

Food and Drug Administration Office of Regulatory Affairs**Collection Report****For Sample Number: 1214092**

This is an accurate reproduction of the original electronic record as of 02/08/2023

Flag	Flag Remarks				
Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic/Import	Compliance	Domestic Import	23326198	In Progress
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3012323885	02/06/2023	64DBO99	Manufacturer	56D800	
Compliance Num	Country of Origin				
	India				
Related Smpl Num	Position Class	Sampling Organization	NDC Number	Permit Number	Storage Rqrmnt.
	INV	PHRM1	72570-122-35		Ambient
Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name	
No				Delsam Pharma's ARTIFICIAL EYE OINTMENT	

Product Description

See "Remarks" section.

Product Label

See continuation.

Reason for Collection

Collected as per sampling assignment from CDER for the ongoing Pseudomonas Aeruginosa Possibly Associated with Artificial Tears/ML/May 2022 incident response.

MFG Codes

"H29"

Expiration Date

"NOV-23"

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
Global Pharma Healthcare Private Limited	A - 9 Sidco Pharmaceutical Complex , Thiruporur Chennai, 609110 IN	Manufacturer	3012323885	
(b) (4)	(b) (4)	Shipper	(b) (4)	
DELSAM PHARMA LLC	55 E Gun Hill Rd Bronx, NY 10467-2103 US	Dealer	3014909559	

Size of Lot	Est. Value	Rcpt Type	Carrier Name	Date Shipped
(b) (4) units of 3.5 g (1/8 oz.) tube	\$ (b) (4)	FDA484		

Description of Sample

Subs 1-17: Each sub consists of a pre-packaged (plastic wrapped) pack of (b) (4) units of product without tamper evident seal on carton.

Method of Collection

See continuation.

How Prepared

See continuation.

Collector's Identification on Package and/or Label

"1214092 02/06/2023 mc" Subs 1-17

Collector's Identification on Seal

"1214092 02/06/2023 Mindy Chou, Investigator"

Sample Delivered To

UPS 1ZA5V5820191577237

Date Delivered

02/07/2023

Orig C/R & Records To

PHRM1

Lab w/Split Sample

0

Lab

PSMPL

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Document Number	Document Date	Document Type	Document Remarks
	02/06/2023	Other	FDA 482 issued to (b) (6) Operations Manager, (b) (4) (3 pages)
	02/06/2023	Other	FDA 484 issued to (b) (6), Operations Manager, (b) (4) covering Sample # 1214092 (2 pages)

Remarks

See continuation.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
\$0.00	No Charge	No	Yes	Mindy M Chou
Name of Signer	Date & Time of Signature	Meaning		
		ET		

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Continuation:

Product Label

Paperboard carton reads in part, "NDC 72570 122 35 Delsam Pharma's ARTIFICIAL EYE OINTMENT***Net Wt. 3.5 g (1/8oz.)***ACTIVE INGREDIENT***Mineral Oil 15%***White Petrolatum 83%***Distributed By: Delsam Pharma Llc, Bronx, New York 10467***Lot No.: H29 Exp. Date: NOV-2023***"

Method of Collection

(b) (4) units of Artificial Eye Ointment (without tamper evident seal), each containing 3.5 g tube of sterile lubricant eye ointment, were collected from the four cases of Artificial Eye Ointment with the same lot number and expiration date.

Subs 1-17: Each sub consists of a pre-packaged (plastic wrapped) pack of (b) (4) units of product without tamper evident seal on carton.

Subs 1-4 were collected from Case (b) (4)
Subs 5-8 were collected from Case (b) (4)
Subs 9-12 were collected from Case (b) (4)
Subs 13-17 were collected from Case (b) (4)

How Prepared

A stick-on label was affixed to the sample and identified as noted in 'Collector's Identification on Package and/or Label' field. The sample was placed in a double brown paper bag, taped closed with clear plastic tape and officially sealed with FDA 415a as in the 'Collector's ID on Seal' field. The paper bag was identified as "1214092 02/06/2023 mc" in black ink. The officially sealed bag was brought back to the White Plains R.P. by CSO Chou on 02/06/2023 and placed in a white plastic bag with FDA 525, then placed in a brown, cardboard box packaged with brown paper as cushion. The box was taped shut with clear plastic tape. The sample was dropped off at The (b) (4) located at (b) (4) by CSO Chou.

Remarks

- This is a domestic import sample. However, sample was collected without adding prefix "DI" to sample number.
- Note: Sample includes 702(b) portion not separately packed
- Analysis to be performed: Sterility testing per USP <71>, to include cetrimide agar for Pseudomonas aeruginosa detection + container closure analysis
- Product Description: Mineral oil, white petrolatum lubricant eye ointment packed in white metal tube with cap (per Delsam Pharma's website photo). Unable to confirm the actual content inside the carton without opening the pre-packaged (plastic wrapped) pack of (b) (4) units.
- Lot Size: The amount of goods on hand before sampling. This is the quantity on-hand at the location where the sample was collected. There's possibly more inventory at another warehouse (b) (4) from (b) (4) fulfillment center where sample was collected). Made request to firm on 2/2/2023 and 2/6/2023 for lot inventory. Firm has not provided the information.
- Point of Contact: Delsam Pharma Llc - Kuppasamy G. Arumugam (b) (6)
- Point of Contact: (b) (4) - (b) (6) Operations Manager (b) (6)
- Documents collected and FDA forms issued will be sent to NYK-DO file room for filing.
- As per Delsam Pharma's website, the retail value of each unit is (b) (4)
- Delsam Pharma Llc: On 02/06/2023, CSO Mindy Chou called Kunnusamy G. Arumugam, President of Delsam Pharma, and informed him that FDA will be going to (b) (4) (b) (4) to collect (b) (4) tubes of Delsam Pharma's Artificial Eye Ointment. Mr. Arumugam stated that the samples will be provided at no charge and that he will notify (b) (4)
- (b) (4) (where sample was collected): On 02/06/2023, CSO Mindy Chou and CSO Tanya Syffrard presented our credentials and issued the FDA 482 to (b) (6) Operations Manager. CSO Mindy Chou inquired about the status of the current

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inventory count for the Delsam Pharma's Artificial Eye Ointment and Artificial Tears Lubricant Eye Drops products. (b) (6) stated they are still working on pulling the information and agreed to send the information by email when available. A FDA 484 was issued to (b) (6) for Sample # 1214092. Firm likely has additionl inventory at their other warchosue (b) (4) away, which was disclosed by (b) (6) to CSO Chou on 2/2/2023.