Enforcement Report - Week of November 13, 2019

Class II Drugs Event

Event ID:
83908

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/01/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/05/2019

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:
Product was distributed to major distributors throughout the United States who may have further distributed the product.

Associated Products

Product Description:
Dr. Reddy's: Ranitidine Capsules 150 mg, Rx a.) 60 count bottles (NDC 5511-1129-60) b.) 500 count bottles (NDC 5511-1129-05)

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0168-2020

Code Information:
Batch Numbers: All lots within expiry.

Product Description:
Ranitidine Tablets, USP 150 mg, 190 count bottles (2x95) Tray (Sam's Club) OTC, NDC 150062076 UPC Code 078742089720

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0169-2020

Code Information:
Batch Numbers: All lots within expiry.

Product Description:
Ranitidine Tablets, USP 150 mg, a.) 24 count bottles (NDC 0363-0010-34), b.) 65 count bottles (NDC 0363-0010-61) , c.) 95 count bottles (NDC 0363-0010-62), d.) 200 count bottles (NDC 0363-0010-01) (Walgreens) OTC

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0170-2020

Code Information:
Batch Numbers: All lots within expiry.

Product Description:
Ranitidine Tablets, USP 150 mg, a.) 65 count bottles (NDC 49035-404-61) b.) 130 count bottles (NDC 49035-404-13) c.) 220 count bottles (NDC 49035-404-65) (Walmart) OTC

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0171-2020

Code Information:
Batch Numbers: All lots within expiry.

Product Description:
Ranitidine Tablets, USP 150 mg, a.) 24 count bottles (NDC 30142-505-34), b.) 50 count bottles (NDC 30142-505-50) (Kroger) OTC

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0172-2020

Code Information:
Batch Numbers: All lots within expiry.

Product Description:
Ranitidine Tablets, USP 75 mg, a.) 30 count bottles (NDC 69842-871-30) b.) 80 count bottles (NDC 69842-871-80) c.)160 count bottles (NDC 69842-871-37) (CVS) OTC

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0173-2020

Code Information:
Batch Numbers: All lots within expiry.

Product Description:
Ranitidine Tablets, USP 75 mg 30 count bottles (NDC 30142-131-30) (Kroger)

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0174-2020

Code Information:
Batch Numbers: All lots within expiry.

Product Description:
Ranitidine Tablets 75 mg, a.) 30 count bottles (NDC 63868-482-30), 60 count bottles (NDC 63868-482-60) (CDMA) OTC

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0175-2020

Code Information:
Batch Numbers: All lots within expiry.

Product Description:
Ranitidine Tablets, USP 150 mg, a.) 95 count bottles (NDC 43598-808-62), b.) 220 count bottles (NDC 43598-808-65) (HCA) OTC.

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0176-2020

Code Information:
Batch Numbers: All lots within expiry.

Product Description:
Ranitidine Tablets, USP 150 mg, a.) 24 count bottles (NDC 71713-203-02), b.)95 count bottles (NDC 71713-203-05) (Thirty Madison) OTC.

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0177-2020

Code Information:
Batch Numbers: All lots within expiry.

Product Description:
Ranitidine Tablets, USP 75 mg, NDC 57896-715-24 (GeriCare) OTC.

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0178-2020

Code Information:
Batch Numbers: All lots within expiry.

Product Description:
Ranitidine Tablets, USP 150 mg, 40 count bottles, NDC 11673-849-40 (Target) OTC.

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0179-2020

Code Information:
Batch Numbers: All lots within expiry.

Product Description:
Dr. Reddy's Ranitidine Capsules, USP 300 mg, a.) 30 count bottles (NDC 5511-1130-30) b.) 100 count bottles (NDC 5511-1130-01)

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0180-2020

Code Information:
Batch Numbers: All lots within expiry.

Product Description:
Dr. Reddy's Ranitidine Tablets, USP 75 mg, 60 count bottles, NDC 55111-131-60, (OTC)

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0181-2020

Code Information:
Batch Numbers: All lots within expiry.

Product Description:
Dr. Reddy's Ranitidine Tablets, USP 150 mg, 24 count bottles, NDC 55111-404-34 (OTC)

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0182-2020

Code Information:
Batch Numbers: All lots within expiry.

Product Description:
Ranitidine Tablets, USP 75 mg, a.) 30- count bottles (NDC 0363-0131-30), b.) 80-count bottles (NDC 0363-0131-80) (Walgreens) OTC

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0183-2020

Code Information:
Batch Numbers: All lots within expiry.

Product Description:
Ranitidine Tablets, USP 150 mg, a.) 24 count bottles (NDC 63868-480-24), b.) 50-count bottles (NDC 63868-480-50) (CDMA) OTC

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0184-2020

Code Information:
Batch Numbers: All lots within expiry.

Product Description:
Ranitidine Tablets, USP 150 mg, NDC 57896-717-05 (GeriCare) OTC

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0185-2020

Code Information:
Batch Numbers: All lots within expiry.

Class II Drugs Event

Event ID:
83997

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/18/2019

Voluntary / Mandated:
FDA Mandated

Center Classification Date:
11/05/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Basic Reset Inc.
260 W Main St Ste 103
Hendersonville TN United States

Distribution Pattern:
United States including Puerto Rico and U.S. Virgin Islands, Canada, Nigeria, United Kingdom, Australia, Israel, Hungary, UAE, Mexico, Philippines, Greece

Associated Products

Product Description:
Basic Reset Earth Wash Cleaner and Personal Care, Eco Friendly, Non Toxic, 2 fl.oz. bottle, Distributed by: Basic Reset Hendersonville, TN 37075.

Product Quantity:
949 bottles

Reason for Recall:
Marketed without an Approved NDA/ANDA

Recall Number:
D-0187-2020

Code Information:
Lots: 120718, 072518, 112017, 120718

Product Description:
Miracle Facelift Masque, All Natural, The Miracle in a Bottle, 2 fl. oz./60 mL bottle, Kim Kaufman Productions Nashville, TN.

Product Quantity:

Reason for Recall:
Marketed without an Approved NDA/ANDA

Recall Number:
D-0188-2020

Code Information:
ALL

Product Description:
Basic Reset Nuovi Skin Toner, Refined Ionyte, 4 FL. OZ., 118.3 mL bottle, Distributed by: Basic Reset Hendersonville, TN 37075

Product Quantity:
1000 bottles

Reason for Recall:
Marketed without an Approved NDA/ANDA

Recall Number:
D-0189-2020

Code Information:
Lots: 28917A, 23918A, 21519A

Product Description:
Nuovi Firming Masque, Renew and Reset, 2 fl. oz. 59 mL bottle, Made in USA exclusively for Basic Reset 260 W. Main St., Ste 103 Hendersonville, TN 37075

Product Quantity:
339 bottles

Reason for Recall:
Marketed without an Approved NDA/ANDA

Recall Number:
D-0190-2020

Code Information:
Lot: 30995

Product Description:
Basic Reset CBD Reset 750 True Full Spectrum Wintergreen, 750 mg CBD, 1 fl. oz. (30 mL) bottle, Distributed by: Basic Reset Hendersonville, TN 37075

Product Quantity:
554 bottles

Reason for Recall:
Marketed without an Approved NDA/ANDA

Recall Number:
D-0191-2020

Code Information:
Lots: 1902411.25, 1916911.25

Product Description:
Basic Reset CBD Reset 750 True Full Spectrum Cinnamon, 750 mg CBD, 1 fl. oz. (30 mL) bottle, Distributed by: Basic Reset Hendersonville, TN 37075

Product Quantity:
598 bottles

Reason for Recall:
Marketed without an Approved NDA/ANDA

Recall Number:
D-0192-2020

Code Information:
Lots: 1902411.25, 1916911.25

Product Description:
Basic Reset CBD Reset 750 True Full Spectrum Natural Flavor 750 mg CBD 1 fl. oz. (30 mL) bottle, Distributed by: Basic Reset Hendersonville, TN 37075

Product Quantity:
98 bottles

Reason for Recall:
Marketed without an Approved NDA/ANDA

Recall Number:
D-0193-2020

Code Information:
Lot: 1916911.25

Product Description:
Basic Reset CBD Reset 2400, True Full Spectrum Natural (unflavored), 2400 mg CBD, 1 fl. oz. (29 mL) bottle, Distributed by: Basic Reset Hendersonville, TN 37075

Product Quantity:
391 bottles

Reason for Recall:
Marketed without an Approved NDA/ANDA

Recall Number:
D-0194-2020

Code Information:
Lot: 1903011.8

Product Description:
BIOGENYX True Full Spectrum CBD Oil Wintergreen, 1 fl. oz. (30 mL) bottle, 750 mg, Distributed by: Biogenyx, Inc. Hendersonville, TN 37075

Product Quantity:
25 bottles

Reason for Recall:
Marketed without an Approved NDA/ANDA

Recall Number:
D-0195-2020

Code Information:
Lots: 1902411.25

Product Description:
BIOGENYX True Full Spectrum CBD Oil Natural Flavor, 1 fl. oz. (30 mL) bottle, 2400 mg, Distributed by: Biogenyx, Inc. Hendersonville, TN 37075

Product Quantity:
25 bottles

Reason for Recall:
Marketed without an Approved NDA/ANDA

Recall Number:
D-0196-2020

Code Information:
Lot: 1903011.80

Product Description:
BIOGENYX True Full Spectrum CBD Oil Cinnamon, 1 fl. oz. (30 mL) bottle, 750 mg, Distributed by: Biogenyx, Inc. Hendersonville, TN 37075

Product Quantity:
25 bottles

Reason for Recall:
Marketed without an Approved NDA/ANDA

Recall Number:
D-0197-2020

Code Information:
Lot: 1902411.25

Class II Drugs Event

Event ID:
84080

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/23/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/05/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Rd
Morgantown WV United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Alprazolam Tablets, USP 0.5 mg, 500-count bottles, Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 Made in Australia, NDC 0378-4003-05

Product Quantity:
5,760 bottles

Reason for Recall:
Presence of Foreign Substance

Recall Number:
D-0186-2020

Code Information:
Lot #: 8082708, Exp. Date September 2020

Class III Drugs Event

Event ID:
84019

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/01/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/07/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sato Pharmaceutical Inc.
20695 S Western Ave Ste 240
Torrance CA United States

Distribution Pattern:
Nationwide in the USA and Guam and Saipan, Northern Mariana Islands

Associated Products

Product Description:
Sankaijo BOTANICAL LAXATIVE (docusate sodium 8.33 mg and sennosides 1.36 mg) tablets, 150-count bottles, Manufactured by SATO PHARMACEUTICAL CO., LTD., 1-5-27 Motoakasaka Minato-KU Tokyo, Japan; SATO PHARMACEUTICAL, INC., 20695 S. Western Ave., Suite 240, Torrance, CA 90501; NDC 49873-404-01.

Product Quantity:
17,284 bottles

Reason for Recall:
Subpotent Drug: Formulated amount of sennosides component is less than labelled claim.

Recall Number:
D-0303-2020

Code Information:
Lot #: TXWT, Exp 01/20; TXTS, Exp 10/20; AXWS, Exp 10/21

Class III Drugs Event

Event ID:
84196

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/01/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/07/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore MD United States

Distribution Pattern:
Product was distributed to major distributors/wholesalers throughout the United States.

Associated Products

Product Description:
Cephalexin for Oral Suspension USP, 250 mg/5mL, 200 mL bottle, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Baltimore, Maryland 21202, United States, Manufactured by: Lupin Limited, Mumbai 400 098 INDIA, NDC 68180-0441-02

Product Quantity:
28,254 bottles

Reason for Recall:
Presence of Foreign substance: identified as a dead ant.

Recall Number:
D-0304-2020

Code Information:
Lot #: F802436, F802437, F802438, F802442, Exp 11/20

Product Description:
Cefdinir for Oral Suspension USP, 250 mg/5mL,100 mL bottle, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202, United States, Manufactured by: Lupin Limited, Mandideep 462 046 INDIA, NDC 68180-723-10

Product Quantity:
30,516 bottles

Reason for Recall:
Presence of Foreign substance: identified as a dead ant.

Recall Number:
D-0305-2020

Code Information:
Lot #: F802345, F802346, F802347, Exp 11/20

Product Description:
Cefdinir for Oral Suspension USP, 125 mg/5mL, packaged in a) 60 mL bottle (NDC 68180-722-20), b) 100 mL bottle (NDC 68180-722-10), Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202, United States, Manufactured by: Lupin Limited, Mandideep 462 046 INDIA

Product Quantity:
a) 4074 bottles b) 30,300 bottles

Reason for Recall:
Presence of Foreign substance: identified as a dead ant.

Recall Number:
D-0306-2020

Code Information:
Lot #: a) F900153, Exp 11/20; b) F802327, F802328, F802329, Exp 11/20

Not Yet Classified Drugs Event

Event ID:
84144

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/25/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
ICU Medical Inc
600 N Field Dr
Lake Forest IL United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
LACTATED RINGER'S Injection, USP, 500 mL flexible container, Rx Only, Hospira, Inc., Lake Forest, IL 60045. NDC 0409-7953-03

Product Quantity:
389,808 bags

Reason for Recall:
Presence of Particulate Matter.

Recall Number:

Code Information:
Lot: 84-603-FW Exp. 01 DEC 2019

Product Description:
0.9% SODIUM CHLORIDE INJECTION, USP, 250 mL VisIV Container, Rx Only, Hospira, Inc. Lake Forest, IL 60045. NDC 0409-7983-25

Product Quantity:
58,464 bags

Reason for Recall:
Presence of Particulate Matter.

Recall Number:

Code Information:
Lot: 95-101-C6 Exp. 01 MAY 2020