Enforcement Report - Week of October 5, 2022

Class II Drugs Event

Event ID:
90862

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/16/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/26/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Novartis Pharmaceuticals Corporation
1 Health Plz
East Hanover NJ United States

Distribution Pattern:
Nationwide and Puerto Rico

Associated Products

Product Description:
Neoral soft gelatin capsules (cyclosporine capsules, USP) Modified, 25 mg, Rx Only, 30 Soft Gelatin Capsules per carton, Mfg by: Novartis Pharmaceuticals Corporation, East Hanover, NJ 07936, NDC # 0078-0246-15.

Product Quantity:
132,999 cartons

Reason for Recall:
CGMP deviations: Out of specification results obtained during routine stability testing for ethanol content.

Recall Number:
D-1543-2022

Code Information:
Lot # APCD162, Exp. 01/2023

Class II Drugs Event

Event ID:
90864

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/15/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/27/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
CIPLA
10 Independence Blvd
Warren NJ United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Budesonide Inhalation Suspension 0.25mg/2mL, For Inhalation Only, Rx Only, 1 envelope x five 2 mL Single Dose Ampules per pouch, Sterile Suspension, Manufactured by: Cipla Ltd., India, Manufactured for Cipla USA Inc., Warren NJ, NDC# 69097-318-86.

Product Quantity:
641,160 ampules

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1545-2022

Code Information:
Lot #s: GA20080, GA20081, GA20094, Exp. 01/2024

Class II Drugs Event

Event ID:
90880

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/21/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/28/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn, Inc.
5605 Centerpoint Ct Ste A
Gurnee IL United States

Distribution Pattern:
USA Nationwide and Puerto Rico

Associated Products

Product Description:
Rifampin Capsules, USP, 150 mg, 30-count bottle, Rx only, Distributed by: Akorn Operating Company, LLC, Gurnee, IL 60031, NDC 61748-015-30

Product Quantity:
18,145 bottles

Reason for Recall:
Failed impurities/degradation specifications: Finished product exceeds the 5 ppm interim limit for 1-Methyl-4-Nitrosopoperazine (MNP).

Recall Number:
D-1547-2022

Code Information:
Lot#: 3192818, Exp 10/31/2022; 3199700, Exp 03/31/2023; 3203853, Exp 02/29/2024

Product Description:
Rifampin Capsules, USP, 300 mg, a) 30-count bottle (NDC 61748-018-30), b) 60-count bottle (NDC 61748-018-60), c) 100-count bottle (NDC 61748-018-01), Rx only, Distributed by: Akorn Operating Company, LLC, Gurnee, IL 60031.

Product Quantity:
177,439 bottles

Reason for Recall:
Failed impurities/degradation specifications: Finished product exceeds the 5 ppm interim limit for 1-Methyl-4-Nitrosopoperazine (MNP).

Recall Number:
D-1548-2022

Code Information:
Lot#: a) 3192827, Exp 10/31/2022; 3196136, Exp 12/31/2022; 3202198, Exp 07/31/2023; 3203658, Exp 07/31/2023; 3209114, Exp 11/30/2023;

3203851, Exp 02/29/2024; b) 3191254, Exp 09/30/2022; 3192820, Exp 09/30/2022; 3192822, Exp 10/31/2022; 3192824, Exp 10/31/2022; 3192825, Exp 10/31/2022; 3196141, Exp 01/31/2023; 3196143, Exp 02/28/2023; 3203870, Exp 11/30/2023; 3203871, Exp 02/29/2024; c) 3190636, Exp 09/30/2022; 3192813, Exp 09/30/2022; 3196132, Exp 12/31/2022; 3196133, Exp 12/31/2022; 3196138, Exp 01/31/2023; 3199702, Exp 03/31/2023; 3199703, Exp 03/31/2023

Class II Drugs Event

Event ID:
90886

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/21/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/23/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Viatris Inc
1000 Mylan Blvd
Canonsburg PA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Ampicillin for Injection, USP, 2 grams/vial NDC 67457-352-02, packaged in 10 x 2 g vials per carton NDC 67457-352-10, Rx only, Mylan Manufactured in India for: Mylan Institutional LLC Rockford, IL 61103 U.S.A

Product Quantity:
3,931 cartons

Reason for Recall:
Presence of Particulate Matter: A complaint was received for the presence of a single strand of hair in one vial.

Recall Number:
D-1542-2022

Code Information:
Lot 7105130, exp 9/2023

Class III Drugs Event

Event ID:
90853

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/23/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/28/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Leading Pharma, LLC
3 Oak Rd
Fairfield NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
ClomiPRAMINE Hydrochloride Capsules, USP 25mg, 100-count bottles, Rx only, LEADING PHARMA, Manufactured by: Leading Pharma, LLC, Fairfield, NJ 07004, NDC 69315-167-01

Product Quantity:
960 bottles (100 capsules)

Reason for Recall:
Superpotent Drug: Assay value found to be 110.6% in Chlomipramine Hydrocholoride capsules

Recall Number:
D-1546-2022

Code Information:
Lot#: B14221, Exp. Date 02/2023

Class III Drugs Event

Event ID:
90877

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/16/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/29/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
ALMIRALL, LLC
101 Lindenwood Dr Ste 400
Malvern PA United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Xolegel (ketoconazole) gel 2%, 45 gram tubes, Rx only, Manufactured by: DPT Laboratories, San Antonio, TX 78215, NDC 16110-080-45

Product Quantity:
5,315 tubes

Reason for Recall:
Failed Viscosity specification: Slightly higher OOS results obtained for viscosity

Recall Number:
D-1549-2022

Code Information:
Lot #: RGAF, Exp. Date 12/2022

Class III Drugs Event

Event ID:
90891

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/21/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/06/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Esomeprazole Magnesium Delayed-Release Capsules, USP 20mg, Rx Only, 90 Capsules per bottle, Manufactured by: Ohm Laboratories Inc. New Brunswick, NJ 08901, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, NDC 63304-734-90.

Product Quantity:
5712 bottles

Reason for Recall:
Superpotent Drug: Out of specification for assay at the 12-month timepoint.

Recall Number:
D-0004-2023

Code Information:
Lot AC14299, Exp 12/2022

Product Description:
Esomeprazole Magnesium Delayed-Release Capsules, USP, 40mg, Rx Only, 90 Capsules per bottle, Manufactured by: Ohm Laboratories Inc. New Brunswick, NJ 08901, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, NDC 63304-735-90.

Product Quantity:
8640 bottles

Reason for Recall:
Superpotent Drug: Out of specification for assay at the 12-month timepoint.

Recall Number:
D-0005-2023

Code Information:
Lot AC14304, Exp 12/2022.

Class III Drugs Event

Event ID:
90898

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/20/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/26/2022

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:
QuVa Pharma, Inc.
519 State Route 173
Bloomsbury NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
oxyTOCIN 30 Units/500 mL (0.06 Units/mL) added to 0.9% Sodium Chloride, Injection for IV Use, High Alert, This is a Compounded Product for

Institutional or Office Use Only, Not for Resale, QuVa PHARMA 519 Route 173, Bloomsbury, NJ 08804, Total volume: 500 mL bag, NDC: 70092-1068-07.

Product Quantity:
1994 bags

Reason for Recall:
Incorrect Product Formulation: Oxytocin 30 units was added to an IV bag of 0.45% Sodium Chloride (500mL) instead of 0.9% Sodium Chloride (500mL).

Recall Number:
D-1544-2022

Code Information:
Lot 30027403, BUD 11/14/2022