Enforcement Report - Week of December 15, 2021

Class I Drugs Event

Event ID:
89075

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/19/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/06/2021

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
American Screening LLC
9742 Saint Vincent Ave Ste 100
Shreveport LA United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
AmericanScreening HAND SANITIZER (ethyl alcohol 70%) ANTIMICROBIAL FORMULA Vitamin E & Moisturizer, 8 FL OZ (237 mL) bottle with either a black or clear top, Distributed by American Screening LLC Shreveport, LA, 71106 UPC 8 40050 51579 2

Product Quantity:
153,336 bottles

Reason for Recall:
Labeling Not Elsewhere Classified: Hand sanitizer packaged in containers resembling drinking water bottles.

Recall Number:
D-0266-2022

Code Information:
Black capped bottles have no lot numbers but include expiration dates of 5/21/2022 and 05/24/2022. Clear capped bottles have neither lot numbers nor expiration dates.

Class II Drugs Event

Event ID:
89011

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/28/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/08/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Apollo Care
3801 Mojave Ct Ste 101
Columbia MO United States

Distribution Pattern:
MO

Associated Products

Product Description:
VANComycin 1g added to 250mL of 0.9% Sodium Chloride (Injection for Intravenous Use Only), 260 mL per bag, Rx Only, This is a

Compounded Drug, Hospital/Office Use Only, Apollo Care 3801 Mojave Ct, Suite 101, Columbia, MO 65202, NDC 71170-254-25

Product Quantity:
225 bags

Reason for Recall:
Crystallization: Product appears to be turbid.

Recall Number:
D-0277-2022

Code Information:
Lot #: AC-016402, Exp 2/12/2022

Class II Drugs Event

Event ID:
89060

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/19/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/07/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ascent Pharmaceuticals, Inc.
400 S Technology Dr
Central Islip NY United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/325 mg, 100-count bottle, Rx only, Manufactured for: Camber Pharmaceuticals, Inc. Piscataway, NJ 08854, Manufactured by: Ascent Pharmaceuticals, Inc., Central Islip, NY 11722, NDC 31722-943-01.

Product Quantity:
9744 bottles

Reason for Recall:
Product Mix-up

Recall Number:
D-0276-2022

Code Information:
Lot #: 21070817, Exp 6/2023

Class III Drugs Event

Event ID:
89042

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/12/2021

Voluntary / Mandated:

Center Classification Date:
12/07/2021

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:
USA Nationwide.

Associated Products

Product Description:
Allergy & Congestion Fexofenadine HCl 60 mg & Pseudoephedrine HCl 120 mg Extended-Release Tablets, USP, 20 Extended-Release Tablets, Distributed by: Rite Aid, 30 Hunter Lane, Camp Hill, PA 17011, NDC 11822-7388-5.

Product Quantity:
4896 cartons

Reason for Recall:
Failed dissolution specifications

Recall Number:
D-0267-2022

Code Information:
Lot #: AC2103329E, Exp 1/2023

Product Description:
Allergy & Congestion Relief Allergy Relief D, Fexofenadine HCl 60 mg/ Pseudoephedrine HCl 120 mg Extended Release Tablets, 20 extended-release tablets, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, Made in India, NDC 69842-249-20

Product Quantity:
14976 cartons

Reason for Recall:
Failed dissolution specifications

Recall Number:
D-0268-2022

Code Information:
Lot #: AC2103329I, Exp 1/2023

Product Description:
Fexofenadine HCl 60 mg/ Pseudoephedrine HCl 120 mg Extended Release Tablets USP Allergy & Congestion, 20 Tablets, Distributed by: Dr. Reddy's Laboratories, Inc. Princeton, NJ 08540, NDC 43598-823-14.

Product Quantity:
5016 cartons

Reason for Recall:
Failed dissolution specifications

Recall Number:
D-0269-2022

Code Information:
Lot #: AC2103329F, Exp 1/2023

Product Description:
Antihistamine & Nasal Decongestant, Fexofenadine HCl 60 mg and Pseudoephedrine HCl 120 mg, Extended Release Tablets USP, Allergy & Congestion, 12 Hour, 20 Tablets, Distributed by: Rugby Laboratories, 17177 N. Laurel Park Drive, Suite 233, Livonia, MI 48152, www.rugbylaboratories.com. NDC 0536-1242-34.

Product Quantity:
2352 cartons

Reason for Recall:
Failed dissolution specifications

Recall Number:
D-0270-2022

Code Information:
Lot #: AC2103329H, Exp 1/2023

Product Description:
Antihistamine & Nasal Decongestant, Fexofenadine HCl 60 mg and Pseudoephedrine HCl 120 mg, Extended Release Tablets USP, Allergy &

Congestion, 12 Hour, 30 Tablets, Distributed by: Rugby Laboratories, 17177 N. Laurel Park Drive, Suite 233, Livonia, MI 48152, www.rugbylaboratories.com. NDC 0638-1242-07.

Product Quantity:
2184 cartons

Reason for Recall:
Failed dissolution specifications

Recall Number:
D-0271-2022

Code Information:
Lot #: AC2103329D, Exp 1/2023

Product Description:
12 HR Allergy & Congestion Relief Fexofenadine HCl, 60 mg I Pseudoephedrine HCl, 120 mg Antihistamine I Nasal Decongestant, 20 Extended-Release Tablets USP, Distributed By Cardinal Health, Dublin, Ohio 43107, Made in India, NDC 70000-0518-1.

Product Quantity:
2496 cartons

Reason for Recall:
Failed dissolution specifications

Recall Number:
D-0272-2022

Code Information:
Lot #: AC2103329G, Exp 1/2023

Product Description:
Allergy Relief D Fexofenadine HCl, 60 mg I Pseudoephedrine HCl, 120 mg, Extended Release Tablets, 30 Extended-Release Tablets USP, Distributed By CVS Pharmacy Inc., One CVS Drive, Woonsocket, RI 02985, Made in India, NDC 69842-249-30

Product Quantity:

Reason for Recall:
Failed dissolution specifications

Recall Number:
D-0273-2022

Code Information:
Lot #: AC2103329C, Exp 1/2023

Product Description:
Allergy Relief D Fexofenadine HCl, 60 mg I Pseudoephedrine HCl, 120 mg, Extended Release Tablets, USP, 30 Extended-Release Tablets USP, Distributed By Walmart Inc., Bentonville, AR 72716, Product of India, NDC 49035-273-30.

Product Quantity:
9,984 cartons

Reason for Recall:
Failed dissolution specifications

Recall Number:
D-0274-2022

Code Information:
Lot #: AC2103329B

Product Description:
Fexofenadine HCl, 60 mg & Pseudoephedrine HCl 120 mg, Extended Release Tablets USP, Allergy and Congestion, 30 Tablets, Distributed by: Dr. Reddy's Laboratories, Inc., Princeton, NJ, 08640, Made in India NDC Walmart Inc., Bentonville, AR 72716, Product of India, NDC 43598-823-31.

Product Quantity:
2,928 cartons

Reason for Recall:
Failed dissolution specifications

Recall Number:
D-0275-2022

Code Information:
Lot #: AC2103329A