

**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** | # **179205**

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
02/17/2023	CHI-DO	CHI-DO	Email	Friend/Relative of Consumer	Wilson, Sharon 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)		

**Complaint/Injury**

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
On 2/15/2023 CHI-DO CCC received a complaint concerning EzriCare Artificial Tears.	Life Threatening Injury/Illness	1/23/2023	Other - identify in Remarks

?My mom has a loss of vision and multi-week+ and continuing inpatient hospitalization due to Pseudomonas aeruginosa bacteria from using EZRI CARE branded eye drops, purchased on (b) (6) She was using lubricant eye drops for eye relief."

Notify OEO?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	02/17/2023	Yes	Yes			

**Remarks**

Bacteria Infection

**Complaint Symptoms**

Symptom	System Affected	Onset Time	Duration	Remarks
Blurred vision	NERVOUS	2 Weeks		
Eye irritation	NERVOUS			
(Children Only) Developmental retardation	NERVOUS			

**Health Care Professional**

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

**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
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**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	3795031011 57

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
.5 Ounces Bottle	PCMI 003	AUG 2024		Yes	

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
			Yes	India	NDC 79503-0101-15

**Retail****Problem Ingredient Group**

Name	Address
www.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
(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
Reaction	

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

Mfg Lic. No: TN 00002176

**Referrals**

Org Name	HHS Mail Code
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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
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Follow-Up Disposition	Disposition Made By	Disposition Date
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**Disposition Remarks****Follow-Up Sent To**

Organization Name	HHS Mail Code
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