Enforcement Report - Week of March 29, 2017

Class II Drugs Event

Event ID:
76611

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/02/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/23/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fougera Pharmaceuticals Inc.
60 Baylis Rd
Melville NY United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Desonide Ointment, 0.05%, NET WT 60 grams tubes, Rx only, E. FOUGERA & CO. A division of Fougera Pharmaceuticals Inc., Melville, New York 11747, NDC 0168-0309-60

Product Quantity:
14,665 tubes

Reason for Recall:
Labeling: Label Mixup; Unit boxes labeled as Desonide Ointment 0.05% may contain tubes of Desonide Ointment labeled as Ketoconazole Cream

Recall Number:
D-0612-2017

Code Information:
Lot GC9231 (exp. 05/2019); Lot GC9232 (exp. 05/2019)

Class II Drugs Event

Event ID:
76617

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/15/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/22/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AVKARE Inc.
615 N 1st St
Pulaski TN United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Famciclovir tablets, 500 mg, packaged in 30-count unit dose cartons, Rx only, Manufactured for: AvKARE, Inc., Pulaski, TN 38478, NDC 50268-307-13

Product Quantity:
116 cartons

Reason for Recall:
Failed impurities/ degradation specifications: Product was above specification for unknown impurities.

Recall Number:
D-0610-2017

Code Information:
Lot #15152, Exp. 02/2018

Class II Drugs Event

Event ID:
76666

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/07/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/21/2017

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:
Legacy Pharmaceutical Packaging LLC
13333 Lakefront Dr
Earth City MO United States

Distribution Pattern:
Product was shipped to distribution centers in TN, IN, and AZ then further shipped the product to retail pharmacies nationwide in the USA.

Associated Products

Product Description:
ATENOLOL Tablets, USP, 50 mg, 30-count bottle, Rx only, Distributed by: The Kroger Co., 1014 Vine Street, Cincinnati, OH 45202; Manufactured for: Zydus Pharmaceuticals USA Inc., Pennington, NJ 08534; Packaged by: Legacy Pharmaceutical Packaging LLC, Earth City, MO 63045; NDC 68645-493-54.

Product Quantity:
48,012 bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules: Customer complaint that a bottle of atenolol 50 mg Tablets USP contained a paroxetine 20 mg tablet.

Recall Number:
D-0606-2017

Code Information:
Lot # 161901, Exp 04/18

Class II Drugs Event

Event ID:
76673

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/06/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/21/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Zydus Pharmaceuticals USA Inc
73 Route 31 N
Pennington NJ United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico.

Associated Products

Product Description:
ATENOLOL Tablets, USP, 50 mg, packaged in a) 100-count bottles (NDC 68382-023-01) and b) 1000-count bottles (NDC 68382-023-10), Rx only, Manufactured by: Cadila Healthcare Ltd., India; Distributed by: Zydus Pharmaceuticals USA Inc., Pennington, NJ 08534.

Product Quantity:
9561 bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules: Customer complaint that a bottle of atenolol 50 mg Tablets USP contained a paroxetine 20 mg tablet.

Recall Number:
D-0605-2017

Code Information:
Lot #: a) Z600724, Exp 04/18; Z600725, Exp 04/18

Class II Drugs Event

Event ID:
76742

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/15/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/23/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sun Pharmaceutical Industries, Inc.
270 Prospect Plains Rd
Cranbury NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Testosterone Cypionate Injection , USP, 200 mg/mL, 1 mL vial , For Intramuscular Use Only, Rx Only, Distributed by Sun Pharma Ind. Inc., NJ 08512, Manufactured by Sun Pharma Ind. Ltd. India, NDC 62756-015-40

Product Quantity:
83,188 single does vials

Reason for Recall:
Presence of Particulate Matter

Recall Number:
D-0611-2017

Code Information:
JKR0744A, JKR0745A, JKR0750A, JKR0795A; Exp. 09/18

Class III Drugs Event

Event ID:
76585

Product Type:
Drugs

Status:
Ongoing

Recall Initiation Date:
02/21/2017

Center Classification Date:
03/21/2017

Recalling Firm:
Bayer HealthCare Pharmaceuticals, Inc.
36 Columbia Rd
Morristown NJ United States

Distribution Pattern:
US Nationwid, Puerto Rico, and Iceland

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
A+D Diaper Rash Cream with Dimethicone 1% and Zinc Oxide 10%, Packaged in a) 1.5 oz (42.5g) (UPC 041100811288), b) 3 oz 85g (UPC 041100811301), c) 4 oz (113g) (UPC 041100811325), Distributed by: Bayer Healthcare LLC, Whippany, NJ 07981

Product Quantity:
a) 468,576 (1.5g); b) 203868 (3 oz) and c) 802,620 (4 oz)

Reason for Recall:
Labeling: Incorrect/Undeclared Excipients: Firm is recalling A+D Diaper Rash Cream due to a labeling claim issue.

Recall Number:
D-0604-2017

Code Information:
a) Lot #: CV0068D, Exp. 12/31/2018; CV008N6, Exp. 2/28/2019; CV008N7, Exp. 3/31/2019; CV00BJA, Exp. 6/30/2019; CV00D0V and CV00DM4, Exp.8/31/2019. b) Lot #: CV0068G, Exp. 12/31/2018; CV008N9, Exp. 3/31/2019; CV008N8, Exp. 4/30/2019; CV00D0U, Exp. 8/31/2019 and CV00G4U, Exp.10/31/2019. c) Lot #: CV0068M, Exp. 12/31/2018; CV0068K, Exp.1/31/2019; CV008N5, Exp. 2/28/2019; CV008NC and CV008NE, Exp. 3/31/2019; CV008ND, CV008NB and CV008NA, Exp.4/30/2019; CV008NH, CV008NG and CV008NJ, Exp. 05/31/2019; CV00BJC, Exp.6/30/2019; CV00BJB, CV00BJE, CV00BJD, CV00BXB, CV00BXA and CV00BX9, Exp.7/31/2019; CV00D7H, CV00D7G, CV00D7E and CV00D7J, Exp. 8/31/2019; CV00E5T, CV00E5S and CV00E5R, Exp. 9/30/19; CV00G69 and CV00G6B, Exp.10/31/2019.

Class III Drugs Event

Event ID:
76663

Status:
Ongoing

Recall Initiation Date:
03/07/2017

Center Classification Date:
03/22/2017

Recalling Firm:
Pfizer Inc
100 North Route 206
Peapack NJ United States

Distribution Pattern:
Nationwide within US

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Quillivant XR (methylphenidate HCl) for extended-release oral suspension, 300 mg/60 mL (25mg/5mL), Rx Only, Distributed by: NextWave Pharmaceuticals, Inc. A subsidiary of Pfizer Inc, New York, NY 10017 Manufactured by: Tris Pharma, Inc., Monmouth Junction, NJ 08852 (NDC 24478-190-10).

Product Quantity:
28,938 units

Reason for Recall:
Failed Dissolution Specifications: Dissolution at 8 hour was out of specification at 12 month at 25 degree Celsius.

Recall Number:
D-0607-2017

Code Information:
Lot #: 03215042A, Exp. 08/17.

Product Description:
Quillivant XR (methylphenidate HCl) for extended-release oral suspension, 750 mg/150 mL (25mg/5mL), Rx Only, Distributed by: NextWave Pharmaceuticals, Inc. A subsidiary of Pfizer Inc, New York, NY 10017 Manufactured by: Tris Pharma, Inc., Monmouth Junction, NJ 08852 (NDC 24478-205-25).

Product Quantity:
11,862 units

Reason for Recall:
Failed Dissolution Specifications: Dissolution at 8 hour was out of specification at 12 month at 25 degree Celsius.

Recall Number:
D-0608-2017

Code Information:
Lot #: 03216026A, Exp. 02/18

Product Description:
Quillivant XR (methylphenidate HCl) for extended-release oral suspension, 900 mg/180 mL (25mg/5mL), Rx Only, Distributed by: NextWave Pharmaceuticals, Inc. A subsidiary of Pfizer Inc, New York, NY 10017 Manufactured by: Tris Pharma, Inc., Monmouth Junction, NJ 08852 (NDC 24478-190-30).

Product Quantity:
9,666 units

Reason for Recall:
Failed Dissolution Specifications: Dissolution at 8 hour was out of specification at 12 month at 25 degree Celsius.

Recall Number:
D-0609-2017