Enforcement Report - Week of January 25, 2023

Class I Drugs Event

Event ID:
91228

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/29/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/13/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Accord Healthcare, Inc.
1009 Slater Rd Ste 210B
Durham NC United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Daptomycin for Injection 350 mg/vial 1 Single-dose vial, Rx only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, India. NDC 16729-0434-05

Product Quantity:
Unknown

Reason for Recall:
Labeling mixup: cartons labeled as Daptomycin 350 mg/vial were found to contain vials of Daptomycin 500 mg per vial

Recall Number:
D-0131-2023

Code Information:
Lot: R2200232 Exp. 01/2025

Class II Drugs Event

Event ID:
90948

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/13/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/13/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn, Inc.
5605 Centerpoint Ct Ste A
Gurnee IL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
AK-POLY-BAC brand of Bacitracin cand Polymixin B Sulfate Ophthalmic Ointment USP, 3.5 g (1/8 oz.) tube, Rx only, Sterile, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-238-35

Product Quantity:
36,025 tubes

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0132-2023

Code Information:
Lot # 0G87A, EXP 06/30/2023

Product Description:
Artificial Tears OINTMENT, Lubricant Eye Ointment, Net Wt. 3.5 g (1/8 oz.) per tube, Sterile, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-062-35

Product Quantity:
1,164,171 tubes

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0133-2023

Code Information:
Lot # 0A08B, EXP 12/31/2022; 0B63A, EXP 1/31/2023; 0C72A, EXP 2/28/2023; 0D14A, 0D19A, EXP 3/31/2023; 0F54A, EXP 5/31/2023; 0G80B, 0G09B, 0G97A, EXP 6/30/2023; 0J78A, EXP 8/31/2023; 0K23A, EXP 9/30/2023; 0L64A, EXP 10/31/2023;1B29A, EXP 1/31/2024; 1C59A, 1C53A, 1C72A,1C78A, EXP 2/29/2024; 1D87A, 1D89A, EXP 3/31/2024; 1G59A, 1G59B, EXP 6/30/2024; 1K60A, EXP 9/30/2024; 1J57A, EXP 8/31/2024; 1H86A, EXP 7/31/2024; 1K75A, EXP 9/30/2024; 1L12A, EXP 10/31/2024; 1M22A, EXP 11/30/2024

Product Description:
Artificial Tears Solution, Lubricant Eye Drops, Polyvinyl Alcohol 1.4%, 15 mL (0.5 fl. oz.) per bottle, Sterile, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-060-12

Product Quantity:
967,075 bottles

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0134-2023

Code Information:
Lot: 0L44A, 0L52A, 0L51A, 0L77A, 0L75A, EXP 10/31/2022; 0M02A, 0M01A, EXP 11/30/2022; 1C81A, EXP 2/28/2023; 1D02A, 1D03A, EXP 3/31/2023; 1E10A, 1E08A, 1E23A, 1E26A, 1E25A, 1E27A, 1E33A, EXP 4/30/2023; 1F46A, EXP 5/31/2023; 1G49A, 1G50A, 1G67A, EXP 6/30/2023; 1H04A, 1H74A,1H76A, 1H05A, 1H07A, 1H15A, 1H13A, 1H95A, EXP 7/31/2023; 1J44A, 1J20A, EXP 8/31/2023;

Product Description:
Betaxolol Ophthalmic Solution, USP 0.5%, (Betaxolol HCl 5.6 mg/mL), 5 mL per bottle, Sterile, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-705-10

Product Quantity:
6,273 bottles

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0135-2023

Code Information:
Lot: 1A08A, EXP 12/31/2022

Product Description:
Ciprofloxacin Ophthalmic Solution, USP 0.3% (Ciprofloxacin HCl), 2.5mL per bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045.

NDC: 17478-714-25

Product Quantity:
1,584 bottles

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0136-2023

Code Information:
Lot: Lot 1E22A, EXP 10/31/2022

Product Description:
Cromolyn Sodium Ophthalmic Solution, USP 4%, 10mL per bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-291-11

Product Quantity:
188,550 bottles

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0137-2023

Code Information:
Lot: 0G75A, 0G12A, EXP 6/30/2023; 0H50A, EXP 7/31/2023; 0J88A, EXP 8/31/2023; 1D98A, EXP 3/31/2024; 1E31A, EXP 4/30/2024; 1D97A, EXP 3/31/2024; 1H14A, EXP 7/31/2024;

Product Description:
ERYTHROMYCIN OPHTHALMIC OINTMENT USP 0.5%, Net Weight: 3.5g (1/8 oz) per tube, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-070-35

Product Quantity:
1,109,600 tubes

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0138-2023

Code Information:
Lot: 0L58A, EXP 10/31/2022; 1B21A, 1B31A, EXP 1/31/2023; 1C44A, 1C58A, 1C58B, EXP 2/28/2023; 1E13A, 1E24A, EXP 4/30/2023; 1C57A, EXP 2/28/2023; 1G60A, 1G62A, 1G63A, EXP 6/30/2023; 1J34B, 1J40A, 1J21A, EXP 8/31/2023; 1K74A, EXP 9/30/2023; 1L93A, 1L96B, 1L96A, EXP 10/31/2023; 1M25A, 1M24A, 1M31A, EXP 11/30/2023; 2A02A, 2A10A, EXP 12/31/2023; 2C07A, EXP 2/29/2024; 2D47A, EXP 3/31/2024; 2E50A, 2E51A, EXP 4/30/2024;

Product Description:
Erythromycin Ophthalmic Ointment USP, 0.5%, Net Weight: 1 g per tube (50 unit-dose tubes per carton), Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-070-31

Product Quantity:
36,455 cartons

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0139-2023

Code Information:
Lot: 1B14B, EXP 1/31/2023; 1C49A, 1C49B, 1C70A, EXP 2/28/2023; 1E09A, 1E34A, 1E34B, 1E09B, EXP 4/30/2023; 1F37C, 1F37A, 1F37B, EXP 5/31/2023; 1G58A, 1G57B, 1G58B, 1G66B, 1G66A, 1G57A, EXP 6/30/2023; 1H77B, 1H80A, 1H80B, 1H77A, EXP 7/31/2023; 1J24A, EXP 8/31/2023; 1K67B, 1K67A, 1K76A, 1K87B, 1K77A, 1K76B, 1K87A, 1K77B, EXP 9/30/2023; 1L90B, 1L90A, 1L92B, 1L92A, EXP 10/31/2023; 1M28A, 1M35A, 1M28B, EXP 11/30/2023; 2D20B, EXP 3/31/2024.

Product Description:
GONAK Hypromellose Ophthalmic Demulcent Solution, (25 mg) 2.5%, 15 mL per dropper bottle, For Professional Use in Goinoscopic

Examinations, Mfd. by: Akorn, INc., Lake Forest, IL 60045. NDC: 17478-064-12

Product Quantity:
196,254 bottles

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0140-2023

Code Information:
Lot: 0C80A, EXP 2/28/2023; 0B71A, 1B32A, EXP 1/31/2023; 0C80B, EXP 2/28/2023; 0F68A, EXP 5/31/2023; 0G85A, 0G01A, 1G54A, 1G71A, EXP 6/30/2023; 0H32A, 0H47A, 1H75A, EXP 7/31/2023; 0K22A, EXP 9/30/2023; 0M90A, EXP 11/30/2023;

Product Description:
Ketorolac Tromethamine Ophthalmic Solution, 0.5%, Packaged as a) 10 mL dropper bottle, NDC 17478-209-11; (b) 3 mL dropper bottle, NDC 17478-209-19; (c) 5 mL dropper bottle, NDC 17478-209-10; Rx only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045.

Product Quantity:
314,543 10ml,3ml, 5ml bottles

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0141-2023

Code Information:
Lot: (a) 1A09A, EXP 12/31/2022; 1H01A, EXP 7/31/2023 ; (b) 1E32A, EXP 4/30/2023; 1F45A, EXP 5/31/2023; 1H99A, EXP 7/31/2023; 1K84A, EXP 9/30/2023; (c) 0L40A, EXP 10/31/2022; 1B38A, EXP 1/31/2023; 1E12A, EXP 4/30/2023; 1F41A, EXP 5/31/2023; 1G73A, 1G68A, EXP 6/30/2023; 1H08A, 1H12A, EXP 7/31/2023

Product Description:
Levofloxacin Ophthalmic Solution 0.5%, 5 mL per bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, Il 60045. NDC: 17478-106-10

Product Quantity:
3108 bottles

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0142-2023

Code Information:
Lot # 1F43A, EXP 5/31/2/023

Product Description:
Lidocaine Hydrochloride Jelly USP, 2%, Packaged as (a) 5 mL tube (NDC 17478-711-10) x10 per box NDC 17478-711-31; (b) 30 mL tube NDC 17478-711-30; Rx only, Manufactured by: Akorn, Inc., Lake Forest, Il 60045.

Product Quantity:
2,369,258 tubes

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0143-2023

Code Information:
Lot: (a) 0A02B, 0A02D, 0A02C, 0A02A, 0A02E, EXP 12/31/2022; 0B60C, 0B46B, 0B60D EXP 1/31/2023; 0B67B, 0B67D, 0B60B, 0B60A, 0B67A, 0B46D, 0B67C, 0B46A, EXP 1/31/2023; 0C78B, 0C78D, 0C78C, EXP 2/28/2023; 0D11A, 0D11C, 0D11B, 0D11D, EXP 3/31/2023 0E35C, 0E35B, 0E35A, EXP 4/30/2023; 0J63B, 0J63C, EXP 8/31/2023; 0K02A, 0K02C, 0K02D, 0K02B, EXP 9/30/2023; 0L47B, 0L47C, 0L47A, EXP 10/31/2023; 1B12B, 1B12A, 1B23A, 1B23F, 1B12C, 1B23B, 1B23D, 1B23E, 1B12D, EXP 1/31/2024; 1C66C, 1C66A, EXP 2/29/2024; 1D93B, 1D93D, 1D93C, 1D99B, 1D99C, 1D99A, 1D93A, 1D99D, EXP 3/31/2024 1H96C, 1H96D, 1H96E, EXP 7/31/2024; 1J37B, 1J47B, 1J47D, 1J37C, 1J37A, 1J47C, EXP 8/31/2024; 1L18D, 1L98C, 1L18C, 1L18A, 1L98B, 1L98D, 1L18B, 1L98E, EXP 10/31/2024; 2D21B, EXP 3/31/2025 (b) 0A06A, 0A37A , EXP 12/31/2022; 0B44A, EXP 1/31/2023; 0C88A, 0C84A, EXP 2/28/2023; 0D21A, 0D08A, EXP 3/31/2023; 0E46A, 0E46B, 0E31A, 0E48A, EXP 4/30/2023; 0F72A, 0F58A, EXP 5/31/2023; 0G05A, EXP 6/30/2023; 0H41A, EXP 7/31/2023; 0J67A, 0J67B, EXP 8/31/2023; 0K15B, 0K15A, EXP

9/30/2023; 0L56B, EXP 10/31/2023; 1B20A, EXP 1/31/2024; 1C47A, 1C52A, EXP 2/29/2024; 1D84B,1D84A, EXP 3/31/2024; 1G61A, 1G64A, 1G72A, EXP 6/30/2024; 1J51A, 1J28A, EXP 8/31/2024; 1K63A, 1K69A, 1K73A, 1K69B, 1K69C, EXP 9/30/2024; 1L15B, EXP 10/31/2024; 2C08A,EXP 2/28/2025;

Product Description:
Moxifloxacin Ophthalmic Solution, USP, 0.5%, 3 mL per dropper bottle, Rx only, Manufactured by: Akorn, Lake Forest, IL 60045. NDC: 17478-519-19

Product Quantity:
2,563 bottles

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0144-2023

Code Information:
Lot, Expiry: Lots 1E28A, exp 4/30/2023

Product Description:
Neomycin and Polymyxin B Sulfates, and Bacitracin Zinc Ophthalmic Ointment, USP, Net Wt. 3.5 g (1/8 oz.), Rx Only, Manufactured by: Akorn, INC., Lake Forest, IL 60045. NDC: 17478-235-35

Product Quantity:
2,082 tubes

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0145-2023

Code Information:
Lot: Lot 1K64A, EXP 9/30/2023

Product Description:
Ofloxacin Ophthalmic Solution, USP 0.3%, 5 mL per bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045; Distributed by: MWI, Boise, ID 83705. NDC: 13985-602-05

Product Quantity:
65,006 bottles

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0146-2023

Code Information:
Lot: 11B26A, EXP 1/31/2023; 1H02A, EXP 7/31/2023;

Product Description:
Olopatadine HCl Ophthalmic Solution, USP 0.1%, 5 mL per dropper bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-105-05

Product Quantity:
31,073 bottles

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0147-2023

Code Information:
Lot: Lot 1B41A, EXP 1/31/2023

Product Description:
Olopatadine HCL Ophthalmic Solution, USP 0.1%, Antihistamine and Redness Reliever, 5 mL (0.17 FL OZ) per bottle, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-308-05

Product Quantity:
1,752 bottles

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0148-2023

Code Information:
Lot: 1L03A, EXP 10/31/2023

Product Description:
Olopatadine HCl Ophthalmic Solution, USP 0.2%, 2.5 mL per bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-305-12

Product Quantity:
173,928 bottles

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0149-2023

Code Information:
Lot: 0L48A, EXP 10/31/2022; 0L55A, EXP 10/31/2022; 1C75A, EXP 2/28/2023; 1E18A, 1E20A , EXP 4/30/2023;

Product Description:
Olopatadine HCl Ophthalmic Solution, USP 0.1%, 5 mL (0.17 FL OZ) per bottle, Antihistamine and Redness Reliever, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. Marketed by: GSMS, Incorporated, Camarillo, CA 93012. NDC: 51407-499-05

Product Quantity:
163,996 bottles

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0150-2023

Code Information:
Lot: 1L16A, 1L17A, EXP 10/31/2023; 1M29A, EXP 11/30/2023; 2A05A, EXP 12/31/2023;

Product Description:
Olopatadine HCl Ophthalmic Solution, USP 0.1%, 5 mL per bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. Marketed by: GSMS, Incorporated, Camarillo, CA 93012. NDC: 60429-957-05

Product Quantity:
121,176 bottles

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0151-2023

Code Information:
Lot: 1C61A, EXP 2/28/2023; 1D86A, 1D07A, EXP 3/31/2023;

Product Description:
PAREMYD (hydroxyamphetamine hydrobromide/ tropicamide ophthalmic solution) 1%/0.25%, 15 mL per dropper bottle, Rx only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-704-12

Product Quantity:
51,601 bottles

Reason for Recall:
CGMP Deviations:

Recall Number:

D-0152-2023

Code Information:
Lot: 0B55A, EXP 1/31/2023; 0D16A, 0D23A, EXP 3/31/2023; 0E51A, EXP 4/30/2023; 1C46A, EXP 2/29/2024;

Product Description:
Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%, 15 mL per dropper bottle, Rx only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031 NDC: 17478-263-12

Product Quantity:
267,678 bottles

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0153-2023

Code Information:
Lot: 0L42A, 0L50A, EXP 10/31/2022; 1C64A, 1C76A, EXP 2/28/2023; 1G53A, EXP 6/30/2023; 1J26A, 1J25A, 1J48A, 1J54A, EXP 8/31/2023

Product Description:
Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%, 15 mL per bottle, Rx only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. Distributed By: MWI Boise, ID 83705, NDC: 13985-611-15

Product Quantity:
23,026 bottles

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0154-2023

Code Information:
Lot: 0L53A, EXP 10/31/2022; 1J49A, EXP 8/31/2023;

Product Description:
Sodium Chloride Ophthalmic Ointment, USP, 5%, Net Wt. 3.5 g (1/8 oz.) per tube, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-622-35

Product Quantity:
524,506 tubes

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0155-2023

Code Information:
Lot: 0F69A, EXP 5/31/2023; 0G92B, 0G92A, EXP 6/30/2023; 0J69A, EXP 8/31/2023; 0K29A, 0K24A, EXP 9/30/2023; 0M93A, 0M92A, 0M92B, EXP 11/30/2023; 1B25A, EXP 1/31/2024; 1C74A, EXP 2/29/2024; 1E19A, EXP 4/30/2024; 1C77A, EXP 2/29/2024;

Product Description:
Timolol Maleate Ophthalmic Solution, USP, 0.5%, Packaged in (a) 5 mL dropper bottle, NDC 17478-288-10; (b) 10 mL dropper bottles: NDC 17478-288-11; (c) 15 mL dropper bottles, NDC 17478-288-12; Rx Only, Sterile, Manufactured by: Akorn, Inc., Lake Forest, IL 60045.

Product Quantity:
1,310,324 bottles

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0156-2023

Code Information:
Lot: (a) 0B50A, 0B69A, EXP 1/31/2023; 0C74A, EXP 2/28/2023; 0D04A, EXP 3/31/2023; 0E37A, EXP 4/30/2023; 0G07A, 0G82A, EXP 6/30/2023; 0H26A, 0H28A, 0H53A, 0H36A, EXP 7/31/2023; 0J64A, 0J58A, 0J66A, EXP 8/31/2023; 0K96A, 0K06A, 0K98A, 0K04A, 0K03A, 0K99A, EXP 9/30/2023; 0L72A, EXP 10/31/2023; 0M81A, 0M85A, 0M80A, 0M84A, 0M82A, 0M83A, EXP 11/30/2023; 1A01A, 1A02A, EXP 12/31/2023; 1B16A,

1B13A, 1B17A, EXP 1/31/2024; 1C51A, EXP 2/29/2024; (b) 0B59A , EXP 1/31/2023;0E49A, EXP 4/30/2023; 0G14A, EXP 6/30/2023; 0H38A, EXP 7/31/2023; 0J84A, EXP 8/31/2023; 0K05A, EXP 9/30/2023; 0L59A, EXP 10/31/2023; 0M86A, 0M87A, EXP 11/30/2023; 1A03A, EXP 12/31/2023; 1B37A, EXP 1/31/2024; 1C63A, EXP 2/29/2024; 1C54A, EXP 2/29/2024; 1D83A, EXP 3/31/2024; (c) 0C82A, EXP 2/28/2023; 0G84A, EXP 6/30/2023; 0H49A, EXP 7/31/2023; 0J77A, EXP 8/31/2023; 0J75A, EXP 8/31/2023; 0L57A, EXP 10/31/2023; 0L74A, EXP 10/31/2023; 0L46A, EXP 10/31/2023; 1G52A, EXP 6/30/2024; 1J52A, EXP 8/31/2024;

Product Description:
Tobramycin Ophthalmic Solution, USP, 0.3%, 5 mL per dropper bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC 17478-290-10

Product Quantity:
2,095,068 bottles

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0157-2023

Code Information:
Lot: 1C56A, EXP 2/28/2023; 1J50A, EXP 8/31/2023; 1K61A, EXP 9/30/2023 ; 1M27A, EXP 11/30/2023;

Product Description:
Tobramycin Ophthalmic Solution, USP, 0.3%, 5 mL per bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045; Distributed by: MWI, Boise, ID 83705. NDC 13985-604-05

Product Quantity:
91,692 bottles

Reason for Recall:
CGMP Deviations:

Recall Number:
D-0158-2023

Code Information:
Lot: 1D94A, EXP 3/31/2023; 1E35A, EXP 4/30/2023; 2A06A, EXP 12/31/2023

Class II Drugs Event

Event ID:
90953

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/06/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/19/2023

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Southwest Iowa Renewable Energy LLC
10868 189th St
Council Bluffs IA United States

Distribution Pattern:
IA, NE

Associated Products

Product Description:
SIREtizer Hand Sanitizer (Ethyl Alcohol) 80%, packaged in a) 3.38 oz (100 mL), b) 10 oz (295 ml), UPC 8 60003 85882 0, and c) 16.9 oz (500 ml), UPC 8 60003 85880 6 bottles, Southwest Iowa Renewable Energy, 10868 189th Street, Council Bluffs, IA 51503; Bottled by Southwest 6th Beverages, LLC, Lincoln, NE 68522 and Bottled by South Tenth Development, LLC, Lincoln, NE 68522.

Product Quantity:

a) 3,008 bottles; b) 120 bottles; c) 9,576 bottles

Reason for Recall:
CGMP Deviations and Superpotent Drug: Levels of acetal and acetaldehyde above allowable limits. Additionally, lot 001 was superpotent.

Recall Number:
D-0166-2023

Code Information:
Lots: 0001, 0005, 0007

Class II Drugs Event

Event ID:
91198

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/22/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/13/2023

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Sensorcaine (Bupivacaine HCl and Epinephrine Injection, USP) with Epinephrine 1:200,000 (as bitartrate), 0.25%, 125 mg per 50 mL (2.5 mg per mL), 50 mL Multiple Dose Vial (NDC 63323-461-01), packaged in 25 Multiple Dose Vials per tray (NDC 63323-461-57), Rx only, Fresenius Kabi, Lake Zurich, IL 60047.

Product Quantity:
40,375 vials

Reason for Recall:
Subpotent Drug: Testing results below the defined limit for the epinephrine portion of this product.

Recall Number:
D-0127-2023

Code Information:
Batch #: 6128061, exp 03/2024; 6128663, 6128664, exp 05/2024

Product Description:
Sensorcaine (Bupivacaine HCl and Epinephrine Injection, USP) with Epinephrine 1:200,000 (as bitartrate), 0.5%, 250 mg per 50 mL (5 mg per mL), 50 mL Multiple Dose Vial (NDC 63323-463-01), packaged in 25 Multiple Dose Vials per tray (NDC 63323-463-57), Rx only, Fresenius Kabi, Lake Zurich, IL 60047.

Product Quantity:
40,025 vials

Reason for Recall:
Subpotent Drug: Testing results below the defined limit for the epinephrine portion of this product.

Recall Number:
D-0128-2023

Code Information:
Batch #: 6128399, 6128400, 6128401, exp 04/2024

Product Description:
Sensorcaine-MPF (Bupivacaine HCl and Epinephrine Injection, USP) with Epinephrine 1:200,000 (as bitartrate), 0.25%, 25 mg per 10 mL (2.5 mg per mL), 10 mL Single Dose Vial (NDC 63323-468-01), packaged in 25 Single Dose Vials per tray (NDC 63323-468-17), Rx only, Fresenius Kabi, Lake Zurich, IL 60047.

Product Quantity:
31,600 vials

Reason for Recall:
Subpotent Drug: Testing results below the defined limit for the epinephrine portion of this product.

Recall Number:
D-0129-2023

Code Information:
Batch #: 6128800, exp 12/2023

Class II Drugs Event

Event ID:
91385

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/28/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/16/2023

Initial Firm Notification of Consignee or Public:
E-Mail

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

Distribution Pattern:
Customers in 19 states: CA, FL, GA, IL, KY, LA, MI, MN, MS, NC, NJ, NY, OH, PA, RI, TN, TX, WA, WI; Puerto Rico

Associated Products

Product Description:
Rasagiline Mesylate Tablets 1 mg; 30 tablets in HDPE bottle; Rx only; NDC 67877-260-30; Manufactured by Alkem Laboratories Ltd., India; Distributed by: Ascend Laboratories, LLC, Parsippany, NJ 07054

Product Quantity:
12192 bottles

Reason for Recall:
Presence of Foreign Substance- A complaint was received of black spots/shiny metallic speck on the tablets.

Recall Number:
D-0159-2023

Code Information:
Lot # 22140903. Exp. Dec. 2024

Class II Drugs Event

Event ID:
91416

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/20/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/18/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amerisource Health Services LLC
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Rifampin Capsules USP, 300 mg, 100 Capsules (10 x 10) per carton, Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217, Carton NDC 60687-586-01 (Individual Dose NDC: 60687-586-11)

Product Quantity:
3,091 cartons

Reason for Recall:
Failed Impurities/Degradations Specifications

Recall Number:
D-0165-2023

Code Information:
Lot #: 1007805, exp. 12/31/2023

Class II Drugs Event

Event ID:
91427

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/17/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/18/2023

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

Recalling Firm:
Fisher Scientific Co., LLC
1 Reagent Ln
Fair Lawn NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Hand Sanitizer, HSANI500ML, (Isopropyl Alcohol), 75% v/v, packaged in a) 500 mL bottle and b) 6 x 500 mL bottles per case, Thermo Fisher Scientific: Janssen Pharmaceuticalaan 3a, 2440 Geel - Belgium, 1 Reagent Lane, Fair Lawn, NJ 07410.

Product Quantity:
a) 1077 bottles, b) 52 cases

Reason for Recall:
CGMP Deviations: Voluntary recall of all hand sanitizer distributed after March 31, 2022, due to FDA issued guidance to cease placing hand sanitizer product, produced under temporary approval, into the market after March 31, 2022.

Recall Number:
D-0163-2023

Code Information:
Lot Numbers: 202160, 202162, 202324, 202368, 202369, 202593, 202594, 202835, 202862, 202863, 202865, 202836, 202864, 203061, 203098, 203099, 203100, 203101, 203102, 203236, 203237, 203239, 203337, 203338, 203335, 203336

Product Description:
Hand Sanitizer, HSANI4LI, (Isopropyl Alcohol), 75% Topical Solution, packaged in 4 L bottles, Thermo Fisher Scientific: Janssen Pharmaceuticalaan 3a, 2440 Geel - Belgium, 1 Reagent Lane, Fair Lawn, NJ 07410.

Product Quantity:
106 bottles

Reason for Recall:
CGMP Deviations: Voluntary recall of all hand sanitizer distributed after March 31, 2022, due to FDA issued guidance to cease placing hand sanitizer product, produced under temporary approval, into the market after March 31, 2022.

Recall Number:
D-0164-2023

Code Information:
Lot Numbers: 202161, 202322, 202323, 202794, 202858, 203188, 203238, 203240, 203722 203723, 203724, 203725, 204852

Class III Drugs Event

Event ID:
91142

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/09/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/16/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lannett Company Inc.
1101 C Ave W
Seymour IN United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Triamterene and Hydrochlorothiazide Capsules, USP (37.5 mg/25 mg), Rx Only, 1000 Capsules per bottle, Distributed by: Lannett Company, Inc., Philadelphia, PA 19136. NDC: 0527-1632-10

Product Quantity:
5,640 bottles

Reason for Recall:
Failed Impurity/Degradation Specifications

Recall Number:
D-0160-2023

Code Information:
Lots: 20256318A (12/2022), 20256321A (12/2022), 21000238A (01/2023)

Product Description:
Triamterene and Hydrochlorothiazide Capsules, USP (37.5 mg/25 mg), Rx Only, [100 or 1000] Capsules per bottle, Distributed by: Lannett Company, Inc., Philadelphia, PA 19136. NDC 100 Count bottle: 0527-1632-01; NDC 1,000 bottle: 0527-1632-10

Product Quantity:
20,040 bottles

Reason for Recall:
Failed Impurity/Degradation Specifications

Recall Number:
D-0161-2023

Code Information:
Lots: 21000279A (exp 01/2023), 20256320A (12/2022)

Class III Drugs Event

Event ID:
91348

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/04/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/19/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Intersect ENT, Inc.
1555 Adams Dr
Menlo Park CA United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
SINUVA (mometasone furoate) sinus implant, 1350 mcg, 1 implant per pouch, Rx Only, intersect ENT, 1555 Adams Drive, Menlo Park, CA 94025, NDC 10599-003-01.

Product Quantity:
9898 pouches

Reason for Recall:
Failed Dissolution Specification; product did not meet the average 24-hour drug release rate (dissolution) specification stability time point at 9 months.

Recall Number:
D-0167-2023

Code Information:
Lot #s: 10111003, Exp 12/31/2022; 10203002, Exp 01/31/2023; 10302002, 10325001, Exp 02/28/2023; 10519001, 10526002, Exp 04/30/2023; 10602002, Exp 05/31/2023; 10819004, Exp 09/30/2023; 21092101, 21111901, Exp 10/31/2023; 21110402, Exp 12/31/2023.

Class III Drugs Event

Event ID:
91441

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/05/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/17/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
MACLEODS PHARMA USA, INC

103 College Rd E Fl 2
Princeton NJ United States

Distribution Pattern:
Nationwide within United States and Puerto Rico.

Associated Products

Product Description:
Levofloxacin Tablets, USP 500 mg; 50-count bottles, Rx Only, Manufactured for: Macleods Pharma USA, Inc. Princeton, NJ 08540; Manufactured by: Macleods Pharmaceuticals Ltd., Baddi, Himachal Pradesh, India. NDC 33342-022-08

Product Quantity:
10052 bottles

Reason for Recall:
Mismatching of the embossing on the tablets (T7) with the embossing mentioned in the package insert (ML63) in the distributed bottles.

Recall Number:
D-0162-2023

Code Information:
Lot #: BLF2214A; Exp. 06/2025