Enforcement Report - Week of February 19, 2020

Class I Drugs Event

Event ID:
84645

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/20/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/07/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Dr
Hawthorne NY United States

Distribution Pattern:
Nationwide in the U.S. and Puerto Rico.

Associated Products

Product Description:
Lamotrigine Tablets, USP, 100 mg, Rx Only, 100-count bottle, Mfd. by: Taro Pharmaceutical Industries Ltd. Haifa Bay, Israel 2624761 Dist. by: Taro Pharmaceuticals U.S.A., Inc. Hawthorne, NY 10532, NDC 51672-4131-1.

Product Quantity:

Reason for Recall:
Cross Contamination; Lamotrigine Tablets 100 mg USP was contaminated with enalapril maleate.

Recall Number:
D-0833-2020

Code Information:
Lot #: 331771, Exp. June 2021

Class II Drugs Event

Event ID:
84797

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/27/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/10/2020

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Methylphenidate hydrochloride Extended-Release ablets USP (CII), 18 mg, 100-count bottle, Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 62037-725-01

Product Quantity:

Reason for Recall:
CGMP deviations: Product bottle may be absent of desiccant.

Recall Number:
D-0836-2020

Code Information:
Lot #: 1332796 A, Exp 11/2020

Product Description:
Methylphenidate hydrochloride Extended-Release ablets USP (CII), 27 mg, 100-count bottle, Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 62037-734-01

Product Quantity:
17,436 bottles

Reason for Recall:
CGMP deviations: Product bottle may be absent of desiccant.

Recall Number:
D-0837-2020

Code Information:
Lot # 1332799A, Exp 11/2020

Class II Drugs Event

Event ID:
84827

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/28/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/12/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
B AND A TRADING CORPORATION
325 Washington Ave
Carlstadt NJ United States

Distribution Pattern:
NY & NJ only

Associated Products

Product Description:
Kushim Tablets (Gushim) 45-count packages, Label in foreign language

Product Quantity:
40 packages

Reason for Recall:
Marketed Without an Approved NDA/ANDA. FDA analysis found product to contain cinobufagin, bufalin, and bufotenine

Recall Number:
D-0840-2020

Code Information:
Lot #: H003

Class II Drugs Event

Event ID:
84833

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/03/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/10/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pfizer Inc.
235 E 42nd St
New York NY United States

Distribution Pattern:
Nationwide in the U.S. and Puerto Rico

Associated Products

Product Description:
Fentanyl Citrate Inj., USP 100 mcg Fentanyl/2 mL (50 mcg/mL), 2 mL Single-dose Vial, Each Tray contains 25 Vials, Intravenous or Intramuscular Use, Rx only, Distributed by Hospira, Inc. Lake Forest, IL 60045, NDC 00409-9094-12 (vial), 00409-9094-22 (tray).

Product Quantity:
38,676 trays

Reason for Recall:
Defective Container: confirmed customer reports for vials with loose metal overseal crimp defects, which may result in lack of assurance of sterility.

Recall Number:
D-0835-2020

Code Information:
Lot #s: 08133DK (tray) 08-133-DK (vial); 08134DK (tray) 08-134-DK (vial), Exp. 2/1/2021.

Class II Drugs Event

Event ID:
84848

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/31/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/10/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Zydus Pharmaceuticals USA Inc
73 Route 31 N
Pennington NJ United States

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Ethacrynate Sodium for Injection, USP, 50mg/vial, Single Dose Vial, Rx Only, Manufactured by: Cadila Healthcare Limited, Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 68382-246-01.

Product Quantity:
2207 Vials

Reason for Recall:
cGMP Deviations

Recall Number:
D-0834-2020

Code Information:
Lot #s: M804062, Exp. 01/2020; M804063, M804064, Exp. 02/2020

Class II Drugs Event

Event ID:
84860

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/05/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/13/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pfizer Inc.
235 E 42nd St
New York NY United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Caduet (amlodipine besylate/atorvastatin calcium) Tablets, 10 mg/20 mg*, 30-count bottle, Rx only, Distributed by: Pfizer Labs, Division of Pfizer Inc. NY, NY 10017, Made in Germany, NDC 0069-2180-30.

Product Quantity:
141 bottles

Reason for Recall:
Defective Container: products potentially could have been packaged in defective bottles, with a notched rim, that could cause inadequate foil sealing resulting in lack of moisture protection.

Recall Number:
D-0841-2020

Code Information:
Lot #: CY0937, Exp 12/2021

Product Description:
Caduet (amlodipine besylate/atorvastatin calcium) Tablets, 10 mg/10 mg*, 30-count bottle, Rx only, Distributed by: Pfizer Labs, Division of Pfizer Inc. NY, NY 10017, Made in Germany, NDC 0069-2160-30.

Product Quantity:
128 bottles

Reason for Recall:
Defective Container: products potentially could have been packaged in defective bottles, with a notched rim, that could cause inadequate foil sealing resulting in lack of moisture protection.

Recall Number:
D-0842-2020

Code Information:
Lot #: CY0963, Exp 07/2022

Class II Drugs Event

Event ID:
84864

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/31/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/14/2020

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Efficient Laboratories, Inc.
7715 NW 64th St
Miami FL United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Rompe Pecho CF Cold & Flu with Honey, 6 FL. Oz (178 mL) bottle, Distributed by: Efficient Laboratories, Inc. Miami, FL 33166.UPC 0 00856 33106 8

Product Quantity:
5249 6 Fl Oz bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:
D-0845-2020

Code Information:
Lot: 19H359 Exp. August 2022

Product Description:
Rompe Pecho EX Expectorant, 6 FL. Oz (178 mL) bottle, Distributed by: Efficient Laboratories, Inc. Miami, FL 33166. UPC 0 00856 30106 1

Product Quantity:
5387 6 Fl Oz bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:
D-0846-2020

Code Information:
Lot: 19F332 Exp. June 2022

Product Description:
New! Rompe Pecho MAX Multi Symptoms, 8 FL. Oz (237 mL) bottle, Distributed by: Efficient Laboratories, Inc. Miami, FL 33166. UPC 0 00856 00309 5

Product Quantity:
4080 8 FL Oz bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:
D-0847-2020

Code Information:
Lot: 19B42 Exp. February 2022

Class II Drugs Event

Event ID:
84910

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/07/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/19/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AuroMedics Pharma LLC
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Amoxicillin and Clavulanate Potassium Tablets, USP, 875 mg/125 mg, 20-count bottles, Distributed by: Aurobindo Pharma USA. Inc. 279 Princeton-Hightstown Road East Windsor, NJ 08520 Made in India; NDC 65862-503-20

Product Quantity:
30432 bottles

Reason for Recall:
Presence of Foreign Substance: Customer complaint of a foreign substance identified as nylon cable tie

Recall Number:
D-0852-2020

Code Information:
Lot #: SM8719040-A, Exp. Date 02/2021

Class II Drugs Event

Event ID:
84913

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/16/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/11/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn Inc
1925 W Field Ct Ste 300
Lake Forest IL United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Hydrocortisone and Acetic Acid Otic Solution, USP, 10 mL dropper bottle, Rx only, HI-TECH PHARMACAL CO., INC., Amityville, NY 11701; NDC 50383-901-10.

Product Quantity:
16,078 bottles

Reason for Recall:
Subpotent Drug: Low Out of specification (OOS) assay results for the hydrocortisone portion of this product.

Recall Number:
D-0839-2020

Code Information:
Lot #: 364667, Exp 12/20/2019

Class III Drugs Event

Event ID:
84912

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/10/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/13/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Par Pharmaceutical Inc.
1 Ram Ridge Rd
Chestnut Ridge NY United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Frovatriptan Succinate Tablets, 2.5mg, packaged in 1 blister card of 9 tablets per carton, Rx Only, Manufactured by: Almac Pharma Services Limited, Craigavon, BT63 5UA, UK; Manufactured for: Par Pharmaceutical, Chestnut Ridge, NY 10977, NDC 0603-3718-34.

Product Quantity:
9,936 cartons

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Product incorrectly labeled with an expiration date of August 2022 rather than the correct expiration date of April 2022.

Recall Number:
D-0843-2020

Code Information:
Lot Number: 9698818; labeled expiration AUG 2022; actual expiration APR 2022

Not Yet Classified Drugs Event

Event ID:
84857

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/03/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Contract Pharmacal Corporation
135 Adams Ave
Hauppauge NY United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Leader Extra Strength Acetaminophen Tablets, 500 mg Pain Reliever/Fever Reducer,100-count bottles,Distributed by Cardinal Health, Dublin OHIO 43017 NDC 7000-0036-1, UPC 0 96295 13807 8

Product Quantity:
5472 bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules: Complaint involving one Women's Prenatal dietary supplement tablet commingled in a bottle of Extra Strength Acetaminophen 500 mg contents 1000 count bottle.

Recall Number:

Code Information:
Lot #: 193005, Exp. Date 08/21

Product Description:
Major Extra Strength Acetaminophen Tablets, 500 mg Pain Reliever/Fever Reducer, packaged in a) 100-count bottles (NDC 0904-6730-60; UPC 3 09046 73060 6) and b) 1000-count bottles (NDC 0904-6730-80; UPC 3 09046 73080 4) Distributed by Major Pharmaceuticals 17177 N. Laurel Park Drive, Suite 233 Livonia, MI 45162 USA

Product Quantity:
a) 1176 bottles b) 6,216 bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules: Complaint involving one Women's Prenatal dietary supplement tablet commingled in a bottle of Extra Strength Acetaminophen 500 mg contents 1000 count bottle.

Recall Number:

Code Information:
Lot #: 193005, Exp. Date 08/21

Not Yet Classified Drugs Event

Event ID:
84898

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/04/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
American Health Packaging
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Raloxifene Hydrochloride Tablets, USP, 60 mg, 30 Tablets (3 x 10 blister cards), Rx Only, Packaged and Distributed by: American Health Packaging, Columbus, Ohio 43217. NDC carton: 60687-266-21; NDC Unit Dose: 60687-266-11

Product Quantity:
973 cartons

Reason for Recall:
Failed Dissolution Specifications: Low out of specification results obtained during stability testing.

Recall Number:

Code Information:
Lot #:180276A, Exp date 02/29/2020

Not Yet Classified Drugs Event

Event ID:
84900

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/27/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Product distributed in OK and LA.

Associated Products

Product Description:
Ketorolac Trom, 30 mg/1mL Inj. for I.V./I.M. Use, Rx Only, QTY: 1 ml, Repackaged by: RemedyRepack Inc., Indiana, PA 15701 NDC 70518-1239-00

Product Quantity:
75 1 ml vials

Reason for Recall:
Presence of Particulate Matter: Medication relabeled at facility was recalled by the manufacturer due to small black particles noticed during routine visual inspection. of retain samples.

Recall Number:

Code Information:
Lot # B0444562-060118, exp. 04/2020, B0537002-112118, exp 07/2020

Not Yet Classified Drugs Event

Event ID:
84931

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/23/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
GSK Consumer Health, Inc
10401 Hwy 6
Lincoln NE United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Theraflu Cough Relief, Dextromethorphan HBr and Guaifensin, 6 packets per carton. Distributed by: GSK Consumer Healthcare, Warren, NJ 07059. NDC carton: 0067-6089-01, NDC packet: 0067-6089-03

Product Quantity:
431,614 cartons

Reason for Recall:
Product recalled due to absence of a warning statement on the product label, Ask a doctor before use if you have a sodium-restricted diet.

Recall Number:

Code Information:
Lot: K79A, K79B, K79C, exp 3/31/2021; XB2W, Y23L, Y23V, exp 5/31/2021; 19N1793000, 19N1895942, 19N1952247, 19N1884668, 19N1936498, 19N1936583, exp 3/31/2021; 19N1920630, 19N1958240, exp 4/30/2021; 19N1957675, M926001MA, M926002MA, M926003MA, M926004MA, M926005MA, M926006MA, M926007MA, M926008MA, M926009MA, M926201MA, M926202MA, exp 5/31/2021; M926201MB, M926202MB, M926203MB, M926204MB, M926205MB, M926206MB, M926207MB, M926208MB, M926209MB, exp 2/28/2021

Not Yet Classified Drugs Event

Event ID:
84948

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/12/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

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:
Nationwide within the United States.

Associated Products

Product Description:
Memantine Hydrochloride Extended Release Capsules, 21 mg, 30-count bottles, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202 United States. Manufactured by: Lupin Limited Pithampur (M.P.)-454 775, INDIA, NDC 68180-248-06

Product Quantity:
6,294 bottles

Reason for Recall:
Failed Dissolution Specifications: Low out of specification results observed in dissolution test at six-month long-term stability study.

Recall Number:

Code Information:
Lot #: H900330, exp. date 11/2020.