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 # 179185

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
02/09/2023	CIN-DO	CIN-DO	Email	Other, identify in Remarks	Boone-Hall,Carla M	(b) (5)

Complainant Identification

Name	Address
Case Reporter (b) (7)(C), (b) (6)	(b) (7)(C), (b) (6)

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

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
Report States: Corneal ulcer with multidrug-resistant Pseudomonas aeruginosa after use of Ezricare artificial tears. Relevant test: Eye culture (b) (7)(C), (b) (6). Results: Greater than or equal to 15 colonies Pseudomonas aeruginosa Resistant to amikacin, cefepime, ceftazidime, ciprofloxacin,gentamicin, meropenem, tobramycin Susceptible to colistin, polymyxin B, cefiderocol Intermediate to piperacillin/tazobactam,aztreonam	Non-Life Threatening Injury/Illness - No Adverse Event Reporting		

Notify OEO?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	02/16/2023					

Remarks
FAERS Case ID (b) (7)(C), (b) (6) Corneal ulcer with multidrug-resistant Pseudomonas aeruginosa

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks

Health Care Professional

Provider Name	Address	Phone	Occupation

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	Artificial Tears	64DBY01	Carboxymethylcellulose Sodium, Emollient,Lubricant;Human - Non/Rx Combination Ingredient;NEC	56R801	UNK

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
	UNK	UNK		No	UNK

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
06/01/2022	07/31/2022	UNK	No		NDC 79503-0101-15

Retail

Problem Ingredient Group

Name **Address**

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**

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

Initial Disposition Remarks

Manufacturer information provided by NCCC (b) (6), (b) (7)(C). 02/16/23Request of consumer information sent to reporter: (b) (6), (b) (7)(C)
02/23/23 2nd attempt

Referrals

Org Name **HHS Mail Code**

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**

Follow-Up Disposition **Disposition Made By** **Disposition Date**

Disposition Remarks

Follow-Up Sent To

Organization Name **HHS Mail Code**