# Enforcement Report - Week of June 2, 2021

## Class I Drugs Event

**Event ID:**
87843

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
04/29/2021

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
05/24/2021

**Initial Firm Notification of Consignee or Public:**
Press Release

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

**Distribution Pattern:**
Nationwide within the United States including Puerto Rico

## Associated Products

**Product Description:**
NP Thyroid 15 Thyroid Tablets, USP 1/4 grain (15 mg), packaged in a) 100-count bottles (NDC 42192-327-01) and b) 7-count bottles (NDC 42192-327-07), Rx Only, Manufactured For: Acella Pharmaceuticals, LLC Alpharetta, GA 30005

**Product Quantity:**
a) 66,155 bottles; b) 26,212 bottles

**Reason for Recall:**
Subpotent Drug

**Recall Number:**
D-0395-2021

**Code Information:**
Lots: a) M327D20-1, M327D20-3 Exp. 03/31/2022, M327H19-3A Exp. 07/31/2021, M327L19-1 Exp. 04/30/2021; b) M327D20-1 Exp. 03/31/2022

**Product Description:**
NP Thyroid 30 Thyroid Tablets, USP 1/2 grain (30 mg), packaged in a) 100-count bottles (NDC 42192-329-01) and b) 7-count bottles (NDC 42192-329-07), Rx Only, Manufactured For: Acella Pharmaceuticals, LLC Alpharetta, GA 30005

**Product Quantity:**
a) 113,019 bottles; b) 44,900 bottles

**Reason for Recall:**
Subpotent Drug

**Recall Number:**
D-0396-2021

**Code Information:**
Lots: a) M329D20-1, M329D20-2, M329D20-3 Exp. 03/31/2022, ; b) M329D20-2 Exp. 03/31/2022

**Product Description:**
NP Thyroid 60 Thyroid Tablets, USP 1 grain (60 mg) 100-count bottles, Rx Only Manufactured For: Acella Pharmaceuticals, LLC Alpharetta, GA 30005, NDC 42192-330-01

**Product Quantity:**
154,726 bottles

**Reason for Recall:**
Subpotent Drug

**Recall Number:**
D-0397-2021

**Code Information:**
Lots: M330D20-1, M330D20-2 Exp. 03/31/2022; M330J19-2A, M330J19-4A , M330J19-5A, M330J19-6A, M330J19-7A, M330J19-9A Exp.

08/31/2021; M330K19-10, M330K19-1A, M330K19-9 Exp. 09/30/2021

**Product Description:**
NP Thyroid 90 Thyroid Tablets, USP 1&1/2 grain (90 mg) 100-count bottles, Rx only, Manufactured For: Acella Pharmaceuticals, LLC Alpharetta, GA 30005, NDC 42192-331-01

**Product Quantity:**
79,344 bottles

**Reason for Recall:**
Subpotent Drug

**Recall Number:**
D-0398-2021

**Code Information:**
Lots: M331J19-10A, M331J19-11, M331J19-2A, M331J19-6A, Exp. 08/31/2021, M331K19-1, M331K19-2, M331K19-6, Exp. 09/30/2021

**Product Description:**
NP Thyroid 120 Thyroid Tablets, USP 2 grain (120 mg), packaged in a) 100-count bottles (NDC 42192-328-01) and b) 7-count bottles (NDC 42192-328-07) Rx Only, Manufactured For: Acella Pharmaceuticals, LLC Alpharetta, GA 30005

**Product Quantity:**
a) 69,289 bottles; b) 9,076 bottles

**Reason for Recall:**
Subpotent Drug

**Recall Number:**
D-0399-2021

**Code Information:**
Lot #: a) M328H19-2B, M328J19-11, M328J19-2A, M328J19-3A, M328J19-4A M328J19-5A, M328J19-6A, M328J19-7A, Exp. 08/31/2021, M328K19-2, M328K19-4A, Exp. 09/30/2021; b) M328J19-9B Exp. 08/31/2021

## Class II Drugs Event

**Event ID:**
87512

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
03/15/2021

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
05/24/2021

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
Cardinal Health Inc.
7000 Cardinal Pl
Dublin OH United States

**Distribution Pattern:**
FL, GA, SC

## Associated Products

**Product Description:**
THERAPEUTIC M 130; NDC/UPC 740985223680; OTC; TABLETS

**Product Quantity:**
55 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0400-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
NIACIN 250MG 110; NDC/UPC 740985228494; OTC; TABLETS

**Product Quantity:**
4 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0401-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
Creon (pancrelipase) Delayed-Release Capsules Dose By Lipase Units Lipase 36,000 USP Units Rx only NDC 0032-3016-13 100 Capsules Marketed by: AbbVie Inc. North Chicago, IL 60064, U.S.A.

**Product Quantity:**
1669 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0402-2021

**Code Information:**
1139494

**Product Description:**
Orilissa elagolix tablets 150 mg per tablet equivalent to 155.2 mg elagolix sodium, 28 Tablets For 28 Days Rx only NDC 0074-0038-28 Each carton contains 28 tablets in 4 weekly blister pack, Each weekly blister pack contains 7 tablets of elagolix 150 mg AbbVie Inc. North Chicago, IL 60064

**Product Quantity:**
210 cartons

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0403-2021

**Code Information:**
1120778

**Product Description:**
Norvir Ritonavir Tablets 100 mg 30 Tablets Rx only NDC 0074-3333-30 Abbott Laboratories North Chicago, IL 60064, U.S.A.

**Product Quantity:**
362 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0404-2021

**Code Information:**
1131141

**Product Description:**
Synthroid (levothyroxine sodium tablets, USP) in all pack sizes, styles and concentrations Rx only Abbott Laboratories North Chicago, IL

**Product Quantity:**
123 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0405-2021

**Code Information:**
1138959

**Product Description:**
METHOCARBAMOL 500MG 500; NDC/UPC 71093014005; RX; TABLETS

**Product Quantity:**
51 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0406-2021

**Code Information:**
UMETA0036A

**Product Description:**
FENOFIBRATE CAPSULES, UPS 67MG 100 CAPSULES NDC/UPC 27241-118-04; RX; CAPSULES

**Product Quantity:**
106 BOXES

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0407-2021

**Code Information:**
PA03410

**Product Description:**
OFLOXACIN 0.3% 5ML OPTH; NDC/UPC 17478071310; RX; DROPS

**Product Quantity:**
339 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0408-2021

**Code Information:**
427297

**Product Description:**
LIDOCAINE HCL VISC 2% 100ML; NDC/UPC 50383077504; RX; SOLUTION (USUALLY NOT OTIC, OPTH, NASAL DROPS)

**Product Quantity:**
240 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0409-2021

**Code Information:**
373577

**Product Description:**
Atropine Sulfate Ophthalmic Solution, USP 1% For Topical Application To The Eye Sterile 5 mL Rx only NDC 17478-215-05 Manufactured by: Akorn, Inc.

**Product Quantity:**
424 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0410-2021

**Code Information:**
071520A

**Product Description:**
COSOPT (Dorzolamide Hydrochloride-Timolol Maleate Ophthalmic Solution) (Dorzolamide Hydrochloride 22.3 mg/mL Timolol Maleate 6.8 mg/mL) 10ML Ocumeter Plus Ophthalmic Dispenser Sterile Ophthlamic Solution Rx only NDC/UPC 174780-605-10 Distributed by: Akorn, Inc. Lake Forest, IL 60045

**Product Quantity:**
12 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0411-2021

**Code Information:**
430358

**Product Description:**
Metoprolol Tartrate and Hydrochlorothiazide Tablets, USP 50 mg/25 mg 100 Tablets Rx only NDC 62332-115-31 Manufactured for: Alembic Pharmaceuticals, Inc. 750 Route 202, Bridgewater, NJ 08807 USA

**Product Quantity:**
71 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0412-2021

**Code Information:**
2005005745

**Product Description:**
BROMFENAC OPHTHALMIC SOLUTION 0.09% 1.7ML NDC/UPC 62332-508-17; RX; DROPS

**Product Quantity:**
152 CARTON

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0413-2021

**Code Information:**
AGV009

**Product Description:**
Vaniqa (eflornithine hydrochloride) Cream, 13.9% For Topical Use Only Net wt. 1.59 oz (45 g) Rx only NDC 0023-4857-45 Manufactured for Allegan, Inc. Irvine, CA 92612

**Product Quantity:**
72 tubes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0414-2021

**Code Information:**
113780

**Product Description:**
UBRELVY 100MG 10UD CPLT; NDC/UPC 23650110; RX; TABLETS

**Product Quantity:**
964 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0415-2021

**Code Information:**
1658641

**Product Description:**
RESTASIS 0.05%30X 0.4ML OPTH PF; NDC/UPC 23916330; RX; DROPS/Restasis 0.05% 60x0.4 mL OPTH PF; NDC/UPC 23916330; RX

**Product Quantity:**
3688 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0416-2021

**Code Information:**
T1202

**Product Description:**
Linzess (linaclotide) capsules 72 mcg/capsule 30 capsules Rx Only NDC 0456-1203-30 Distributed by: Allergan USA, Inc. Irvine, CA 92612

**Product Quantity:**
1529 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0417-2021

**Code Information:**
W04411

**Product Description:**
Namzaric (memantine HCl extended release and donepezil HCl) capsules 14 mg/10 mg per capsule 30 capsules Rx Only NDC 0456-1214-30 Distributed by Forest Pharmaceuticals, Inc. Subsidiary of Forest Laboratories, LLC.

**Product Quantity:**
659 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0418-2021

**Code Information:**
W04815

**Product Description:**
Rectiv (nitroglycerin) Ointment 0.4% For Intra-anal Use Only 30 g Rx Only NDC 58914-301-80 Mfd. by: Pharbil Waltrop GmbH, Im Wirrigen 25, 45731 Waltrop, Germany Distributed by: Aptalis Pharma US, Inc. Birmingham, AL 35242

**Product Quantity:**
31 tubes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0419-2021

**Code Information:**
2399070

**Product Description:**
Vraylar (cariprazine) capsules in all pack sizes, styles and strengths Rx only Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054

**Product Quantity:**
759 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0420-2021

**Code Information:**
W04494

**Product Description:**
Nitrofurantoin Macrocrystals Capsules 25 mg 100 Capsules Rx Only NDC 47781-306-01 Manufactured by: Norwich Pharmaceuticals, Inc. Norwich, NY 13815 Distributed by: Alvogen, Inc. Parsippany, NJ 07054 U.S.A.

**Product Quantity:**
15 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0421-2021

**Code Information:**
486942

**Product Description:**
BUPRENORPHINE AND NALOXONE SUBLINGUAL FILM 4MG/1MG 30 POUCHES EACH CONTAINING 1 SUBLINGUAL FILM NDC/UPC 47781-0356-03; RX; FILM

**Product Quantity:**
249 CARTONS

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0422-2021

**Code Information:**
37890

**Product Description:**
Oseltamivir Phosphate for Oral Suspension 6 mg/mL* *Each mL contains 6 mg oseltamivir base after constitution. 60 mL (usable volume after constitution) Rx Only NDC 47781-384-26 Distributed by: Alvogen, Inc. Pine Brook, NJ 07058 USA

**Product Quantity:**
15885 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0423-2021

**Code Information:**
484241

**Product Description:**
ERYTHROMYCIN TABLETS, USP 250MG 30; NDC/UPC 69238-1484-3; RX; TABLETS

**Product Quantity:**
135 CARTON

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0424-2021

**Code Information:**
AM200540

**Product Description:**
TRAVOPROST OPHTHALMIC SOLUTION, USP 0.004% 2.5ML ; NDC/UPC 60505-0593-4; RX; DROPS

**Product Quantity:**
325 CARTONS

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0425-2021

**Code Information:**
RW4409

**Product Description:**
ENOXAPARIN DOFIUM INJRVYION, UPD 150MG/1ML 10X1ML SINGLE DOSE SYRINGES; NDC/UPC 60505-0798-4; RX; SYRINGES

**Product Quantity:**
64 BOXES

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0426-2021

**Code Information:**
CV006

**Product Description:**
Butorphanol Tartrate Nasal Solution USP 10 mg/mL 2. 5 mL bottles Rx Only NDC 60505-0813-1 Mfg by: Apotex Inc. Toronto, Ontario Canada M9L 1T9

**Product Quantity:**
38 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0427-2021

**Code Information:**
RT7113

**Product Description:**
Timolol Maleate Ophthalmic Solution, USP 0.5% 2.5 mL Sterile For Topical Application In The Eye Rx Only NDC 60505-1005-4 Manufactured by: Apotex Inc. Toronto, Ontario Canada M9L 1T9 Manufactured for: Apotex Corp. Weston, FL 33326

**Product Quantity:**
31 droptainers

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0428-2021

**Code Information:**
RV7378

**Product Description:**
Edarbi (azilsartan medoxomil) tablets 80 mg 30 Tablets Rx Only NDC 60631-080-30 Manufactured for: arbor Pharmaceuticals Atlanta, GA 30328

**Product Quantity:**
328 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0429-2021

**Code Information:**
78902-1

**Product Description:**
edarbyclor Azilsartan Medoxomil and Chlorthalidone Tablets 40 mg*/12.5 mg 30 Tablets Rx Only NDC 60631-412-30 Manufactured for: arbor Pharmaceuticals, LLC. Atlanta, GA 30328

**Product Quantity:**
244 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0430-2021

**Code Information:**
78520

**Product Description:**
edarbyclor Azilsartan Medoxomil and Chlorthalidone Tablets 40 mg*/25 mg *Each tablet contains: 42.68 mg azilsartan kamedoxomil (equivalent to 40 mg azilsartan medoxomil) and 25 mg chlorthalidone. 30 Tablets Rx Only NDC 60631-425-30 Manufactured for Arbor Pharmaceuticals Atlanta, GA 30328

**Product Quantity:**
273 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0431-2021

**Code Information:**
79551

**Product Description:**
GEMCITABINE INJECTION 200MG/5.26ML; NDC/UPC 72485-221-02; RX; SINGLEDOSE VIAL

**Product Quantity:**
3 CARTON

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0432-2021

**Code Information:**
7T10050A

**Product Description:**
Brilinta ticagrelar tablets 60 mg 60 tablets Rx only NDC 0186-0776-60 Mfd. for: AstraZeneca LP, Wilmington, DE 19850

**Product Quantity:**
1278 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0433-2021

**Code Information:**
MP0138

**Product Description:**
Bevespi Aerosphere (glycopyrrolate and formoterol fumarate) Inhalation Aerosol 9 mcg/4.8 mcg per inhalation For Oral Inhalation only 120 inhalations Rx Only NDC 0310-4600-12 Mfd for: AstraZeneca Pharmaceuticals, LP, Wilmington, DE 19850

**Product Quantity:**
355 inhalers

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0434-2021

**Code Information:**
6030180A00

**Product Description:**
xigduo XR (dapgliflozin/metformin HCl extended-release) tablets 10 mg/1000 mg 30 Tablets Rx only NDC 0310-6280-30 Manufactured for: AstraZeneca Pharmaceuticals LP Wilmington, DE 19850 Manufactured by: Bristol-Myers Squibb Manufacturing Company Humacao, Puerto Rico 00791

**Product Quantity:**
664 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0435-2021

**Code Information:**
MP0077

**Product Description:**
xigduo XR (dapagliflozin/metformin HCl extended-release) tablets 5 mg/1000 mg 60 Tablets Rx only NDC 0310-6260-60 Manufactured for: AstraZeneca Pharmaceuticals LP Wilmington, DE 19850

**Product Quantity:**
378 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0436-2021

**Code Information:**
ML0171

**Product Description:**
IBUPROFEN ORAL SUSPENSION USP 100MG/5ML 120ML ; NDC/UPC 59651-032-12; RX; SUSPENSION (NO DROPS)

**Product Quantity:**
345 CARTONS

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0437-2021

**Code Information:**
BO1020069-A

**Product Description:**
Eletriptan Hydrobromide Tablets 20 mg* 6(1x6) Unit-dose Tablets Rx only NDC 59651-104-69 Distributed by: Aurobindo Pharma USA, Inc. 279 Princeton-Highstown Road East Windsor, NJ 08520

**Product Quantity:**
20 CARTONS

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0438-2021

**Code Information:**
EA2020001-A

**Product Description:**
AMOXICILLIN 500MG 100; NDC/UPC 65862001401; RX; TABLETS

**Product Quantity:**
373 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0439-2021

**Code Information:**
SE5019062-A

**Product Description:**
ONDANSETRON HCL 4MG 30; NDC/UPC 65862018730; RX; TABLETS

**Product Quantity:**
1935 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0440-2021

**Code Information:**
ON0420015-A

**Product Description:**
ESZOPICLONE 3MG 100 C4; NDC/UPC 65862096901; RX; TABLETS

**Product Quantity:**
29 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0441-2021

**Code Information:**
GS0320010-A

**Product Description:**
Nuedexta (dextromethorphan HBr and quinidine sulfate) Capsules 20 mg/10 mg 60 capsules Rx only NDC 64597-301-60 Manufactured by Patheon, Inc. Whitby, ON L1N 5Z5, Canada

**Product Quantity:**
255 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0442-2021

**Code Information:**
CFBFP

**Product Description:**
LOTEMAX SM (loteprednol etabonate ophthalmic gel) 0.38% 5GM; NDC/UPC 24208-0507-07; RX; GEL

**Product Quantity:**
463 boxes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0443-2021

**Code Information:**
352162

**Product Description:**
BENZEFOAM EMOLLIENT FOAM BENZOYL PEROXIDE 5.3% 100GM TOP EMOL NDC 187-0194--10; OTC; FOAMS

**Product Quantity:**
2 carton

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0444-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
MURO-128 2% 15ML OPTH; NDC/UPC 324208276150; OTC; DROPS

**Product Quantity:**
64 droptainers

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0445-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
TOBRAMY/DEX 0.3-0.1% 10ML OPTH; NDC/UPC 24208029510; RX; DROPS

**Product Quantity:**
47 droptainers

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0446-2021

**Code Information:**
350861

**Product Description:**
DEXAMETH SOD PHOS 0.1% 5ML; NDC/UPC 24208072002; RX; DROPS

**Product Quantity:**
318 droptainers

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0447-2021

**Code Information:**
353351

**Product Description:**
Belbuca (buprenorphine hydrochloride) buccal film 300 mcg 60 pouches containing 1 buccal film each Rx only NDC 59385-023-60 Manufactured for: BioDelivery Sciences International, Inc. Raleigh, NC 27612.

**Product Quantity:**
96 cartons

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0448-2021

**Code Information:**
37674B

**Product Description:**
Belbuca (buprenorphine hydrochloride) buccal film 600 mcg 60 pouches containing 1 buccal film each Rx only NDC 59385-025-60 Manufactured for: BioDelivery Sciences International, Inc. Raleigh, NC 27612 USA

**Product Quantity:**
47 cartons

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0449-2021

**Code Information:**
BL6002004

**Product Description:**
SYMPROIC (NAIDEMEDINE) TABLETS 0.2MG 30 TABLETS; NDC 59385-041-30; RX; TABLETS

**Product Quantity:**
67 BOXES

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0450-2021

**Code Information:**
2003060A

**Product Description:**
NURTEC ODT (RIMEGEPANT) 75MG 8 BPK; NDC/UPC 72618-3000-2; RX; TABLETS FOR RAPID DISSOLUTION (NOT SUBLINGUAL)

**Product Quantity:**
1240 CARTON

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0451-2021

**Code Information:**
4170326

**Product Description:**
CATAPRES-TTS-2 1X4; NDC/UPC 597003234; RX; ADHESIVE PATCHES

**Product Quantity:**
17 patches

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0452-2021

**Code Information:**
1905666/2

**Product Description:**
Spiriva HandiHaler (tiotropium bromide inhalation powder) For Oral Inhalation Only 18 mcg (as tiotropium) per capsule Rx only NDC 0597-0075-41 Manufactured by: Boehringer Ingelheim (BI) Pharma GmbH & Co. KG Ingelheim, Germany Marketed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 USA and Pfizer, Inc. New York, NY 10017 USA

**Product Quantity:**
2611 inhalers

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0453-2021

**Code Information:**
5098

**Product Description:**
ATROVENT HFA 17MCG 12.9GM; NDC/UPC 597008717; RX; INHALER MEDICAL INTERNAL - MAY OR MAY NOT BE AEROSOL

**Product Quantity:**
667 inhalers

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0454-2021

**Code Information:**
200155

**Product Description:**
Glyxambi (empagliflozin and linagliptin) Tablets 25 mg/5 mg 30 tablets Rx only NDC 0597-0164-30 Dist. by: Boehringer Ingelheim (BI) Pharmaceuticals, Inc. Ridgefield, CT 06877 USA

**Product Quantity:**
592 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0455-2021

**Code Information:**
3513

**Product Description:**
Synjardy (empagliflozin and metformin hydrochloride) Tablets 12.5 mg/1000 mg 60 tablets Rx only NDC 0597-0168-69 Distributed by: Boehringer Ingleheim (BI) Pharmaceuticals, Inc. Ridgefield, CT 06877 USA

**Product Quantity:**
284 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0456-2021

**Code Information:**
C80102

**Product Description:**
Jentadueto XR (linagliptin and metformin hydrochloride extended-release) Tablets 5 mg/1000 mg 30 tablets Rx only NDC 0597-0275-33 Dist. by: Boehringer Ingleheim (BI) Pharmaceuticals, Inc. Ridgefield, CT 06877 USA

**Product Quantity:**
52 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0457-2021

**Code Information:**
3189866

**Product Description:**
Synjardy XR (empagliflozin and metformin hydrochloride extended-release) Tablets 25 mg/1000 mg 30 tablets Rx only NDC 0597-0295-88 Dist. by: Boehringer Ingelheim (BI) Pharmaceuticals, Inc., Ridgefield, CT 06877 USA

**Product Quantity:**
269 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0458-2021

**Code Information:**
3191432

**Product Description:**
Synjardy XR (empagliflozin and metformin) hydrochloride extended-release) Tablets 12.5 mg/1000 mg 60 tablets Rx only NDC 0597-0300-45 Dist. by: Boehringer Ingelheim (BI) Pharmaceuticals, Inc. Ridgefield, CT 06877 USA

**Product Quantity:**
751 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0459-2021

**Code Information:**
3190949

**Product Description:**
PRAVACHOL 40MG 90; NDC/UPC 3519410; RX; TABLETS

**Product Quantity:**
3 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0460-2021

**Code Information:**
ABA4203A1

**Product Description:**
Valsartan Tablets USP 40 mg 30 Scored Tablets Rx Only NDC 59746-360-30 Manufactured by: Jubilant Generics Ltd. Roorkee-247661, India

**Product Quantity:**
20 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0461-2021

**Code Information:**
VR120022A

**Product Description:**
Sodium Sulfacetamide 9.8% & Sulfur 4.8% Cleanser (sodium sulfacetamide 9.8% and sulfur 4.8%) Net Wt. 10 oz. (285 g) Rx Only NDC 50096-502-10 Manufactured for: Rosemar Labs, LLC 2100 West Loop South Suite 900 Houston, TX 77027

**Product Quantity:**
16 tubes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0462-2021

**Code Information:**
59314

**Product Description:**
Meloxicam Tablets, USP 7.5 mg 100 Tablets Rx Only NDC 69097-158-07 Manufactured for: Cipla USA, Inc. 9100 S. Dadeland Blvd., Suite 1500 Miami, FL 33156

**Product Quantity:**
576 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0463-2021

**Code Information:**
KA03034

**Product Description:**
Nadolol Tablets, USP 40 mg 100 Tablets Rx Only NDC 69097-868-07 Manufactured for: Cipla USA Inc. 9100 S. Dadeland Blvd., Suite 1599 Miami, FL 33156

**Product Quantity:**
40 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0464-2021

**Code Information:**
NB100156

**Product Description:**
CIPROFLOX/D5W 400/200 24X200ML; NDC/UPC 36000000924; RX; IV SOLUTION (PIGGYBACK)

**Product Quantity:**
40 bags

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0465-2021

**Code Information:**
A0D0924A

**Product Description:**
Prilosec (Omeprazole Magnesium) For Delayed-Release Oral Suspension 10 mg Rx only NDC 70515-610-01 Mfd. for: Covis Pharma, Zug, 6300 Switzerland

**Product Quantity:**
13 packets

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0466-2021

**Code Information:**
CACU

**Product Description:**
Iron 100 with Vitamin C Tablets Dietary Supplement 100 Tablets NDC 60258-099-01 Distributed By: Cypress Pharmaceutical, Inc. 135 Industrial Blvd. Madison, MS 39110

**Product Quantity:**
1 bottle

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0467-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
BENICAR 40MG 30; NDC/UPC 65597010430; RX; TABLETS

**Product Quantity:**
75 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0468-2021

**Code Information:**
1703296

**Product Description:**
PREGABALIN CAPSULES 300MG 90 ; NDC 43598-298-90; RX; CAPSULES

**Product Quantity:**
6 CONTAINERS

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0469-2021

**Code Information:**
T2000309

**Product Description:**
Phenobarbital Tablets, USP 32.4 mg 100 tablets Rx only NdC 13517-111-01 Manufactured for: e5 Pharma, LLC., Boca Raton, FL 33432

**Product Quantity:**
1 bottle

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0470-2021

**Code Information:**
20ZHX2R

**Product Description:**
Ivermectin Tablets USP 3 mg 20 Tablets (2 Foil Strips of 10 tablets each) Rx Only NDC 4799-806-01 Manufactured for: Edenbridge Pharmaceuticals, LLC Parsippany, NJ 07054 877-381-3336

**Product Quantity:**
504 cartons

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0471-2021

**Code Information:**
A1003273A

**Product Description:**
Banzel (rufinamide) tablets 200 mg 120 tablets Rx only NDC 62856-582-52 Manufactured by Eisai Co., Ltd. Marketed by Eisai Inc. Woodcliff Lake, NJ 07677

**Product Quantity:**
30 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0472-2021

**Code Information:**
80643

**Product Description:**
Narcan (naloxone HCl) Nasal Spray 4 mg Two Pack This box contains two (2) 4-mg doses of naloxone HCl in 0.1 mL of nasal spray. 0.1 mL intranasal spray per unit For use in the nose only Rx only NDC 69547-353-02 Distributed by Adapt Pharma, Inc. Radnor, PA 19087 USA

**Product Quantity:**
11189 plungers

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0473-2021

**Code Information:**
201701

**Product Description:**
BROMPHENIRAMINE MALEATE, PSEUDOEPHEDRINE HYDROCHLORIDE, AND DEXTROMETHORPHAN HYDROBROMIDE SYRUP 10-30-2MG/5ML 473ML; NDC/UPC 71930-026-43; RX; SYRUP

**Product Quantity:**
73 carton

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0474-2021

**Code Information:**
13120103A

**Product Description:**
Prenatal Tablets Gluten Free Multivitamin/ Multimineral Dietary Supplement for Pregnant and Lactating Women UD 100 Tablets (10x10) NDC 77333-715-10 GenDose Pharmaceuticals

**Product Quantity:**
41 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0475-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
cathflo activase (ALTEPLASE) 2 mg Rx Only NDC 50242-041-64 Genentech

**Product Quantity:**
1473 vials

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0476-2021

**Code Information:**
3410425

**Product Description:**
FLOVENT DISKUS 100MCG 60; NDC/UPC 173060202; RX; INHALER MEDICAL INTERNAL - MAY OR MAY NOT BE AEROSOL

**Product Quantity:**
237 inhalers

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0477-2021

**Code Information:**
9E9A

**Product Description:**
ADVAIR HFA 45-21MCG 12GM; NDC/UPC 173071520; RX; INHALER MEDICAL INTERNAL - MAY OR MAY NOT BE AEROSOL

**Product Quantity:**
297 inhalers

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0478-2021

**Code Information:**
TH4K

**Product Description:**
ARNUITY ELLIPTA 100MCG 30INH; NDC/UPC 173087410; RX; INHALER MEDICAL INTERNAL - MAY OR MAY NOT BE AEROSOL

**Product Quantity:**
513 inhalers

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0479-2021

**Code Information:**
F79E

**Product Description:**
Arnuity Ellipta (fluticasone furoate inhalation powder) 200 mcg 1 Ellipta Inhaler containing 1 Foil Strip of 30 Blisters Rx Only NDC 0173-0876-10 GlaxoSmithKline Research Triangle Park, NC 27709

**Product Quantity:**
353 inhalers

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0480-2021

**Code Information:**
5U3D

**Product Description:**
TRELEGY ELLIPTA (FLUTICASONE FUROATE, UMEDIDINIUM AND VILANTEROL INHALATION POWDER) 100-62.5-25MCG 60; NDC/UPC 0173-0893-10; RX; INHALER MEDICAL INTERNAL - MAY OR MAY NOT BE AEROSOL

**Product Quantity:**
4065 CARTON

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0481-2021

**Code Information:**
FN2J

**Product Description:**
Trelegy Ellipta (fluticasone furoate, umeclidinium, and vilanterol inhalation powder) 100 mcg/62.5 mcg/25 mcg; 1 ELLIPTA Inhaler containing 30 doses (60 blisters total) Rx Only NDC 0173-0887-10 GlaxoSmithKline Research Triangle Park, NC 27709

**Product Quantity:**
903 inhalers

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0482-2021

**Code Information:**
3X8P

**Product Description:**
Verapamil Hydrochloride Extended-Release Tablets USP 120 mg Rx Only NDC 68462-292-01 Manufactured by: Glenmark Generics Ltd Colvale-Bardez, Goa 403513, India Manufactured for: Glenmark Generics Inc., USA Mahwah, NJ 07430

**Product Quantity:**
513 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0483-2021

**Code Information:**
19205584

**Product Description:**
EZETIMIBE AND SIMVASTATIN TABLETS 10-10MG 30; NDC/UPC 68462-321-30; RX; TABLETS

**Product Quantity:**
7 CARTON

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0484-2021

**Code Information:**
17201603

**Product Description:**
Theophylline (Anhydrous) Extended-Release Tablets 400 mg 100 Tablets Rx Only NDC 68462-380-01 Manufactured by: Glenmark Pharmaceuticals Limited Colvale-Bardez, Goa 403513, India Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430

**Product Quantity:**
141 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0485-2021

**Code Information:**
19205025

**Product Description:**
Triumeq (abacavir, dolutegravir, and lamivudine) 600 mg/50 mg/300 mg Tablets 30 Tablets Rx Only NDC 49702-231-13 Manufactured for: Viiv Healthcare Research Triangle Park, NC 27709 by GlaxoSmithKline Research Triangle Park, NC 27709

**Product Quantity:**
2264 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0486-2021

**Code Information:**
GS5G

**Product Description:**
Hydrocortisone Ointment USP 1% Maximum Strength Net Wt. 1 oz (28 g) NDC 0472-0345-56 Manufactured by: Actavis Mid Atlantic LLC 1877 Kawai Road, Lincolnton, NC 28902

**Product Quantity:**
23 tubes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0487-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021

**Product Description:**
FaBB Vitamin B6 (as Pyridoxine Hydrochloride) 25 mg Folic Acid 2.2 mg Vitamin B12 (as Cyanocobalamin) 1.0 mg Dietary Supplement 100 Tablets Distributed by: H2-Pharma, LLC 2010 Berry Chase Place Montgomery, AL 36117

**Product Quantity:**
54 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0488-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
bupropion Hydrochloride Tablets, USP 75 mg 100 Tablets Rx only NDC 23155-191-01 Manufactured for: Heritage Pharmaceuticals Inc. Eatontown, NJ 07724

**Product Quantity:**
32 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0489-2021

**Code Information:**
L200791

**Product Description:**
AcetaZOLAMIDE Tablets, USP 125 mg 100 Tablets Rx only NDC 23155-287-01 Manufactured for: Heritage Pharmaceuticals Inc. Eatontown, NJ 07724

**Product Quantity:**
122 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0490-2021

**Code Information:**
M200833

**Product Description:**
Calcium Acetate Capsules 667 mg 200 Capsules Rx only NDC 23155-531-02 Manufactured for: Heritage Pharmaceuticals Inc. Eatontown, NJ 07724

**Product Quantity:**
35 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0491-2021

**Code Information:**
L200801

**Product Description:**
LITHIUM CARB 150MG 100; NDC/UPC 54252625; RX; CAPSULES

**Product Quantity:**
298 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0492-2021

**Code Information:**
AB1024A

**Product Description:**
LEUCOVORIN 15MG 24; NDC/UPC 54449810; RX; TABLETS

**Product Quantity:**
12 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0493-2021

**Code Information:**
064159A

**Product Description:**
Levofloxacin Injection in 5% Dextrose 500 mg in 100 mL 5% Dextrose (5 mg/mL) 24x100 mL Single Dose Flexible Containers NDC 0143-9721-24 West-Ward Pharmaceutical Corp Eatontown, NJ 07724 USA

**Product Quantity:**
35 bags

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0494-2021

**Code Information:**
2007046.1

**Product Description:**
TIROSINT(levothyroxine sodium) capsules 175MCG 3 blisters X10 capsules; NDC/UPC 71858-0055-4; RX; CAPSULES

**Product Quantity:**
25 boxes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0495-2021

**Code Information:**
200606

**Product Description:**
Enbrace HR 30 ct. Softgels Enhanced Prenatal Vitamin Supplement Rx NDC 64661-650-30 Manufactured for: JAYMAC Pharmaceuticals, LLC, Sunset, LA 70584

**Product Quantity:**
11 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0496-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
Tylenol Acetaminophen Pain Regular Strength Liquid Gels Pain Reliever Fever Reducer 20 Liquid Gels 325 mg each NDC 50580-487-20

**Product Quantity:**
37 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0497-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
INVEGA SUSTENNA 156MG/1ML; NDC/UPC 50458056301; RX; SYRINGES

**Product Quantity:**
534 syringes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0498-2021

**Code Information:**
KIB0M00

**Product Description:**
Auryxia (ferric citrate) tablets 210 mg* 200 Tablets Rx Only NDC 59922-631-01 Manufactured for and distributed by: Keryx Biopharmaceuticals, Inc. 750 Lexington Avenue, 20th Floor New York, NY 10022 USA

**Product Quantity:**
136 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0499-2021

**Code Information:**
AN0142D

**Product Description:**
Livalo (pitavastatin) tablets 2 mg* Rx Only NdC 66869-204-90 Manufactured under license from: Kowa Company, Limited Tokyo 103-8433 Japan Tablets Manufactured by: Patheon, Inc. Cincinnati, OH 45237 USA or by Kowa Company, Ltd Nagoya 462-0024 Japan

**Product Quantity:**
453 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0500-2021

**Code Information:**
3193479

**Product Description:**
PHENTERMINE HCL 30MG 100 C4; NDC/UPC 10702002801; RX; CAPSULES

**Product Quantity:**
16 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0501-2021

**Code Information:**
16667A

**Product Description:**
PHENTERMINE HCL 37.5MG 100 C4; NDC/UPC 10702002901; RX; CAPSULES

**Product Quantity:**
237 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0502-2021

**Code Information:**
16649A

**Product Description:**
Infants Aqueous Vitamin D Oral Drops 400 IU/mL 50 mL (1 2/3 fl oz) Manufactrued by: Silarx Pharmaceuticals, Inc. 19 West Street Spring Valley, NY 10977 USA

**Product Quantity:**
422 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0503-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
Ferrous Sulfate 75 mg (equivalent to 15 mg Iron) Per 1.0 mL Alcohol 0.2% v/v Drops Iron Supplement Drops For Infants and Toddlers 50 mL (1 2/3 fl oz) NDC 54838-011-50 Manufactured by: Silarx Pharmaceuticals, Inc. 19 West Street Spring Valley, NY 10977 USA

**Product Quantity:**
357 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0504-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
SILADRYL 12.5/5ML 118ML SF AF; NDC/UPC 354838135404; OTC; LIQUID

**Product Quantity:**
78 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0505-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
Pantoprazole Sodium Delayed-Release Tablets, USP 20 mg* 90 Tablets Rx Only NDC 62175-180-46 Distributed by: Kremers Urban Pharmaceuticals Inc. Princeton, NJ 08540, USA

**Product Quantity:**
4 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0506-2021

**Code Information:**
20249489A

**Product Description:**
NOHIST-DM Antihistamine/Antitussive Nasal Decongestant 16 fl. oz. (473 mL) NDC 68047-186-16 Distributed by: Larken Laboratories, Inc. Canton, MS 39046

**Product Quantity:**
24 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0507-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
TRI-LO-MARZIA 0.180MG/0.025MG; 0.215 MG/0.025MG AND 0.250MG/0.025MG 3X28 BPK; NDC/UPC 68180-837-73; RX; TABLETS

**Product Quantity:**
60 CARTON

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0508-2021

**Code Information:**
L001911

**Product Description:**
Amlodipine and Olmesartan Medoxomil Tablets 10 mg/20 mg 30 Tablets Rx Only NDC 33342-192-07 Manufactured for: Macleods Pharma USA, Inc. Plainsboro, NJ 08536 Manufactured by: Macleods Pharmaceuticals Ltd. Baddi, Himachal Pradesh, India

**Product Quantity:**
33 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0509-2021

**Code Information:**
BAD62005A

**Product Description:**
TRAZODONE HYDROCHLORIDE TABLETS, USP 50MG 100 TABLET 10X10UD; NDC/UPC 0904-6868-61; RX; TABLETS

**Product Quantity:**
91 CARTON

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0510-2021

**Code Information:**
R01580

**Product Description:**
MICONAZOLE 7 2% 45GM APL; NDC/UPC 009047734459; OTC; CREAM

**Product Quantity:**
71 tubes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0511-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
Banophen Diphenhydramine HCl 25 mg Antihistamine 100 capsules NDC 0904-5306-60 Distributed by: Major Pharmaceuticals 31778

Enterprise Drive Livonia, MI 48150 USA

**Product Quantity:**
88 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0512-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021

**Product Description:**
Acne Medication Benzoyl Peroxide Gel USP, 5% Net Wt 1.5 oz (42.5 g) NDC 0536-1055-56 Distributed by: Rugby Laboratories 31778 Enterprise Drive, Livonia, MI 48150

**Product Quantity:**
189 tubes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0513-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
VITAMIN D3 50MCG 100 SOFTGELS; NDC/UPC 880681009000; OTC; GELCAP

**Product Quantity:**
380 BOTTLE

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0514-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
VITAMIN D3 25MCG 90 TABLETS; NDC/UPC 880681168004; OTC; TABLETS

**Product Quantity:**
53 BOTTLE

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0515-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
VITAMIN D3 25MCG 180 TABLETS; NDC/UPC 880681168011; OTC; TABLETS

**Product Quantity:**
19 BOTTLE

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0516-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
DIBUCAINE TOPICAL ANESTHETIC 1% HEMORRHOIDAL OINTMENT 28GM ; NDC/UPC 0536-1211-95; OTC; OINTMENT

**Product Quantity:**
701 CARTON

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0517-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
BENZOYL PEROXIDE WASH 5% 148ML; NDC/UPC 0536-1259-63; OTC; LIQUID

**Product Quantity:**
37 BOTTLE

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0518-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
VITAMIN D3 50MCG 100 CALC; NDC/UPC 880681170007; OTC; TABLETS

**Product Quantity:**
427 BOTTLE

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0519-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
CARBIDOPA AND LEVORDOPA TABLETS, USP 25MG/100MG 100 TABLETS; NDC/UPC 51862-856-01; RX; TABLETS

**Product Quantity:**
407 BOXES

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0520-2021

**Code Information:**
FG12532

**Product Description:**
PEDIA-LAX 66ML; NDC/UPC 301320202205; OTC; ENEMA

**Product Quantity:**
147

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0521-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
Belsomra (suvorexant) tablets 10 mg Each tablet contains 10 mg suvorexant. This package contains 30 Tablets in 3 Blister Cards. Each Blister Card contains 10 Tablets Rx only NDC 00006-0033-30 Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. Whitehouse Station, NJ 08889, USA

**Product Quantity:**
119 cartons

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0522-2021

**Code Information:**
1791139

**Product Description:**
Belsomra (suvorexant) tablets 20 mg Each tablet contains 20 mg suvorexant. This package contains 30 Tablets in 3 Blister Cards. Each Blister Card contains 10 Tablets. Rx only NDC 0006-0335-30 Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. Whitehouse Station, NJ 08880, USA

**Product Quantity:**
299 cartons

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0523-2021

**Code Information:**
1778598

**Product Description:**
Steglatro (ertugliflozin) tablets 15 mg 30 Tablets Rx only NDC 0006-5364-03 Manuf. for: Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station, NJ 08889, USA

**Product Quantity:**
215 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0524-2021

**Code Information:**
T013566

**Product Description:**
ASMANEX TWST 220MCG 60INH PWD; NDC/UPC 85134102; RX; INHALER MEDICAL INTERNAL - MAY OR MAY NOT BE AEROSOL

**Product Quantity:**
122 inhalers

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0525-2021

**Code Information:**
T023471

**Product Description:**
Levothyroxine Sodium Tablets, USP 125 mcg (0.125 mg) 90 Tablets Rx only NDC 0378-1813-77 Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.

**Product Quantity:**
112 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0526-2021

**Code Information:**
3109046

**Product Description:**
Estradiol Transdermal System, USP 0.1 mg/day (Twice-Weekly) Delivers 0.1 mg/day Rx only NDC 0378-4623-26 Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.

**Product Quantity:**
72 cartons

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0527-2021

**Code Information:**
3108206

**Product Description:**
Epinephrine Injection, USP Auto-Injectors in all strengths, packs and styles Manufactured for Mylan Specialty L.P., Morgantown, WV , NDC: 9502-500-01, 49502-500-02, 49502-500-92, 49502-501-01

**Product Quantity:**
620 injector

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0528-2021

**Code Information:**
0FM544

**Product Description:**
Proctofoam HC (hydrocortisone acetate 1% and pramoxine hydrochloride 1%) topical aerosol 10 g net wt Rx Only NDC 0037-6822-10 Distributed by: Meda Pharmaceutical Inc. Somerset, New Jersey

**Product Quantity:**
834 aerosol containers

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0529-2021

**Code Information:**
33119

**Product Description:**
NAT B VIT D3 2000U 100; NDC/UPC 079854041125; OTC; TABLETS

**Product Quantity:**
47 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0530-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
Vitamin D3 Cholecalciferol 50,000 IU Dietary Supplement 100 Capsules NDC 75834-020-01 Marketed by: Nivagen Pharmaceuticals, Inc. Sacramento, CA 95827

**Product Quantity:**
523 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0531-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
Vitamin D3 Cholecalciferol 50,000 IU Dietary Supplement 12 Capsules NDC 75834-020-12 Marketed by: Nivagen Pharmaceuticals, Inc. Sacramento, CA 95827 USA

**Product Quantity:**
205 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0532-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
TOBREX 0.3% 3.5GM OPTH; NDC/UPC 65064435; RX; OINTMENT

**Product Quantity:**
28 tubes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0533-2021

**Code Information:**
20B14E

**Product Description:**
Ilevro (nepafenac ophthalmic suspension) 0.3% 3 mL Sterile Rx Only NDC 0065-1750-14 Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, Texas 76134

**Product Quantity:**
348 droptainers

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0534-2021

**Code Information:**
10CPE

**Product Description:**
CIPRODEX (CIPROFLOXACIN 0.3 AND DEXAMETHASONE 0.1%) 7.5ML; NDC/UPC 0078-0799-75; RX; DROPS

**Product Quantity:**
341 CARTON

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0535-2021

**Code Information:**
20F02UA

**Product Description:**
Rybelsus (semaglutide) Tablets 7 mg Once daily Each tablet contains 7 mg semaglutide 30 tablets 3 blister packs. Each pack contains 10 tablets. Rx only NDC 0169-4307-13 Manufactured by: Novo Nordisk A/S DK-2880 Bagsvaerd, Denmark

**Product Quantity:**
1189 cartons

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0536-2021

**Code Information:**
K082347

**Product Description:**
Benztropine Mesylate Tablets, USP in all pack sizes, styles and strengths Manufactured for: Qualitest Pharmaceuticals Huntsville, AL 35811

**Product Quantity:**
60 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0537-2021

**Code Information:**
S2008031

**Product Description:**
Lamotrigine Extended-Release Tablets 250 mg 30 Tablets Rx Only NDC 49884-604-11 Manufactured by: Zhejiang Huahai Pharmaceutical Co., Ltd. Zhejiang 317024 China For Par Pharmaceutical Companes, Inc. Spring Valley, NY 10977 U.S.A.

**Product Quantity:**
131 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0538-2021

**Code Information:**
10116

**Product Description:**
ZOLPIDEM TARTRATE SUBLINGUAL TABLET 3.5 MG 30 UNIT DOSE POUCHES; NDC/UPC 49884089911; RX; EACH POUCH CONTAINS ONE SUBLINGUAL TABLET

**Product Quantity:**
55 Boxes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0539-2021

**Code Information:**
12699501

**Product Description:**
HySept Solution 0.25% Sodium Hypochlorite Solution 473 mL (16 fl. oz.) NDC 39328-063-25 Manufactured in USA Patrin Pharma, Skokie, IL 60076

**Product Quantity:**
236 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0540-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
RISPERIDONE 1MG/ML 30ML; NDC/UPC 50458059601; RX; SOLUTION (USUALLY NOT OTIC, OPTH, NASAL DROPS)

**Product Quantity:**
39 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0541-2021

**Code Information:**
KHB2701

**Product Description:**
Benzoyl Peroxide 2.5% Aqueous Base, Acne Treatment Gel Net Wt. 2.1 oz (60 g) NDC 45802-101-96 Distributed By Perrigo Allegan, MI 49010

**Product Quantity:**
5 tubes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0542-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
Benzoyl Peroxide 10% Acne Medication Wash Net Wt 5 oz (142 g) Distributed By Perrigo Allegan, MI 49010, NDC 45802-318-01

**Product Quantity:**
31 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0543-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
Polyethylene Glycol 3350 Powder for Solution, Laxative Net Wt 4.1 oz (119 g) 7 Once-Daily Doses NDC 45802-868-01 Distributed by Perrigo Allegan, MI 49010

**Product Quantity:**
163 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0544-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
POLYETHYLENE GLYCOL 3350 Powder for Solution Osmotic Laxative 14 once-daily doses 14 Packet- Newt Wt. 0.5 oz (17g) each NDC 45802-868-66

**Product Quantity:**
934 boxes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0545-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
Fexofenadine Hydrochloride Tablets, 180 mg Antihistamine Non-Drowsy 100 Tablets 180 mg Each NDC 45802-571-78 Distributed By Perrigo Allegan, MI 49010

**Product Quantity:**
321 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0546-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
LORATADINE 10MG 100 ND 24H; NDC/UPC 345802650788; OTC; TABLETS

**Product Quantity:**
2854 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0547-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
Cetirizine Hydrochloride Tablets, 10 mg, 300 Count; NDC/UPC 345802919878; OTC; TABLETS

**Product Quantity:**
1371 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0548-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
Podofilox Topical Solution 0.5% 3.5ML, Rx Only, For Topical Use Only, Manufactured by Perrigo, Minneapolis, MN 55427, NDC 0574-0611-05.

**Product Quantity:**
180 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0549-2021

**Code Information:**
402995

**Product Description:**
HYDROCORTISONE ACET 30MG 12; RX; SUPPOSITORY,Rx Only, Distributed by: Perrigo, Allegan, MI 49010, NDC: 0574-7093-12

**Product Quantity:**
95 suppositories

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0550-2021

**Code Information:**
433202

**Product Description:**
Triamcinolone Acetonide Ointment, USP, 0.025% 80g; Rx Only, Distributed by: Perrigo, Allegan, MI 49010,NDC 45802-054-36

**Product Quantity:**
178 tubes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0551-2021

**Code Information:**
0MT0286

**Product Description:**
LYRICA (pregabalin) capsules, 200mg 90-count bottle, Rx Only, Distributed by: Parke-Davis, Division of Pfizer Inc., NY, NY 10017, MADE IN SINGAPORE

**Product Quantity:**
49 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0552-2021

**Code Information:**
CK1081

**Product Description:**
Methotrexate Injection, USP 50 mg/2mL (25 mg/mL) 5 x 2mL Single-Dose Vials, Sterile, Rx Only, Distributed by Hospira, Inc. Lake Forest, IL 60045. NDC 61703-350-38.

**Product Quantity:**
341 vials

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0553-2021

**Code Information:**
H074437AA

**Product Description:**
Chantix (varenicline) Tablets Continuing Month Box Contains: 4 Continuing Weeks (1 mg x 56 tablets) Rx only NDC 0069-0469-03 Distributed by Pfizer Labs Division of Pfizer Inc., NY, NY 10017

**Product Quantity:**
940 cartons

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0554-2021

**Code Information:**
EC5910

**Product Description:**
Chantix (varenicline) Tablets Continuing Month Box Contains: 4 Continuing Weeks (1 mg x 56 tablets) Rx only ; Rx only Distributed by Pfizer Labs Division of Pfizer, Inc., NY, NY ,10017NDC 0069-0469-56

**Product Quantity:**
848 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0555-2021

**Code Information:**
EM1069

**Product Description:**
Chantix (varenicline) Tablets Starting Pack Contains: 1 Starting Week (0.5 mgx11 tablets) 3 Continuing Weeks (1 mgx42 tablets) Rx only NDC 0069-0471-03 Distributed by Pfizer Labs Division of Pfizer, Inc., NY, NY 10017

**Product Quantity:**
1040 cartons

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0556-2021

**Code Information:**
EC5911

**Product Description:**
LEVOXYL Tablets, USD, 150MCG, 100-count bottle, Rx Only, Distributed by Pfizer Inc., New York, NY 10017, MADE IN AUSTRIA, NDC: 60793-858-01

**Product Quantity:**
13 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0557-2021

**Code Information:**
20D27

**Product Description:**
PROMETHAZINE PLAIN ORAL SOLUTION 6.25MG/5ML 473ML; ; RX; SOLUTION (USUALLY NOT OTIC, OPTH, NASAL DROPS), Rx Only, NDC 0211-0927-16

**Product Quantity:**
49 CARTON

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0558-2021

**Code Information:**
20001481

**Product Description:**
Nature's Truth Absorbable Calcium 1200 mg plus D3 5000 IU 120 Softgels Dietary Supplements Carefully Designed and Distributed by Nature's Truth LLC. Ronkonkoma, NY 11779, UPC 840093100672

**Product Quantity:**
8 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0559-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
Intrarosa Prasterone Vaginal Inserts 6.5 mg 28 inserts/applicators Rx Only Manufactured for: Ednoceutics, Inc. Quebec City, Canada, G1V 4M7 Distributed by: AMAG Pharmaceuticals, Inc. Waltam, MA 02451, NDC 64011-601-28

**Product Quantity:**
205 cartons

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0560-2021

**Code Information:**
R81339

**Product Description:**
Budesonide and Formoterol Fumarate Dihydrate Inhalation Aerosol 80/4.5 budesonide 80 mcg/formoterol fumarate dihydrate 4.5 mcg Inhalation Aerosol 120 inhalations Rx only Manufactured for: AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850, NDC 0310-7372-20

**Product Quantity:**
905 inhalers

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0561-2021

**Code Information:**
2000655C00

**Product Description:**
Medroxyprogesterone acetate injectable suspension, USP 150 mg per mL 1 mL Prefilled Syringe Rx only NDC 59762-4538-2 Distributed by: Greenstone, LLC. Peapack, NJ 07977

**Product Quantity:**
286 syringes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0562-2021

**Code Information:**
EC4744

**Product Description:**
medroxyprogesterone acetate injectable suspension, USP, 150MG/ML 1ML, Rx Only, Distributed by: Greenstone LLC, Peapack, NJ 07977, NDC 59762-4538-02

**Product Quantity:**
148 syringes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0563-2021

**Code Information:**
DN0428

**Product Description:**
Cefazolin for Injection, USP 1 gram per vial Rx Only Single-use Vial Sterile Manufactured in Austria by Sandoz GmbH for Sandoz, Inc., Princeton, NJ 08540, NDC 0781-3451-70

**Product Quantity:**
8 vials

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0564-2021

**Code Information:**
JZ9830

**Product Description:**
HYDROCORTISONE 1% 30gm cream

**Product Quantity:**
143 tubes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0565-2021

**Code Information:**
KK4912

**Product Description:**
Tuberculin Purified Protein Derivative (Mantous) TUBERSOL, Stabilized Solution 5 US Units, Rx Only Sanofi Pasteur Limited, NDC 49281-752-21

**Product Quantity:**
406 vials

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0566-2021

**Code Information:**
C5804AA

**Product Description:**
Collagenase Santyl Ointment 250 units/g 30 grams Rx Only Marketed by Smith & Nephew, Inc., Fort Worth, TX 76107, NDC 50484-010-30

**Product Quantity:**
1391 tubes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0567-2021

**Code Information:**
191960

**Product Description:**
CLINDAMYCIN HYDROCHLORIDE CAPSULES, USP,150MG 100-count bottles, Rx Only, Manufactured by: Ohm Laboratories Inc. New Brunswick, NJ 08901, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, NDC 63304-692-01

**Product Quantity:**
223 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0568-2021

**Code Information:**
AB77104

**Product Description:**
COREG CR (carvedilol phosphate) Extended Release Capsules, 80 mg, 30-count bottle, Rx Only,/UPC 57664066683

**Product Quantity:**
133 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0569-2021

**Code Information:**
P0978

**Product Description:**
Trokendi XR (topiramate) extended-release capsules 100 mg 30 Capsules Rx only, Manufactured by: Catalent Pharma Solutions Winchester, KY 40391 USA Manufactured for: Supernus Pharmaceuticals, Inc. Rockville, MD 20850 USA, NDC 17772-103-30

**Product Quantity:**
490 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0570-2021

**Code Information:**
1741214

**Product Description:**
Colcrys (colchicine, USP) tablets 0.6 mg 30 tablets Rx only Distributed by: Takeda Pharmaceuticals America, Inc. Deerfield, IL 60015,NDC 64764-119-07

**Product Quantity:**
160 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0571-2021

**Code Information:**
11888415

**Product Description:**
Children's Loratadine Oral Solution USP, 5 mg/5 mL (Antihistamine) Allergy Grape Flavor 4 FL OZ (120 mL) NDC 51672-2131-8 Distributed by: Taro Pharmaceuticals U.S.A., Inc. Hawthorne, NY 10532

**Product Quantity:**
2907 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0572-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
Proair HFA (albuterol sulfate) Inhalation Aerosol 90 mcg per actuation With Dose Counter 200 Metered Inhalation 8,5 g Net Contents Rx only NDC 59310-579-22 Mktd by: Teva Respiratory, LLC Horsham, PA 19044 Mfd by: IVAX Pharmaceuticals Ireland Waterford, Ireland

**Product Quantity:**
26895 inhalers

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0573-2021

**Code Information:**
DAF02A

**Product Description:**
NEOMYCIN SULF TABLETS, USP, 500mg, 100-count bottle, Rx Only, Distributed by: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC: 0093-1177-01

**Product Quantity:**
41 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0574-2021

**Code Information:**
3006910

**Product Description:**
BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE TABLETS 2.5 mg/6.25 mg, 100-count bottles, Rx Only, Distributed by: Teva Pharmaceuticals USA, Inc., Parsippany, NJ 07054 NDC 0093-3241-01 RX; TABLETS

**Product Quantity:**
235 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0575-2021

**Code Information:**
1417295A

**Product Description:**
PENICILLIN V POT for Oral Solution, USP 125mg/5mL 100mL (when mixed) Rx Only, Manufactured for: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0093-4125-73

**Product Quantity:**
91 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0576-2021

**Code Information:**
35446365A

**Product Description:**
EPINEPHRINE INJECTION USP, 0.3MG (AUTO-INJECTORS) FOR ALLERGIC EMERGENCIES (ANAPHYLAXIS) 2 Auto-Injectors and 1

Trainer, Manufactured for: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454 NDC 0093-5986-27

**Product Quantity:**
414 boxes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0577-2021

**Code Information:**
033J20AA

**Product Description:**
EPINEPHRINE INJECTION USP, 0.15 MG (AUTO-INJECTORS) FOR ALLERGIC EMERGENCIES (ANAPHYLAXIS) 2 Auto-Injectors and 1 Trainer, Manufactured for: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454 NDC 0093-5985-27

**Product Quantity:**
1776 boxes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0578-2021

**Code Information:**
025C20AA

**Product Description:**
Balziva 28 Day (norethindrone and ethinyl estradiol tablets USP) 6 Blister Card Dispensers, 28 tablets each, Rx Only, Manufactured for: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0555-9034-58

**Product Quantity:**
23 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0579-2021

**Code Information:**
100016785

**Product Description:**
Levalbuterol tartrate HFA Inhalation Aerosol 45 mcg/actuation 200 Metered Inhalations Net Contents: 15 g Rx Only NDC 0591-2927-54 Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054 USA

**Product Quantity:**
828 inhalers

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0580-2021

**Code Information:**
200093

**Product Description:**
Desvenlafaxine Extended-Release Tablets 25 mg 30 Tablets Rx Only NDC 0591-4060-30 Manufactured by: Actavis Laboratories FL, Inc. Fort Lauderdale, FL 33314 USA Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054 USA

**Product Quantity:**
57 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0581-2021

**Code Information:**
1399650A

**Product Description:**
Sulindac Tablets, USP, 200mg 100-count bottles, Rx Only, Manufactured by: Epic Pharma, LLC, Laurelton, NY 11413, NDC 42806-011-01

**Product Quantity:**
92 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0582-2021

**Code Information:**
1578F201

**Product Description:**
Darifenacin Extended-release Tablets 7.5 mg 30 Tablets Rx only Manufactured by: Torrent Pharmaceuticals LTD. Indrad-382 721, India Manufactured for: Torrent Pharma Inc. Basking Ridge, NJ 07920, NDC 13668-202-30

**Product Quantity:**
52 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0583-2021

**Code Information:**
BDZ7G005

**Product Description:**
Darifenacin Extended-release Tablets 15 mg 30 Tablets Rx only, Manufactured by: Torrent Pharmaceuticals, LTD Indrad-382 721, India Manufactured for: Torrent Pharma Inc. Basking Ridge, NJ 07920, NDC 13668-203-30

**Product Quantity:**
37 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0584-2021

**Code Information:**
BDZ9G005

**Product Description:**
Folivane-Plus with Ascorbic Acid Precursors Iron/Folic Acid/Vitamin Supplement Capsules 90 Capsules Rx Only NDC 13811-539-90 Manufactured for: Trigen Laboratories, Inc., Sayreville, NJ 08872

**Product Quantity:**
80 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0585-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
TRAMADOL HYDROCHLORIDE TABLETS USP 100MG, 100-count bottle, Rx Only, Manufactured by: Rubicon Research :Private Limited, Ambernath, Dist. Thane, 421506 India, NDC: 52817-0196-10

**Product Quantity:**
86 BOTTLE

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0586-2021

**Code Information:**
200340H1

**Product Description:**
Restora Omega-3 enhanced Lactobacillus Casei KE-99 30 Capsules 1 A Day Nutritional Supplement NDC 52747-200-30 Marketed by US Pharmaceutical Corporation, P.O. Box 360465, Decatur, GA 30036

**Product Quantity:**
31 cartons

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0587-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
INTEGRA 325/40/3mg 90-count bottle, NDC: 52747-710-60

**Product Quantity:**
32 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0588-2021

**Code Information:**
All Lots distributed 02/23/2021 through 03/10/2021.

**Product Description:**
VIMPAT(lacosamide) Tablets ,100 mg, 60-count bottle; Rx Only, Manufactured for: UCB, Inc. Smyrna, GA 30080

**Product Quantity:**
796 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0589-2021

**Code Information:**
912056

**Product Description:**
VIMPAT (lacosamide) Tablets, 200mg, 60-count bottle, Rx Only, Manufactured for: UCB, Inc. Smyrna, GA 30080, NDC 0131-2480-35

**Product Quantity:**
882 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0590-2021

**Code Information:**
912064

**Product Description:**
Briviact (brivaracetam) tablets 50 mg, 60-count bottle, Rx only Manufactured for UCB, Inc. Smyrna, GA 30080, NDC 50474-570-66

**Product Quantity:**
101 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0591-2021

**Code Information:**
309750

**Product Description:**
Amantadine Hydrochloride Tablets 100 mg 100-count bottle, Rx Only Manufactured by Upsher-Smith Laboratories, Inc. Maple Grove, MN

55369, NDC 0832-0111-00

**Product Quantity:**
271 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0592-2021

**Code Information:**
395310

**Product Description:**
HALOPERIDOL TABLETS 20mg, USP, 100-count bottle, Rx Only Distributed by: Usher-Smith Laboratories, LLC, Maple Grove, MN 55369, NDC: 0832-1560-11

**Product Quantity:**
35 BOTTLE

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0593-2021

**Code Information:**
2007346C

**Product Description:**
Corgard (nadolol tablets, USP) 40 mg 100 Tablets Rx only NDC 27505-101-01 Distributed by US WorldMeds, LLC, Louisville, KY 40241

**Product Quantity:**
2 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0594-2021

**Code Information:**
19T28

**Product Description:**
CYANOCOBAL Injection 1000MCG/ML 25X1ML; NDC/UPC 69680-112-25; RX; MULTI DOSE VIAL

**Product Quantity:**
6 boxes

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0595-2021

**Code Information:**
303824

**Product Description:**
Brompheniramine Maleate, Pseudoephedrine Hydrochloride and Dextromethorphan Hydrobromide Oral Syrup Net: 1 Pint (473 mL) Bulk Container-Not for Household Use Rx Only NDC 60432-275-16 Distributed By: Wockhardt USA, LLC Parsippany, NJ 07054

**Product Quantity:**
15 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0596-2021

**Code Information:**
UV1092

**Product Description:**
Enalapril Maleate Tablets, USP 2.5 mg 100 tablets Rx only Distributed by: Cardinal Health, NDC 64679-923-02

**Product Quantity:**
10 bottles

**Reason for Recall:**
CGMP Deviations: Intermittent exposure to temperature excursion during storage.

**Recall Number:**
D-0597-2021

**Code Information:**
DV10467

## Class II Drugs Event

**Event ID:**
87944

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
05/13/2021

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
05/26/2021

**Initial Firm Notification of Consignee or Public:**
E-Mail

**Recalling Firm:**
Accupac, Inc.
1501 Industrial Boulevard
Mainland PA United States

**Distribution Pattern:**
Naitonwide in the US and Puerto Rico.

## Associated Products

**Product Description:**
Native Fluoride Toothpaste for Sensitive Teeth, with Fluoride, 5% potassium nitrate, 0.243% sodium fluoride (0.14% w/v fluoride ion), Net Wt. 4.1 oz.,116 g, , Distr by Native, San Francisco, CA 94111 NDC: 69423-903-41, UPC 0 37000 28803 9

**Product Quantity:**
2,261 cases/24 tubes per case = 54,264 tubes

**Reason for Recall:**
Labeling: Not Elsewhere Classified; the primary label (tube) may be incorrectly labeled as Fluoride-Free instead of With Fluoride

**Recall Number:**
D-0598-2021

**Code Information:**
LOT 0317M107 with expiry Oct 12 2022 LOT1075M107 with expiry Feb 16 2023

## Class II Drugs Event

**Event ID:**
87980

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
05/20/2021

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
05/24/2021

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
Noven Pharmaceuticals Inc
11960 Sw 144th St
Miami FL United States

**Distribution Pattern:**
Nationwide in the USA

## Associated Products

**Product Description:**
Daytrana (methylphenidate transdermal system), Delivers 10 mg over 9 hours (1.1 mg/hr), 30 Patches (NDC 68968-5552-1) per box (NDC 68968-5552-3), Rx only, Manufactured for Noven Therapeutics, LLC., Miami, FL 33186; By Noven Pharmaceuticals, Inc., Miami, FL 33186.

**Product Quantity:**
9,587 boxes

**Reason for Recall:**
Defective Delivery System: The number of customer complaints for ripping patches and tight release/adhesive transfer have exceeded the action limits.

**Recall Number:**
D-0393-2021

**Code Information:**
Lot: 88528 Exp. 09/2021

**Product Description:**
Daytrana (methylphenidate transdermal system), Delivers 15 mg over 9 hours (1.6 mg/hr), 30 Patches (NDC 68968-5553-1) per box (NDC 68968-5553-3), Rx only, Manufactured for Noven Therapeutics, LLC., Miami, FL 33186; By Noven Pharmaceuticals, Inc., Miami, FL 33186.

**Product Quantity:**
6,689 boxes

**Reason for Recall:**
Defective Delivery System: The number of customer complaints for ripping patches and tight release/adhesive transfer have exceeded the action limits.

**Recall Number:**
D-0394-2021

**Code Information:**
Lot: 88530 Exp. 10/2021

## Class III Drugs Event

**Event ID:**
87817

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
04/29/2021

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
05/24/2021

**Initial Firm Notification of Consignee or Public:**
Letter

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

**Distribution Pattern:**
Nationwide

## Associated Products

**Product Description:**
Olmesartan Medoxomil Tablets, USP, 20 mg, Rx Only, 30 Tablets, Manufactured by Alkem Laboratories Ltd, Mumbai, 400 013. INDIA, Distributed by: Ascend Laboratories LLC, Parsippany, NJ, 07054, NDC 67877-446-30.

**Product Quantity:**
34296 bottles

**Reason for Recall:**
Presence of Foreign Tablet/Capsule

**Recall Number:**
D-0392-2021

**Code Information:**
Batch No. 20122548, Exp Date: Aug. 2022

## Class III Drugs Event

**Event ID:**
87879

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
05/04/2021

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
05/27/2021

**Initial Firm Notification of Consignee or Public:**
Letter

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

**Distribution Pattern:**
Distributed Nationwide in the USA

## Associated Products

**Product Description:**
Atorvastatin Calcium Tablets, USP 10 mg*, Rx Only, 500 count bottle, Mfd By: Dr. Reddy's Laboratories Limited, Bachupally 500 090, India, NDC 55111-121-05.

**Product Quantity:**
2980 500 count -bottles

**Reason for Recall:**
Failed Impurities -Degradation Specifications:due to presence of ATV cyclo IP and FP impurities

**Recall Number:**
D-0599-2021

**Code Information:**
Lot # C905063, Exp 07/2021