Enforcement Report - Week of January 26, 2022

Class I Drugs Event

Event ID:
89272

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/21/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/18/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lohxa, LLC
600 Main St Ste 110
Worcester MA United States

Distribution Pattern:
Product was distributed to one wholesale who may have further distributed the product.

Associated Products

Product Description:
Senna Syrup (sennosides) Natural Vegetable Laxative 8.8 mg/5mL unit-dose cups, Mfg for: AvKARE TN 38478, NDC 50268-731-24

Product Quantity:
87,840 unit dose cups

Reason for Recall:
Microbial Contamination of Non-Sterile Product

Recall Number:
D-0377-2022

Code Information:
Lot #: AM1115S, Exp. Date 01/2023

Class II Drugs Event

Event ID:
89192

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/08/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/14/2022

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Brinzolamide Ophthalmic Suspension, USP 1%, packaged as a)10 ml dropper bottles (NDC 0591-2127-79), and b) 15 ml dropper bottles (NDC 0591-2127-12), Rx Only, Manufactured in India By: Indoco Remedies Limited Verna, Goa - 403722, India, Manufactured For: Teva

Pharmaceuticals USA, Inc. Parsippany, NJ

Product Quantity:
a) 66,099 dropper bottles; b) 21,243 dropper bottles

Reason for Recall:
Defective Container: The notch in the cap that fits into the nozzle of the dropper could break off and block the dropper possibly resulting in the product not dispensing.

Recall Number:
D-0373-2022

Code Information:
Lots: a)BCB1LB2, BCB2LB2, BCB7LB2, Exp. 11/2022; Lots: BCB11AC2, BCB12AC2, BCB3AC2, BCB4AC2, BCB5AC2, BCB6AC2, BCB10AC2, Exp. 12/2022; b) Lots: BCB4LB2, BCB5LB2, Exp. 11/2022; Lots: BCB1AC2, BCB2AC2, Exp. 12/2022; Lots: BCB1DC2, BCB2DC2, Exp. 03/2023

Class II Drugs Event

Event ID:
89356

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/06/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/20/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Medique Products
17080 Alico Commerce Ct Ste 1
Fort Myers FL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Physicians CARE Extra Strength PAIN RELIEVER [Acetaminophen, Aspirin (NSAID), and Caffeine], 250 mg, 250 mg, 65 mg, packaged as 100-count Tablets (50 Packets, 2 tablets each) per carton, Manufactured for: Acme United Corporation 55 Walls Dr, Fairfield, CT 06824, UPC 0 73577 90316 6

Product Quantity:
3,260,400 tablets

Reason for Recall:
CGMP Deviations: manufacturer recalled after an FDA inspection noted that these products were not manufactured under Current Good Manufacturing Practices.

Recall Number:
D-0389-2022

Code Information:
Lots: (Packet, Carton) 6151, 4360 Exp. 10/2021; 6240, 4446 Exp. 12/2021; 6331, 4484 Exp. 02/2022; 6413, 4551 Exp. 04/2022; 6699, 4679 Exp. 10/2022; 6751, 4714 Exp. 12/2022; 6855, 4750 Exp. 01/2023; 6868, 4761 Exp. 02/2023; 6899, 4776 Exp. 02/2023; 6899, 4776 Exp. 02/2023; 7061, 4821 Exp. 05/2023.

Product Description:
Medique Pain-Off (Acetaminophen 250 mg, Aspirin (NSAID*) 250 mg, Caffeine 65 mg) Tablets, packaged in 2-count Tablets per Unit Dose Packet, packaged as a) 200-count Tablets (100 x 2) Unit Dose packets per carton, UPC 3 47682 22847 7, Reorder #22847; b) 500-count Tablets (250 x 2) Unit Dose packets per carton, UPC 3 47682 22813 2, Reorder #22813; c) 100-count Tablets (50 x 2) Unit Dose packets per carton, UPC 3 47682 22833 0, Reorder #22833; d) 24-count Tablets (12 x 2) Unit Dose packets per carton, UPC 3 47682 22864 4, Reorder #22864; Manufactured for Medique Products, Fort Myers, FL 33967.

Product Quantity:
16,630,118 tablets

Reason for Recall:
CGMP Deviations: manufacturer recalled after an FDA inspection noted that these products were not manufactured under Current Good Manufacturing Practices.

Recall Number:
D-0390-2022

Code Information:
Lots: (packet lot, carton lot) a) 7062, 10611 Exp. 05/2023; 7062, 10110 Exp. 05/2023; 7062, 10067 Exp. 05/2023; 6414, 07378 Exp. 04/2022; 6700, 08047 Exp. 10/2022; 6152, 05553 Exp. 10/2022; 6239, 07120 Exp. 12/2021; 6239, 06504 Exp. 12/2021; 6152, 05737 Exp. 10/2021; 6700, 08653 Exp. 10/2022; 6330, 07217 Exp. 02/2022; 6414, 07360 Exp. 04/2022; 6749, 08717 Exp. 12/2022; 6794, 09012 Exp. 12/2022; b) 6856, 09108 Exp. 01/2023; 6867, 09460 Exp. 02/2023; 6900, 10105 Exp. 02/2023; 6749, 09139 Exp. 12/2022; 6152, 05944 Exp. 10/2021; 6152, 05483 Exp. 10/2021; 6414, 07488 Exp. 04/2022; 6493, 07662 Exp. 06/2022; 6414, 07286 Exp. 04/2022; 6493, 07709 Exp. 06/2022; 6414, 07524 Exp. 04/2022; 6330, 06728 Exp. 02/2022; 6330, 06366 Exp. 02/2022; 6239, 06503 Exp. 12/2021; 6330, 06460 Exp. 02/2022; c) 7070, 10605 Exp. 06/2023; 7063, 11089 Exp. 06/2023; 7070, 11020 Exp. 06/2023; 6867, 09545 Exp. 02/2023; 7062, 10066 Exp. 05/2023; 6749, 08650 Exp. 12/2022; 6493, 07784 Exp. 06/2022; 6493, 07920 Exp. 06/2022; 6330, 06949 Exp. 02/2022; 6239, 06945 Exp. 12/2021; 6239, 05973 Exp. 12/2021; 6152, 05687 Exp. 10/2021; 6493, 07950 Exp. 06/2022; 6493, 07825 Exp. 06/2022; d) 7062, 10265 Exp. 05/2023; 7070, 10980 Exp. 06/2023; 6867, 09607 Exp. 02/2023; 6152, 06039 Exp. 10/2021; 6330, 07121 Exp. 02/2022; 6700, 08040 Exp. 10/2022; 6493, 07985 Exp. 06/2022; 6152, 05783 Exp. 10/2021; 6749, 08866 Exp. 12/2022.

Product Description:
Extra Strength Headache (acetaminophen 250 mg, aspirin 250 mg, caffeine 65 mg) tablets, packaged in 2-count tablets per packet, Manufactured for: Lil' Drug Store Products, Inc., Cedar Rapids, IA 52404

Product Quantity:
6,639,838 tablets

Reason for Recall:
CGMP Deviations: manufacturer recalled after an FDA inspection noted that these products were not manufactured under Current Good Manufacturing Practices.

Recall Number:
D-0391-2022

Code Information:
Lots: 6492 Exp. 06/2022; 6701 Exp. 10/2022; 6750 Exp. 12/2022; 6853 Exp. 01/2023; 6854 Exp. 01/2023; 6869 Exp. 02/2023; 6898 Exp. 02/2023; 6901 Exp. 02/2023; 7059 Exp. 05/2023; 7060 Exp. 05/2023; 7064 Exp. 06/2023; 7065 Exp. 06/2023

Class II Drugs Event

Event ID:
89393

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/10/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/14/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ingenus Pharmaceuticals Llc
4190 Millenia Blvd
Orlando FL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Clobetasol Propionate Foam, 0.05%, packaged in a) 50 g can (NDC 50742-304-50), and b) 100 g can (NDC 50742-304-01), Rx only, Manufactured for: Ingenus Pharmaceuticals, LLC, Orlando, FL 32839-6408.

Product Quantity:
45,173 cans

Reason for Recall:
CGMP Deviations

Recall Number:
D-0374-2022

Code Information:
a) Lots: 32921 Exp. 07/14/2020; 33152 Exp. 08/2022; 33340 Exp. 11/2022; b) Lots: 33152 Exp. 08/2022; 33340 Exp. 11/2022.

Class II Drugs Event

Event ID:
89395

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/07/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/18/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
VistaPharm, Inc.
7265 Ulmerton Rd
Largo FL United States

Distribution Pattern:
Nationwide within the United States including Puerto Rico

Associated Products

Product Description:
Clobazam Oral Suspension 2.5 mg/mL, 120 mL bottles, Rx only, Manufactured by: VistaPharm, Inc. Largo, FL 33771, NDC 66689-058-04

Product Quantity:
18,456 bottles

Reason for Recall:
Failed Stability Specifications

Recall Number:
D-0376-2022

Code Information:
Lots #: 678900, 682000, 682400, Exp. 5/31/2022; 680600, 680800, 681000 Exp. 5/30/2022; 683200, 685200 Exp. 6/30/2022; 728900, 733100 Exp. Date 12/31/2022; 738600 Exp. 1/31/2023; 740600, 741600 Exp. 2/28/2023; 749800, 750900, 752400 Exp. 3/31/2023; 775700 Exp. 6/30/2023

Class II Drugs Event

Event ID:
89397

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/14/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/19/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mayne Pharma Inc
1240 Sugg Pkwy
Greenville NC United States

Distribution Pattern:

Nationwide within the United States

Associated Products

Product Description:
Lexette (halobetasol propionate) Topical Foam, 0.05% 50 g canisters, Rx ONLY, Distributed by: Mayne Pharma Greenville, NC 27834, NDC 51862-604-50

Product Quantity:
17,113 canisters

Reason for Recall:
CGMP Deviation: Difficulty dispensing/does not dispense or dispensing liquid instead of foam.

Recall Number:
D-0387-2022

Code Information:
Lot #: 32451 Exp. 03/2022; 32532 Exp. 04/2022; 32552 Exp. 05/2022; 32701 32733 Exp. 10/2022; 32855 Exp. 02/2023; 32872 Exp. 03/2023.

Class III Drugs Event

Event ID:
89364

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/04/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/18/2022

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 in the USA

Associated Products

Product Description:
Wal-Fex D, Fexofenadine HCl 60mg/Antihistamine & Pseudoephedrine HCl 120mg/Nasal Decongestant, Extended Release Tablets USP, a) 20 Extended Release Tablets per box, NDC 0363-1606-20, b) 30 Extended Release Tablets per box, NDC 0363-1606-30, Distributed by: Walgreen Co, 200 Wilmot Rd., Deerfield, IL 60015, Made in India.

Product Quantity:
67,848 boxes

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0378-2022

Code Information:
Lot #s: a) (20-count box): AC2000968D, Exp. 8/31/2022; AC2103330J, Exp. 1/31/2023; AC2106452A; AC2106452H, Exp. 3/31/2023. b) (30-count box): 79C002624C, Exp. 4/30/2022; AC2103328B; AC2103328C; AC2103330A; AC2103330B, Exp. 1/31/2023.

Product Description:
Rugby, Antihistamine and Nasal Decongestant, Fexofenadine HCl 60mg and Pseudoephedrine HCl 120mg, Extended-Release Tablets USP, 30 Tablets per box, NDC 0536-1242-07, Distributed by: Rugby Laboratories, 17177 N Laurel Park Drive, Suite 233, Livonia, MI, 49152, Made in India.

Product Quantity:
2,352 boxes

Reason for Recall:

Failed Dissolution Specifications

Recall Number:
D-0379-2022

Code Information:
Lot #: AC2106452F, Exp. 3/31/2023

Product Description:
Rite Aid Pharmacy, Allergy & Congestion, Fexofenadine HCl 60mg & Pseudoephedrine HCl 120mg, Extended Release Tablets USP, 20 Extended-Release Tablets per box, UPC 011822738873, Distributed by Rite Aid, 30 United Lane, Camp Hill, PA 17011, Made in India.

Product Quantity:
7,080 boxes

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0380-2022

Code Information:
Lot #: AC2103330D, Exp.1/31/2023; AC2106452E, Exp. 3/31/2023.

Product Description:
Kroger, Allergy Relief-D, Fexofenadine HCl 60mg/Antihistamine Pseudoephedrine HCl 120mg/Nasal Decongestant, Extended-Release Tablets USP, 20 tablets per box, NDC 30142-611-14, Distributed by the Kroger Co., Cincinnati, Ohio, 45202, Made in India.

Product Quantity:
11,064 boxes

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0381-2022

Code Information:
Lot #s: AC2000968E, Exp. 8/31/2022; AC2103328A; AC2103330I, Exp. 1/31/2023; AC2106452B, Exp. 3/31/2023.

Product Description:
Dr. Reddys, Fexofenadine HCl 60 mg & Pseudoephedrine HCl 120 mg Extended-Release Tablets USP, a) 10 tablets per box, UPC 343598823355, b) 20 tablets per box, UPC 343598823140, c) 30 tablets per box, UPC 343598823317, Distributed by: Dr. Reddy's Laboratories, Inc. Princeton, NJ 08540, Made in India.

Product Quantity:
9,912 boxes

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0382-2022

Code Information:
Lot #s: a) (10-count): AC2103328D, Exp. 1/31/2023. b) (20-count) :AC2000968C, Exp. 8/31/2022. c) (30-count): AC2103330C, Exp. 1/31/2023; AC2106452D, Exp. 3/31/2023.

Product Description:
equate, Allergy Relief D, Fexofenadine HCl 60mg/Antihistamine, Pseudoephedrine HCl 120mg/Nasal Decongestant Extended-Release Tablets USP, a) 20 Extended Release Tablets per box, NDC 49035-273-20, b) 30 Extended Release Tablets per box, NDC 49035-273-30, Distributed by: Walmart Inc., Bentonville, AR 72716, Product of India.

Product Quantity:
137,856 boxes

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0383-2022

Code Information:
Lot #s: a) (20-count): 79C002624A, Exp. 4/30/2022; AC2000968B, Exp. 8/31/2022; AC2103328F; AC2103330E, Exp.1/31/2023; AC2106452I, Exp. 3/31/2023. b) (30-count): 79C002625A, Exp. 4/30/2022; AC2103328E; AC2103330F, Exp. 1/31/2023; AC2106452G,

Exp. 3/31/2023.

Product Description:
QC QUALITY CHOICE, Fexofenadine HCl 60mg and Pseudoephedrine HCl 120mg, Extended-Release Tablets, USP, Allergy & Congestion, 10 Tablets per box, NDC 63868-729-10, Distributed by C.D.M.A., Inc., 43157 W 9 Mile Rd, Novi, MI 48375, Made in India.

Product Quantity:
9,984 boxes

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0384-2022

Code Information:
Lot #s: 79C002624D; 79C002625C, Exp. 4/30/2022.

Product Description:
CVS Health, Allergy Relief D, Fexofenadine HCl 60mg/Antihistamine Pseudoephedrine HCl 120mg/Nasal Decongestant, a) 20 Extended Release Tablets per box, UPC 050428436189, b) 30 Extended Release Tablets per box, UPC 050428290538, Distributed by CVS Pharmacy Inc., One CVS Drive, Woonsocket, RI, 02895, Made in India.

Product Quantity:
41,784 boxes

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0385-2022

Code Information:
Lot #s: a) (20-count): AC2000968A; AC2000968F, Exp. 8/31/2022. b) (30-count): 79C002624B, Exp. 4/30/2022; AC2103330G; AC2103330H, Exp. 1/31/2023.

Product Description:
Leader, 12HR Allergy & Congestion Relief, Fexofenadine HCl, 60mg Pseudoephedrine HCl 120mg Antihistamine Nasal Decongestant, 20 Extended Release Tablets per box, NDC 70000-0518-1, Distributed by Cardinal Health, Dublin, Ohio 43077, Made in India.

Product Quantity:
10,536 boxes

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0386-2022

Code Information:
Lot #s: 79C002625B, Exp. 4/30/2022; AC2103328G, Exp. 1/31/2023; AC2106452C, Exp. 3/31/2023.

Class III Drugs Event

Event ID:
89388

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/10/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/19/2022

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:
Mucus Relief D, Guaifenesin Pseudoephedrine HCl ER Tablets, 600 mg/60mg, packaged in 36-count blister pack packed into cartons, Distributed by: Walgreen Co., 200 Wilmot Rd., Deerfield, IL 60015, Made in India, NDC 0363-164-3

Product Quantity:
18336 cartons

Reason for Recall:
Subpotent drug

Recall Number:
D-0388-2022

Code Information:
Lot #: AT2102065A, AT2102065B, Exp 04/2023.