Enforcement Report - Week of June 19, 2024

Class I Drugs Event

Event ID:
94707

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/28/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/12/2024

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

Recalling Firm:
Sagent Pharmaceuticals
1901 N Roselle Rd Ste 450
Schaumburg, IL 60195
United States

Distribution Pattern:
Nationwide within the USA.

Associated Products

Product Description:
Docetaxel Injection, USP, 80 mg per 8 mL (10 mg per mL), 1 x 8 mL Multi-Dose Vial, Rx only, Mfd. for Sagent Pharmaceuticals, Schaumburg, IL 60195 (USA), Made in India. NDC 25021-254-08

Product Quantity:
762 vials

Reason for Recall:
Presence of Particulate Matter: Presence of particulate matter from the stopper in the drug product.

Recall Number:
D-0553-2024

Code Information:
Lot #: F1040001, Exp. Date 12/31/2024

Product Description:
Docetaxel Injection, USP, 160 mg per 16 mL (10 mg per mL), 1 x 16 mL Multi-Dose Vial, Rx only, Mfd. for Sagent Pharmaceuticals, Schaumburg, IL 60195 (USA), Made in India. NDC 25021-254-08

Product Quantity:
2806 vials

Reason for Recall:
Presence of Particulate Matter: Presence of particulate matter from the stopper in the drug product.

Recall Number:
D-0554-2024

Code Information:
Lot #: F1030001, Exp. Date 12/31/2024

Class II Drugs Event

Event ID:
94552

Product Type:
Drugs

Status:

Date Terminated:

Ongoing

Recall Initiation Date:
05/14/2024

Center Classification Date:
06/07/2024

Recalling Firm:
Imprimis NJOF, LLC
1705 Route 46 Ste 6B
Ledgewood, NJ 07852-9720
United States

Distribution Pattern:
US Nationwide

N/A

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
N/A

Associated Products

Product Description:
Prednisolone-Moxifloxacin-Bromfenac Sterile Ophthalmic Suspension, 1%, 0.5%, 0.075%, 5mL, Quantity: 20mL, Rx Only, Compounded by: Imprimis NJOF, LLC. 1705 Route 46 West, Unit 6B Ledgewood, NJ NDC 71384-310-05

Product Quantity:
4,280 boxes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0548-2024

Code Information:
Lot: 23NOV018 Exp. 6/17/24

Class II Drugs Event

Event ID:
94554

Status:
Ongoing

Recall Initiation Date:
05/14/2024

Center Classification Date:
06/07/2024

Recalling Firm:
Imprimis NJOF, LLC
1705 Route 46 Ste 6B
Ledgewood, NJ 07852-9720
United States

Distribution Pattern:
US Nationwide

Product Type:
Drugs

Date Terminated:
N/A

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
N/A

Associated Products

Product Description:
Klarity-C (cyclosporine) Preservative-Free Sterile Ophthalmic Emulsion 0.1% 5.5mL, Rx Only, This is a compounded drug. NOT FOR RESALE. OFFICE USE ONLY Compounded by: Imprimis NJOF, LLC., 1705 Route 46 West, unit 6B, Ledgewood, NJ 07852 NDC: 71384-514-05

Product Quantity:
136,005 units

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:
D-0547-2024

Code Information:
Lot:23APR005 Exp. 5/1/2024 Lot:23MAY024 Exp. 5/15/2024 Lot:23JUN010 Exp. 5/30/2024 Lot:23JUN016 Exp. 6/7/2024 Lot:23JUN047 Exp. 7/4/2024 Lot:23JUL013 Exp. 7/11/2024 Lot:23JUL029 Exp. 7/25/2024 Lot:23JUL030 Exp. 8/1/2024 Lot:23AUG016 Exp. 8/7/2024 Lot:23AUG042 Exp. 9/27/2024 Lot:23SEP017 Exp. 7/13/2024 Lot:23OCT039 Exp. 8/3/2024 Lot:23NOV022 Exp. 8/24/2024 Lot:23NOV036 Exp. 8/29/2024 Lot:23DEC021 Exp. 10/4/2024 Lot:24JAN018 Exp. 10/11/2024 Lot:24JAN026 Exp. 10/24/2024 Lot:24JAN040 Exp. 11/2/2024 Lot:24FEB021 Exp. 11/16/2024 Lot:24MAR005 Exp. 12/12/2024

Class II Drugs Event

Event ID:
94568

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/07/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/07/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
PACIRA PHARMACEUTICALS INC
10578 Science Center Dr
San Diego, CA 92121-1143
United States

Distribution Pattern:
U.S. Nationwide.

Associated Products

Product Description:
Drug Vial Label: Zilretta¿ (triamcinolone acetonide extended-release injectable suspension), 32 mg per vial, Rx only, Manufactured for: Pacira Pharmaceuticals Inc., San Diego, CA 92121, NDC 65250-001-01. Diluent Vial Label: Diluent, 5mL, Sterile single use, Rx only, Manufactured for Pacira Pharmaceuticals Inc., NDC 65250-002-01. Carton Label: Drug Vial Label: Zilretta¿ (triamcinolone acetonide extended-release injectable suspension), 32 mg per vial, Rx only, Manufactured for: Pacira Pharmaceuticals Inc., San Diego, CA 92121, NDC 65250-003-01.

Product Quantity:
43,768 kits

Reason for Recall:
Failed Stability Specifications - at 12 months 2-8 degrees C followed by 6 weeks at 25 degrees C.

Recall Number:
D-0546-2024

Code Information:
Lot: 082657 (kit 23-9004), Exp: July 2024.

Class II Drugs Event

Event ID:
94727

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/28/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:

06/07/2024

E-Mail

Recalling Firm:
Winder Laboratories, LLC
716 Patrick Industrial Ln
Winder, GA 30680-8333
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Phenazopyridine HCl Tablets USP, 100 mg, 100-count bottles, Rx Only, Manufactured by: Winder Laboratories, LLC. 716 Patrick Industrial Lane, Winder, GA 30680, NDC 75826-114-10,

Product Quantity:
473 cases (5676 Bottles)

Reason for Recall:
Product Mix Up. A bottle of Phenazopyridine HCl tablets USP 100 mg contained Phenobarbital tablets 16.2 mg.

Recall Number:
D-0545-2024

Code Information:
Lot#: 1142404 Exp. Date 02/27/2027

Class II Drugs Event

Event ID:
94738

Product Type:
Drugs

Status:
Completed

Date Terminated:
N/A

Recall Initiation Date:
05/31/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/10/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RemedyRepack Inc.
625 Kolter Dr Ste 4
Indiana, PA 15701-3571
United States

Distribution Pattern:
Product was distributed to one medical facility.

Associated Products

Product Description:
Phenazopyridine HCl, 100mg tablets, 6 count bottles, Rx Only, Repackaged by: RemedyRepack, Inc., Indiana, PA NDC#: 70518-0218-00, Source NDC: 75826-0114-10 MFG: Winder Laboratories, LLC, Winder, GA

Product Quantity:
8 bottles

Reason for Recall:
Product Mix Up. A bottle labeled as Phenazopyridine HCl tablets USP 100 mg contained Phenobarbital tablets 16.2 mg.

Recall Number:
D-0549-2024

Code Information:
Lot # B2906961-042524, exp. date 02/26/2027

Class III Drugs Event

Event ID:
94703

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/28/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/10/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Organon Llc
30 Hudson St Fl 33
Jersey City, NJ 07302-4804
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Asmanex Twisthaler, mometasone furoate inhalation powder, 220 mcg per actuation, 60 Metered Doses, Rx Only, Manuf. for: Organon LLC, a subsidiary of Organon & Co. Product of Singapore. NDC 78206-114-02

Product Quantity:
2,886 units

Reason for Recall:
Defective Container

Recall Number:
D-0550-2024

Code Information:
Lot #: X025346, Exp 3/3/2025

Product Description:
Asmanex Twisthaler, mometasone furoate inhalation powder, 220 mcg per actuation, 14 Metered Doses, Rx Only, Manuf. for: Organon LLC, a subsidiary of Organon & Co. Product of Singapore. NDC 78206-114-03

Product Quantity:
2,551 units

Reason for Recall:
Defective Container

Recall Number:
D-0551-2024

Code Information:
Lot #: X024051, Exp 04/25/2025

Product Description:
Asmanex Twisthaler, mometasone furoate inhalation powder, 220 mcg per actuation, 30 Metered Doses, Rx Only, Manuf. for: Organon LLC, a subsidiary of Organon & Co. Product of Singapore. NDC 78206-0114-04

Product Quantity:
0

Reason for Recall:
Defective Container

Recall Number:
D-0552-2024

Code Information:
Lot #: Y000085, Exp 4/25/2025