Enforcement Report - Week of December 29, 2021

Class II Drugs Event

Event ID:
88811

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/03/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/21/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
The Harvard Drug Group
17187 N Laurel Park Dr Ste 300
Livonia MI United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Fexofenadine Hydrochloride Tablets, 60 mg, 500 Tablets per bottle, Distributed by: Major Pharmaceuticals, 17177 N. Laurel Park Drive, Suite 233, Livonia, MI 48152 NDC 0904-6979-40

Product Quantity:
2,239 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0289-2022

Code Information:
Lot, expiry: Lot H00005, exp 01/2022; Lot H00006, exp 04/2022; Lot H00007, exp 07/2022

Class II Drugs Event

Event ID:
89036

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/08/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/17/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Medline Industries Inc
3 Lakes Dr
Northfield IL United States

Distribution Pattern:
Nationwide in the USA, Canada, Hong Kong, and Peru

Associated Products

Product Description:
Hand Sanitizer Foam (ethyl alcohol), 62% v/v, packaged in a) 1.5 Oz. cans, NDC 53329-970-12; b) 8 Oz. (227 g) cans, NDC 53329-970-08; and c) 16 Oz. (453 g) cans, NDC 53329-970-06; Manufactured for: Medline Industries, Inc., Northfield, IL 60093.

Product Quantity:
470,555 bottles

Reason for Recall:
Defective Container: Customer complaints for leaking bottles and dispensing issues.

Recall Number:
D-0287-2022

Code Information:
Lot #: a) 32890, exp 04/2022; 33141, 33215, exp 10/2022; 33350, exp 12/2022; 33461, exp 03/2023; b) 32858, exp 02/2022; 32889, exp 03/2022; 32968, 32977, 32975, 32984, exp 06/2022; 33294, 33295, 33322, 33323, exp 12/2022; 33384, exp 01/2023; Lot 33620, exp 07/2023; c) 32728, exp 10/2021; 32859, 32889, exp 03/2022; 32985, 32988, 33004, exp 06/2022; 33339, exp 12/2022; 33501, exp 03/2023; 33502, exp 04/2023; 33621, 33622, exp 07/2023

Class II Drugs Event

Event ID:
89136

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/29/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/17/2021

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Denver Solutions, LLC DBA Leiters Health
13796 Compark Blvd
Englewood CO United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Moxifloxacin, 1 mg/mL, 1mL in 2mL vial, solution for intracameral injection, 10 vials/carton, Rx only, Leiters 13796 Compark Blvd, Englewood, CO 80112, (800) 292-6772, NDC 71449-096-42

Product Quantity:
1440 vials

Reason for Recall:
Labeling: Label Mix-up: Vials labeled as moxifloxacin 1 mg/mL may actually contain moxifloxacin 5 mg/mL

Recall Number:
D-0288-2022

Code Information:
Lot #: 2130958; Expiration Date 03/31/2022

Class II Drugs Event

Event ID:
89205

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/24/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/22/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Efficient Laboratories, Inc.

7715 NW 64th St
Miami FL United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Rompe Pecho CF Cold & Flu Advanced Formula, 6 Fl. oz. (178 mL) bottles, Distributed by: Efficient Laboratories, Inc. Miami, FL 33166, NDC 58593-235-06

Product Quantity:
10,833 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:
D-0290-2022

Code Information:
Lot #: 19F88 Exp. June 2022; 19G164 Exp. July 2022.

Product Description:
Rompe Pecho DM, 6 Fl Oz (178 mL) bottles, Distributed by: Efficient Laboratories, Inc. Miami, FL 33166, NDC 58593-275-06

Product Quantity:
27,206 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:
D-0291-2022

Code Information:
Lot #: 19F168 Exp. June 2022; 19G145, 19G361,19G449 19G491 Exp. July 2022.

Product Description:
Rompe Pecho Ex Expectorant, packaged in a) 4 Fl. Oz. (118 mL) bottles NDC 58593-829-04 and b) 6 Fl. Oz. (178 mL) bottles NDC 58593-829-06, Distributed by Efficient Laboratories, Inc. Miami, FL 33166

Product Quantity:
a) 7,800 bottles; b) 16,417 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:
D-0292-2022

Code Information:
Lot #: a) 19H20 Exp. August 2022; 19A418 Exp. January 2022; 19E411 Exp. May 2022; b) 19H20 Exp. August 2022; 19J98 Exp. September 2022; 19A418 Exp. January 2022; 19E411 Exp. May 2022

Product Description:
Rompe Pecho Max Multi-Symptoms Maximum Strength, 8 Fl. Oz. (237 mL) bottles, Distributed by: Efficient Laboratories, Inc. Miami, FL 33166 UPC 0 00856 00309 5, NDC 58593-828-08

Product Quantity:
4,026 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:
D-0293-2022

Code Information:
Lot #: 19G219 Exp. July 2022

Class II Drugs Event

Event ID:
89255

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/16/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/23/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
400 Interpace Pkwy
Parsippany NJ United States

Distribution Pattern:
nationwide

Associated Products

Product Description:
Penicillin V Potassium for Oral Solution, USP 125 mg (200,000 U) per 5 mL a) 100 mL (NDC 00093-4125-73) and b) 200 mL (NDC 00093-4125-74) (when mixed) bottles, Rx Only, Manufactured For: Teva Pharmaceuticals USA, Inc. North Wales, PA 19454

Product Quantity:
a) 86,790 and b) 25,416 bottles

Reason for Recall:
Subpotent

Recall Number:
D-0294-2022

Code Information:
a) Lots, 35446365A, Exp 03/2022; 35447040A, Exp 08/2022 & 35447948B, Exp 03/2023. b) Lots 35446318B, Exp 05/2022 & 35447947A, Exp 03/2023.