Enforcement Report - Week of August 25, 2021

Class II Drugs Event

Event ID:
88293

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/19/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/18/2021

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Econazole Nitrate Cream 1%, 85 grams bulk shippers, Rx Only, Teligent Pharma, Inc. Buena, New Jersey 08310, NDC 52565-022-85 ; packaged in tubes.

Product Quantity:
14688 tubes

Reason for Recall:
Correct Labeled Product Mispack

Recall Number:
D-0751-2021

Code Information:
Lot # 16630; Exp 03/2023

Product Description:
Triamcinolone Acetonide Ointment USP, 0.1% 80 g cartons, Rx Only, Teligent Pharma, Inc. Buena, New Jersey 08310, NDC 52565-014-80 ; packaged in tubes.

Product Quantity:

Reason for Recall:
Correct Labeled Product Mispack

Recall Number:
D-0752-2021

Code Information:
Lot # 16630; Exp 03/2023

Class II Drugs Event

Event ID:
88309

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/19/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/18/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Tizanidine HCl Tablets, USP 4 mg, 150-count bottles, Rx only, Mfd By: Dr. Reddy's Laboratories limited, Srikakulam District, 532 409 INDIA, NDC 55111-180-15.

Product Quantity:
37560 bottles

Reason for Recall:
Failed Tablet/Capsule Specification: Some tablets are shaved

Recall Number:
D-0750-2021

Code Information:
Lot #: T2000471, exp date 09/2023

Class II Drugs Event

Event ID:
88310

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/26/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/15/2021

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

Recalling Firm:
High Performance Formulas, L.L.C. (HPF, L.L.C.)
2001 Makefield Rd
Yardley PA United States

Distribution Pattern:
Product was distributed nationwide.

Associated Products

Product Description:
Cholestene capsules, 1200 mg of red yeast rice per 2 capsules, 120-count bottle, Manufactured by: High Performance Formulas, L.L.C. (HPF, L.L.C.) P.O. Box 1311, Morrisville, PA 19067, UPC 640485-10093-4

Product Quantity:
14,848 bottles

Reason for Recall:
Marketed Without an Approved NDA/ANDA

Recall Number:
D-0727-2021

Code Information:
Lot #30317, exp. date 02/2026

Class II Drugs Event

Event ID:
88322

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/16/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/16/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Spirit Pharmaceuticals
2004 Orville Dr N Ste 2
Ronkonkoma NY United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Acetaminophen 325 mg tablets, Regular Strength Pain Reliever, 100-count bottle, Distributed by: Walmart Inc., Bentoville, AR 72716, NDC 79903-052-10

Product Quantity:

Reason for Recall:
cGMP deviations: Discolored acetaminophen

Recall Number:
D-0729-2021

Code Information:
Lot #: S210240, Exp. 03/2023

Class II Drugs Event

Event ID:
88342

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/30/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/13/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Noven Pharmaceuticals Inc
11960 Sw 144th St
Miami FL United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Combipatch (estradiol/norethindrone acetate transdermal system) 0.05/0.14 mg per day, 50/140 Twice Weekly, Rx Only a) 2 Systems NDC 68968-0514-2 b) 8 Systems NDC 68968-0514-8, Mfd. by: Noven Pharmaceuticals, Inc., Miami, Florida 33186, Dist. by: Noven Therapeutics LLC, Miami, Florida 33186

Product Quantity:
223,382 boxes

Reason for Recall:
Failed Stability Specifications; out of specification for shear.

Recall Number:
D-0724-2021

Code Information:
Lots: 88542 Exp. 03/2022; 88227 Exp. 12/2021; 88696 Exp. 05/2022; 89357 Exp. 08/2022

Product Description:
Combipatch (estradiol/norethindrone acetate transdermal system) 0.05/0.25 mg per day 50/250 Twice Weekly Rx Only a) 2 Systems NDC 68968-0525-2; b) 8 Systems NDC 68968-0525-8, Mfd. by: Noven Pharmaceuticals, Inc., Miami, Florida 33186, Dist. by: Noven Therapeutics LLC, Miami, Florida 33186

Product Quantity:
70,638 boxes

Reason for Recall:
Failed Stability Specifications; out of specification for shear.

Recall Number:
D-0725-2021

Code Information:
Lots: 88540 Exp. 03/2022; 89118 Exp. 05/2022; 89244 Exp. 07/2022; 89244 (sample lot) Exp. 07/2022

Class II Drugs Event

Event ID:
88390

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/29/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/13/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Novel Laboratories, Inc. d.b.a LUPIN
400 Campus Dr
Somerset NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
GaviLyteTM - C PEG-3350 (240g) and Electrolytes for Oral Solution, USP with Flavor Pack Manufactured by Novel Laboratories, Inc. Somerset, NJ 08873, USA Manufactured for Lupin Pharmaceuticals, Inc. Baltimore, MD 21202 NDC 43386-060-19

Product Quantity:
20,814 bottles

Reason for Recall:
Failed Stability Specification; Out of specification for Osmolarity

Recall Number:
D-0726-2021

Code Information:
Lot S001133, exp 7/2022

Class II Drugs Event

Event ID:
88442

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/29/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/16/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA

400 Interpace Pkwy
Parsippany NJ United States

Distribution Pattern:
Product was distributed Nationwide, including Puerto Rico.

Associated Products

Product Description:
DAUNOrubicin Hydrochloride Injection 20 mg/4mL, 4mL Single Dose vials, 10 in 1 carton, Rx only, Teva Parenteral Medicines, Inc. Irvine, CA 92618 Vial NDC# 0703-5233-11, Carton NDC # 0703-5233-13

Product Quantity:
1,351 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0730-2021

Code Information:
Lot #: 31329250B, exp. date 08/2022

Product Description:
Methylprednisolone Acetate Injectable Suspension USP, 40 mg/mL, packaged in a) 1 mL Single-Dose vials (0703-0031-01), and b) 5mL Multi Dose Vials (NDC 0703-0043-01), and c) 10 mL Multi-Dose Vials (NDC 0703-0045-01), Rx only, TEVA PHARMACEUTICALS USA, INC. North Wales, PA 19454.

Product Quantity:
193,845 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0731-2021

Code Information:
Lot #: a) 31328455B, exp. date 09/2021; 31329340B, exp. date 12/2021; 31329439B, exp. date 01/2022; 31328347B, exp. date 07/2021 b) 31328321B, exp. date 07/2021; c) 31328368B, 31328394B, exp. date 07/2021; 31328699B, exp. date 09/2021; 31328834B, exp. date 10/2021; 31329286B, exp. date 12/2021

Product Description:
Haloperidol Decanoate Injection 100 mg/mL, packaged in a) 1 mL single-dose vials (NDC 0703-7131-01), b) 5 mL multi-dose vials (NDC 0703-7133-01), Rx only, Teva Pharmaceuticals USA, Inc. North Wales, PA 19454.

Product Quantity:
16,226 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0732-2021

Code Information:
Lot #: a) 31327056B, exp. date 03/2022; 31328547B, exp. date 01/2023; b) 31327066B, exp. date 03/2022

Product Description:
Amikacin Sulfate Injection USP 1 gram/4mL (250mg/ML), 4 mL single-dose vials, Rx only, Teva Pharmaceuticals USA Inc. North Wales, PA 19454, NDC 0703-9040-01

Product Quantity:
4,712 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0733-2021

Code Information:
Lot #: 31329243B, exp. date 05/2022

Product Description:
Idarubicin Hydrochloride Injection 20 mg/20 mL, 20 mL single-dose vial, Rx only, Teva Pharmaceuticals USA, Inc. North Wales, PA 19454, NDC 0703-4156-11

Product Quantity:
2,091 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0734-2021

Code Information:
Lot #: 31328668B, exp. date 04/2023

Product Description:
Vecuronium Bromide for Injection 10 mg, 10mL vial, Rx only, Teva Pharmaceuticals USA, North Wales, PA 19454, NDC 0703-2914-01

Product Quantity:
62,358 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0735-2021

Code Information:
Lot #: 31325960B, exp. date12/2021; 31326111B, exp. date 01/2022; 31326875B, exp. date 03/2022; 31326915B, exp. date 03/2022; 31326916B, 31326917B, exp. date 04/2022; 31329079B, exp. date 04/2023; 31329085B, exp. date 05/2023

Product Description:
Octreotide Acetate Injection 1000 mcg/5mL, 5 mL multi-dose vial, Rx only, Teva Pharmaceuticals USA. Inc. North Wales, PA 19454, NDC 0703-3333-01

Product Quantity:
16,644 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0736-2021

Code Information:
Lot #: 31329150B, exp. date 06/2022

Product Description:
Leucovorin Calcium for Injection, USP 350 mg/vial, 17.5 mL single-use vials, Rx only, Teva Parenteral Medicines, Inc. Irvine, CA 92618, NDC 0703-5145-01

Product Quantity:
434,229 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0737-2021

Code Information:
Lot #: 31325852B, 31325985B, exp. date 10/2021; 31326349B, exp. date 01/2022; 31326873B, exp. date 03/2022; 31326995B, exp. date 05/2022 31327158B, exp. date 06/2022; 31328946B, 31329180B, exp. date 05/2023.

Product Description:
Epoprostenol Sodium for Injection, 1.5 mg/vial, 10 mL vials, Rx only, Teva Pharmaceuticals USA, Inc. North Wales, PA 19454, NDC 0703-1995-01

Product Quantity:
12,698 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0738-2021

Code Information:
Lot #: 31329113B, exp. date 05/2022

Product Description:
Norepinephrine Bitartrate Injection, USP 4 mg/4 mL, 4 mL single dose vials, packaged in 10 vial cartons (NDC 0703-1153-03) Rx only, Teva Pharmaceuticals USA Inc. North Wales, PA 19454, vial NDC 0703-1153-01

Product Quantity:
34,100 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0739-2021

Code Information:
Lot #: 31329045B, exp. date 07/2021; 31329077B, exp. date 08/2021; 31329312B, exp. date 09/2021

Product Description:
Adenosine Injection, USP, 60mg/20mL (3 mg/mL), 20 mL single-dose vial, Rx only, Manufactured by: Teva Pharmaceuticals USA Inc. Parsippany, NJ 07054, NDC 0703-8776-01

Product Quantity:
4,249 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0740-2021

Code Information:
Lot #: 100022400, exp. date 04/2023

Product Description:
Metoclopramide Injection USP, 10 mg/2mL (5 mg/mL) 2 mL single-use vial, Rx only, Teva Parenteral Medicines, Inc. Irvine, CA 92618, NDC 0703-4502-01

Product Quantity:
25,653 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0741-2021

Code Information:
Lot #: 31326043B, exp. date 10/2021; 31326138B, exp. date 11/2021 31329399B, 31329539B, exp. date 08/2023; 31329599B, exp. date 09/2023

Product Description:
Alprostadil Injection USP, 500 mg/mL, 1 mL single dose, vials, 5 mL single use vial per carton (NDC 0703-1501-02), Rx only, Teva Pharmaceuticals USA, Inc. Parsippany, NJ 07054, Vial NDC 0703-1501-01

Product Quantity:
2,199 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0742-2021

Code Information:
Lot #: 31329295B, exp date. 01/2022

Product Description:
Methylprednisolone Acetate Injectable Suspension USP, 80 mg/mL, packaged in a) 1 mL Single-Dose vials (0703-0051-01), and b) 5mL Multi Dose Vials (NDC 0703-0063-01), Rx only, TEVA PHARMACEUTICALS USA, INC. North Wales, PA 19454.

Product Quantity:
50,713 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0743-2021

Code Information:
Lot #: a) 31329363B, exp. date 01/2022; 31329484B, exp. date 03/2022 b) 31328367B, 31328431B, exp. date 07/2021; 31329014B, exp. date 11/2021

Product Description:
Octreotide Acetate Injection 100 mcg/mL, 1 mL single-dose vial, Rx only, Teva Pharmaceuticals USA. Inc. North Wales, PA 19454, NDC 0703-3311-01

Product Quantity:
3,067 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0744-2021

Code Information:
Lot #: 31327466B, exp. date 08/2021

Product Description:
Octreotide Acetate Injection 50 mcg/mL, 1 mL single-dose vial, Rx only, Teva Pharmaceuticals USA. Inc. North Wales, PA 19454, NDC 0703-3301-01

Product Quantity:
6,184 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0745-2021

Code Information:
Lot #: 31329169B, 31329231B, exp. Date 06/2022

Product Description:
Leucovorin Calcium for Injection, USP 100 mg/vial, 10 mL single-use vials, Rx only, Teva Parenteral Medicines, Inc. Irvine, CA 92618, NDC 0703-5140-01

Product Quantity:
476,275 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0746-2021

Code Information:
Lot #: 31325596B, exp. date 08/2021; 31328129B, exp. date 11/2022; 31328356B, exp. date 01/2023; 31329297B, exp. date 06/2023; 31329569B, 31329821B, exp. date 08/2023

Product Description:
Leucovorin Calcium for Injection, USP 350 mg/vial, 17.5 mL single-use vials, Rx only, Manufactured by: Teva Pharmaceuticals USA, Inc. North Wales, PA 19454, NDC 0703-5145-91

Product Quantity:
42,046 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0747-2021

Code Information:
Lot #: 313282585B, exp. date 11/2022

Product Description:
Adenosine Injection, USP, 60mg/20 mL (3 mg/mL), 20 mL single-dose vial, Rx only, Mfd in the USA for: NorthStar Rx LLC Memphis, TN 38141, NDC 16714-180-01

Product Quantity:
20,800 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0748-2021

Code Information:
Lot #: 100022401, exp. date 04/2023

Class II Drugs Event

Event ID:
88482

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/13/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/19/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Zydus Pharmaceuticals (USA) Inc
73 Route 31 N
Pennington NJ United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Carvedilol Tablets, USP 25 mg, 500 Tablets bottles, Rx Only, Manufactured by: Cadila Healthcare Ltd., India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 0853, NDC 68382-095-05

Product Quantity:
2880 bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules; report of two Paroxetine tablets were found in the bottle

Recall Number:
D-0753-2021

Code Information:
Z006279, exp 12/31/2022

Class III Drugs Event

Event ID:
88428

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/05/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/16/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
DuPont Nutrition USA, Inc
1301 Ogletown Rd
Newark DE United States

Distribution Pattern:
Product was distributed nationwide, including Puerto Rico and to foreign accounts abroad.

Associated Products

Product Description:
Avicel, Mirocrystalline cellulose, packaged in bulk as PH101 NF, PH102 NF, PH200 NF, Manufactured by: DuPont Nutrition USA, Inc., 1301

Ogletown Road, Newark, DE 19711

Product Quantity:
2,384,720 kg

Reason for Recall:
Out of specification results for conductivity.

Recall Number:
D-0728-2021

Code Information:
Lot Numbers: P120834253, PN20834314, PN20834326, P220834329, P120834471, 2173728724, 2173731307, 2173739294, 2173742956, 2173743721, 2173747040 217374970, 2173749846, 2173751395, 2173751995, 2173753080, 2173749460, 2173755135, 2173755142, 2173758869, 22173758869 2173759101, 2173759087, 2173760958, 21737606959, 2173762248, 217376233, 2173763871 2173763872, 2173755139, 2173763875, 2173764734, 2173763870, 2173764735, 2173769670, 2173775381, 2173776518, 217377536, 2173779284, 2173800414, 2173801736, 2173801737, 2173802516, 2173805796, 2173805797, 2173806449, 2173806450, 2173809474, 2173809473 2173810873, 2173811314, 2173811315, 2173806441, 217381169, 2173811666 These excipients are noted not to have an expiration date.