Enforcement Report - Week of January 6, 2021

Class II Drugs Event

Event ID:
87005

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/17/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/31/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fresenius Kabi USA, LLC
3 Corporate Dr
Lake Zurich IL United States

Distribution Pattern:
USA Nationwide and Puerto Rico

Associated Products

Product Description:
Ketorolac Tromethamine Injection, USP, 60 mg per 2 mL (30 mg per mL), packaged in 2 mL Single Dose Vial, Rx only, Fresenius Kabi, Lake Zurich, IL 60047, NDC 63323-162-02

Product Quantity:
490,633 vials

Reason for Recall:
Presence of Particulate Matter - found in reserve sample vials at the firm.

Recall Number:
D-0184-2021

Code Information:
Batch # 6121125, Exp 02/2021

Class II Drugs Event

Event ID:
87018

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/21/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/29/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Merck Sharp & Dohme
126 E Lincoln Ave
Rahway NJ United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Zerbaxa (ceftolozane and tazobactam) 1.5g per vial for injection, Single-Dose vial, Rx only ,Manuf. for: Merck Sharp % Dohme Corp. a subsidiary of Merck & Co., Inc., NDC 67919-030-01

Product Quantity:
106,503 vials

Reason for Recall:
Lack of assurance of sterility: The results of sterility tests of seven batches of product were out of specification. Five of these batches tested positive for Ralstonia pickettii and two batches produced turbid results that could not be further identified. While all product distributed to the market has met the registered specifications for release, including for sterility, it was manufactured on the same equipment as the affected batches.

Recall Number:
D-0176-2021

Code Information:
All lots within expiry: SP1488 08-Jun-21; SP1490 11-Jun-21; SP1492 13-Jun-21; SP1493 15-Jun-21; SP1494 21-Jun-21; SP1495 23-Jun-21; SP1496 25-Jun-21; SP1497 27-Jun-21; SP1498 29-Jun-21; SP1509 20-Sep-21; SP1510 26-Sep-21; SP1515 16-Oct-21; SP1517 23-Oct-21; SP1518 25-Oct-21; SP1519 30-Oct-21; SP1520 01-Nov-21; SP1521 06-Nov-21; SP1522 08-Nov-21; SP1523;13-Nov-21; SP1524; 15-Nov-21; SP1525 20-Nov-21; SP1526 27-Nov-21; SP1537 11-Jan-22; SP1564 17-Oct-22; SP1567 16-Oct-22; SP1572 24-Oct-22; SP1573; 28-Oct-22; SP1574 29-Oct-22; SP1584; 14-Nov-22; SP1586; 15-Nov-22; SP1588; 19-Nov-22; SP1593 03-Dec-22; SP1602 18-Dec-22; SP1603; 19-Dec-22; SP1606 08-Jan-23; SP1609 15-Jan-23; SP1610 20-Jan-23; SP1611 22-Jan-23; SP1626 13-Apr-23; SP1629 17-Apr-23; SP1633 21-Apr-23

Class II Drugs Event

Event ID:
87029

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/17/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/30/2020

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

Recalling Firm:
Imprimis NJOF, LLC
1705 Route 46 Ste 6B
Ledgewood NJ United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Dexamethasone - Moxifloxacin PF Injection (1/5) mg/mL, Imprimis Rx Volume: 1mL/vial, Imprimis NJOF, LLC. 1705 Route 46 West, Unit 6B Ledgewood, NJ - 07852 (844)446-6979

Product Quantity:
6520 vials

Reason for Recall:
Lack of assurance of sterility: 13 vials were discovered to have faulty crimps.

Recall Number:
D-0177-2021

Code Information:
Lot#: 20JUN010, Exp 5/12/21

Class II Drugs Event

Event ID:
87032

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/17/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/30/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ascend Laboratories LLC
339 Jefferson Rd Ste 101
Parsippany NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Ascend Laboratories, llc Cephalexin for Oral Suspension, USP 250 mg per 5 mL 100 ml (when mixed) Rx Only Manufactured by: Alkem Laboratories, Ltd, Mumbai -400 013 INDIA Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054 NDC 67877-545-88

Product Quantity:
29,317 bottles

Reason for Recall:
Failed Impurity/Degradation Specifications

Recall Number:
D-0178-2021

Code Information:
20141674, 20141675, 20141676, 20141677, 20141678,

Product Description:
Ascend Laboratories, llc Cephalexin for Oral Suspension, USP 250 mg per 5 mL 200 ml (when mixed) Rx Only Manufactured by: Alkem Laboratories, Ltd, Mumbai -400 013 INDIA Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054 NDC 67877-545-68

Product Quantity:
9,524 bottles

Reason for Recall:
Failed Impurity/Degradation Specifications

Recall Number:
D-0179-2021

Code Information:
20141680, 20141681, 20141759

Class II Drugs Event

Event ID:
87038

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/17/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/30/2020

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

Recalling Firm:
CIPLA
10 Independence Blvd
Warren NJ United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Esomeprazole Magnesium for Delayed-Release Oral Suspension 10mg, packaged in unit dose packets, Rx only, Manufactured by: Cipla Ltd., Kurkumbh, India, Manufactured for: Cipla USA, Inc. 10 Independence Boulevard, Suite 300 Warren, NJ 07059, NDC 69097-527-34

Product Quantity:
284,610 packets

Reason for Recall:
Cross- contamination with other products: The excipient, Crospovidone, NF is contaminated with theophylline

Recall Number:
D-0181-2021

Code Information:
Lot #: KA00411, KA00412, KA00460, Exp 11/2021

Product Description:
Esomeprazole Magnesium for Delayed-Release Oral Suspension 20mg, packaged in unit dose packets, Rx only, Manufactured by: Cipla Ltd., Kurkumbh, India, Manufactured for: Cipla USA, Inc. 10 Independence Boulevard, Suite 300 Warren, NJ 07059, NDC 69097-528-34

Product Quantity:
289350 packets

Reason for Recall:
Cross- contamination with other products: The excipient, Crospovidone, NF is contaminated with theophylline

Recall Number:
D-0182-2021

Code Information:
Lot #: KA00413, KA00414, KA00461, Exp 11/2021

Product Description:
Esomeprazole Magnesium for Delayed-Release Oral Suspension 40mg, packaged in unit dose packets, Rx only, Manufactured by: Cipla Ltd., Kurkumbh, India, Manufactured for: Cipla USA, Inc. 10 Independence Boulevard, Suite 300 Warren, NJ 07059 NDC 69097-529-34

Product Quantity:
6,491 packets

Reason for Recall:
Cross- contamination with other products: The excipient, Crospovidone, NF is contaminated with theophylline

Recall Number:
D-0183-2021

Code Information:
Lot #: KA00415, KA00416, Exp 11/2021

Class III Drugs Event

Event ID:
86929

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/25/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/29/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
US Compounding Inc
1270 Dons Ln
Conway AR United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Neostigmine Methylsulfate PF Inj. 5 mg/5 mL, 5 mL Single Use Syringes, Hospital/Office Use Only. US Compounding 1270 Don's Lane Conway, AR 72032 (800) 718-3588 NDC 62295-3324-05

Product Quantity:
1640 syringes

Reason for Recall:
Labelling: Missing label.

Recall Number:
D-0175-2021

Code Information:
Lot: 20202109@3 BUD: 3/20/2021

Class III Drugs Event

Event ID:
87027

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/22/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/30/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Strides Pharma Inc.
2 Tower Center Blvd Ste 1102
East Brunswick NJ United States

Distribution Pattern:
PA

Associated Products

Product Description:
NDC 64380-721-06 TACROLIMUS CAPSULES, USP 1mg 100 Capsules Rx Only Manufactured by: Strides Pharma Science Ltd. Bengaluru - 562106, India Distributed by: Strides Pharma Inc. East Brunswick, NJ 08816

Product Quantity:
960 bottles

Reason for Recall:
Failed Moisture Limits

Recall Number:
D-0180-2021

Code Information:
Lot 7242728A; June 2023

Not Yet Classified Drugs Event

Event ID:
86709

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/25/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Wishgarden Herbs, Incorporated
321 S Taylor Ave Unit 100
Louisville CO United States

Distribution Pattern:
Distributed Nationwide in the USA, Egypt and Canada.

Associated Products

Product Description:
Happy Ducts Compress, 3 oz. plastic jar, WishGarden Herbal Remedies Boulder CO 80301. UPC 6-56490-20223-5

Product Quantity:
46 jars

Reason for Recall:
Microbial Contamination of a Non-Sterile Product: Product tested positive for Cronobacter Sakazakii.

Recall Number:

Code Information:
Lot # 53664, Exp 08/2022

Product Description:
Cord Care Powder, 0.25 oz. (7 g) plastic jars, WishGarden Herbs Inc, Boulder CO 80301. UPC 6-56490-24730-4

Product Quantity:
1651 jars

Reason for Recall:
Microbial Contamination of a Non-Sterile Product: Product tested positive for Cronobacter Sakazakii.

Recall Number:

Code Information:
Lot #: P227 - Exp. 11/2020; P228 - Exp. 12/2020; P229 - Exp. 02/2021; P230 - Exp. 04/2021; P231 - Exp. 06/2021; P232 - Exp. 09/2021; P233 - Exp. 01/2022; P234 - Exp. 05/2022; P235 - Exp. 08/2022

Product Description:
Goldenseal Powder, 0.25 oz. (7 g) plastic jars, WishGarden Herbs LLC, Boulder CO 80301. UPC 6-56490-64137-9

Product Quantity:
298 jars

Reason for Recall:
Microbial Contamination of a Non-Sterile Product: Product tested positive for Cronobacter Sakazakii.

Recall Number:

Code Information:
P116 - Exp. 12/2020; P117 - Exp. 05/2021; P118 - Exp. 10/2021; P119 - Exp. 01/2022; P120 - Exp. 04/2022