Enforcement Report - Week of November 3, 2021

Class II Drugs Event

Event ID:
88693

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/13/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/26/2021

Initial Firm Notification of Consignee or Public:

Recalling Firm:
First Royal Care Co. LLC, dba Red Mountain Compounding Pharmacy
6828 E Brown Rd Ste 101
Mesa AZ United States

Distribution Pattern:
494 patients/consumers received prescriptions and are located in AZ, CA FL, MN, MT, TX, and UT.

Associated Products

Product Description:
Calcium Chloride, 100 mg/mL MDV INJ, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0028-2022

Code Information:
all lots within expiry

Product Description:
Magnesium Chloride, 200 mg/mL MDV INJ, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0029-2022

Code Information:
all lots within expiry

Product Description:
LEVOCARNITINE 100MG/ML MDV SOLN, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0030-2022

Code Information:
all lots within expiry

Product Description:
ASCORBIC ACID (NON-CORN) 500MG/ML MDV SOLN, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0031-2022

Code Information:
all lots within expiry

Product Description:
ASCORBIC ACID (NON-CORN) 500MG/ML SOLN (PF), Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0032-2022

Code Information:
all lots within expiry

Product Description:
ASCORBIC/GLUTATHIONE 1.25/1.25% OPTH SOLN, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0033-2022

Code Information:
all lots within expiry

Product Description:
CYCLOSPORIN 0.2% OIL OPTH SUSP, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0034-2022

Code Information:
all lots within expiry

Product Description:
CYCLOSPORINE 2% MCT OIL SUSP, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0035-2022

Code Information:
all lots within expiry

Product Description:
DEXPANTHENOL 250MG/ML INJ SOLN, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0036-2022

Code Information:
all lots within expiry

Product Description:
ESTRADIOL VALERATE 5MG/ML MDV INJ, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0037-2022

Code Information:
all lots within expiry

Product Description:
GLUTATHIONE 200MG/ML MDV, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0038-2022

Code Information:
all lots within expiry

Product Description:
HYDROXYPROG CAPROATE 250MG/ML OIL INJ, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0039-2022

Code Information:
all lots within expiry

Product Description:
LEVOCARNITINE 100MG/ML MDV SOLN, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0040-2022

Code Information:
all lots within expiry

Product Description:
PYRIDOXINE HCL (B6) 100MG/ML MDV, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0041-2022

Code Information:
all lots within expiry

Product Description:
TEST CYP 100MG/ML IN ETHYL OLEATE OIL, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0042-2022

Code Information:
all lots within expiry

Product Description:
TEST CYP 200MG/ML IN SESAME OIL MDV, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0043-2022

Code Information:
all lots within expiry

Product Description:
TEST CYP 200MG/ML MDV ETHYL OLEATE, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0044-2022

Code Information:
all lots within expiry

Product Description:
TEST CYP 25MG/ML IN ETHYL OLEATE MDV, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0045-2022

Code Information:
all lots within expiry

Product Description:
TEST CYP 50MG/ML IN ETHYL OLEATE OIL, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0046-2022

Code Information:
all lots within expiry

Product Description:
TEST CYP/PROP 160/40MG/ML MDV IN ETHYL OLEATE, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0047-2022

Code Information:
all lots within expiry

Product Description:
TEST CYP/PROP/DECA-NAN 125MG/ML (80/10/10) IN SESAME OIL, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0048-2022

Code Information:
all lots within expiry

Product Description:
TEST CYP/PROP/DECA-NAN 125MG/ML (80/10/10) IN SESAME OIL, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0049-2022

Code Information:
all lots within expiry

Product Description:
TESTOSTERONE ULTRA 250MG/ML MDV IN SESAME OIL, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0050-2022

Code Information:
all lots within expiry

Product Description:
VIT B COMPLEX INJ SOLN (HP), Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0051-2022

Code Information:
all lots within expiry

Product Description:
VIT B COMPLEX INJ SOLN (HP), Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0052-2022

Code Information:
all lots within expiry

Product Description:
ACETYLCYSTEINE 10% OPTH SOLN, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0053-2022

Code Information:
all lots within expiry

Product Description:
ACETYLCYSTEINE 2% OPTH SOLN, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0054-2022

Code Information:
all lots within expiry

Product Description:
BENZALKONIUM CHLORIDE 0.013% SOLUTION, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0055-2022

Code Information:
all lots within expiry

Product Description:
CALCIUM GLUCONATE 10% INJ (PF), Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0056-2022

Code Information:
all lots within expiry

Product Description:
FOLIC ACID 10MG/ML MDV INJ, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0057-2022

Code Information:
all lots within expiry

Product Description:
METHYLCOBALAMIN 10,000MCG/ML MDV INJ, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0058-2022

Code Information:
all lots within expiry

Product Description:
METHYLCOBALAMIN 1000MCG/ML MDV INJ, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0059-2022

Code Information:
all lots within expiry

Product Description:
METHYLCOBALAMIN 12.5MG/ML MDV INJ SOLN, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0060-2022

Code Information:
all lots within expiry

Product Description:
METHYLCOBALAMIN 5000MCG/ML MDV INJ, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0061-2022

Code Information:
all lots within expiry

Product Description:
MIC 25/50/50MG/ML MDV, Rx only,Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0062-2022

Code Information:
all lots within expiry

Product Description:
MIC/B12A 25/50/50MG/ML 1MG/ML MDV, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0063-2022

Code Information:
all lots within expiry

Product Description:
MIC/B12A/B6 15/50/100 5MG/50MG/ML MDV, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0064-2022

Code Information:
all lots within expiry

Product Description:
MIT/B12 25/50/50MG/ML 1MG/ML MDV, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0065-2022

Code Information:
all lots within expiry

Product Description:
PROGESTERONE 100MG/ML MDV OIL INJECTION, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0066-2022

Code Information:
all lots within expiry

Product Description:
SODIUM SELINITE 200MCG/ML FOR INJ, Rx only, Red Mountain Compounding Rx

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection raised sterility assurance concerns

Recall Number:
D-0067-2022

Code Information:
all lots within expiry

Class III Drugs Event

Event ID:
88806

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/12/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/26/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Loratadine-D Extended-Release Tablets (Loratadine and Pseudoephedrine Sulfate, Extended-Release Tablets, USP 10mg/240mg) , 10-count blister packs, Distributed By Major Pharmaceuticals, 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152, NDC 0904-5833-15

Product Quantity:
22,752 blister packs

Reason for Recall:
Failed Moisture Limits

Recall Number:
D-0068-2022

Code Information:
Lot #: AC14635, Exp. Date 12/2022

Product Description:
AllerClear D-24 hr, (Loratadine and Pseudoephedrine Sulfate, Extended-Release Tablets, USP 10/240mg), 15-count blister packs, Manufactured by: Ohm Laboratories Inc., 1385 Livingston Avenue, North Brunswick, NJ 08902, NDC 63981-724-15

Product Quantity:
46,584 blister packs

Reason for Recall:
Failed Moisture Limits

Recall Number:
D-0069-2022

Code Information:
AC09723, Exo, Date 11/2022

Class III Drugs Event

Event ID:
88843

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/13/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/26/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ultra Seal Corporation
521 Main St
New Paltz NY United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
PainAway II (Acetaminophen 250 mg/Aspirin 250 mg/Caffeine 65 mg) tablets , 2 tablets/pk, packaged in 12,000 Packets/Case, Material # 11161, Mfg. for Respond Industries First Aid, Mason, OH 45040 (Shipping Label)

Product Quantity:
2,484,274 tablets

Reason for Recall:
Failed Stability Specifications: Out-of-Specification results observed for Aspirin related compound Salicylic Acid.

Recall Number:
D-0070-2022

Code Information:
Lot #: AK-9336, exp. date 21-Oct; K9406, AK-9407, exp. date 21-Dec; K-9860, exp. date 22-Oct; AK-1057, exp. date 23-Feb

Product Description:
Vica-Cet BACK PAIN RELIEF (Acetaminophen 250 mg/Aspirin 250 mg/Caffeine 65 mg) tablets, 2 tablets/pk, packaged in 10,000 packets, PO# 8967, Mfg. for Tellus/The Provision First Aid Line (Shipping Label)

Product Quantity:
1,367,525 tablets

Reason for Recall:
Failed Stability Specifications: Out-of-Specification results observed for Aspirin related compound Salicylic Acid.

Recall Number:
D-0071-2022

Code Information:
Lot #: AK-9455, exp. date 22-Jan; AK-1109, AK-1110, exp. date 23-Mar; K-9821, exp. date 22-Sep

Product Description:
ZEE+ painaid ESF Extra-Strength Formula (Acetaminophen 250 mg, Aspirin 250 mg (NSAID), Caffeine 65 mg) tablets, 2 Tablets per/package, Packaged in a) 50-count packages/carton, b) 125-count packages/carton, PA-ESF 1414Z, Dist. by: Zee Medical Distributors, LLC Mason, OH 45040 (Shipping Label)

Product Quantity:
1,968,150 tablets

Reason for Recall:
Failed Stability Specifications: Out-of-Specification results observed for Aspirin related compound Salicylic Acid.

Recall Number:
D-0072-2022

Code Information:
Lot #: AK-9547, exp. date 22- Apr; AK-9941, exp. date 22-Dec

Product Description:
AERO Tab PAIN RELIEVER (Acetaminophen 250 mg/Aspirin 250 mg/Caffeine 65 mg) tablets , 2 tablets Per Packet, Packaged in 10,000 Packets/Case, PO# 11938, Mfg. for: Aero Healthcare, Valley Cottage, NY 10989 (Shipping Label)

Product Quantity:
1,480,981 tablets

Reason for Recall:
Failed Stability Specifications: Out-of-Specification results observed for Aspirin related compound Salicylic Acid.

Recall Number:
D-0073-2022

Code Information:
Lot #: K-1278, exp. date 23-Jul; K-9371, AK-9463, exp. date 21-Nov; AK-9821, AK-9819, exp. date 22-Sep; 1107, exp. date 23-Mar.

Product Description:
North by Honeywell PAIN STOPPER EXTRA STRENGTH (Acetaminophen 250 mg, Aspirin 250 mg, Caffeine 65 mg) tablets, 2 tablets per packet, Packaged in 5,000 Packets/Case, PO# B121242, Item# 853500-01, Dist. By Honeywell Safety Products USA, Smithfield, RI 02917

Product Quantity:
250,000 tablets

Reason for Recall:
Failed Stability Specifications: Out-of-Specification results observed for Aspirin related compound Salicylic Acid.

Recall Number:
D-0074-2022

Code Information:
Lot #: AK-9371, exp. date 21-Nov

Product Description:
Advance Formula Pain Reliever (Acetaminophen 250 mg/Aspirin 250 mg/Caffeine 65 mg) tablets, 2 tablets Per Packet, Packaged in 12,000 Packets/Case, PO# 007564-00, Item# 1170, Mfg. for: Advanced First Aid, Baltimore, MD 21237; American Safety & First Aid, Osceola, IN 46561 (Shipping Label)

Product Quantity:
991,310 tablets

Reason for Recall:
Failed Stability Specifications: Out-of-Specification results observed for Aspirin related compound Salicylic Acid.

Recall Number:
D-0075-2022

Code Information:
Lot #: AK-9457, exp. date 22-Jan; AK-9521, exp. date 22-Mar; AK-9959, exp. date 22-Dec; AK-1017, exp. date 23-Jan

Product Description:
Xpect First aid Extra Strength PAIN AWAY (Acetaminophen 250 mg/Aspirin 250 mg/Caffeine 65 mg) tablets, 2 Tablets/package, Packaged in 12,000 Packets/Case, Material# 111519, Mfg. for: Cintas First Aid & Safety, Mason, OH 45040 (Shipping Label)

Product Quantity:
42,394,018 tablets

Reason for Recall:
Failed Stability Specifications: Out-of-Specification results observed for Aspirin related compound Salicylic Acid.

Recall Number:
D-0076-2022

Code Information:
Lot #: K-9335, AK-9419, exp. date 21-Oct; AK-9369, exp. date 21- Nov; AK-9403, exp. date 21-Dec; AK-9452, K-9455, 9455, exp. date 22-Jan; AK-9586, exp. date 22-Feb; AK-9525, AK-9526, AK-9639, exp. date 22-Mar; AK-9568, AK-9569, AK-9567, AK-9692, exp. date 22-Apr; AK-9615, exp. date 22-May; AK-9666, exp. date 22-Jun; AK-9714, K-9714, AK-9718, K-9718, 9718, exp. date 22-Jul, AK-9719, exp. date 22-Jul; AK-9771, AK-9765, AK-9769, exp. date 22-Aug; AK-9822, AK-9818, exp. date 22-Sep; AK-9860, exp. date 22-Oct; AK-9957, exp. date 22-Dec; AK-1011, K-1014, 1014, AK-9489, exp. date 23-Jan; 1055, K-1057, 1057, AK-1058, exp. date 23-Feb; AK-1108, AK-1113, K-1199, AK-1199,

exp. date 23-May; AK-1240, 1240, exp. date 23-Jun; AK-9335, exp. date 10/21; AK-9406, exp. date 21-Dec; AK-1278, exp. date 23-Jul; K-1240, exp. date 23-Jun

Product Description:
Afassco Pain Free Plus X-STRENGTH PAIN RELIEVER (Acetaminophen 250 mg/Aspirin 250 mg/Caffeine 65 mg) tablets, 2 Tablets/package, Packaged in 12,000 Packets/Case, PO# 19540, Mfg. for: Afassco Minden, NV 89423 (Shipping Label)

Product Quantity:
519,600 tablets

Reason for Recall:
Failed Stability Specifications: Out-of-Specification results observed for Aspirin related compound Salicylic Acid.

Recall Number:
D-0077-2022

Code Information:
Lot #: 9819, K-9819, exp. date 22-Sep

Class III Drugs Event

Event ID:
88872

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/18/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/28/2021

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 the United States

Associated Products

Product Description:
Rizatriptan Benzoate Film Coated Tablets, 10 mg, packaged in a) 12 Tablets (2X6 Unit-Dose Tablets) Blister Packs, NDC 33342-088-45), b) 18 Tablets (3 x 6 Unit-Dose Tablets, NDC 33342-088-41) Rx only, Manufactured for: Macleods Pharma USA, Inc. Plainsboro, NJ 08536l Manufactured by: Macleods Pharmaceuticals Ltd. Baddi, Himachal Pradesh, INDIA

Product Quantity:
135,082 Blister Packs/2,431,476 tablets

Reason for Recall:
Out-of-specification test results obtained in Organic Impurities test during analysis of controlled samples.

Recall Number:
D-0078-2022

Code Information:
Lot #: BRJ2112A, BRJ2113A, BRJ2114A, BRJ2114B, exp. date 04/2024

Product Description:
Rizatriptan Benzoate Orally Disintegrating Tablets 5mg, 12 Tablets (2 x 6 Unit-Dose Tablets) Blister Packs, Rx only, Manufactured for: Macleods Pharma USA Inc. Plainsboro, NJ 08536, Manufactured by: Macleods Pharmaceuticals Ltd. Baddi, Himachal Pradesh, INDIA, NDC 33342-093-41

Product Quantity:
13,260 Blister Packs/238,680 tablets

Reason for Recall:
Out-of-specification test results obtained in Organic Impurities test during analysis of controlled samples.

Recall Number:
D-0079-2022

Code Information:
Lot #: BRL2102A, BRL2103A, exp. date 04/2025

Product Description:
Rizatriptan Benzoate Orally Disintegrating Tablets 10mg, 18 Tablets (3 x 6 Unit-Dose Tablets) Blister Packs, Rx only, Manufactured for: Macleods Pharma USA Inc. Plainsboro, NJ 08536, Manufactured by: Macleods Pharmaceuticals Ltd. Baddi, Himachal Pradesh, INDIA, NDC 33342-094-41

Product Quantity:
643,800 Blister Packs /888,336 Tablets

Reason for Recall:
Out-of-specification test results obtained in Organic Impurities test during analysis of controlled samples.

Recall Number:
D-0080-2022

Code Information:
Lot #: BRM2111A, BRM2112A, BRM2113A, BRM2114A, BRM2115A, BRM2116A, exp. date 04/2025

Class III Drugs Event

Event ID:
88885

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/20/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/02/2021

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:
16,272 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-0091-2022

Code Information:
Lot # H002512, exp. date March 2022