Enforcement Report - Week of October 25, 2023

Class I Drugs Event

Event ID:
93007

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/08/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/16/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Church & Dwight Inc
469 N Harrison St
Princeton NJ United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
TheraBreath for Kids! Oral Rinse, sodium fluoride 0.05% (0.02% w/v fluoride ion), 16 fl. oz. 473 mL bottles, Strawberry Splash, UPC 6 97029 70000 6, manufactured for Church & Dwight Co, Inc., Ewing, NJ 08628

Product Quantity:
5,316 bottles

Reason for Recall:
Microbial contamination of Non-Sterile Product; presence of yeast identified as Candida parapsilosis

Recall Number:
D-0046-2024

Code Information:
Lot # PA3083011, Exp 3/31/2025

Class I Drugs Event

Event ID:
93096

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/15/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/16/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
VistaPharm LLC
7265 Ulmerton Rd
Largo FL United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Sucralfate Oral Suspension, 1g per 10mL, 16 oz (414 mL) PET bottle (12 bottles per case), Rx Only, Manufactured and Distributed by: VistaPharm, Inc. Largo, FL 33771 USA, NDC 66689-305-16

Product Quantity:
180 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products: identified as Bacillus cereus.

Recall Number:
D-0047-2024

Code Information:
Lot#: 810300, Exp 10/2023

Class I Drugs Event

Event ID:
93101

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/20/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/18/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
KVK-Tech, Inc.
110 Terry Dr
Newtown PA United States

Distribution Pattern:
Nationwide in the USA and PR

Associated Products

Product Description:
Betaxolol Tablets, USP 10 mg, Rx Only, 100 count bottles, Mfd by: KVK Tech Inc., Newtown, PA 18940, Made in USA, NDC# 10702-013-01.

Product Quantity:
1488 bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules: There is a potential presence of oxycodone HCl tablets, USP 5 mg in bottles.

Recall Number:
D-0049-2024

Code Information:
Lot # 17853A, Exp. 06/30/2027

Class II Drugs Event

Event ID:
93154

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/02/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/19/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pine Pharmaceuticals, LLC
355 Riverwalk Pkwy
Tonawanda NY United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Bevacizumab 1.25 MG/0.05 ML Solution for Injection, 1 mL syringes, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.

Product Quantity:
2862 Syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0050-2024

Code Information:
Lot #: 68861, Exp. Date 10/13/2023; 69105, Exp. Date 10/25/2023; 70204, Exp. Date 11/24/2023; 70218, Exp. Date 11/25/2023; 68620 Exp. Date 10/3/2023; 68632 Exp. Date 10/4/2023; 68789 Exp. Date 10/12/2023; 68822 Exp. Date 10/12/2023; 68914 Exp. Date 10/17/2023; 68952, 68954 Exp. Date 10/18/2023; 69105 Exp. Date 10/25/2023; 69731 Exp. Date 11/7/2023; 69991 Exp. Date 11/15/2023; 70142 Exp. Date 11/22/2023; 70233 Exp. Date 11/28/2023; 70258 Exp. Date 11/29/2023; 70297 Exp. Date 11/30/2023; 70355 Exp. Date 12/5/2023; 70404 Exp. Date 12/6/2023; 70516 Exp. Date 12/12/2023; 70579 Exp. Date 12/14/2023; 70659, 70664 Exp. Date 12/19/2023; 70700 Exp. Date 12/20/2023; 68757, Exp. Date 10/10/2023; 68912, Exp. Date 10/17/2023; 69071, Exp. Date 10/24/2023; 69725, Exp. Date 10/31/2023; 69749, Exp. Date 11//2023; 69841, Exp. Date 11/8/2023; 69961, Exp. Date 11/14/2023; 70112, Exp. Date 11/21/2023; 70228, Exp. Date 11/28/2023; 70353, Exp. Date 12/5/2023; 70403, Exp. Date 12/9/2023; 70513, Exp. Date 2/12/2023; 70569, 70570 Exp. Date 12/14/2023; 70692, Exp. Date 12/20/2023; 70726, Exp. Date 12/21/2023; 70853, Exp. Date 12/27/2023; 68757, Exp. Date 10/10/2023; 68912, Exp. Date 10/17/2023; 69071, Exp. Date 10/24/2023; 69725, Exp. Date 10/31/2023; 69749, Exp. Dat e1/7/2023; 69841, Exp. Date 11/8/2023; 69961, Exp. Date 11/14/2023; 70112, Exp. Date 11/21/2023; 70228, Exp. Date 11/28/2023; 70353, Exp. Date 12/5/2023; 70403, Exp. Date 12/9/2023; 70513, Exp. Date 12/12/2023; 70569,70570, Exp. Date 12/14/2023; 70 692, Exp. Date 12/20/2023; 70726, Exp. Date 12/21/2023; 70853, Exp. Date 12/27/2023; 69749, Exp. Date 11/7/2023; 69841, Exp. Date 11/8/2023 67538, Exp. Date 10/11/2023; 68535, Exp. Date 10/4/2023; 68611, 68613 Exp. Date 10/3/2023; 68612, 68633, 68637 Exp. Date 10/4/2023; 68638, 68673, 68674,68675, Exp. Date 10/5/2023; 68634, 68699, 68700, 68701, 68702, 68709 Exp. Date 10/6/2023; 68703, 68708, 68728, 68729, 68736, 68737, 68738, 68739, Exp. Date 10/7/2023; 68758, 68759, Exp. Date 10/10/2023; 68784, 68785, 68786, 68787, 68788, Exp. Date 10/11/2023; 68821, 68823, 68824,Exp. Date 10/12/2023; 68843, 68844, 68850, 68851, 68852, 10/13/2023;68853, Exp. Date 10/13/2023; 68877, 68878, 68879, exp. date 10/14/2023; 68880, exp. date 10/14/2023; 68886, exp. date 10/14/2023; 68896, exp. date 10/13/2023; 68897, exp. date 10/13/2023; 68913, exp. date 10/17/2023; 68915, exp. date 10/17/2023; 68922, exp. date 10/18/2023; 68923, exp. date 10/17/2023; 68953, exp. date 10/18/2023; 68959, exp. date 10/20/2023; 68976, exp. date 10/18/2023; 68977, exp. date 10/19/2023; 68978, exp. date 10/19/2023; 68979, exp. date 10/19/2023; 68980, exp. date 10/18/2023; 68981, exp. date 10/19/2023; 68982, exp. date 10/20/2023; 69016, exp. date 10/20/2023; 69017, exp. date 10/20/2023; 69018, exp. date 10/21/2023; 69019, exp. date 10/20/2023; 69047, exp. date 10/21/2023; 69048, exp. date 10/21/2023; 69049, exp. date 10/21/2023; 69050, exp. date 10/21/2023; 69051, exp. date 10/21/2023; 69052, exp. date 10/21/2023; 69056, exp. date 10/21/2023; 69072, exp. date 10/24/2023; 69073, exp. date 10/24/2023; 69074, exp. date 10/24/2023; 69075, exp. date 10/24/2023; 69101, exp. date 10/28/2023; 69102, exp. date 10/25/2023; 69103, exp. date 10/25/2023; 69104, exp. date 10/25/2023; 69109, exp. date 10/25/2023; 69127, exp. date 10/26/2023; 69128, exp. date 10/27/2023; 69129, exp. date 10/26/2023; 69130, exp. date 10/28/2023; 69131, exp. date 10/28/2023; 69132, exp. date 10/28/2023; 69142, exp. date 10/27/2023; 69143, exp. date 10/28/2023; 69144, exp. date 10/28/2023; 69166, exp. date 10/28/2023; 69167, exp. date 10/28/2023; 69168, exp. date 10/28/2023; 69169, exp. date 10/28/2023; 69170, exp. date 10/28/2023; 69171, exp. date 10/28/2023; 69726, exp. date 10/31/2023; 69727, exp. date 10/31/2023; 69745, exp. date 11/4/2023; 69746, exp. date 11/2/2023; 69748, exp. date 11/2/2023; 69750, exp. date 11/2/2023; 69751, exp. date 11/4/2023; 69754, exp. date 11/3/2023; 69755, exp. date 11/3/2023; 69768, exp. date 11/3/2023; 69770, exp. date 11/3/2023; 69779, exp. date 11/4/2023; 69780, exp. date 11/4/2023; 69781, exp. date 11/4/2023; 69782, exp. date 11/4/2023; 69783, exp. date 11/4/2023; 69784, exp. date 11/4/2023; 69793, exp. date 11/4/2023; 69794, exp. date 11/7/2023; 69839, exp. date 11/8/2023; 69863, exp. date 11/9/2023; 69864, exp. date 11/18/2023; 69865, exp. date 11/9/2023; 69866, exp. date 11/9/2023; 69867, exp. date 11/9/2023; 69868, exp. date 11/14/2023; 69890, exp. date 11/10/2023; 69892, exp. date 11/10/2023; 69893, exp. date 11/10/2023; 69894, exp. date 11/10/2023; 69895, exp. date 11/10/2023; 69896, exp. date 11/10/2023; 69897, exp. date 11/10/2023; 69928, exp. date 11/11/2023; 69929, exp. date 11/11/2023; 69930, exp. date 11/11/2023; 69931, exp. date 11/11/2023; 69932, exp. date 11/11/2023; 69933, exp. date 11/11/2023; 69962, exp. date 11/18/2023; 69963, exp. date 11/16/2023; 69964, exp. date 11/14/2023; 69965, exp. date 11/15/2023; 69987, exp. date 11/15/2023; 69988, exp. date 11/15/2023; 69990, exp. date 11/15/2023; 69998, exp. date 11/18/2023; 70011, exp. date 11/18/2023; 70031, exp. date 11/16/2023; 70032, exp. date 11/16/2023; 70033, exp. date 11/16/2023; 70034, exp. date 11/16/2023; 70035, exp. date 11/21/2023; 70066, exp. date 11/17/2023; 70067, exp. date 11/17/2023; 70094, exp. date 11/18/2023; 70095, exp. date 11/18/2023; 70113, exp. date 11/21/2023; 70114, exp. date 11/21/2023; 70115, exp. date 11/21/2023; 70116, exp. date 11/22/2023; 70138, exp. date 11/22/2023; 70139, exp. date 11/22/2023; 70140, exp. date 11/22/2023; 70147, exp. date 11/22/2023; 70163, exp. date 11/23/2023; 70164, exp. date 11/23/2023; 70165, exp. date 11/23/2023; 70166, exp.

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Product Description:
Vancomycin 1 MG/0.1 ML Solution for Intraocular Injection, 0.8 ML Single Dose Vial, Rx only, Compounded by: Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.

Product Quantity:
26 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0051-2024

Code Information:
Lot #: 69985, exp. date 11/15/2023

Product Description:
Endophth Kit (Vancomycin 1mg/0.1 mL - Ceftazidime 2.25mg/0.1 mL), Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.

Product Quantity:
201 kits

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0052-2024

Code Information:
Lot #: 69986, Exp. Date 11/15/2023

Product Description:
Calcium Gluconate Ophthalmic Irrigation Solution 1%, 500 mL bags, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.

Product Quantity:
128 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0053-2024

Code Information:
Lot #: 69802, Exp. Date 02/28/2024

Product Description:
Calcium Gluconate 2.5% solution for inhalation, 5mL pre-filled syringes, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.

Product Quantity:
881 pre-filled syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0054-2024

Code Information:
Lot #: 70363, Exp. Date 03/20/2024

Product Description:
Tropi-Phen (Tropicamide 1% phenylephrine HCl 2.5%) ophthalmic solution, 15 mL multi-use Droppers, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.

Product Quantity:
2181 droppers

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0055-2024

Code Information:
Lot #: 67008, Exp. Date 10/04/2023; 67685, Exp. Date 10/21/2023; 67853, Exp. Date 10/25/2023; 69967, Exp. Date 01/13/2024

Product Description:
Moxifloxacin in Balanced Salt Solution, Solution for Intraocular Injection, 600 mcg/0.4mL (150 mcg/0.1mL) Syringe, Rx only, Compounded by: Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.

Product Quantity:
2484 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0056-2024

Code Information:
Lot #: 67480, Exp. Date 10/9/2023; 68640,Exp. Date 12/3/2023; 68769, Exp. Date 12/9/2023; 68760, Exp. Date 12/10/2023; 68925, Exp. Date 12/16/2023;70119, Exp. Date 1/20/2024

Product Description:
Cefuroxime 4mg /0.4 mL (10 mg/mL), 1mL syringe, Rx only, Compounded by: Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.

Product Quantity:
4972 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0057-2024

Code Information:
Lot #: 67918, Exp. Date 10/29/2023; 68033, Exp. Date 11/4/2023; 68515, Exp. Date 11/26/2023; 68528, Exp. Date 11/27/2023; 68618, Exp. Date 12/2/2023; 68651, Exp. Date 12/3/2023; 68767, Exp. Date 12/9/2023; 68829, Exp. Date 12/11/2023; 69820, Exp. Date 1/9/2024; 70733, Exp. Date 2/19/2024; 71068, Exp. Date 3/9/2024; 67345, Exp. Date 10/3/2023

Product Description:
Moxifloxacin in Balanced Salt Solution 400 mcg/0.4 mL (100 mcg/0.1 mL) 1 mL syringes, Rx only, Compounded by: Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.

Product Quantity:
2176 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0058-2024

Code Information:
Lot #: 67623, Exp. Date 10/15/2023; 67919, Exp. Date 10/29/2023; 68917, Exp. Date 12/16/2023; 69079, Exp. Date 12/23/2023; 69120, Exp. Date 12/24/2023

Product Description:
Lidocaine-phenylephrine 1%-1.5% 1mL Single Dose Vial, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.

Product Quantity:
9673 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0059-2024

Code Information:
Lot #: 67849, Exp. Date 10/25/2023; 67887, Exp. Date 10/28/2023; 68260, Exp. Date 11/14/2023; 68534, Exp. Date 11/27/2023; 68816, Exp. Date 12/12/2023; 69046, Exp. Date 12/20/2023; 69971, Exp. Date 1/13/2024

Product Description:
TPC Drops (tropicamide 1%- phenylephrine 2.5%- cyclopentolate HCl 1% ophthalmic solution, 5 mL droppers, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.

Product Quantity:
1693 droppers

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0060-2024

Code Information:
Lot #: 68184, Exp. Date 10/9/2023; 68623, Exp. Date 11/2/2023

Product Description:
Calcium chloride Solution for Intravenous Injection, 20 mg/mL, 500 mL bags, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.

Product Quantity:
130

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0061-2024

Code Information:
Lot #: 70101, Exp. Date 1/17/2024

Product Description:
Lidocaine HCl 4% ophthalmic solution, 3 mL single-use dropper, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.

Product Quantity:
1598 droppers

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0062-2024

Code Information:
Lot #: 67443, Exp. Date 10/8/2023; 68775, Exp. Date 12/9/2023

Product Description:
Tropi-Phen (tropicamide 1%, phenylephrine 2.5%) ophthalmic solution, 5mL multi-use dropper, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.

Product Quantity:
662 dropper

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0063-2024

Code Information:
Lot #: 67659, Exp. Date 10/16/2023; 70316, Exp. Date 1/30/2024

Product Description:
Lidocaine HCL 2% and Oxymetazoline HCl 0.025% Solution for intranasal administration, 2 mL syringes, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.

Product Quantity:
860 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0064-2024

Code Information:
Lot #: 67808, Exp. Date 10/23/2023

Product Description:
Foscarnet Sodium 2.4mg/0.1 mL solution for injection, 0.2 mL single-dose Staclear Luer Slip Syringe, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.

Product Quantity:
136 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0065-2024

Code Information:
Lot #: 68680, Exp. Date 12/4/2023

Class II Drugs Event

Event ID:
93187

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/05/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/16/2023

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Dollar Tree Distribution, Inc.
500 Volvo Pkwy
Chesapeake VA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Certain Over-The-Counter (OTC) drug products sold by Family Dollar retail stores.

Product Quantity:
4,261,383 units of various products

Reason for Recall:
CGMP Deviations: OTC products were stored outside of labeled temperature requirements.

Recall Number:
D-0045-2024

Code Information:
Certain drug products sold by Family Dollar retail stores located in AL, AR, AZ, CA, CO, FL, GA, ID, KS, LA, MS, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, and WY.

Class II Drugs Event

Event ID:
93201

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/24/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/17/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Baxter Healthcare Corporation
1 Baxter Pkwy
Deerfield IL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Doxil (doxorubicin hydrochloride liposome injection) 50 mg in 25 mL (2 mg/mL), Single-Dose Vial, Rx only, Manufactured for: Baxter Healthcare Corporation, Deerfield, IL 60015. NDC 0338-0067-01

Product Quantity:
472 vials

Reason for Recall:
CGMP Deviations: Product was exposed to temperatures exceeding the labeled storage conditions during transportation were released by mistake.

Recall Number:
D-0048-2024

Code Information:
Lot# MKZSU02, Exp 6/30/2024

Class III Drugs Event

Event ID:
93093

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/20/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/13/2023

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Product was distributed to physician's offices nationwide.

Associated Products

Product Description:
MYDRIATIC-4: Tropicamide - Proparacaine - Phenylephrine - Ketorolac Sterile Ophthalmic Solution Drops 1% - 0.5% - 2.5% - 0.5%, 5mL bottle, Imprimis, NJOF, 1705 Route 46 West, Unit 6B, Ledgewood, NJ 07852 (844)-446-6979, NDC:71384-632-05

Product Quantity:
6,228 bags + 15,360 boxes

Reason for Recall:
Subpotent: Out of Specification result observed for Ketorolac assay levels, below the 90.0-110.0% of label claim.

Recall Number:
D-0043-2024

Code Information:
Lot#s: 22DEC065 (MDU), exp: 09/29/2023; 23JAN024 (MDU), exp: 10/13/2023; 23FEB024 (SDU), exp: 11/09/2023; 23MAR013 (SDU), exp: 12/01/2023; 23MAR033 (SDU), exp: 12/16/2023; 23MAY044 (SDU), exp: 03/23/2024;

Class III Drugs Event

Event ID:
93166

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/04/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/16/2023

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:
Bupropion Hydrochloride Extended-Release Tablets USP (SR), 150 mg, 60 tablets bottle, Rx Only, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Limited Halol-Baroda Highway, Halol-389 350, Gujarat, India, NDC 47335-737-86

Product Quantity:
144 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0044-2024

Code Information:
Lot #: HAD0360A, Exp. 12/2023