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 # 179119

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
02/14/2023	NWE-DO	NWE-DO	Email	CDC	Squire,Maura 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
(b) (7)(C), (b) (6)	(b) (7)(C), (b) (6)	n/a	n/a

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
-Product: EzriCare Artificial Tears- --This complaint referral was received from CDC. On 2/3/2023 CDC reported consumers (cases) in the state of (b) (4) diagnosed with Pseudomonas Aeruginosa, and the consumers may have used used EzriCare Artificial Tears that may be contaminated and available. The lot codes possibly used by consumers are PCMI005, PCMJ002, PCMJ001, and these lots are remaining and available. CDC provided contact information for the Department of Public Health in (b) (4) The Department of Public Health identified the remaining lots are with (b) (7)(C), (b) (6)	Life Threatening Injury/Illness	02/2023	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	02/14/2023	Unknown	Yes	Unknown	Reported to Other Source, identify in Remarks	Yes

Remarks

-The consumers were diagnosed with Pseudomonas Aeruginosa. No medical outcomes or further patient information is available. An FDA laboratory has been identified to test the available samples. A CSO has been identified to collect the samples.

-NWE-DO ERC, Kim Langello is coordinating with PHRM1 team, CSO, and the pharmacy.

-This complaint was received by NWE-DO CCC on 02/14/23 (emails are included as background information).

-Injury/Illness: unknown symptoms of medically diagnosed cases of Pseudomonas Aeruginosa.

-Per FDA, on 02/02/23, "Global Pharma Healthcare is voluntarily recalling all lots within expiry of their Artificial Tears Lubricant Eye Drops, distributed by /EzriCare, LLC- and Delsam Pharma, to the consumer level, due to possible contamination. The Centers for Disease Control and Prevention (CDC) alerted FDA to (b) (5) possibly associated with the use of the artificial tears manufactured by Global Pharma Healthcare."

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks
NEC - Identify in Remarks	NEC	unk	unk	unknown symptoms reported from CDC regarding consumers diagnosed with Pseudomonas Aeruginosa.

Health Care Professional

Provider Name	Address	Phone	Occupation

Hospital Information

Hospital Name	Address	Phone	Dates of Stay
(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	not provided

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	379503101157

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
15 Milliliters Bottle	PCMI005, PCMJ002, PCMJ001	not provided	not provided	Yes	not provided

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
not provided	not provided	3 to 4 bottles	No	India	-NDC: 79503-0101-15 -Active ingredient: Carboxymethylcellulose Sodium 1 BOTTLE, DROPPER in 1 CARTON / 15 mL in 1 BOTTLE, DROPPER

Retail

Problem Ingredient Group

Name	Address
(b) (7)(C), (b) (6)	(b) (7)(C), (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
3022210898	EzriCare, LLC. 1525 Prospect St Ste 204 Lakewood New Jersey United States 08701-4662	NWJ-DO	Distributor
3022210898	EzriCare, LLC. 1525 Prospect St Ste 204 Lakewood New Jersey United States 08701-4662	NWJ-DO	Importer

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Reaction	unknown symptoms of medically diagnosed cases of Pseudomonas Aeruginosa
Other, identify in Details	Recalled 02/02/23 due to possible contamination

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	(b) (5)	Squire,Maura A	02/14/2023

Initial Disposition Remarks

-NCCC verified the manu,importer. and dist, and advised, "we will be announcing this finding in our incident briefing.".

-Per NWE-DO ERC: The samples are in the (b) (7)(C), (b) (6)
POC (b) (7)(C), (b) (6) . The CSO is Samir Gala, Hartford RP, and he'll be collecting the samples on 02/14/23 There is no sample assignment and sample numbers will be provided upon receipt by ERC. Sample collection analysis. Samples should be sent to FDA's Irvine Medical Products Lab (IRVL-MP) for micro analysis.

-CSO Gala collected Samples, #1142508, 1142509, and 1142510 and
Forms FDA 482 (Notice of Inspection) and 484 (Receipt for Samples) were issued. A Form FDA 463a (Affidavit) was collected. Additionally, the Samples were packaged and dropped off at UPS for shipment under tracking # 1ZA5F8300195568220. Expected delivery to Irvine Laboratory on 2/16/2023 or 2/17/2023.

-As of 04/05/23: Lab results for Sample 114258, Class II, "growth found"; Sample 1142509, Class 1-in compliance; Sample 1142510- in-progress. This is pending Sample 1142510 sample analysis completion. NWJ-DO CCC was apprised for importer jurisdiction.

Referrals

Org Name	**HHS Mail Code**

There are no Cosmetics details for this Complaint.

Related Complaints

178719, 179044, 179082, 179083

Complaint #

ADVERSE EVENT DETAILS | **Product Name** Artificial Tears | **Product Code** 64DBY01

Birth Date	Age	Gender	Race	Previous Adv Effects of Product?
			Other	Unknown

Consumption Site	Recommended Dosage/Serving Size	Label Indications for Use
Other - identify in Remarks	1-2 drops as needed	

Recommended Duration of Use	Product Label Available?	Sample Available?
n/a	Yes	Yes

Product Ingredients

Please see this CC, pg. 1, "Label Remarks"

Duration of Product Used	Frequency of Product Used	How was Product Taken?
Other	Other	unk

Remarks

this involved patient cases reported by CDC with further patient information not provided.

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?
Unknown	Unknown	Unknown

Did adverse event result in Congenital Anomaly?	Did adverse event require intervention to prevent permanent impairment / damage?
Unknown	Yes

Medications / Other Products Used

Medical Test Performed	Results

Medical History

Preexisting Conditions	Treatment	Remarks

Medical Diagnosis	Medical Treatment
Pseudomonas Aeruginosa	not provided

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
11853853	31	12270943	PHRM1	PHRM1-1-G4	1142508		Completed	03/22/2023
11853898	31	12270948	PHRM1	PHRM1-1-G4	1142509		Completed	03/22/2023
11853966	31	12270987	PHRM1	PHRM1-1-G4	1142510		Completed	03/22/2023

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**