Enforcement Report - Week of May 27, 2020

Class I Drugs Event

Event ID:
85625

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/08/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/19/2020

Initial Firm Notification of Consignee or Public:
Press Release

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

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
LACTATED RINGER'S Injection, USP 1000 mL flexible container, Rx Only, Hospira, Inc., Lake Forest, IL 60045, NDC 0409-7953-09

Product Quantity:
93,648 flexible container

Reason for Recall:
Presence of Particulate Matter: confirmed customer complaint for the presence of particulate matter identified as iron oxide.

Recall Number:
D-1270-2020

Code Information:
Lot #: 07-514-FW Exp. 01-JUL-2021

Class II Drugs Event

Event ID:
85624

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/05/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/20/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Institutional LLC
4901 Hiawatha Dr
Rockford IL United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Aloprim (allopurinol sodium) for Injection, 500 mg Single-Dose Vial, Rx only, Manufactured for: Mylan Institutional LLC, Rockford, IL 61103 USA. NDC: 67457-187-50

Product Quantity:
3,010 vials

Reason for Recall:
Discoloration: Out-of-specification results for appearance obtained during routine stability testing at the end of shelf-life for the parameters Appearance and Color of Solution.

Recall Number:
D-1271-2020

Code Information:
Lot #: Lot N1700771, EXP October 2020; Lot N1800127, EXP February 2021

Class III Drugs Event

Event ID:
85646

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/14/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/21/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
InvaGen Pharmaceuticals, Inc.
7 Oser Ave
Hauppauge NY United States

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Gabapentin Tablets USP, 600 mg, Rx Only, 500-count bottle, Manufactured for: Exelan Pharmaceuticals, Inc., Lawrenceville, GA 30046, Manufactured by: InvaGen Pharmaceuticals, Inc., Hauppauge, NY 11788, NDC 76282-405-05.

Product Quantity:
2,202 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications; failure of Impurity A test at the 12-month long-term stability testing.

Recall Number:
D-1272-2020

Code Information:
Lot # NB900413, Exp. 12/2020

Not Yet Classified Drugs Event

Event ID:
85709

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/24/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
West-Ward Columbus Inc
1809 Wilson Rd
Columbus OH United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Ethacrynic Acid Tablets USP, 25 mg, 100 Tablets per Bottle, Rx only, Distr. by: West-Ward Pharmaceuticals Corp., Eatontown, NJ 07724, NDC: 0054-0415-25.

Product Quantity:
3336 Bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of Specification for impurity 6 and total degradants.

Recall Number:

Code Information:
Lot #: AA4424A, Exp. 07/31/2020