

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 | # **179238**

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
02/21/2023	NYK-DO	NWJ-DO	Telephone	Consumer	Younger,Sandra	(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
Complainant called about EzriCare Artificial Tears. In June 2022, he bought the product from (b) (6). They come 2 in one-pack. On 2/2/2023, he received a notice from (b) (6) about the eyedrops. He called EzriCare and they told him to call FDA.	Non-Life Threatening Injury/Illness - No Adverse Event Reporting	unk	Other - identify in Remarks

Compl. used product once or twice a day, 4 or 5 times a week. He reported that he had eye pain. His eyes was burning and he was scratching them. He didn't know when it began. The burning lasted a little while or a couple of hours, and the itching lasted for a couple of weeks. No medical attention sought.

He threw one bottle away and has 1 opened and 2 unopened bottles left.

Notify OEO?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	02/21/2023	No	No	No	Not Reported to Manufacturer	No

Remarks

Eye pain, scatching/itching and burning of the eyes

Complaint Symptoms

Symptom	System Affected	Onset Time	Duration	Remarks
Burning	SKIN	unk	1-3 Hours	
Itching (pruritis)	SKIN	unk	1 Weeks	
Eye irritation	NERVOUS	unk	unk	eye pain

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
Ezri Care	Artificial Tears Lubricant Eyedrops	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
15 Milliliters Bottle	PC MJ012	March 2025	9/6/2022	No	Once or twice a day

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
2022 - 1/2023	unk	4 unopened bottle	No		NDC: 79503-0101-15

Retail

Name	Address
Amazon.com	

Problem Ingredient Group**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
Other, identify in Details Reaction	RES 91621 eye pain, burning and itching eyes

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	(b) (5)	Price,Linda L	03/02/2023

Initial Disposition Remarks

Verifying NDC with Consumer that should be NDC:79503-0101-15.

** The Importer (b) (4) is OOB.

**Importer FEI# 3018035065 Delsam Pharma LLC, 925 Protano Ln, Mamaroneck, NY 10543

**Distributor for EzriCare: FEI# 3022210898 EzriCare, LLC., 1525 Prospect St, Ste 204, Lakewood, New Jersey, 08701.
The phone number listed on the box is for EzriRx.

**The Accomplishing District for EzriCare is NWJ-DO.

NWJ-DO Received from NYK-DO. This lot number is included in RES 91621. Dispositioning (b) (5) per
Sheila Vantwuyver, NCCC. (b) (5) India. Emailing Nerizza Guerin, DIB Pharm1, William
Muszynski, ERC, and Sheila.

Referrals

Org Name	HHS Mail Code
NWJ-DO	HFR-MA300

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
-------------------	---------------