Enforcement Report - Week of October 16, 2019

Class II Drugs Event

Event ID: 83798
Status: Ongoing
Recall Initiation Date: 09/13/2019
Center Classification Date: 10/09/2019
Recalling Firm: GUERBET LLC
821 Alexander Rd, Ste 204 120 W 7th St Suite
Princeton NJ United States
Distribution Pattern: Nationwide in the USA

Associated Products

Product Type: Drugs

Event ID: 83835
Status: Ongoing
Recall Initiation Date: 09/18/2019
Center Classification Date: 10/07/2019
Recalling Firm: GCP Laboratories Inc
3600 25th Ave
Gulfport MS United States
Distribution Pattern: Distributed in MI and further distributed Nationwide.

Associated Products

Reason for Recall:
Labeling: Not Elsewhere Classified: RFID formatting error which reads product in Ultraject syringe as expired and will not allow injection of product by the Optivantage injector.

Product Description:
Optiray 320 (ioversol) Injection 68%, 320 mg/mL Organically Bound Iodine, packaged in 1 - 100 mL Ultraject Prefilled Syringe For Power Injection per carton, RFID Technology, Rx Only, Manufactured by: Liebel-Flarsheim Company, LLC., Raleigh, NC 27616; NDC 0019-1323-00.

Product Quantity:
3860 syringes

Recall Number:
D-0137-2020

Code Information:
Lots: L141C, L162A Exp. 06/2021; L146DS, Exp. 05/2021

Voluntary / Mandated:
Voluntary: Firm initiated
Initial Firm Notification of Consignee or Public:
Letter

Voluntary / Mandated:
Voluntary: Firm initiated
Initial Firm Notification of Consignee or Public:
Letter
Class II Drugs Event

Event ID: 83849
Status: Ongoing
Recall Initiation Date: 09/26/2019
Center Classification Date: 10/09/2019
Recalling Firm: Epic Pharma, LLC
22715 N Conduit Ave
Laurelton NY United States
Distribution Pattern: Nationwide within the United States

Associated Products

Product Description: Estradiol tablets, 0.5 mg, 100-count bottles, Rx only, Distributed by Epic Pharma, LLC Laurelton, NY 11413, NDC 42806-087-01
Product Quantity: 11,472 (bottles of 100)
Reason for Recall: Presence of Foreign Tablets/Capsules: Estradiol 1 mg was found in a 100 count bottle of Estradiol 0.5 mg Tablets.
Recall Number: D-0135-2020
Code Information: Lot #: 19094A, Exp. 2021

Class II Drugs Event

Event ID: 83858
Status: Ongoing
Recall Initiation Date: 09/23/2019
Center Classification Date: 10/08/2019
Recalling Firm: Epic Pharma, LLC
22715 N Conduit Ave
Laurelton NY United States
Distribution Pattern: Nationwide within the United States

Associated Products

Product Description: Major Infants’ Gas Relief Drops, Simethicone Oral Suspension USP, 1 FL OZ (30 mL) bottle, Distributed by: Major Pharmaceuticals 17177 N Laurel Park Drive, Suite 233 Livonia, MI 48152 USA. NDC 0904-5894-30
Product Quantity: 31,392 30 mL bottles
Reason for Recall: Microbial Contamination of Non-Sterile Product.
Recall Number: D-0126-2020
Code Information: Lot: WBD003 Exp. 03/21
### Associated Products

**Product Description:**
Prednisolone Sodium Phosphate Oral Solution, 15 mg/5 mL, packaged in an 8 fl oz (237 mL) bottle, Rx only, Manufactured By Morton Grove Pharmaceuticals, Inc., Morton Grove, IL 60053. NDC 60432-212-08

**Product Quantity:**
196,408 bottles

**Reason for Recall:**
Failed Impurities/Degradation Specifications - failed specs for Prednisolone Impurity 14

**Recall Number:**
D-0130-2020

**Code Information:**
Lot #: US1450, Exp 10/31/19; US1570, Exp 12/31/19; UT1018, Exp 1/31/19; UT1173, Exp 6/30/20; UT1348, UT1354, Exp 8/31/20

---

### Class II Drugs Event

**Event ID:**
83875

**Status:**
Ongoing

**Recall Initiation Date:**
09/23/2019

**Center Classification Date:**
10/07/2019

**Recalling Firm:**
Sandoz, Inc
506 Carnegie Ctr Ste 400
Princeton NJ United States

**Distribution Pattern:**
U.S. Nationwide

**Associated Products**

**Product Description:**
Sandoz Ranitidine Hydrochloride Capsules 150mg 60 Capsules Rx Only Manufactured by Sandoz Inc. Princeton, NJ Product of India NDC 0781-2855-60

**Product Quantity:**
100,314 bottles

**Reason for Recall:**
CGMP Deviations: Detection of a trace amount of an unexpected impurity, N-nitrosodimethylamine (NDMA).

**Recall Number:**
D-0127-2020

**Code Information:**
### Class II Drugs Event

<table>
<thead>
<tr>
<th>Event ID:</th>
<th>83881</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status:</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Recall Initiation Date:</td>
<td>09/23/2019</td>
</tr>
<tr>
<td>Center Classification Date:</td>
<td>10/09/2019</td>
</tr>
<tr>
<td>Recalling Firm:</td>
<td>Unipharma, Llc. 10200 NW 67th St Tamarac FL United States</td>
</tr>
<tr>
<td>Distribution Pattern:</td>
<td>U.S.A. Nationwide</td>
</tr>
</tbody>
</table>

**Associated Products**

<table>
<thead>
<tr>
<th>Product Description:</th>
</tr>
</thead>
<tbody>
<tr>
<td>DrKids Children's Natural Cough Syrup English Ivy Leaf, packaged in Pre-measured Single-Use Vials 0.17 fl. oz. (5 mL) Each 3.4 fl. oz. (100 mL), Manufactured in USA by: UNIPHARMA, LLC Tamarac, FL 33321 UPC 370302489026</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Quantity:</th>
</tr>
</thead>
<tbody>
<tr>
<td>144 cartons</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reason for Recall:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CGMP Deviations: Recall as a precautionary measure due to potential risk of product contamination with the bacteria B. cepacia.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recall Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>D-0132-2020</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code Information:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot: 80047 Exp. 07/31/20</td>
</tr>
</tbody>
</table>

### Product Description:

<table>
<thead>
<tr>
<th>Product Description:</th>
</tr>
</thead>
<tbody>
<tr>
<td>DrKids Himasal Natural Nasal Saline Solution, packaged in Pre-measured Single-Use Vials a) 0.5 mL Each (20 count) UPC 37030244608; b) 1.5 mL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Quantity:</th>
</tr>
</thead>
<tbody>
<tr>
<td>13,130 bottles</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reason for Recall:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CGMP Deviations: Detection of a trace amount of an unexpected impurity, N-nitrosodimethylamine (NDMA).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recall Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>D-0128-2020</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code Information:</th>
</tr>
</thead>
<tbody>
<tr>
<td>HD1862 4/30/2020 HP9438 9/30/2020 HP9439 9/30/2020 HP9440 9/30/2020</td>
</tr>
</tbody>
</table>

### Product Description:

<table>
<thead>
<tr>
<th>Product Description:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sandoz Ranitidine Hydrochloride Capsules 300mg 30 Capsules Rx Only Manufactured by Sandoz Inc. Princeton, NJ 08540 Product of India NDC 0781-2865-31</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Quantity:</th>
</tr>
</thead>
<tbody>
<tr>
<td>136,788 bottles</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reason for Recall:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CGMP Deviations: Detection of a trace amount of an unexpected impurity, N-nitrosodimethylamine (NDMA).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recall Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>D-0129-2020</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code Information:</th>
</tr>
</thead>
</table>

### Event ID:

83881
Class II Drugs Event

Event ID: 83914

Status: Ongoing

Recall Initiation Date: 10/07/2019

Center Classification Date: 10/10/2019

Recalling Firm:
Mylan Laboratories Limited (Sterile Products Division)
Opp. Iim-B, Bilekahalli , Bannerghatta Road
Bangalore India

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Rifampin for Injection, USP, 600 mg/vial, Rx only. Manufactured for: Mylan Institutional LLC, Rockford, IL 61103; NDC 67457-445-60.

Product Quantity:
19,165 vials

Reason for Recall:
Failed Impurities/Degradation Specifications: discoloration due to elevated unknown impurity results which could decrease the effectiveness of the product.

Recall Number:
D-0139-2020

Code Information:
Associated Products

Product Description:
10% LMD in 5% Dextrose Injection Dextran 40 in Dextrose Injection, USP, 500 mL bags, Rx only, Hospira, Inc., Lake Forest, IL 60045, NDC 0409-7418-13

Product Quantity:
17832 bags

Reason for Recall:
Lack of Assurance of Sterility: Bag has the potential to leak.

Recall Number:
D-0136-2020

Code Information:
Lot #: 87-095-JT Exp. 1MAR2020

Class III Drugs Event

Event ID:
83730

Status:
Ongoing

Recall Initiation Date:
09/06/2019

Center Classification Date:
10/09/2019

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

Distribution Pattern:
Product was distributed to 42 wholesalers and 11 retailers who may have further distribute the product throughout the United States, including Hawaii and Puerto Rico.

Associated Products

Product Description:
Matzim LA (Diltiazem Hydrochloride) Extended-Release Tablets, 240 mg, 30 count bottle, Rx only, Manufactured by: Actabis Laboratories FL, Inc., Fort Lauderdale, FL, Distributed by: Actavis Pharma, Inc., Parsippany, NJ NDC 52544-692-30

Product Quantity:
5,849 bottles

Reason for Recall:
GMP Deviation: lot not intended for commercial distribution.

Recall Number:
D-0131-2020

Code Information:
Lot # 1344864A, exp. date 10/2020
Class III Drugs Event

Event ID: 83798
Status: Ongoing
Recall Initiation Date: 09/13/2019
Center Classification Date: 10/09/2019
Recalling Firm: GUERBET LLC
Distribution Pattern: Nationwide in the USA

Associated Products

Event ID: 83798
Product Type: Drugs
Status: Ongoing
Recall Initiation Date: 09/13/2019
Center Classification Date: 10/09/2019
Recalling Firm: GUERBET LLC
Distribution Pattern: Nationwide in the USA

Product Description:
Sodium Chloride Injection USP 0.9%, packaged in 1 - 125 mL Ultraject Prefilled Syringe For Power Injection per carton, RFID Technology, Rx Only, Manufactured by: Liebel-Flarsheim Company, LLC., Raleigh, NC 27616; NDC 0019-1188-27.

Product Quantity: 3140 syringes
Reason for Recall:
Labeling: Not Elsewhere Classified: RFID formatting error which reads product in Ultraject syringe as expired and will not allow injection of product by the Optivantage injector.
Recall Number: D-0138-2020
Code Information:
Lots: L159A, Exp. 06/2021; L169A, Exp. 07/2021

Class III Drugs Event

Event ID: 83915
Status: Ongoing
Recall Initiation Date: 09/24/2019
Center Classification Date: 10/09/2019
Recalling Firm: Amneal Pharmaceuticals, Inc.
Distribution Pattern: Product was distributed to 13 major distributors throughout the United States who may have further distribute the product.

Associated Products

Event ID: 83915
Product Type: Drugs
Status: Ongoing
Recall Initiation Date: 09/24/2019
Center Classification Date: 10/09/2019
Recalling Firm: Amneal Pharmaceuticals, Inc.
Distribution Pattern: Product was distributed to 13 major distributors throughout the United States who may have further distribute the product.

Product Description:
Benazepril HCl Tablets, USP 40 mg, 100 count bottles, Rx only, Distributed by Amneal Pharmaceuticals, Bridgewater, NJ NDC 65162-754-10

https://www.accessdata.fda.gov/scripts/ires/index.cfm?action=print.getPrintData&ts=916201910336
<table>
<thead>
<tr>
<th><strong>Product Quantity:</strong></th>
<th>9,720 100 count bottles</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reason for Recall:</strong></td>
<td>Presence of Foreign Tablet/Capsule; Promethazine HCl tablet found in the Benazepril HCl bottle</td>
</tr>
<tr>
<td><strong>Recall Number:</strong></td>
<td>D-0134-2020</td>
</tr>
<tr>
<td><strong>Code Information:</strong></td>
<td>Lot # BB02619A, exp. date 04/2021</td>
</tr>
</tbody>
</table>