

Enforcement Report - Week of November 6, 2024

Class II Drugs Event

Event ID:

95500

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

10/09/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/28/2024

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:

USA Nationwide.

Associated Products

Product Description:

Cinacalcet Tablets, 30 mg, 30-count bottle, Rx Only, Dr. Reddy's Laboratories Inc, Princeton, NJ 08540, Made in India, NDC 43598-367-30.

Product Quantity:

285126 bottles

Reason for Recall:

CGMP Deviations: Presence of N-nitroso Cinacalcet impurity above FDA recommended interim limit

Recall Number:

D-0026-2025

Code Information:

Lot# T2200120, T2200121, T2200119, T2200116, T2200118, T2200117, Exp 11/2024; T2200695, T2200694, T2200696, T2200697, Exp 01/2025; T2201426, T2201428, T2201432, T2201427, T2201430, T2201429, T2201431, Exp 03/2025; T2202743, T2202742, T2202741, Exp 06/2025; T2203081, T2203079, T2203080, T2203082, T2203083 & T2203084, Exp 07/2025; T2300770, T2300771, T2300769, T2300766, T2300767 & T2300768, Exp 12/2025 Lots T2301663, T2301665, T2301662, T2301664, T2301667, T2301661, T2301666, T2301660, T2301658 & T2301659, Exp Date 02/2026 Lots T2304704, T2304703, T2304705, T2304706, Exp Date 08/2026 Lots T2400468, T2400469, T2400473 & T2400474 Exp Date 11/2026

Product Description:

Cinacalcet Tablets, 60 mg, 30-count bottles, Rx Only, Dr. Reddy's Laboratories Inc, Princeton, NJ 08540, Made in India, NDC 43598-368-30.

Product Quantity:

35880 bottles

Reason for Recall:

CGMP Deviations: Presence of N-nitroso Cinacalcet impurity above FDA recommended interim limit

Recall Number:

D-0027-2025

Code Information:

Lot# T2200698, Exp 01/2025; T2201444, Exp 03/2025; T2202827, Exp 06/2025; T2300531, Exp 12/2025; T2301696, Exp 02/2026; T2304726, Exp 08/2026; T2400480, Exp 11/2026.

Product Description:

Cinacalcet Tablets, 90 mg, 30-count bottle, Rx Only, Dr. Reddy's Laboratories Inc, Princeton, NJ 08540, Made in India., NDC 43598-369-30.

Product Quantity:

10584 bottles

Reason for Recall:

CGMP Deviations: Presence of N-nitroso Cinacalcet impurity above FDA recommended interim limit

Recall Number:

D-0028-2025

Code Information:

Lot# T2201443, Exp 03/2025; T2300664, Exp 12/2025.

Class II Drugs Event

Event ID:

95501

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

10/10/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/31/2024

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

ACCORD HEALTHCARE, INC.
8041 Arco Corporate Dr Ste 200
Raleigh, NC 27617-2010
United States

Distribution Pattern:

Nationwide in the USA and PR

Associated Products

Product Description:

Cinacalcet Tablets 30 mg, Rx Only, a) 30 Tablets per bottle, NDC: 16729-440-10, b) 90 Tablets per bottle, NDC: 16729-440-15, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703, Manufactured by: Intas Pharmaceuticals Limited, Ahmedabad - 382 210, INDIA.

Product Quantity:

N/A

Reason for Recall:

Failed Impurities/Degradation Specifications: the presence of a nitrosamine impurity, N-nitroso-cinacalcet, above the acceptable daily intake (ADI) limits.

Recall Number:

D-0030-2025

Code Information:

a) Lot #: Expiry Date: M2118190 11/2024 M2201091 11/2024 M2206241 11/2024 M2206451 04/2025 M2208674 06/2025 M2213850 08/2025 M2215221 09/2025 M2216236 11/2025 M2217098 11/2025 M2300664 11/2025 b) Lot #: Expiry Date: M2210808 06/2025 M2212212 08/2025 M2214435 09/2025 M2217097 11/2025 M2301921 01/2026

Product Description:

Cinacalcet Tablets, 60 mg, Rx Only, a) 30 Tablets per bottle, NDC: 16729-441-10, b) 90 Tablets per bottle, NDC: 16729-441-15, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Ahmedabad - 382 210, INDIA.

Product Quantity:

N/A

Reason for Recall:

Failed Impurities/Degradation Specifications: the presence of a nitrosamine impurity, N-nitroso-cinacalcet, above the acceptable daily intake (ADI) limits.

Recall Number:

D-0031-2025

Code Information:

a) Lot #: Expiry Date: M2204481 02/2025 M2212389 08/2025 M2214271 09/2025 M2215970 10/2025 M2216458 10/2025 b) Lot #: Expiry Date: M2212869 08/2025 M2216362 09/2025 M2215969 10/2025

Product Description:

Cinacalcet Tablets, 90 mg, Rx Only, a) 30 Tablets per bottle, NDC: 16729-442-10, b) 90 Tablets per bottle, NDC: 16729-442-15, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Ahmedabad - 382 210, INDIA.

Product Quantity:

N/A

Reason for Recall:

Failed Impurities/Degradation Specifications: the presence of a nitrosamine impurity, N-nitroso-cinacalcet, above the acceptable daily intake (ADI) limits.

Recall Number:

D-0032-2025

Code Information:

a) Lot #: Expiry Date: M2303264 01/2026 b) Lot #: Expiry Date: M2306979 04/2026

Class II Drugs Event

Event ID:

95590

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

10/21/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/30/2024

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

BLI International, Inc.
75 N Industry Ct
Deer Park, NY 11729-4601
United States

Distribution Pattern:

Product was shipped to two private label customers (OH & MO) as a final packaged product.

Associated Products

Product Description:

Chlorpheniramine Maleate 4 mg tablets, 24-count bottle, Manufactured For: Athlete's Needs, Novi, MI 48377, NDC 53185-277-24

Product Quantity:

4,901 cases/24 count each case

Reason for Recall:

Superpotent Drug: Stability failure for assay at 6 months test time-point.

Recall Number:

D-0029-2025

Code Information:

Lot # 24A27724, Exp 01/31/2027