Enforcement Report - Week of June 13, 2018

Class II Drugs Event

Event ID:
80202

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/31/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/06/2018

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Apotex Inc.
150 Signet Dr
North York Canada

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Fluticasone propionate Nasal Spray, USP, 50 mcg, packaged in 50 mcg per spray 120 Metered Sprays bottles, 16 g net fill weight, Rx Only, Manufactured by: Apotex Inc. Toronto, Ontario Canada M9L 1T9 Manufactured for: Apotex Corp. Weston, FL 33326, NDC 60505-0829-1

Product Quantity:
Unknown

Reason for Recall:
Presence of foreign substance: glass particles

Recall Number:
D-0841-2018

Code Information:
Lot: NJ4501 Exp. 07/2020

Not Yet Classified Drugs Event

Event ID:
80133

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/25/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Jubilant Cadista Pharmaceuticals, Inc.
207 Kiley Dr
Salisbury MD United States

Distribution Pattern:
IN, MI, MS, NC, NJ, NY and OH

Associated Products

Product Description:
Valsartan Tablets USP, 320 mg, 90 tablet, Rx Only, Manufactured by: Jubliant Generics Ltd. Roorkee - 247661, India, Marketed by: Jubliant Cadista Pharmaceuticals, Inc., Salisbury, MD 21801, NDC 59746-363-90

Product Quantity:
2,328 bottles (Lot VR417065A) and 2,352 bottles (Lot VR417066A)

Reason for Recall:
Product batches were released into commercial distribution with a larger grade size of excipient (Crospovidone).

Recall Number:

Code Information:
Lot #: VR417065A, VR417066A, Exp 10/2019

Not Yet Classified Drugs Event

Event ID:
80167

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/04/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
HOSPIRA INC, LAKE FOREST
275 NORTH FOREST DRIVE
LAKE FOREST IL United States

Distribution Pattern:
Nationwide in the U.S., Puerto Rico, and Guam

Associated Products

Product Description:
Naloxone Hydrochloride Injection, USP, 0.4 mg/mL, 1 mL in 2.5 mL Carpuject Single-use cartridge syringe, Single unit (NDC 0409-1782-03) and 10 count box (NDC 0409-1782-69), Rx Only, Hospira Inc., Lake Forest, IL

Product Quantity:
164,860 syringes

Reason for Recall:
Presence of Particulate Matter; Potential for particulate matter on the syringe plunger.

Recall Number:

Code Information:
72680LL, Exp. 1DEC2018 (NDC 0409-1782-03); 76510LL, Exp. 1APR2019 (NDC 0409-1782-69)

Not Yet Classified Drugs Event

Event ID:
80190

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/29/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pharmaceutical Associates Inc
201 Delaware St
Greenville SC United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Nystatin Oral Suspension, USP, 500,000 units/5 mL, For Institutional Use Only, packaged in 5 mL cups, Rx Only, Pharmaceutical Associates, Inc. Greenville, SC 29605, NDC 0121481005

Product Quantity:
275400 cups

Reason for Recall:
Resuspension problems: Out of specification for appearance and resuspendability.

Recall Number:

Code Information:
Lot: B5B8 Exp. 07/2019