in (b) (6), (b) (. The daughter reported the hospital allowed the family to bring in and administer eye drops to the patient. The daughter reported her mother still has eye drops at home and will hold them. The patient's daughter reported the eye drops were purchased from (b) (6) . The following information was derived in part from the chart abstract provided by CDC. On 8/24/2022, the patient presented to the (b) (6), (b) (7)(C) , for (b) (6), (b) (7)(C) and complaining of (b) (6), (b) (7)(C). He was instructed to re-start (b) (6), (b) (7)(C) After one dose, he had multiple incidents of urinary incontinence. His daughter describes his urine as "weird looking	Death	(b) (6), (b) (7)(C)	Other - identify in Remarks

with a gross smell."

On 8/25/2022, patient lost consciousness while using the restroom at home, and once again prior to patient's daughter calling 911.

CONITINUED IN REMARKS:

Notify OEO?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	02/09/2023	Yes	Yes	Yes	Not Report to Other Source	Yes

Remarks

Patient's daughter reported he had a fever of 101 F prior to admission to hospital, poor appetite, and dehydration due to minimal fluid intake.

On (b) (6), (b) (7)(C) he was initially admitted to (b) (6), (b) (7)(C) for treatment of his (b) (6), (b) (7)(C) syndrome. He was noted to have C. difficile colitis and was treated. During hospitalization, he was found to have (b) (6), (b) (7)(C) with reduced ejection fraction.

On (b) (6), (b) (7)(C), he was admitted to (b) (6), (b) (7)(C) with (b) (6), (b) (7)(C) He had worsening evidence of Vaso-distributive shock and fluid accumulation in his lungs. The patient continued to worsen despite vasopressor support and broad antibiotics, and experienced significantly worsening respiratory failure. His prognosis was poor, likely requiring intubation, bronchoscopy, and bilateral chest tube placement, and was unlikely to return home in an independent capacity. His family elected for DNR/DNI and palliative care. He died in the hospital on (b) (6), (b) (7)(C)

(b) (6), (b) (7)(C) reported eye drops were not documented as given while hospitalized, however standard of care for patients in medically induced comas is to receive eye drops. The hospital confirmed they did not have EzriCare products in their formulary. The patient was seen by his ophthalmologist in (b) (6), (b) (7)(C) (different hospital) for follow up concerning suspected glaucoma involving the right and left eye (mild in severity). The patient reported using artificial tears at home at bedtime and waking up, and using warm compresses for comfort.

Patient's medical history includes (b) (6), (b) (7)(C) in (b) (6), (b) (7)(C), (b) (6) (b) (6), (b) (7)(C)

CONT INIT DISP.

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks
Change in urine volume	METABOLIC			(b) (7)(C), (b) (6), urinary retention
Dizziness or problems with balance	NERVOUS			(b) (7)(C), (b) (6) loss of consciousness 2 X (syncope)
Change in body temperature	CARDIOVASCULAR			(b) (7)(C), (b) (6) fever, temperature of 101 deg F
Other Blood and Lymphatic	BLOOD OR LYMPHATIC			(b) (7)(C), (b) (6) admitted to (b) (7)(C), (b) (6), for symptoms of (b) (7)(C), (b) (6) syndrome (cancer)
Other gastrointestinal	GASTROINTESTINAL			(b) (7)(C), (b) (6) admitted to (b) (7)(C), (b) (6) for (b) (7)(C), (b) (6)
Other cardiovascular	CARDIOVASCULAR			(b) (7)(C), (b) (6), admitted to (b) (7)(C), (b) (6)
Other cardiovascular	CARDIOVASCULAR			(b) (7)(C), (b) (6)
Other Respiratory	RESPIRATORY			(b) (4) failure
Death	CARDIOVASCULAR			died in hospital (b) (4)
Eye irritation	NERVOUS			Eye drops used for comfort for dry eyes from glaucoma and cataract surgery

Health Care Professional

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

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
(b) (7)(C), (b) (6)	(b) (7)(C), (b) (6)	(b) (7)(C), (b) (6)	(b) (7)(C), (b) (6)

Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
EzriCare	Artificial Tears, Lubricant Eye Drops	64DBY01	Carboxymethylcellulose Sodium, Emollient,Lubricant;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	See Label Remarks	Label Rmks	4/09/22 & 9/12/22	Yes	1/2 bottle

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
04/12/2022	09/14/2022	1/2 & 1 intct; 2 closed*	Yes	India	Samples/ Results: PCMJ 015 EXP MAR 2025 (SEA-DO C/R# 555158) (Positive for Pseudamonas monteilii & Pseudamonas mosselii) PCMI 004 EXP AUG 2024 (SEA-DO C/R# 555156) (Positive for Pseudamonas aeruginosa) PCMI 004 EXP AUG 2024 (SEA-DO C/R# 555157) (Positive for Pseudamonas aeruginosa) PCMJ 015 MAR 2025 (SEA-DO C/R# 555159) (Positive for Pseudamonas monteilii & Pseudamonas mosselii)(intact sample) Other packaging codes: NDC: 79503-0101-15 Manufacturing Lic. No.: TN 0002176

Retail

Problem Ingredient Group

Name	Address
(b) (6)	Ordered (b) (6) (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
Other, identify in Details	RES 91621
Reaction	(b) (6), (b) (7)(C),
Death	died (b) (6), (b) (7)(C) in hospital of (b) (6), (b) (7)(C)

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	(b) (5)	Bennett Hoffman,Camille	02/09/2023

Initial Disposition Remarks

On 2/10/2023, HAFW6 CCC contacted the patient's daughter to obtain additional product details and coordinate sample collection. She asked that I maintain her family's anonymity. She confirmed she and her father lived at the same home address indicated. She was aware of the recall and had the notification. She purchased 2 bottles of the product from the EzriCare store on (b) (6) on (b) (6) and had a half bottle and one full, unused bottle from same lot from that purchase. She purchased another 2 bottles (from a different lot) on (b) (6) and has one intact bottle, and one used bottle. The daughter reported her father used the bottle from April until his passing, and the daughter used the bottle from September, without any reported illness.
On 1/11/2022, HAFW6 CCC called patient's daughter and she emailed labeling photographs and the sales invoices (email correspondence attached). She explained her father used the drops from 4/12/2022 until his passing. He kept them with him at home and in the hospitals. Other eyedrop brands were used prior to 4/11/2022, but they were discarded. She does not possess the medical records, but said FDA could get them from (b) (7)(C), (b) (6). She specified her father attended the (b) (7)(C), (b) (6) on (b) (7)(C), (b) (6) and was admitted for 12-days and was transferred directly to (b) (7)(C), (b) (6) on (b) (7)(C), (b) (6) for 3-days. No autopsy was performed.
She added her father lived in (b) (6), (b) (7)(C) from 2008 to 2022 and was diagnosed with (b) (6), (b) (7)(C) while there and attend a different provider. He moved to (b) (7)(C), (b) (6) in 2022 and transferred his care to (b) (7)(C), (b) (6) where he also joined a clinical trial.
NWJ emailing PHARM 1 and CB 4/3/2023. This complaint was shared with (b) (5). CDER documented the report as FAERS Case ID 21983780. Complaint (b) (5). Lot PCMJ 015 Samples 555158, 555159 and NJ sample 1214711. Lot PCMI 004 Samples 555156 and 555157. Email L. Price to team on 4/3/2023.

Referrals

Org Name	HHS Mail Code
NWJ-DO	HFR-MA300

There are no Cosmetics details for this Complaint.

Related Complaints

Complaint #

ADVERSE EVENT DETAILS	Product Name	Artificial Tears, Lubricant Eye Drops	Product Code	64DBY01

Birth Date	Age	Gender	Race	Previous Adv Effects of Product?
	(b) (7)	(b) (7)(C), (b	(b) (7)(C), (b) (6)	Unknown

Consumption Site	Recommended Dosage/Serving Size	Label Indications for Use
Clinic/Hospital	unk	yes

Recommended Duration of Use	Product Label Available?	Sample Available?
unk	Yes	Yes

Product Ingredients

Artificial Tears, Lubricant Eyedrops

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

Remarks

Patient's medical history includes (b) (7)(C), (b) (6) .

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?
No	Unknown	Unknown

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

Medical History

Preexisting Conditions	Treatment	Remarks
(b) (7)(C), (b) (6)	(b) (7)(C), (b) (6)	
	artificial tears	
	unknown	(b) (7)(C), (b) (6)
	(b) (7)(C), (b) (6)	
	unknown	
	unknown	(b) (7)(C), (b) (6)
Other, identify	unknown	

Medical Diagnosis	Medical Treatment

His prognosis was poor, likely requiring (b) (7)(C), (b) (6) and was unlikely to return home in an independent capacity. His family elected for DNR/DNI and palliative care. He died in the hospital 9/14/22.

(b) (7)(C), (b) (6) and (b) (7)(C), (b) (6). DNR/DNI and palliative care.

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date
11852575	31	12270712	PHRM4	PHRM4-GRP3	555158		In Progress	02/16/2023
11852576	41	12270712	IRVLMP	IRVMP-MIC	555158-0	MIC	Completed	03/20/2023
11882680	41	12270712	IRVLMP	IRVMP-MIC	555158-1	MIC	Completed	04/07/2023
4650844	31	1147538	SAN-DO	SAN-JCH	555168		Completed	04/06/2010
4650846	41	1147538	SANLHAF	SANL-MICRO	555168-0	MIC	Completed	03/02/2010
4666298	41	1147538	DENLHAF	DEN-LAB-L	555168-1	MIC	Completed	03/11/2010
4666305	41	1147538	SANLHAF	SANL-MICRO	555168-2	MIC	Completed	03/04/2010
4737262	41	1147538	DENLHAF	DEN-LAB-L	555168-3	MIC	Completed	04/20/2010
11852490	31	12270698	PHRM4	PHRM4-GRP3	555157		In Progress	02/16/2023
11852491	41	12270698	IRVLMP	IRVMP-MIC	555157-0	MIC	Completed	03/17/2023
11881560	41	12270698	IRVLMP	IRVMP-MIC	555157-1	MIC	Completed	04/06/2023
11852596	31	12270715	PHRM4	PHRM4-GRP3	555159		In Progress	02/16/2023
11852597	41	12270715	IRVLMP	IRVMP-MIC	555159-0	MIC	Completed	03/20/2023
11881691	41	12270715	IRVLMP	IRVMP-MIC	555159-1	MIC	Completed	04/08/2023
11849285	31	12270142	PHRM4	PHRM4-GRP3	555156		Completed	03/29/2023
11851597	41	12270142	IRVLMP	IRVMP-MIC	555156-0	MIC	Completed	03/17/2023
11880274	41	12270142	IRVLMP	IRVMP-MIC	555156-1	MIC	Completed	04/07/2023
11849784	13	12268917	PHRM4	PHRM4-GRP1			In Progress	02/15/2023
11849792	31	12268917	PHRM4	PHRM4-GRP1			In Progress	02/15/2023
11851518	31	12268917	PHRM4	PHRM4-GRP1			Pending at Branch	02/16/2023
11849285	31	12270142	PHRM4	PHRM4-GRP3	555156		Completed	03/29/2023

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**