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 # 178719

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
01/20/2023	DEN-DO	NWJ-DO	Email	CDC	Scholze,Gina M	(b) (5)

Complainant Identification

Name	Address
(b) (6), (b) (7)(C)	none (b) (4)

Phone (W)	Phone (H)	Source POC Name	Source Phone
	none	(b) (6), (b) (7)(C)	none

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
On Thursday 1/19/23 CDC reported Pseudomonas Aeruginosa contamination of FDA regulated product, EzriCare Artificial Tears eye drops, and product may be related to 50 adverse reactions, including 9 patient hospitalizations, and one death. Remaining product is reportedly available for collection in (b) (4) and (b) (4). The (b) (4) Complainant is reportedly (b) (6) . DEN-DO ERC made contact with (b) (6) and identified Artificial Tears NDC 79503-0101-15 used by 3 patients. Un-open product is currently available and ERC is working with (b) (6) to identify the lot codes. Product samples collected in other parts of the country by CDC, and tested by CDC lab were allegedly positive for Pseudomonas Aeruginosa. CDER requested follow-up sample collections and testing by FDA laboratory. 3 patients in (b) (4) are diagnosed with Pseudomonas Aeruginosa, and the three patients reportedly used EzriCare Artificial Tears eye drops. Outcome and care of these 3 patients is currently unknown. Other medically confirmed patients are also being investigated by the (b) (6) . -Email from (b) (6), (b) (7)(C) on 1/20/2023 with all complaintant information. -Email on 1/20/2023 from Holly Miller, ERC stating (b) (5) that was administered to the patients. Most likely, an OBPO CSO will be collecting the sample from the facility if needed as there are no (b) (2) . We have an incident call this morning. More info to come. Complaint was reported to FDA by CDC and (b) (6) . Cases in (b) (4) with possible permenant vison loss and light perception but no vision. Conditions of 3(b) (4)	Life Threatening Injury/Illness	(b) (6), (b) (7)(C)	Other - identify in Remarks

patients is unknown currently.

Notify OEO?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	01/20/2023	Unknown	Unknown	Unknown	Reported to Other Source, identify in Remarks	No

Remarks

per the firm, the relationship between Global Pharma and EzriCare LLC (Lakewood, NJ) is via an agreement with ARU PHARMA. Aru Pharma is the improter for EzriCare.

Lot Numbers: PCMJ005, PCMJ006, PCMJ008 PCMJ009, all with Exp Mar 2025

Yes. 7 FDA Complaint samples were collected from (b) (6)

FDA Sample Numbers: 1212916, 1212917, 1212918, 1212919, 1212920, 1212921, 1212922

FDA Sample Analysis is Pending

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks
Change in vision	NERVOUS		Persists	vision loss

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 eye drops, NDC 79503-0101-15	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
15 Milliliters Bottle	Multiple, see label Remarks:	Unknown	Unknown	Yes	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 Lots reported: PCMJ 003; PCMJ 005; PCMJ 006; PCMJ 008, and PCMJ 009

Retail

Problem Ingredient Group

Name	Address
(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	(b) (4)
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	Pseudomonas Aeruginosa

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	(b) (5)	Chastagner,Stephanie C	01/23/2023

Initial Disposition Remarks

Firm informaiton confirmed via NCCC 2/15/23 email. 3/10/2023 NWJ-DO Awaiting lab results. Emailing Nerizza Guerin, DIB Pharm1, William Muszynski, ERC, and Sheila.

Referrals

Org Name	HHS Mail Code
NWJ-DO	HFR-MA300
NYK-DO	HFR-NE100
ORAHQ	HFC-1

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
11823854	31	12264260	BIOL2	BIOL2-GRP7	1212916		In Progress	01/24/2023
11824011	41	12264260	IRVLMP	IRVMP-MIC	1212916-0	MDS	Completed	02/27/2023
11823854	31	12264260	BIOL2	BIOL2-GRP7	1212916		In Progress	01/24/2023
11824011	41	12264260	IRVLMP	IRVMP-MIC	1212916-0	MDS	Completed	02/27/2023
11823854	31	12264260	BIOL2	BIOL2-GRP7	1212916		In Progress	01/24/2023

Disposition Summary

Is Consumer Responsible? **Responsible FEI** **Address** **Name** **Firm Type**

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

Disposition Remarks

No growth was found in 1 out of 1 subs analyzed for sterility.
No microorganisms were found in 1 out of 1 subs analyzed for direct staining.
Method suitability was perfomred satisfactorily according to USP <71>, refer to sample # 1212918-1212919.
QA/QC elements have been reviewed by management and verified to meet requirements.
All laboratory controls were satisfactory.

Note: Sub sample unit was not intact upon receipt as the tamper evident seal was observed to be broken; therefore the classification of the sample is LC4.

Follow-Up Sent To

Organization Name **HHS Mail Code**