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 # 179172

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
02/08/2023	PHI-DO	NWJ-DO	Email	Other, identify in Remarks	Anderson,Daniell e	(b) (5)

Complainant Identification

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

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

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
Complaint recieved by email from CDER 02/15/2023. Describe Event, Problem, or Product Use Error: Following use of EzriCare artificial tears lubricant eye drops, the patient developed descemet stripping automated endothelial keratoplasty (DSAEK) with orbital cellulitis secondary to corneal perforation resulting in open globe and endopthalmitis of left eye. Eye cultures grew CPO Pseudomonas aeruginosa. The patient underwent enucleation of the left eye with implant insertion on (b) (7)(C), (b) (6) and is currently being treated with IV cefiderocol.	Life Threatening Injury/Illness	02/05/2023	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	02/16/2023	Yes	Yes	Unknown	Unknown	Unknown

Remarks

Eye Replaced with Implant. This complaint was reported by (b) (7)(C), (b) (6). It is unclear if (b) (7)(C), (b) (6) is her Primary Care Physichian or Surgeon. It is unclear what hospital treated the patient.

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks
Blindness	NERVOUS			

Health Care Professional

Provider Name	Address	Phone	Occupation
See Remarks			

Hospital Information

Hospital Name	Address	Phone	Dates of Stay
See Remarks			

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	Unknown

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

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
Unknown	Unknown	Unknown	Yes	India	NDC 79503-0101-15 Active Ingredient: Carboxymethylcellulose Sodium

Retail

Problem Ingredient Group

Name	Address
Unknown	

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	Importer

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Reaction	Pseudomonas Aeruginosa
Other, identify in Details	Eye implant, Recall 91621

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	(b) (5)	Price,Linda L	02/21/2023

Initial Disposition Remarks

Importer for EzriCare: FEI# 3013306108 (b) (4) The Importer (b) (4) is OOB. Referring to NWJ-DO per recall instructions.
NWJ-DO EzriCare Recall 91621. Cannot verify lot number. Date of Recall 2/2/2023. Emailing Nerizza Guerin, DIB PHARM 1, William Muszynski, ERC. Dispositioning to (b) (5) per Sheila Vantwuyver, NCCC. The complaint report was shared with CDC and OCI by OEO on March 13, 2023.

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

There are no Follow Up Operations related to this complaint.

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