Enforcement Report - Week of April 12, 2023

Class II Drugs Event

Event ID:
91710

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/15/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/31/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Azurity Pharmaceuticals, Inc.
841 Woburn St
Wilmington MA United States

Distribution Pattern:
US Nationwide

Associated Products

Product Description:
Testosterone Cypionate Injection, USP, CIII, 200 mg/mL, packaged in: a) 10 mL multiple-dose vials (NDC 52536-625-10) and b) 1 mL single dose vials (NDC 52536-625-01), Rx only, Mfd for: Wilshire Pharmaceuticals, Inc., Atlanta, GA 30328.

Product Quantity:
a) 16,471 vials; b) 43,096 vials

Reason for Recall:
cGMP: complaints of crystals not redissolving into solution after warming and shaking the vials.

Recall Number:
D-0489-2023

Code Information:
Lot #23804.034A, 23803.061A, Exp 9/2024

Class II Drugs Event

Event ID:
91952

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/23/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/06/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Preferred Pharmaceuticals, Inc.
1250 N Lakeview Ave Ste O
Anaheim CA United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Atorvastatin Calcium Tablets, USP, 10 mg, 90-count bottle, Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703, NDC 68788-7630-9

Product Quantity:
158 Bottles

Reason for Recall:
cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.

Recall Number:
D-0511-2023

Code Information:
Lot #: A0523D, Exp 5/31/2024, F14220, Exp 7/31/2023, J0622Q; Exp 1/31/2024.

Product Description:
Atorvastatin Calcium Tablets, USP, 20 mg, packaged in: a) 90-count bottle (NDC 68788-7631-9); b) 30-count bottle (NDC 68788-7631-3), Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703

Product Quantity:
a) 375 Bottles b) 323 Bottles

Reason for Recall:
cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.

Recall Number:
D-0512-2023

Code Information:
a) Lot: B1522B, Exp 4/30/2023; lot:C0222H, C0322B, Exp 5/31/2023; lot: E1022H, F13220, H2222P, Exp 6/30/2023; Lot: I1422V, K01220, Exp 12/31/2023; Lot: L2722H, Exp 3/31/2024; b) Lot:C0322B, Exp 5/31/2023; lot:H1122G, 12322Q, Exp 6/30/2023; lot: J1222U, Exp 12/31/2023.

Product Description:
Clopidogrel Tablets USP, 75 mg, 90-count bottles, Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703, NDC 68788-8190-9

Product Quantity:
72 Bottles

Reason for Recall:
cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.

Recall Number:
D-0513-2023

Code Information:
Lot: E0922W, G1222E, I0922W and K3022W Exp 10/31/2023.

Product Description:
Doxazosin Tablets, USP, 2 mg, 100-count bottle, Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703, NDC 68788-7328-1

Product Quantity:
3 Bottles

Reason for Recall:
cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.

Recall Number:
D-0514-2023

Code Information:
Lot: H3122K, Exp 5/31/2024.

Product Description:
Doxazosin Tablets, USP, 4 mg, 100-count bottle, Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703, NDC 68788-7149-1

Product Quantity:
4 Bottles

Reason for Recall:
cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.

Recall Number:
D-0515-2023

Code Information:
Lot: L1522V, Exp 4/30/2025.

Product Description:
Finasteride Tablets, USP, 5 mg, packaged in: a) 30-count bottles (NDC 68788-6976-3); b) 90-count bottles (NDC 68788-6976-9), Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703.

Product Quantity:
a) 135 Bottles, b) 24 Bottles

Reason for Recall:
cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.

Recall Number:
D-0516-2023

Code Information:
a) Lot: A1321V, D0221J, Exp. Date:8/31/2023; Lot: A1322J, Exp. Date: 5/31/2024; Lot: F0221Q, I0121E, I1021R, J1122D, Exp. Date: 10/31/2023; b) Lot: B0422J, Exp. Date: 5/31/2024; Lot: C1721K, Exp. Date: 8/31/2023; Lot: K1022Q, Exp. Date:11/30/2024.

Product Description:
Glimepiride Tablets, USP, 2 mg, 90-count bottle, Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703, NDC 68788-8095-9

Product Quantity:
17 Bottles

Reason for Recall:
cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.

Recall Number:
D-0517-2023

Code Information:
Lot: D0122K, Exp. Date: 6/30/2024; Lot: I1422N, Exp. Date: 9/30/2024; Lot: I2721B, Exp. Date: 1/31/2024.

Product Description:
Montelukast Sodium Tablets, USP, 10 mg, packaged in: a) 30-count bottle (NDC 68788-9438-3); b) 60-count bottle (NDC 68788-9438-6); c) 90-count bottle (NDC 68788-9438-9), Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703.

Product Quantity:
a) 266 Bottles, b) not reported, c) 216 Bottles

Reason for Recall:
cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.

Recall Number:
D-0518-2023

Code Information:
a) Lot: F3021D, Exp 12/31/2023, Lot: L0722T, Exp 5/31/2025; b) Lot: F1021I, Exp 12/31/2023; c) Lot:H1721R, Exp 12/31/2023, Lot: L0722E, Exp 5/31/2025.

Product Description:
Rosuvastatin Tablets, USP, 10 mg, Packaged as: a) 30-count bottle (NDC 68788-7086-3); b) 90-count bottle (NDC 68788-7086-9), Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703.

Product Quantity:
a) 59 Bottles, b) 77 Bottles

Reason for Recall:
cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.

Recall Number:
D-0519-2023

Code Information:
a) Lot: F2022N, Exp. Date: 2/29/2024; b) Lot: F0322I, Exp. Date: 8/31/2023; Lot: J1322H, Exp. Date: 2/29/2024; Lot: K0222N, Exp. Date: 6/30/2024; Lot: L2322D and Lot: L2822J, Exp. Date:7/31/2025.

Product Description:
Rosuvastatin Tablets, USP, 5mg, 30-count bottle, Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703, NDC 68788-7971-3

Product Quantity:
264 Bottles

Reason for Recall:
cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.

Recall Number:
D-0520-2023

Code Information:
Lot: A1723C, Exp 8/31/2025; Lot: A1922B, Exp 6/30/2024; Lot: D0622M and Lot: F2922I, Exp 7/31/2024; Lot: G3021L, Exp 1/31/2024; Lot:H2622P & Lot: J0722C, Exp 10/31/2024.

Product Description:
Pravastatin Sodium Tablets, USP, 20 mg, 90-count bottle, Rx only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703, NDC 68788-8215-9

Product Quantity:
24 Bottles

Reason for Recall:
cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.

Recall Number:
D-0521-2023

Code Information:
Lot: F1021I; H3122J, Exp 4/30/2024

Product Description:
Simvastatin Tablets, USP, 10 mg, 90-count bottle, Rx only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703, NDC 68788-9747-9

Product Quantity:
82 Bottles of 90 Tablets

Reason for Recall:
cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.

Recall Number:
D-0522-2023

Code Information:
Lot: C2222P, D1522L, E3122D, G2522J, Exp 9/30/2023; Lot: J1222R, Exp 10/31/2023.

Product Description:
Simvastatin Tablets, USP, 80 mg, 90-count bottle, Rx only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703, NDC 68788-9429-9

Product Quantity:
57 Bottles

Reason for Recall:
cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.

Recall Number:
D-0523-2023

Code Information:
Lot: B0222S, Exp 2/29/2024; Lot: F1121B, G2721L, Exp 11/30/2023.

Product Description:
Simvastatin Tablets, USP, 20 mg, Packaged as: a) 90-count bottle (NDC 68788-9869-9); b) 60-count bottle (NDC 68788-9869-6); c) 30-count bottle (NDC 68788-9869-3), Rx only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703.

Product Quantity:
a) 305 Bottles, b) 72 Bottles, c) 617 Bottles

Reason for Recall:
cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.

Recall Number:
D-0524-2023

Code Information:
a) Lot: A0923R, Exp. Date: 2/28/2025, A1222K, B1822C, Exp. Date: 5/31/2024, C3022D, F2322V, Exp. Date: 6/30/2024, H1522H, Exp. Date: 8/31/2024, I1621O, Exp. Date: 1/31/2024, I2222G, J1822R, Exp. Date: 9/30/2024, L1621N, Exp. Date: 5/31/2024; b) Lot: F0822Q, Exp. Date: 6/30/2024, I0122J, Exp. Date: 8/31/2024, L0821C, Exp. Date: 5/31/2024; c) Lot: I1521P, Exp. Date: 1/31/2024, J1322R, Exp. Date: 9/30/2024, J1821H, Exp. Date: 2/29/2024.

Product Description:
Simvastatin Tablets, USP, 40 mg, Packaged as: a) 90-count bottle (NDC 68788-9868-9); b) 60-count bottle (NDC 68788-9868-6); c) 30-count bottle (NDC 68788-9868-3), Rx only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703.

Product Quantity:
a) 88 Bottles, b) 3 Bottles, c) 175 Bottles

Reason for Recall:
cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.

Recall Number:
D-0525-2023

Code Information:
a) Lot: B0922G, Exp. Date: 5/31/2023, F0322G, Exp. Date: 7/25/2024, H2622M, Exp. Date: 8/31/2024, J1422B, K0722G, Exp. Date: 10/31/2024, L1922A, Exp. Date: 2/28/2025; b) Lot: F2922S, Exp. Date: 8/31/2023, H0322G Exp. Date: 7/31/2023; c) Lot: A1322I, Exp. Date: 3/31/2023, H1122C, Exp. Date: 8/31/2024.

Product Description:
Tadalafil Tablets, USP, 20 mg, 7-count bottle, Rx only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703, NDC 68788-8153-7

Product Quantity:
32 Bottles

Reason for Recall:
cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.

Recall Number:
D-0526-2023

Code Information:
Lot: C0822E, Exp 1/31/2024, F1121B, Exp 1/31/2024, G2721L, Exp 1/31/2024.

Product Description:
Glimepiride Tablets USP, 4 mg, 90-count bottle, Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703, NDC 68788-8066-9

Product Quantity:
15 Bottles

Reason for Recall:
cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.

Recall Number:
D-0527-2023

Code Information:
Lot: H1221Z, I0121J, J0622X, Exp 10/31/2023.

Class II Drugs Event

Event ID:
91980

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/20/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:

03/31/2023 Letter

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

Distribution Pattern:
RemedyRepack distributed product to consignees nationwide within the United States

Associated Products

Product Description:
Aripiprazole 5mg tablets, 30-count bottles, Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC 70518-2921-03

Product Quantity:
3 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0490-2023

Code Information:
Lot #: J0620431-052322, Exp. Date 05/31/23

Product Description:
Atorvastatin 10 mg tablets, packaged in a) 30-count bottles (NDC 70518-1946-00) and b) 90-count bottles (NDC 70518-1946-01), Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701.

Product Quantity:
a) 3,497 bottles, b) 729 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0491-2023

Code Information:
Lot #: a) J0679046-020123, Exp. Date 02/28/2024; J0669807-122122, Exp. Date 01/31/2024; J0662695-112222, Exp. Date 12/31/2023; J0654076-101822, J0654076-101822, Exp. Date 11/30/2023; J0642765-082922, Exp. Date 09/30/2023 Lot #: b) B1672408-050322, B1765902-071322, B1769634-071622, Exp. Date 04/30/2023; B1776907-072122, Exp. Date 09/30/2023; B1836636-090322, Exp. Date 11/30/2023; B1870344-092422, Exp. Date 01/31/2024; B1908452-101522, B1966455-111722, B2043099-010423, Exp. Date 05/31/2024

Product Description:
Doxazosin 2 mg tablets, packaged in a) 30-count (NDC 70518-1560-00) and b) 90-count bottles (NDC 70518-1560-01), Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701.

Product Quantity:
a) 58 bottles, b) 6 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0492-2023

Code Information:
Lot #: a) J0665197-120522, Exp. Date 12/31/2023; J0642497-082722, Exp. Date 09/30/2023 J0638552-080922, Exp. Date 08/31/2023. Lot #: b) B1808799-081622, Exp. Date 05/31/2024

Product Description:
Glimepiride 2 mg tablets, packaged in a) 30-count bottles (NDC 70518-0405-03), b) 90-count bottles (NDC 70518-0405-00) and c)180-count bottles (NDC 70518-0405-02), Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701

Product Quantity:
a) 147 bottles, b)70 bottles, c) 3 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0493-2023

Code Information:
Lot #: a) J0674153-010923, Exp. Date 01/31/2024; J0649447-092822, Exp. Date 10/31/2023; J0644887-090722, Exp. Date 09/30/2023; J0627309-062222, Exp. Date 06/30/2023; J0622569-060222, Exp. Date 06/30/2023. b) B1646259-041222, Exp. Date 04/30/2023; B2032846-122722, Exp. Date 01/31/2025 B2018675-121722, Exp. Date 05/31/2025; B1708230-060122, B1709748-060122, Exp. Date 06/30/2023; B1692572-051822, Exp. Date 05/31/2023; B1803110-081122, Exp. Date 12/31/2024. c) B1820672-082422, B1814883-082022, Exp. Date 09/30/2024.

Product Description:
Ropinirole 0.5 mg tablets, packaged in 90-count bottles, Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC 70518-2439-00.

Product Quantity:
17 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0494-2023

Code Information:
Lot #: B1789178-080122, Exp. Date 07/31/2023; B1675475-050522, Exp. Date 05/31/2023

Product Description:
Rosuvastatin 5mg tablets, 30-count bottles, Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC 70518-3519-00.

Product Quantity:
399 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0495-2023

Code Information:
Lot #: J0668398-121422, Exp. Date 12/31/2023; J0661225-111522, J0654053-101822 Exp. Date 11/30/2023; J0646383-091422, Exp. Date 09/30/2023

Product Description:
Simvastatin 10 mg tablets, packaged in a) 30-count bottles (NDC 70518-0064-01) and b) 90-count bottles (NDC 70518-0064-00), Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701

Product Quantity:
a) 1,262 bottles, b) 95 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0496-2023

Code Information:
Lot #: a) J0675206-011223, J0669260-121922, Exp. Date 01/31/2024; J0656820-103122, J0647161-091722, Exp. Date 09/30/2023 Exp. Date 11/30/2023; J0621491-052722, Exp. Date 06/30/2023; J0638138-080822, Exp. Date 08/31/2023, J0610887-041122, Exp. Date 04/30/2023. Lot # b) B1887315-100422, Exp. Date 02/28/2024; B1829906-083122, B1769715-071622, Exp. Date 09/30/2023; B1906605-101422, Exp. Date 02/28/2024; B1965118-111622, Exp. Date 02/28/2025.

Product Description:
Tadalafil 5 mg tablets, 30-count bottles, Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC 70518-2972-00

Product Quantity:
16 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0497-2023

Code Information:
Lot #: B1635780-040522, Exp. Date 04/30/2023

Product Description:
Atorvastatin 20 mg tablets, packaged in a) 30-count bottles (NDC 70518-1977-00) and b)90-count bottles (NDC 70518-1977-01), Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701.

Product Quantity:
3,426 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0498-2023

Code Information:
Lot #: a) J0659819-110922, Exp. Date 11/30/2023; J0649932-093022, J0649917-093022 Exp. Date 10/31/2023, B2010060-121222, Exp. Date 03/31/24 Lot #: b) B1708575-060122, Exp. Date 05/31/2023; B1879236-092922, Exp. Date 12/31/2023

Product Description:
Ropinirole 2mg tablets, packaged in 180-count bottles, Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC70518-2750-00

Product Quantity:
3 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0499-2023

Code Information:
Lot#: B1630017-040122, Exp. Date 04/30/2023

Product Description:
Rosuvastatin 5mg tablets, 30-count bottles, Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC 70518-3519-00

Product Quantity:
132 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0500-2023

Code Information:
Lot#: J0668398-121422, Exp. Date 12/31/2023; J0661225-111522, J0654053-101822 Exp. Date 11/30/2023; J0646383-091422, Exp. Date 09/30/2023

Product Description:
Rosuvastatin 10mg tablets, packaged in a) 30-count bottles (NDC 70518-0375-03 and 70518-0375-01) and b) 90-count bottles (NDC 70518-0375-00), Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701.

Product Quantity:
a) 399 bottles, b)445 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0501-2023

Code Information:
Lot#: a) NDC 70518-0375-03: J0674788-011123, Exp. Date 01/31/2024; J0664118-112922 J0664118-112922, Exp. Date 12/31/2023; J0653727-101722, Exp. Date 10/31/2023. NDC 70518-0375-01: B2057931-011223, Exp. Date 07/31/2025 b) Lot #: B2075815-012523, Exp. Date 09/30/2025;

B2011634-121322, Exp. Date 07/31/2025 B1970205-112022, Exp. Date 06/30/2024; B1862598-092022, Exp. Date 03/31/2024; B2077226-012523, B2070444-012023, Exp. Date 07/31/2025.

Product Description:
Rosuvastatin 40mg tablets, packaged in a) 45-count bottles (NDC 70518-1311-01), and b) 90-count bottles (NDC 70518-0484-00), Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701.

Product Quantity:
a) 76 bottles, b)151 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0502-2023

Code Information:
Lot # a): B2038806-123022, B2014185-121422, B1925528-102522, Exp. Date 07/31/2025. Lot #: b): B2080829-012823, B1938007-110222, B2038746-123022, Exp. Date 07/31/2025.

Product Description:
Simvastatin 40 mg tablets, packaged in a) 30-count bottles (NDC 70518-0060-01) and b) 90-count bottles (NDC 70518-0060-00), Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701

Product Quantity:

Reason for Recall:
cGMP Deviations

Recall Number:
D-0503-2023

Code Information:
Lot # a): J0656821-103122, Exp. Date 11/30/2023; J0638547-080922, Exp. Date 08/31/2023; J0633575-071822, Exp. Date 07/31/2023 Lot #: b): B1965081-111622, Exp. Date 03/31/2025; B1857922-091922, B1765298-071322, B1786319-072922, B1706842-053122, Exp. Date 04/30/2023; B2003311-120822, Exp. Date 04/30/2025; B1955679-111122, Exp. Date 02/28/2025; B1878942-092922, Exp. Date 11/30/2024; B1823203-082622. Exp. Date 10/31/2024; B1706843-053122, Exp. Date 05/31/2023

Class II Drugs Event

Event ID:
92008

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/27/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/05/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Preferred Pharmaceuticals, Inc.
1250 N Lakeview Ave Ste O
Anaheim CA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Alprazolam Tab, USP 0.25mg, (CIV), 30-count bottle, Rx Only, Preferred Pharmaceuticals, Inc. Manufactured by: Breckenridge Pharmaceuticals, Inc., Boca Raton, FL. Ins:NDC 68788-7594-3

Product Quantity:
30 Bottles

Reason for Recall:
CGMP Deviations: Downstream recall from Breckenridge Pharmaceuticals, Inc due to potential risk of Cross Contamination.

Recall Number:
D-0504-2023

Code Information:
Lot: G1822K, Exp. Date:5/31/2023.

Product Description:
Alprazolam Tab, USP 0.5mg, (CIV), packaged in: a) 30-count bottle (NDC 68788-7595-3), b) 60-count bottle (NDC 68788-7595-6), c) 90-count bottle (NDC 68788-7595-9); Rx Only, Preferred Pharmaceuticals, Inc. Manufactured by: Breckenridge Pharmaceuticals, Inc., Boca Raton, FL.

Product Quantity:
320 x 30-count; 46 x 60-count; 10 x 90-count bottles

Reason for Recall:
CGMP Deviations: Downstream recall from Breckenridge Pharmaceuticals, Inc due to potential risk of Cross Contamination.

Recall Number:
D-0505-2023

Code Information:
Lot # a) D2022P, Exp. Date:4/30/2023; F1022Y, E2022, I2822U, Exp. Date:6/30/2023; L2122W, Exp. Date: 8/31/2024; b) Lot #L0522A, Exp. Date:8/31/2024; B0823J, Exp. Date:11/31/2024; c) Lot# L1522P, Exp. Date: 10/31/2024.

Product Description:
Alprazolam Tab, USP 1mg, (CIV), packaged in: a) 30-count bottle (NDC 68788-7596-3), b) 60-count bottle (NDC68788-7596-6); Rx Only, Preferred Pharmaceuticals, Inc. Manufactured by: Breckenridge Pharmaceuticals, Inc., Boca Raton, FL.

Product Quantity:
33 x 30-count; 78 x 60-count bottles

Reason for Recall:
CGMP Deviations: Downstream recall from Breckenridge Pharmaceuticals, Inc due to potential risk of Cross Contamination.

Recall Number:
D-0506-2023

Code Information:
Lot # a) H3122D, Exp. Date:8/31/2024; b) Lot #A1123R, L0522E, J2622H, I1622F, H2422E, Exp. Date:8/31/2024.

Class II Drugs Event

Event ID:
92054

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/22/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/06/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Direct Rx
94 Worldwide Dr
Dawsonville GA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Alprazolam C-IV, 0.5 mg, 30 Tabs per bottle, Rx only, Packaged and Distributed By: Direct Rx Dawsonville, GA 30534, NDC 72189-0240-30.

Product Quantity:
20 bottles

Reason for Recall:
CGMP Deviations: Repackaging firm recalling due to potential product cross contamination concerns at the manufacturer.

Recall Number:
D-0507-2023

Code Information:
Lot: 11AP2219 Exp. 4/30/23

Product Description:
Alprazolam C-IV, 1 mg, packaged in a) 30 Tabs per bottle, NDC 72189-213-30; b) 60 Tabs per bottle, NDC 72189-213-60; Rx only, Packaged and Distributed By: Direct Rx Dawsonville, GA 30534.

Product Quantity:
349 bottles

Reason for Recall:
CGMP Deviations: Repackaging firm recalling due to potential product cross contamination concerns at the manufacturer.

Recall Number:
D-0508-2023

Code Information:
Lots: a) 03FE2318, Exp. 8/31/24; b) 27FE2315, 28FE2313, 02MA2306, 21SE2201, 16NO2216, 17NO2216, 24FA2314, Exp. 8/31/24; 17FE2203, 12AP2204, 17MA2205, Exp. 3/31/23; 21JU2206, 22JU2220, 12JY2206, Exp. 5/31/23; 10AU2209, Exp. 6/30/23; 14DE2215, Exp. 9/30/24; 05JA2304, 27JA2301, Exp. 11/30/24.

Product Description:
Alprazolam C-IV, 2 mg, 60 Tabs per bottle, Rx only, Packaged and Distributed By: Direct Rx Dawsonville, GA 30534, NDC 72189-121-60.

Product Quantity:
9 bottles

Reason for Recall:
CGMP Deviations: Repackaging firm recalling due to potential product cross contamination concerns at the manufacturer.

Recall Number:
D-0509-2023

Code Information:
Lots: 03FE2319 Exp. 2/28/25, 13MY2217 Exp. 5/31/23

Class III Drugs Event

Event ID:
91958

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/27/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/06/2023

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Montelukast Sodium Oral Granules USP, 4 mg, packaged in a carton containing 30 packets, Rx only, Distributed By: Teva Pharmaceuticals USA, Inc., Parsippany, NJ 07054, Carton NDC 0093-7487-56, Packet NDC 0093-7487-19

Product Quantity:
3,772 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: failed impurities for Sulphoxide and Impurity A.

Recall Number:
D-0510-2023

Code Information:
Lot # 3007556A, Exp 5/2023

Class III Drugs Event

Event ID:
91977

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/29/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/06/2023

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Accord Healthcare, Inc.
1009 Slater Rd Ste 210B
Durham NC United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Dodex Injectable Cyanocobalamin Injection, USP 1,000 mcg/mL, 25 x1 ML Multiple dose vials, For Intramuscular or Subcutaneous Use Only, Rx Only, Sterile, Manufactured by: Intas Pharmaceuticals Limited Pharmaz Ahnedabad 382 213, INDIA, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703, NDC 16729-533-08.

Product Quantity:
4574 cartons

Reason for Recall:
Sub-potent drug: assay test result below specifications at 9-month timepoint.

Recall Number:
D-0528-2023

Code Information:
Lot #: R2200394 Exp. 03/2024