

Enforcement Report - Week of June 27, 2018

Class II Drugs Event

Event ID:

80208

Status:

Ongoing

Recall Initiation Date:

05/30/2018

Center Classification Date:

06/18/2018

Recalling Firm:

Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:

Nationwide in the USA

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Atorvastatin Calcium Tablets, 80 mg*, 90-count bottles, Rx Only, Mfd. By: Dr. Reddy's Laboratories Limited, Srikakulam - 532 409 INDIA, NDC 55111-124-90 UPC 355111124900

Product Quantity:

6,397 bottles

Reason for Recall:

Presence of Foreign Substance: A product complaint was received for a defective tablet with an embedded foreign object observed in a bottle.

Recall Number:

D-0878-2018

Code Information:

Lot #: T800064, Exp 12/2019

Class II Drugs Event

Event ID:

80213

Status:

Ongoing

Recall Initiation Date:

05/31/2018

Center Classification Date:

06/20/2018

Recalling Firm:

ICU Medical Inc
600 N FIELD DRIVE
LAKE FOREST IL United States

Distribution Pattern:

Nationwide and Canada

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

0.45% Sodium Chloride Injection, USP, 100 mL bag, Rx Only, Hospira, Inc. Lake Forest, IL 60045, NDC 0409-7730-37

Product Quantity:

88960 bags

Reason for Recall:

Lack of assurance of sterility: Bags have potential to leak.

Recall Number:

D-0881-2018

Code Information:

Lot #: 85-023-JT, Exp 7/1/2019

Product Description:

0.9% Sodium Chloride Injection, USP, 250 mL bag, Rx Only, Hospira, Inc. Lake Forest, IL 60045, NDC 0409-7983-02

Product Quantity:

941496 bags

Reason for Recall:

Lack of assurance of sterility: Bags have potential to leak.

Recall Number:

D-0882-2018

Code Information:

Lot #: 85-018-JT, 85-031-JT, Exp. 01/01/2020

Product Description:

0.9% Sodium Chloride Injection, USP, 100 mL bag, Rx Only, Hospira, Inc. Lake Forest, IL 60045, NDC 0409-7984-23

Product Quantity:

525984 bags

Reason for Recall:

Lack of assurance of sterility: Bags have potential to leak.

Recall Number:

D-0883-2018

Code Information:

Lot #: 85-016-JT, Exp 01/01/2020

Product Description:

0.9% Sodium Chloride Injection, USP, 100 mL bag, Rx Only, Hospira, Inc. Lake Forest, IL 60045, NDC 0409-7984-37

Product Quantity:

1247200 bags

Reason for Recall:

Lack of assurance of sterility: Bags have potential to leak.

Recall Number:

D-0884-2018

Code Information:

Lot #: 85-021-JT, Exp 01/01/2020; 86-001-JT, Exp 02/01/2020

Product Description:

5% Dextrose Injection, USP, 250 mL bag, Rx Only, Hospira, Inc. Lake Forest, IL 60045, NDC 0409-7922-02

Product Quantity:

267288 bags

Reason for Recall:

Lack of assurance of sterility: Bags have potential to leak.

Recall Number:

D-0885-2018

Code Information:

Lot #: 86-033-JT, Exp 08/01/2019

Class III Drugs Event

Event ID:

80275

Status:

Ongoing

Recall Initiation Date:

06/12/2018

Center Classification Date:

06/21/2018

Recalling Firm:

Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:

Nationwide in the USA and Puerto Rico

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Atorvastatin Calcium Tablets, 10 mg*, 90-count bottle, Rx Only, Mfd. By: Dr. Reddy's Laboratories Limited, Srikakulam - 532 409 INDIA, NDC 55111-121-90

Product Quantity:

55,126 bottles

Reason for Recall:

Failed Impurities/Degradation Specifications

Recall Number:

D-0886-2018

Code Information:

Lot #: T600327, Exp 07/18; T700213, T700215, Exp 04/19

Product Description:

Atorvastatin Calcium Tablets, 20 mg*, 90-count bottle, Rx Only, Mfd. By: Dr. Reddy's Laboratories Limited, Srikakulam - 532 409 INDIA, NDC 55111-122-90

Product Quantity:

44,894 bottles

Reason for Recall:

Failed Impurities/Degradation Specifications

Recall Number:

D-0887-2018

Code Information:

Lot #: T600328, Exp 07/18; T700214, T700216, Exp 04/19

Product Description:

Atorvastatin Calcium Tablets, 40 mg*, packaged as a) 90-count bottle (NDC 55111-123-90 and b) 500-count bottle (NDC 55111-123-05), Rx Only, Mfd. By: Dr. Reddy's Laboratories Limited, Srikakulam - 532 409 INDIA

Product Quantity:

130,081 bottles

Reason for Recall:

Failed Impurities/Degradation Specifications

Recall Number:

D-0888-2018

Code Information:

Lot #: a) T600392, T600384, T600353, Exp 08/18; T600427, Exp 09/18; T600435, Exp 10/18; T600492, Exp 11/18; T700006, T700014, T700033, T700035, T700036 12/18; b) T600407, Exp 09/18