Enforcement Report - Week of May 6, 2020

Class I Drugs Event

Event ID:
85507

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/18/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/28/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
B. Braun Medical Inc
2525 Mcgaw Ave
Irvine CA United States

Distribution Pattern:
Product was distributed nationwide within the United States.

Associated Products

Product Description:
Ceftazidime for Injection USP and Dextrose for Injection USP, 2 g, 50 mL Duplex Container, RX only, B Braun Medical Inc., Bethlehem, PA 18018-3524, NDC 0264-3145-11

Product Quantity:
22,488 Duplex containers

Reason for Recall:
Failed Stability Specifications: Out-of-Specification (OOS) results for High Molecular Weight Polymers.

Recall Number:
D-1257-2020

Code Information:
Lot #: H8J812, Exp. Date 31 JUL 2020

Class II Drugs Event

Event ID:
85386

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/15/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/24/2020

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Amneal Pharmaceuticals of New York, LLC
50 Horseblock Rd
Brookhaven NY United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Nizatidine Oral Solution, 15 mg/mL (75 mg/5mL) USP 480 mL bottles, Rx Only Distributed by: Gemini Laboratories, LLC Bridgewater, NJ 08807 NDC 60846-301-15

Product Quantity:
11258 bottles

Reason for Recall:
CGMP Deviations: potential N-Nitrosodimethylamine (NDMA) amounts above levels established by the FDA.

Recall Number:
D-1253-2020

Code Information:
06598004A 04/2020 06599001A 12/2020 06599002A 12/2020

Class III Drugs Event

Event ID:
85557

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/24/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/28/2020

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:
Nationwide within the United States

Associated Products

Product Description:
Esomeprazole Magnesium Delayed Release Capsules USP, 40 mg*, 1000-count bottles, Rx only, Mfd. By: Dr. Reddy's Laboratories Limited Bachupally - 500 090 INDIA, NDC 43598-510-10

Product Quantity:
1752 bottles

Reason for Recall:
Discoloration: product contains brown pellets

Recall Number:
D-1256-2020

Code Information:
Lot #: C900642, Exp. 06/2020