Enforcement Report - Week of January 12, 2022

Class II Drugs Event

Event ID:
88384

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/27/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/05/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Perrigo Company PLC
515 Eastern Ave
Allegan MI United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
EQUALINE aller-ease fexofenadine hydrochloride tablets, 180 mg, 24 HR, packaged as a) 15 count bottle, NDC 41163-571-22, UPC 0 41163 48067 4; b) 70 tablets per bottle, NDC 41163-571-01, UPC 0 41163 49847 1; Made in the Czech Republic, Distributed by: UNFI Providence, RI 02908.

Product Quantity:
55,032 units

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0328-2022

Code Information:
Lot # a)0HE2530 Exp 12/31/2021, 0KE2980 EXP 02/28/2022 b)0FR0461 Exp 2/28/2022

Product Description:
GoodSense Aller.Ease, Fexofenadine hydrochloride 12 HR, 60 mg tablets, 24 count bottle, UPC 3 0113 0425 62 7; Made in the Czech Republic, Distributed by: Perrigo Allergan MI 49010.

Product Quantity:
36,048 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0329-2022

Code Information:
Lot# 0JE2487 , 0KE2982, Exp 1/31/2022

Product Description:
amazon, Allergy Fexofenadine Hydrochloride Tablets, 180 mg/Antihistamine, 24 HR, 30 count bottle, Made in the Czech Republic, Distributed by: Amazon.com Services LLC 410 Terry Avenue N. Seattle, WA 98109 UPC 3 70030 11466 5

Product Quantity:
32,232 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0330-2022

Code Information:
Lot # 1BR0462, Exp 10/31/2022

Product Description:
basic+care, allergy Fexofenadine Hydrochloride Tablets, 180 mg/Antihistamine, 24 HR, 150 count bottle, Made in the Czech Republic, Distributed by: Perrigo Allergan, MI 49010, NDC 0113-7571-47 UPC 3 70030 11470 2

Product Quantity:
28,320 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0331-2022

Code Information:
Lot # 0GR0528, Exp 03/31/22; 0KR0473, Exp 04/30/22; 0LR0369, Exp 06/30/22

Product Description:
basic+care, allergy Fexofenadine Hydrochloride Tablets, 60 mg/Antihistamine, 12HR, 100 count bottle, Made in the Czech Republic, Distributed by: Perrigo Allergan, MI 49010, NDC 0113-7425-78 UPC 3 70030 14536 2

Product Quantity:
62,568 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0332-2022

Code Information:
Lot # 0CR0510, Exp 9/30/2021; 0LR0361, Exp 04/30/2022

Product Description:
berkley jensen, ALLERGY RELIEF, Fexofenadine Hydrochloride Tablets, 180 mg Antihistamine, 24HR, 150 count bottle, Made in the Czech Republic, Distributed by: BJ's WHolesale Club 25 Research Drive Westborough, MA 01581

Product Quantity:
7,670 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0333-2022

Code Information:
Lot # 0HV1442, Exp 3/1/2022, 1CV1619, Exp 10/1/2022

Product Description:
CAREONE Allergy Relief, Fexofenadine Hydrochloride Tablets, 180 mg Antihistamine, 24HR, packaged as a)30 count bottle, NDC 41520-229-39, UPC 3 41520 31984 6; b)45 count bottle, NDC 41520-229-95 UPC 3 41520 31983 9; Made in the Czech Republic, Distributed by: Foodhold U.S.A. LLC Landover, MD 20785. Made in Czech Republic

Product Quantity:
28776 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0334-2022

Code Information:
Lot a) 0FR0459, Exp 2/28/2022; 0LR0362, Exp 6/30/2022; 1BR0462, Exp 10/31/2022 b) 0LR0363, Exp 6/30/2022

Product Description:
CVS Allergy Relief, Fexofenadine Hydrochloride Tablets, 60 mg Antihistamine, 12HR, packaged as a) 12 count bottle, NDC 59779-425-53, UPC 0 50428 25414 1; b)24 count bottle, NDC 59779-425-62, UPC 0 50428 53435 9; Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895, Made in Czech Republic

Product Quantity:
138,144 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0335-2022

Code Information:
Lot # a) 0ME2516, Exp 4/30/2022 b)0ME2515, Exp 4/30/2022; 0KE2982, Exp 1/31/2022

Product Description:
DG/health Aller.Ease, Fexofenadine Hydrochloride Tablets, 180 mg/Antihistamine, 24HR, 10 count bottle, Distributed by: Made in Czech Republic. Distributed by Dolgencorp, LLC, 100 Mission Ridge Goodlettsville, TN 37072. UPC 3 70030 65779 7

Product Quantity:
24,912 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0336-2022

Code Information:
Lot 0KE2979, 0ME2088, Exp 2/28/2022

Product Description:
Health Mart, Fexofenadine Hydrochloride tablets, 12HR, 60mg . Antihistamine 12 count bottle, Distributed by: Mckesson 6555 State Highway 161, Irvine, TX 75039. Made in the Czech Republic, NDC 62011-0413-1, UPC 0 52569 14278 3

Product Quantity:
12,384 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0337-2022

Code Information:
Lot 0JE2491, Exp 1/31/2022

Product Description:
Health Mart, Fexofenadine Hydrochloride tablets, 24HR, 180mg . Antihistamine 70 count bottle, Distributed by: Mckesson 6555 State Highway 161, Irvine, TX 75039. Made in the Czech Republic, NDC 62011-0233-1, UPC 0 52569 13787 1

Product Quantity:
6,960 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0338-2022

Code Information:
Lot 0FR0461, Exp 2/25/2022

Product Description:
H.E.B Allergy Relief, Fexofenadine Hydrochloride tablets, 12HR, 60mg/Antihistamine 12 count bottle, Made with Pride & Care for H.E.B. San Antonio TX 78204, Product of Czech Republic, NDC 37808-425-53, UPC 0 41220 53080 9

Product Quantity:
26,304 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0339-2022

Code Information:
Lot 0JE2491, 0LE2178, Exp 01/31/2022; 0ME2516, Exp 4/30/2022

Product Description:
H.E.B Allergy Relief, Fexofenadine Hydrochloride tablets, 24HR, 180mg/Antihistamine packaged as a) 15 count bottle, NDC 37808-571-22, UPC 0 41220 53081 6; b) 30 count bottle, NDC 37808-571-39, UPC 0 41220 53082 3; c) 45 count bottle, NDC 37808-571-95, UPC 0 41220 53083 0; Made with Pride & Care for H.E.B. San Antonio TX 78204, Product of Czech Republic,

Product Quantity:
13,920 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0340-2022

Code Information:
Lot a) 0HE2530, Exp 12/31/2021; 0JE2407, Exp 2/28/2022: b) 1BR0462, Exp 10/31/2022 c) 0FR0460, Exp 2/28/2022: 0LR0363, Exp 6/30/2022

Product Description:
Kroger Allergy Relief, Fexofenadine Hydrochloride tablets, 12HR, 60mg Antihistamine, 12 count bottle, Distributed by the Kroger CO. Cincinnati, Ohio 45202. Made in the Czech Republic, NDC 30142-555-53 UPC 0 41260 35588 2

Product Quantity:
48,816 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0341-2022

Code Information:
lot 0LE2178, Exp 1/31/2022; 0ME2516, Exp 4/30/2022

Product Description:
MAJOR, Fexofenadine Hydrochloride tablets, 12HR, 60mg Antihistamine, 100 count bottle, Distributed by Major Pharmaceuticals 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152. Made in the Czech Republic, NDC 0904-6979-60 UPC 3 09046 97960 9

Product Quantity:
65,796 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0342-2022

Code Information:
Lot 0GR0445, Exp 1/31/2022; 0LR0361, Exp 4/30/2022; 1AR0558, Exp 7/31/2022

Product Description:
Meijer allergy relief, Fexofenadine Hydrochloride tablets, 24HR, 1800mg Antihistamine, packaged as a) 15 count bottle, NDC 41250-060-22 UPC 7 60236 18716 5; b) 30 count bottle, NDC 41250-060-39, UPC 7 60236 18717 2; c) 45 count bottle, NDC 41250-060-95, UPC 7 60236 18732 5; Made in the Czech Republic, Distributed by Meijer Distribution Inc, Grand Rapids, MI 49544.

Product Quantity:
4536 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0343-2022

Code Information:
Lot a) 0HE2530, Exp 12/31/2021; 0KE2430, Exp 2/28/2022 b) 0LR0362, Exp 6/30/2022; 1BR0462, Exp 10/31/2022 c) 0FR0460, Exp 2/28/2022

Product Description:

allergyrelief, Fexofenadine Hydrochloride tablets, 24HR, 1800mg Antihistamine, packaged as a) 15 count bottle, NDC 56062-571-22 UPC 0 41415 38973 1; b) 45 count bottle, NDC 56062-571-95 UPC 0 41415 38773 7; Distributed by PubliX SUpermarket Inc 3300 Publix Corporate Parkway Lakeland, FL 33811, Made in the Czech Republic

Product Quantity:
2280 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0344-2022

Code Information:
Lot a) 0JE2407, Exp 2/28/2022 b) 1BR0463, Exp 10/31/2022

Product Description:
Perrigo Fexofenadine Hydrochloride tablets, 24HR, 180mg Antihistamine, 100 count bottle, Made in the Czech Republic, Distributed by Perrigo Allergan, MI 49010 NDC 45802-571-78 UPC 3 45802 571 78 6

Product Quantity:
89,664 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0345-2022

Code Information:
Lot 0FR0563, Exp 02/28/22; 0GR0530, Exp 03/31/22; 0KR0434, 0KR0435, 0LR0366, 0LR0367, 0LR0368, Exp 06/30/22.

Product Description:
Perrigo Fexofenadine Hydrochloride tablets, 12HR, 60mg Antihistamine, 100 count bottle, Made in the Czech Republic, Distributed by Perrigo Allergan, MI 49010 NDC 45802-425-78 UPC 3 45802 425 78 2

Product Quantity:
41,472 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0346-2022

Code Information:
Lot# 0CR0510, Exp 09/30/21, 0GR0445, Exp 01/31/22, 0LR0361, Exp 04/30/22, 1AR0558 , Exp 07/31/22

Product Description:
Rite Aid ALLERGY RELIEF Fexofenadine Hydrochloride tablets, 12HR, 60mg Antihistamine, 24 count bottle, Made in the Czech Republic, Distributed by Rite Aid 30 Hunter Lane Camp Hill PA 17011 NDC 11822-0425-0 UPC 0 11822 85410 8

Product Quantity:
79,776 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0347-2022

Code Information:
Lot # 0JE2487, EXP 01/31/2022; 0ME2515, Exp 04/30/2022

Product Description:
Rite Aid ALLERGY RELIEF Fexofenadine Hydrochloride tablets, 24HR, 180mg Antihistamine, packaged as a) 30 count bottle, NDC 11822-0571-2 UPC 0 11822 99908 3; b) 150 count bottle, NDC 11822-0571-5 UPC 0 11822 85411 5; Made in the Czech Republic, Distributed by Rite Aid 30 Hunter Lane Camp Hill PA 17011

Product Quantity:
44,688 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0348-2022

Code Information:
Lot # a) 1BR0462, Exp 10/31/2022 b) 0GR0528, Exp 3/31/2022; 0KR0473, Exp 4/30/2022; 0LR0369, Exp 6/30/2022

Product Description:
TopCare Allergy Relief, Fexofenadine Hydrochloride tablets, 12HR, 60mg Antihistamine, 12 count bottle, Distributed Topco Associates LC, Elk Grove Village, IL 60007, Made in the Czech Republic, NDC 36800-954-53 UPC 0 36800 33284 3

Product Quantity:
26,304 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0349-2022

Code Information:
Lot # 0LE2178, Exp 01/31/2022

Product Description:
TopCare Allergy Relief, Fexofenadine Hydrochloride tablets, 24HR, 180mg Antihistamine, packaged as a) 5 count bottle, NDC 36800-319-13 UPC 0 36800 33277-5 b) 15 count bottle, NDC 36800-319-22 UPC 0 36800 33278 2; c) 45 count bottle, NDC 36800-319-95 UPC 0 36800 33280-5; d) 90 count bottle, NDC 36800-319-75 UPC 0 36800 33282 9; Distributed Topco Associates LC, Elk Grove Village, IL 60007, Made in the Czech Republic,

Product Quantity:
13,656 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0350-2022

Code Information:
Lot # a) 0KE2429, Exp 02/28/2022; b) 0HE2530, Exp 12/31/2021; c)0FR0460, Exp 02/28/2022; d)0GR0531, Exp 03/31/2022 ; 0KR0465, Exp 04/302022

Product Description:
up&up allergy relief, Fexofenadine Hydrochloride tablets, 24HR, 180mg/antihistamine, packaged as a) 15 count bottle, NDC 11673-571-22 UPC 3 70030 62303 7; b) 30 count bottle, NDC 11673-571-39 UPC 3 70030 62301 3; Distributed by Target Corp., Mpls., MN 55403, Made in the Czech Republic,

Product Quantity:
7,272 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0351-2022

Code Information:
Lot a) 1AE2334, Exp 02/28/2022; b) 1BR0462, Exp 10/31/2022

Product Description:
Wal-Fex Fexofenadine Hydrochloride tablets, 180mg/antihistamine, 24HR, packaged as a) 5 count bottle, NDC 0363-0600-13,UPC 3 11917 12267 0, b)30 count bottle, NDC 0363-0600-39 UPC 3 11917 16172 3 c) 90 count bottle, NDC 0363-0600-75 UPC 3 11917 12271 7 ; Distributed by Walgreen Co. 200 Wilmot Rd Deerfield IL 60015, Made in the Czech Republic,

Product Quantity:
14,160 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0352-2022

Code Information:
Lot # a)0JE2406, Exp 02/28/2022 b) 0FR0459, Exp 02/28/2022. c) 0KR0465, Exp 04/30/2022

Product Description:
Wal-Fex Fexofenadine Hydrochloride tablets, 60mg/antihistamine, 12HR, 24 count bottle, Distributed by Walgreen Co. 200 Wilmot Rd Deerfield IL 60015, Made in the Czech Republic, NDC 0363-0903-62 UPC 3 11917 18625 2

Product Quantity:
4,536 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0353-2022

Code Information:
Lot # 0KE2447, 0KE2982, Exp 01/31/2022; 0ME2515, Exp 04/30/2022

Product Description:
amazon basic+care, Allergy Fexofenadine Hydrochloride Tablets, 60 mg/Antihistamine, 12HR, 100 count bottle, Made in the Czech Republic, Distributed by: Amazon.com services LLC 410 Terry Avenue N., Seattle WA 98109, NDC 72288-425-78 UPC 3 70030 14536 2

Product Quantity:
38,352 bottles

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0354-2022

Code Information:
Lot # 1AR0558, Exp 7/31/2022

Product Description:
KIRKLAND ALLER-FEX, Fexofenadine Hydrochloride Tablets, 180 mg/Antihistamine, 24HR, 180 count bottle, Made in the Czech Republic, Packaged by Perrigo 515 Eastern Ave., Allegan, MI 49010, For Costco Wholesale Corporation. P.O. Box 34535 Seattle, WA 98124-1535, NDC 63981-571-48, UPC 0 96619 98776 4

Product Quantity:
42,026 containers

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0355-2022

Code Information:
Lot # 0HV1246, exp 1/1/2022; 0GV1974, 0GV1459, exp 2/1/2022, 0HV1438, exp 3/1/2022, 0KV2116, 0KV2117, exp 5/1/2022; 0KV2119, 0LV2196, 0MV2203, 0MV2204, 0MV2205, exp 6/1/2022;

Product Description:
CVS Allergy Relief, Fexofenadine Hydrochloride Tablets, 180 mg Antihistamine, 24HR, 30 count bottle, NDC 69842-698-39, UPC 0 50428 62564 4

Product Quantity:
2,784 bottles

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0356-2022

Code Information:
Lot # 1DV1855, exp 4/1/2022

Product Description:
GoodSense Aller.Ease, Fexofenadine hydrochloride 24 HR, 180 mg tablets, 30 count bottle, Made in the Czech Republic, Distributed by Perrigo Allergan MI., 49010, UPC 3 0113 0571 39 3; NDC 0113-0571-30,

Product Quantity:
3,168 bottles

Reason for Recall:
Out of specification impurity A result obtained during stability testing.

Recall Number:
D-0357-2022

Code Information:
Lot # 0MV2158, exp 6/1/2022

Class II Drugs Event

Event ID:
88927

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/22/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/06/2022

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:
Pregabalin Capsules, 50 mg, 100 count bottle, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Ltd., Survey No. 259/15 Dadra-396 191, (U.T. of D & NH), India, NDC 47335-687-88.

Product Quantity:
696 Bottles

Reason for Recall:
Failed Tablet/Capsule Specifications: Out of Specification results for particle Size Distribution and Bulk Density of the Active Pharmaceutical Ingredient.

Recall Number:
D-0361-2022

Code Information:
Lot number: DNC0342A, expiration 01/2023

Class II Drugs Event

Event ID:
89214

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/29/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/04/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
ULTRAtab Laboratories, Inc.
50 Toc Dr
Highland NY United States

Distribution Pattern:

Product was distributed to one customer who may have further distributed the product.

Associated Products

Product Description:
PAIN AID ESF- (Acetaminopehn USP 250mg, Asprin USP 250mg Caffeine 65mg) coated, bulk OTC tablets packaged in corrugated boxes lined with 2 polyethylene bags 100 lb, ULTRAtab Laboratories, Inc. NDC# 62959-560-00, Product Code M560L

Product Quantity:
14 bulk lots (approximately 1,987,951 tablets each)

Reason for Recall:
CGMP Deviations: failed stability results, inadequate laboratory investigations,

Recall Number:
D-0327-2022

Code Information:
Bulk Lots: 18K070, exp. date Nov-21; 19A046, exp. date Jan-22; 19C073, exp. date Mar-22; 19E014, exp. date May-22; 19G039, exp. date Jul-22; 19K002, exp. date Nov-22; 20A013, exp. date Jan-23; 20B050, exp. date Feb-23; 20C011, exp. date Mar-23; 20C049, exp. date Mar-23; 20F071, exp. date Jun-23; 20F072, exp. date Jun-23; 20G033, exp. date Jul-23; 20G041, exp. date Jul-23.

Class II Drugs Event

Event ID:
89259

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/21/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/05/2022

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
USA nationwide.

Associated Products

Product Description:
Cefixime Capsules, 400 mg, 50-count bottles, Rx only, Manufactured by: Alkem Laboratories Ltd., Mumbai, India, Distributed by: Ascend Laboratories, LLC, Parsippany, NJ, NDC 67877-584-50

Product Quantity:
42,698 bottles

Reason for Recall:
Failed impurities/degradation specifications

Recall Number:
D-0359-2022

Code Information:
Lot #: 20140293, Exp Dec 2021; 20141525, 20141526, 20141527, Exp Mar 2022; 20143019, 20143020, 20143021, 20143022, Exp July 2022; 20144759, 20144760, 20144761, Exp Nov 22

Class II Drugs Event

Event ID:
89322

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/29/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/05/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RemedyRepack Inc.
625 Kolter Dr Ste 4
Indiana PA United States

Distribution Pattern:
Product was distributed to two direct accounts in MI and PA.

Associated Products

Product Description:
Cefixime 400 mg capsule, packaged in a) 2-count bottle (NDC 70518-2749-02), b) 2-count blister pack (NDC 70518-2749-03), Rx only, MFG: Ascend Labs, LLC, Montvale, NJ 07645

Product Quantity:
a) 716 bottles/ 1432 capsules b) 223 blister packs/ 466 capsules

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0360-2022

Code Information:
Lot #: a) B1429436-110821, Exp 07/2022; B1429434-110821, Exp 11/2022; B1429435-110821, Exp 11/2022; B1279449-072021, Exp 07/2022; B1279457-072021, Exp 07/2022; B1279442-072021,Exp 07/2022; B1057718-012621, Exp 01/2022; B1057727-012621, Exp 01/2022; b) B1358139-092121, Exp 03/2022; B1424654-110421, B1437578-111421, Exp 05/2022

Class III Drugs Event

Event ID:
89268

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/22/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/04/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore MD United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Gatifloxacin Ophthalmic Solution, 0.5%, 2.5 mL bottle, Rx only, Manufactured by: Lupin Limited, Pithampur (M.P.) 454 775, INDIA, NDC 68180-435-01.

Product Quantity:
50,832 bottles

Reason for Recall:
Failed Stability Specifications: Out-of-specification results observed in a water loss test that might affect the assay content and alter drug concentration.

Recall Number:
D-0326-2022

Code Information:
Lot #: H003037, exp. date May 2022; H100132, exp. date June 2022; H100847, exp. date October 2022

Class III Drugs Event

Event ID:
89324

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/29/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/05/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore MD United States

Distribution Pattern:
Product Distributed in NY and OH.

Associated Products

Product Description:
Oxycodone Hydrochloride Tablets, USP C-II, 5 mg, 100 count bottles, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, MD 21202. Manufactured by: Novel Laboratories, Inc. Somerset, NJ 08873. NDC 43386-432-01

Product Quantity:
23,965 100 count bottles

Reason for Recall:
Out-of-specification impurity test result observed at 18-month long term stability time point.

Recall Number:
D-0358-2022

Code Information:
Lot # S000268, Exp. date January 2022