Food and Drug Administration Office of Regulatory Affairs Collection Report

For Sample Number: 555157

This is an accurate reproduction of the original electronic record as of 04/17/2023

Flag Flag Remarks

Complaint Sample Follow up to Consumer Complaint #179044

Episode Number Origin Basis Sample Type FIS Smpl Num Status

Domestic/Import Compliance Official 23326467 In Progress

FEI Date Collected Product Code Responsible Firm PAC Hours

3012323885 02/15/2023 64DAK01 Manufacturer 56R801

Compliance Num Country of Origin

India

Related Smpl Num Position Class Sampling Organization NDC Number Permit Number Storage Rqrmnt.

INV PHRM4 79503-0101-15 Ambient

Dealer is Consumer Crx/DEA Schedule Recall Num Consumer Compl. Num Brand Name

No 179044 Erzicare Artificial Tears (10mg/ml)

Product Description

Lubricant Eye Drops in white plastic bottle with blue plastic cap.

Product Label

See continuation.

Reason for Collection MFG Codes Expiration Date

Follow up to Consumer Complaint #179044 for microbial analysis. Printed on bottle "Lot No: PCMI 004" Aug-2024

Type of Firm Firm FEI **FCE** Firm Legal Name Address Global Pharma Healthcare Private A - 9 Sidco Pharmaceutical Complex. Manufacturer 3012323885 Limited Thiruporur Chennai, 609110 IN 1525 Prospect St Ste 204 Lakewood, NJ EZRICARE, LLC Shipper 3022210898 08701-4662 US

Size of Lot Est. Value Rcpt Type Carrier Name Date Shipped
4 bottles of eye drops \$ (b) (4) FDA484 02/15/2023

Description of Sample

1 - 15mL bottle of eye drops (full but opened)

Method of Collection

1 partial bottle of Ezri Care Artificial Tears were provided by the consumer. Product transported via POV to Seattle District Office.

How Prepared

See continuation.

Collector's Identification on Package and/or Label Collector's Identification on Seal

"555157 2/15/2023 SMK" "555157 2/15/2023 Sangeeta.M. Khurana, Investigator"

Sample Delivered To Date Delivered Orig C/R & Records To

UPS Tracking # "1Z A46 W83 01 9232 8324" 02/16/2023 PHRM1 **Lab w/Split Sample Lab**

0 PSMPL

Document Number Document Date Document Type Document Remarks

 3
 02/15/2023
 Other
 Photos of product Lot PCMI004 - 5 Pages

 1
 02/15/2023
 Affidavit
 Affidavit from (b) (6) - 1 Page

 2
 02/15/2023
 Other
 FDA Form 484 Reciept for Samples - 1 Page

Remarks

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See continuation.

Payment AmountPayment Method704(d) Sample702(b) PortionCollector's Name\$0.00No ChargeNo No Sangeeta M KhuranaName of SignerDate & Time of SignatureMeaning

ET

Date: 04/17/2023 **Page:** 2 of 3

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Continuation:

Product Label

Labeled in part: "***EZRICARE***Artificial Tears Lubricant Eye Drops 1/2 fl oz (15ml)***NDC 79503-0101-15***Mfg Lic Number TN00002176 73921 101 15***-Lot No: PCMI 004 Exp. Date: AUG-2024***Active Ingredient Carboxymethylcellulose Sodium 10mg in 1 mL***Distributed by EzriCare, LLC Lakewood NJ***"Non-Rx

How Prepared

The sample was in my possession and control under lock and key from the time of collection until it was shipped. The sample bottle was labelled with sample number and sealed with FDA seal and placed in Form FDA 525 envelope. It was then placed in a brown cardboard shipping container along with other three samples. The cardboard container was selated with FDA seal and shipped via UPS.

Remarks

Related to samples 555156, 555158, and 555159

RES #91621 initiated on 2/2/2023

No 702(b) portion collected.

Official Sample - interstate documents can be collected as needed. Consumer name and address is in complaint #179044, a receipt of sample was provided to the consumer and an affidavit was created that was signed by the consumer was colle affidavit and

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