Enforcement Report - Week of May 15, 2024

Class I Drugs Event

Event ID:
94369

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/08/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/06/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton, NJ 08540-6623
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Javygtor (sapropterin dihydrochloride) Powder for Oral Solution 100mg, 30 individual packets per carton, Rx Only, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540 Made in India, NDC 43598-097-30.

Product Quantity:
17,332 cartons

Reason for Recall:
Sub-potent Drug; powder discoloration associated with decreased potency

Recall Number:
D-0485-2024

Code Information:
Lot #: T2202812, Exp. 07/31/2025; T2204053, Exp. 10/31/2025; T2300975, T2300976, Exp. 02/28/2026; T2304356, Exp. 08/31/2026.

Product Description:
Sapropterin Dihydrochloride Powder for Oral Solution 100mg, 30 individual packets per carton, Rx Only, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540, Made in India, NDC 43598-477-30.

Product Quantity:
2402 cartons

Reason for Recall:
Sub-potent Drug; powder discoloration associated with decreased potency

Recall Number:
D-0486-2024

Code Information:
Lot # T2200352, Exp. 12/31/2024

Class II Drugs Event

Event ID:
94442

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/19/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/08/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton, NJ 08540-6620
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Amphotericin B Liposome for Injection, 50mg vials, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Medicare Limited, Baska Ujeti Road, Ujeti Halol-389350, Gujarat, India. NDC 62756-233-01

Product Quantity:
11,016 vials

Reason for Recall:
Out of specification for assay

Recall Number:
D-0493-2024

Code Information:
Lot #: BAE0055A, BAE0056A, BAE0068A, Exp. Date 03/2026

Class II Drugs Event

Event ID:
94466

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/25/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/07/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
FDC Limited
B-8 MIDC Industrial Area Waluj District
Aurangabad, Maharashtra State
India

Distribution Pattern:
New Jersey Only

Associated Products

Product Description:
Timolol Maleate Ophthalmic Solution, USP, 0.5%, packaged in a) 5mL bottles (NDC 64980-514-05), and b) 15 mL bottles (NDC 64980-514-15), Rx only, Manufactured by: FDC Limited, Maharashtra, India, Distributed by: Rising Pharmaceuticals, Inc, NJ

Product Quantity:
382,104 units

Reason for Recall:
Defective Container: yellow-colored spike from cap lodged in the nozzle. Firm received several complaints from customers.

Recall Number:
D-0488-2024

Code Information:
Lot #: a) 083H008, Exp. Date 07/2025; 083G003, Exp. Date 06/2025; 083J017, Exp. Date 09/2025; b) 083I013, Exp. Date 08/2025.

Class II Drugs Event

Event ID:
94467

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/26/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/07/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Rubicon Research Private Limited
4 & K30 5 Plot No K - 30 District
Ambarnath
India

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
traMADol Hydrochloride Tablets, USP 50 mg, 1000-count bottle, Rx Only, Distributed by: Advagen Pharma Limited, 666 Plainsboro Road Suite 605, Plainsboro, NJ, 08536, USA, Manufactured by: Rubicon Research, Private Limited, Ambernath, Dist. Thane, 421506 India NDC 72888-080-00

Product Quantity:
2,592 1000-count Bottles

Reason for Recall:
Presence of Foreign Tablets: Pharmacist reported a tablet of baclofen in a bottle of 1000-count tramadol

Recall Number:
D-0487-2024

Code Information:
Lot #: 230774HI, Exp 4/30/2026

Class II Drugs Event

Event ID:
94483

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/29/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/04/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Breckenridge Pharmaceutical, Inc
15 Massirio Dr Ste 201
Berlin, CT 06037-2352
United States

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Duloxetine Delayed-Release Capsules, USP, 30mg, Rx Only, (a) 90-count bottles (NDC 51991-747-90), (b) 1000-count bottles (NDC 51991-747-10), Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Dist. by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922.

Product Quantity:
281,554/90 & 1000 count bottles

Reason for Recall:
CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-nitroso-duloxetine, above the proposed interim limit.

Recall Number:
D-0482-2024

Code Information:
220265: Exp. Feb 2025 220088: Exp. Nov 2024 220267: Exp. Feb 2025 220256: Exp. Feb 2025 220225: Exp. Jan 2025 220269: Exp. Feb 2025

Product Description:
Duloxetine Delayed-Release Capsules, USP, 20 mg, , 500-count bottles, Rx Only, Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Dist. by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922, NDC 51991-746-05.

Product Quantity:
7,188/ 500 count bottles

Reason for Recall:
CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-nitroso-duloxetine, above the proposed interim limit.

Recall Number:
D-0483-2024

Code Information:
220456: Exp. Feb 2025

Product Description:
Duloxetine Delayed-Release Capsules, USP, 60 mg, 90-count bottles, Rx Only, Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Dist. by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922, NDC: 51991-748-90.

Product Quantity:
281,554/90 count bottles

Reason for Recall:
CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-nitroso-duloxetine, above the proposed interim limit.

Recall Number:
D-0484-2024

Code Information:
230028C: Exp. Nov 2025 230106C: Exp. Dec 2025 230170C: Exp. Dec 2025 220039: Exp. Dec 2024 220363: Exp. Feb 2025

Class II Drugs Event

Event ID:
94500

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/24/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/08/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aurobindo Pharma USA Inc.

279 Princeton Hightstown Rd
East Windsor, NJ 08520-1401
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Clorazepate Dipotassium Tablets, USP, 3.75 mg, a) 100 tablets per bottle, NDC 13107-282-01 b) 500 tablets per bottle, NDC 13107-282-05, Rx Only, Distributed by Aurobindo Pharma USA, Inc., 279 Princeton-Hightstown Road, East Windsor, NJ 08520, Made in India.

Product Quantity:
6696 bottles

Reason for Recall:
Discoloration: Dotted and yellow spots on tablets

Recall Number:
D-0491-2024

Code Information:
Lot #s: a) CZA124001B, CZA124002B, CZA124003B, Exp. 12/31/2025; b) CZA124001A, CZA124003A, Exp. 12/31/2025.

Product Description:
Clorazepate Dipotassium Tablets, USP, 7.5 mg, a) 100 tablets per bottle, NDC 13107-283-01, b) 500 tablets per bottle, NDC 13107-283-05, Rx Only, Distributed by Aurobindo Pharma USA, Inc., 279 Princeton-Hightstown Road, East Windsor, NJ 08520, Made in India.

Product Quantity:
6909 bottles

Reason for Recall:
Discoloration: Dotted and yellow spots on tablets

Recall Number:
D-0492-2024

Code Information:
Lot #s: a) CZB124001B, CZB124002B, CZB124003B, Exp. 12/31/2025; b) CZB124001A, CZB124003A, Exp. 12/31/2025.

Class III Drugs Event

Event ID:
94485

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/24/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/08/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Acella Pharmaceuticals, LLC
1880 Mcfarland Pkwy Ste 110
Alpharetta, GA 30005-1795
United States

Distribution Pattern:
Nationwide in the US and Puerto Rico.

Associated Products

Product Description:
Sodium Sulfacetamide 10% - Sulfur 5% Cleanser, Rx Only, 6 oz (170.3 g) Bottle, Manufactured for Acela Pharmaceuticals, LLC Alphareta, GA

30005, NDC 42192-136-06

Product Quantity:
7104 Bottles

Reason for Recall:
Subpotent drug

Recall Number:
D-0490-2024

Code Information:
Lot # 22085 Exp. date 08/02/2024