Enforcement Report - Week of June 30, 2021

Class I Drugs Event

Event ID:
87981

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/18/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/22/2021

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Miracle 8989
2001 W Northwest Hwy
Dallas TX United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
PremierZEN Gold 7000 capsule, 1-count blister card, packaged in 12 cards per box (UPC 7 28175 42183 2), Distributed by: New Premier Group, Los Angeles, CA 90006

Product Quantity:
Unknown

Reason for Recall:
Marketed without an approved NDA/ANDA - Product found to be tainted with Sildenafil and Tadalafil.

Recall Number:
D-0633-2021

Code Information:
All lots remaining within expiry.

Product Description:
PremierZEN Platinum 8000 capsule, 1-count blister card (UPC 7 28175 42185 6), packaged in 12 cards per box (UPC 7 28175 42183 2), Distributed by: New Premier Group, Los Angeles, CA 90006

Product Quantity:
Unknown

Reason for Recall:
Marketed without an approved NDA/ANDA - Product found to be tainted with Sildenafil and Tadalafil.

Recall Number:
D-0634-2021

Code Information:
All lots remaining within expiry.

Product Description:
maXXzen Platinum 12000 capsule, 1-count blister card (UPC 7 18122 04072 8), Distributed by: Maxx Inc, Los Angeles, CA 90028

Product Quantity:
Unknown

Reason for Recall:
Marketed without an approved NDA/ANDA - Product found to be tainted with Sildenafil and Tadalafil.

Recall Number:
D-0635-2021

Code Information:
All lots remaining within expiry.

Class II Drugs Event

Event ID:
87950

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/14/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/23/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teligent Pharma, Inc.
105 Lincoln Avenue
Buena NJ United States

Distribution Pattern:
Nationwide in the United States

Associated Products

Product Description:
Diflorasone Diacetate Ointment USP, 0.05%, packaged in a)15 g (NDC 52565-063-15) and b) 30 g (NDC 52565-063-30) tubes, Rx only, Manufactured by: Teligent Pharma, Inc, Buena, NJ 08310.

Product Quantity:
6,240 tubes

Reason for Recall:
Presence of Foreign Substance: Foreign particles observed during routine stability testing.

Recall Number:
D-0636-2021

Code Information:
Lot #: 16264, Exp Date Nov 2022

Class II Drugs Event

Event ID:
87990

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/21/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/23/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hill Dermaceuticals, Inc.
2650 S Mellonville Ave
Sanford FL United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
DermOtic Oil (fluocinolone acetonide oil) 0.01% Ear Drops 20 mL bottles, Rx only, Manufactured by: Hill Dermaceuticals, Inc. Sanford, FL 32773 for: Royal Pharmaceuticals Manasquan, NJ 08736, NDC 68791-103-20

Product Quantity:
34,561 bottles for sale; 773 bottles for samples

Reason for Recall:
Presence of Foreign Substance: Potential for broken glass within the glass pipette of the dropper.

Recall Number:
D-0637-2021

Code Information:
Lot #: 19K036D, 19L039E Exp. 05/21; 20A001E, 20A003D, 20A003E, Exp. 07/21; 20C013G Exp. 09/21; 20E025F, 20E025G, 20E025H Exp. 12/21; 20H041D, 20H041F Exp. 02/22; 20J043E Exp. 03/22; 20K050F Exp. 04/22; 20L055E Exp. 06/22; 21C015E, 21C018E Exp. 09/22

Class II Drugs Event

Event ID:
88033

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/01/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/24/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
VIONA PHARMACEUTICALS INC
20 Commerce Dr Ste 340
Cranford NJ United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Metformin Hydrochloride Extended-Release Tablets, USP 750 mg, 100 Tablets, Rx only, Manufactured by: Cadila Healthcare Ltd. Ahmedabad, India. Distributed by: Viona Pharmaceuticals Inc. Cranford, NJ 07016 NDC 72578-036-01

Product Quantity:
21240 bottles

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) levels in excess of the Acceptable Daily Intake Limit.

Recall Number:
D-0640-2021

Code Information:
Lot M1915601 & M915602, Oct 2021

Class III Drugs Event

Event ID:
88079

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/08/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/23/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Bausch Health Companies, Inc.
400 Somerset Corporate Blvd
Bridgewater NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Mephyton (Phytonadione) 5 mg tablets, 100-count tablets, Rx Only, Manufactured for: Valeant Pharmaceuticals North America, LLC, Bridgewater, NJ, 08807, USA, NDC 0187-1704-05.

Product Quantity:
2,691 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0638-2021

Code Information:
Lot #: 19D012P, Exp Date 07/2021; 20D096P, Exp Date 10/2022

Product Description:
Phytonadione Tablets, 5 mg, 30-count ablets, Rx only, Manufactured for: Oceanside Pharmaceuticals, a division of Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA, NDC 68682-170-30

Product Quantity:
37,797 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0639-2021

Code Information:
Lot #:19D013P, Exp Date 07/2021; 20D099P, Exp Date 10/2022