Enforcement Report - Week of February 19, 2020

Class I Drugs Event

Event ID: 84645

Status: Ongoing

Recall Initiation Date: 12/20/2019

Center Classification Date: 02/07/2020

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.

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

Associated Products

Class II Drugs Event

Event ID: 84797

Status: Ongoing

Recall Initiation Date: 01/27/2020

Center Classification Date: 02/10/2020

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

Distribution Pattern: USA Nationwide

Product Type: Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Product Description:

Product Quantity:

Reason for Recall:

Recall Number:

Code Information:

Associated Products
### Product Description:
Methylphenidate hydrochloride Extended-Release tablets 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

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### Product Description:
Methylphenidate hydrochloride Extended-Release tablets 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

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### Class II Drugs Event

<table>
<thead>
<tr>
<th>Event ID:</th>
<th>84827</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status:</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Recall Initiation Date:</td>
<td>01/28/2020</td>
</tr>
<tr>
<td>Center Classification Date:</td>
<td>02/12/2020</td>
</tr>
<tr>
<td>Recalling Firm:</td>
<td>B AND A TRADING CORPORATION</td>
</tr>
<tr>
<td></td>
<td>325 Washington Ave</td>
</tr>
<tr>
<td></td>
<td>Carlstadt NJ United States</td>
</tr>
<tr>
<td>Distribution Pattern:</td>
<td>NY &amp; NJ only</td>
</tr>
</tbody>
</table>

### Product Type:
Drugs

### Date Terminated:

### Voluntary / Mandated:
Voluntary: Firm initiated

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

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### Associated Products

<table>
<thead>
<tr>
<th>Product Description:</th>
<th>Kushim Tablets (Gushim) 45-count packages, Label in foreign language</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Quantity:</td>
<td>40 packages</td>
</tr>
<tr>
<td>Reason for Recall:</td>
<td>Marketed Without an Approved NDA/ANDA. FDA analysis found product to contain cinobufagin, bufalin, and bufotenine</td>
</tr>
<tr>
<td>Recall Number:</td>
<td>D-0840-2020</td>
</tr>
<tr>
<td>Code Information:</td>
<td>Lot #: H003</td>
</tr>
</tbody>
</table>
Class II Drugs Event

Event ID: 84833
Status: Ongoing
Recall Initiation Date: 02/03/2020
Center Classification Date: 02/10/2020
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 00409-9084-12 (vial), 00409-9084-22 (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
Status: Ongoing
Recall Initiation Date: 01/31/2020
Center Classification Date: 02/10/2020
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:
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

Status:
Ongoing

Recall Initiation Date:
02/05/2020

Center Classification Date:
02/13/2020

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

Status: Ongoing

Recall Initiation Date: 01/31/2020

Center Classification Date: 02/14/2020

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
Status: Ongoing
Recall Initiation Date: 02/07/2020
Center Classification Date: 02/19/2020
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
Status: Ongoing
Recall Initiation Date: 12/16/2019
Center Classification Date: 02/11/2020
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.
Class III Drugs Event

Event ID:
84912

Status:
Ongoing

Recall Initiation Date:
02/10/2020

Center Classification Date:
02/13/2020

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

Status:
Ongoing

Recall Initiation Date:
02/03/2020

Center Classification Date:

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

https://www.accessdata.fda.gov/scripts/ires/index.cfm?action=print.getPrintData&ts=120202010524
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 096295138078

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 0904673060 6) and b) 1000-count bottles (NDC 0904-6730-80; UPC 3 0904673080 4) Distributed by Major Pharmaceuticals 17177 N. Laurel Park Drive, Suite 233 Livonia, MI 48162 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

Status:
Ongoing

Recall Initiation Date:
12/04/2019

Center Classification Date:

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
### Not Yet Classified Drugs Event

**Event ID:**
84900

**Status:**
Ongoing

**Recall Initiation Date:**
12/27/2019

**Center Classification Date:**

**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

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### Not Yet Classified Drugs Event

**Event ID:**
84931

**Status:**
Ongoing

**Recall Initiation Date:**
12/23/2019

**Center Classification Date:**

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

**Product Type:**
Drugs

**Date Terminated:**

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

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

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https://www.accessdata.fda.gov/scripts/ires/index.cfm?action=print&PrintData&ts=120202010524
**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:**

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**Not Yet Classified Drugs Event**

**Event ID:**
84948

**Status:**
Ongoing

**Recall Initiation Date:**
02/12/2020

**Center Classification Date:**

**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.