

# Enforcement Report - Week of September 27, 2023

## Class I Drugs Event

**Event ID:**

92975

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

09/08/2023

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

09/21/2023

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Novartis Pharmaceuticals Corp.  
1 Health Plz  
East Hanover NJ United States

**Distribution Pattern:**

Nationwide in the USA

## Associated Products

**Product Description:**

SANDIMMUNE Oral Solution (cyclosporine oral solution, USP) 100 mg/mL, 50 mL bottle, Rx Only, Manufactured by: DELPHARM Huningue S.A.S., Huningue, France, Distributed by: Novartis Pharmaceuticals Corporation, East Hanover, New Jersey 07936, NDC 0078-0110-22.

**Product Quantity:**

1272 bottles

**Reason for Recall:**

Crystallization: bottles of Sandimmune Oral Solution were determined to contain crystals.

**Recall Number:**

D-1174-2023

**Code Information:**

FX001691, Exp. 12/31/2025

## Class II Drugs Event

**Event ID:**

92917

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

08/25/2023

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

09/15/2023

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

CareFusion 213, LLC  
1550 Northwestern Dr  
El Paso TX United States

**Distribution Pattern:**

Distributed nationwide to 100 consignees. Please refer to consignee list.

## Associated Products

**Product Description:**

BD ChloroPrep Clear, 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA) Sterile Solution, 0.03mL (1 ml) each, 60 applicators in carton, applicator is sterile if package is intact. CareFusion 213, LLC, El Paso, TX 79912, subsidiary of Becton, Dickinson and Co., NDC 54365-400-31 REF 930480 Product is packaged in the following manner: There is one (1) sterile applicator (sponge) per pouch. Each inner carton contains sixty (60) pouches. There are four (4) inner cartons per shipping case (total of 240 pouches per case).

**Product Quantity:**

398,160 cartons

**Reason for Recall:**

Stability data does not support expiry: Shelf-life of the impacted lots of BD ChloroPrep" Clear 1 mL Applicator cannot be substantiated beyond 12-months although labeled with 36-month expiry. Stability studies indicate that the impacted lots, if stored at 30°C/75% relative humidity continuously beyond 12 months, may exhibit growth of Aspergillus penicillioides.

**Recall Number:**

D-1168-2023

**Code Information:**

Lot # 2272350, Exp. Date 09/30/2025 and Lot # 2301939, Exp. Date 09/30/2025

## Class II Drugs Event

**Event ID:**

92948

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

08/02/2023

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

09/18/2023

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Aurobindo Pharma USA Inc.  
279 Princeton Hightstown Rd  
East Windsor NJ United States

**Distribution Pattern:**

USA nationwide

## Associated Products

**Product Description:**

Rasagiline Tablets 0.5mg, 30-count bottle, Rx only, Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A., NDC 0378-1270-93

**Product Quantity:**

9,890 bottles

**Reason for Recall:**

Failed dissolution specifications - results obtained were below spec average.

**Recall Number:**

D-1171-2023

**Code Information:**

Lot #: 3112444, Exp 8/2023

## Class II Drugs Event

**Event ID:**

92954

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

**Recall Initiation Date:**  
08/18/2023

**Voluntary / Mandated:**  
Voluntary: Firm initiated

**Center Classification Date:**  
09/21/2023

**Initial Firm Notification of Consignee or Public:**  
Letter

**Recalling Firm:**  
HUMANRACE  
9350 Civic Center Dr  
Beverly Hills CA United States

**Distribution Pattern:**  
Nationwide in the USA, Spain, Italy, UK, and France.

### Associated Products

**Product Description:**  
Humanrace Suncare, Ozone Face Protection Daily Moisturizer, Broad Spectrum Sunscreen SPF 30, packaged as a 53mL (1.8 fl oz.) bottle, 100% mineral, Active Ingredient: Zinc oxide 15%, Snow Mushroom, Dist. By: @Humanrace 2022 Beverly Hills, CA 90210, USA, NDC 82779-01

**Product Quantity:**  
5046 units

**Reason for Recall:**  
Subpotent Drug: Product does not contain SPF that is declared on the label.

**Recall Number:**  
D-1175-2023

**Code Information:**  
Lot #: 1732A, 1732B, 1742A, 1742B, 1742C, 1742D; Exp. 06/2024.

**Product Description:**  
Humanrace Suncare, Ozone Body Protection Cream, Broad Spectrum Sunscreen SPF 30, packaged as a 148mL (5 fl oz.) bottle, PA +++++, 100% mineral, Active Ingredient: Zinc oxide 15%, Snow Mushroom, Squalene, Aloe, Dist. By: @Humanrace 2022 Beverly Hills, CA 90210, USA, NDC 82779-002

**Product Quantity:**  
2942 units

**Reason for Recall:**  
Subpotent Drug: Product does not contain SPF that is declared on the label.

**Recall Number:**  
D-1176-2023

**Code Information:**  
Lot #: 1752A, 1752B, 1782E, 1782G, 1782C, 1752C, 1782B; Exp. 06/2024.

### Class II Drugs Event

**Event ID:**  
92974

**Product Type:**  
Drugs

**Status:**  
Ongoing

**Date Terminated:**

**Recall Initiation Date:**  
09/01/2023

**Voluntary / Mandated:**  
Voluntary: Firm initiated

**Center Classification Date:**  
09/15/2023

**Initial Firm Notification of Consignee or Public:**  
Letter

**Recalling Firm:**  
AMMAN PHARMACEUTICAL INDUSTRIES  
Building 108 Street A3, King Abdullah II Industrial City  
Amman Jordan

**Distribution Pattern:**

Product was distributed to two (2) direct accounts in RI and CO.

## Associated Products

**Product Description:**

TRP Natural Eyes, Aging Eye Relief, Sterile Eye Drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502 NDC: 17312-027-15.

**Product Quantity:**

8,747 units

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1151-2023

**Code Information:**

Lot#:DB001 EXP: 06/24

**Product Description:**

TRP Natural Eyes, Allergy Eyes Relief, Sterile Eye Drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-032-15.

**Product Quantity:**

8,747

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1152-2023

**Code Information:**

Lot: IY001; EXP 07/24

**Product Description:**

TRP Natural Eyes, Allergy Relief PF, Sterile Eye Drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-097-19.

**Product Quantity:**

8,810 units

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1153-2023

**Code Information:**

Lot: FT001; EXP: 07/24

**Product Description:**

TRP Natural Eyes, Blur Relief, Sterile Eye Drops, Homeopathic 0.5 FL OZ (15 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-002-11.

**Product Quantity:**

5,509

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1154-2023

**Code Information:**

Lot: DC001 EXP: 06/24

**Product Description:**

TRP Natural Eyes, Dryness Relief, Sterile Eye Drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company,

Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC:17312-178-15.

**Product Quantity:**

196,111 units

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1155-2023

**Code Information:**

Lot: IX001 EXP: 07/24; Lot: IX002 EXP: 12/24

**Product Description:**

TRP Natural Eyes, Dryness Relief PF, Sterile Eye Drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-096-19.

**Product Quantity:**

83,898 units

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1156-2023

**Code Information:**

Lot: FR001 EXP: 07/24; Lot: FR004 EXP: 04/25; Lot:FR005 EXP: 04/25; Lot:FR006 EXP: 04/25; Lot: FR007 Exp: 04/25

**Product Description:**

TRP Natural Eyes, Eye Lid Relief PF, Sterile Eye Drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-417-19.

**Product Quantity:**

8,000 units

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1157-2023

**Code Information:**

Lot: FV005 EXP:03/25

**Product Description:**

TRP Natural Eyes, Eye Lid Relief, Sterile Eye ointment, Homeopathic 0.14 oz (4 grams), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-165-13.

**Product Quantity:**

16,500 units

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1158-2023

**Code Information:**

Lot: 180001 EXP: 01/25

**Product Description:**

TRP Natural Eyes, Floaters Relief, Sterile Eye drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-098-15.

**Product Quantity:**

18,171 units

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1159-2023

**Code Information:**

Lot: DA001 EXP: 06/24; Lot: DA002 EXP: 11/24

**Product Description:**

MAJOR LubriFresh P.M. Nighttime Ointment, Lubricant Eye Ointment, Sterile, 0.125 OZ (3.5g), Distributed by: MAJOR PHARMACEUTICALS, Indianapolis, IN 46268, Made in Jordan, NDC: 0904-6488-38.

**Product Quantity:**

282,564 units

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1160-2023

**Code Information:**

Lot: 184001 EXP: 11/24; 184002 EXP: 11/24; 184003 EXP: 11/24; Lot: 184004 EXP: 12/24; Lot: 184005 EXP: 12/24; Lot:184006 EXP:12/24;

**Product Description:**

TRP Natural Eyes, Pink Eye Relief, Sterile Eye drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502 NDC: 17312-013-15.

**Product Quantity:**

293,400 units

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1161-2023

**Code Information:**

Lot: IV001 EXP:06/25; Lot:IV002 EXP: 11/24; Lot:IV004 EXP:01/25

**Product Description:**

TRP Natural Eyes, Pink Eye Relief PF, Sterile Eye drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502 NDC: 17312-094-19.

**Product Quantity:**

8,873

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1162-2023

**Code Information:**

Lot: FP001 EXP:07/24

**Product Description:**

TRP Natural Eyes, Red Eye Relief, Sterile Eye drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-058-15.

**Product Quantity:**

8,868 units

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1163-2023

**Code Information:**

Lot: FQ001 EXP:07/24

**Product Description:**

TRP Natural Eyes, Red Eye Relief PF, Sterile Eye drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company,

Inc., 1575 Delucchi Lane, Reno, NV 89502 NDC: 17312-095-19.

**Product Quantity:**

196,442 units

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1164-2023

**Code Information:**

Lot: IW001 EXP:07/24; Lot: IW002 EXP: 12/24

**Product Description:**

TRP Natural Eyes, Styel Relief, Sterile Eye Ointment, Homeopathic 0.14 oz (4 grams), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-014-13.

**Product Quantity:**

180,315 units

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1165-2023

**Code Information:**

Lot:182002 EXP: 11/24; Lot:182003 EXP: 11/24; Lot:182004 EXP: 12/24; Lot:182005 EXP:02/25; Lot:182006 EXP:02/25; Lot:182007EXP:02/25; Lot:182008 EXP:02/25; Lot:182009 EXP:02/25; Lot:182010 EXP:03/25; Lot:182011 EXP:03/25;

**Product Description:**

TRP Natural Eyes, Twitching Relief, Sterile Eye Ointment, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-099-15.

**Product Quantity:**

8,819

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1166-2023

**Code Information:**

Lot:DD001 EXP: 07/24;

**Product Description:**

octiq Lubricating Eye Drops, Dextran 70.01%, Hypromellose 0.3%, 0.5 FL OZ Each (2X 15 mL Bottles), Manufactured for Innovus Pharmaceuticals, Inc., Englewood, CO 80112, Made in Jordan, NDC:57483-610-15.

**Product Quantity:**

30,490 units

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1167-2023

**Code Information:**

Lot: YM308 EXP:10/24;

## Class III Drugs Event

**Event ID:**

93006

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

**Recall Initiation Date:**

09/07/2023

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

09/20/2023

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

SUN PHARMACEUTICAL INDUSTRIES INC

2 Independence Way

Princeton NJ United States

**Distribution Pattern:**

Nationwide wide in the USA

## Associated Products

**Product Description:**

Cequa (cyclosporine ophthalmic solution) 0.09%, 60 Single-Use Vials (6 pouches x 10 single-use vials (0.25 mL each)), Rx only, Manufactured for Sun Pharma Global FZE by: Laboratoire Unither, Coutances, France NDC 47335-506-96

**Product Quantity:**

69,707 cartons

**Reason for Recall:**

Subpotent: Out of Specification result observed for low assay

**Recall Number:**

D-1172-2023

**Code Information:**

Lot# 10026, Lot 10027, Exp. 09/2023.