Enforcement Report - Week of August 9, 2017

Class II Drugs Event

Event ID:
77484

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/30/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/01/2017

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Alka-Seltzer Original (325 mg Aspirin (NSAID), 1916 mg Analgesic, Sodium bicarbonate/Antacid, 1000 mg Anhydrous Citric Acid) Effervescent Tablets, 12-count carton, Made in Germany, Distributed by Bayer HealthCare, LLC Whippany, NJ 07981, UPC 016500040194

Product Quantity:
1,067,520 12-count cartons

Reason for Recall:
Defective Container: Confirmed customer compliant of small holes or cracks in the foil of blister packs.

Recall Number:
D-1044-2017

Code Information:
BTAH340; Exp. 02/19 BTAHCP0; Exp. 04/19 BTAHLW0; Exp. 06/19 BTAHLX0; Exp. 08/19 BTAHP10; Exp 08/19

Product Description:
Alka-Seltzer Extra Strength (500 mg Aspirin (NSAID), 1985 mg Analgesic Sodium bicarbonate/Antacid, 1000 mg Anhydrous Citric Acid) Effervescent Tablets, 24-count carton, Made in Germany, Distributed by Bayer HealthCare, LLC Whippany, NJ 07981, UPC 016500044048

Product Quantity:
24,672 24-count cartons

Reason for Recall:
Defective Container: Confirmed customer compliant of small holes or cracks in the foil of blister packs.

Recall Number:
D-1050-2017

Code Information:
BTAHDG0; Exp. 04/19

Product Description:
Alka-Seltzer Gold (1000 mg Anhydrous citric acid, 344 mg Antacid Potassium bicarbonate, 1050 mg Antacid Sodium bicarbonate/Antacid) Effervescent Tablets, 36-count carton, Made in Germany, Distributed by Bayer HealthCare, LLC Whippany, NJ 07981, UPC 016500041085

Product Quantity:
56,064 36-count cartons

Reason for Recall:
Defective Container: Confirmed customer compliant of small holes or cracks in the foil of blister packs.

Recall Number:
D-1051-2017

Code Information:
BTAHGR0; Exp. 05/19 BTAHGR1; Exp. 05/19 BTAHGR2; Exp. 05/19 BTAJ0K3; Exp. 07/19

Class II Drugs Event

Event ID:
77533

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/15/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/01/2017

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Hospira a Pfizer Company
4285 N Wesleyan Blvd
Rocky Mount NC United States

Distribution Pattern:
U.S. (including Puerto Rico), Dutch Antilles, Barbados, Canada, Philippines, Kuwait, and Singapore

Associated Products

Product Description:
Potassium Phosphates Inj., USP, 45 mM (3 mM P/mL) Also contains: 66 mEq K+ (4.4 mEq/mL) 15 mL, Single-dose, Caution: Must Be Diluted, Rx

Product Quantity:
20,337,650 15 mL single dose vials

Only, Mfd by Hospira, Inc. Lake Forest, IL 60045 USA, NDC: 0409-7295-01

Reason for Recall:
Lack of Sterility Assurance

Recall Number:
D-1046-2017

Code Information:
Lot: 74119EV Exp. 02/01/2019 Lot: 74120EV Exp. 02/01/2019 Lot: 74121EV Exp. 02/01/2019 Lot: 74307EV Exp. 02/01/2019 Lot: 75326EV Exp. 03/01/2019 Lot: 75327EV Exp. 03/01/2019 Lot: 75215EV Exp. 03/01/2019

Product Description:
8.4% Sodium Bicarbonate Inj., USP 50 mL Single-dose, 50 mEq (1 mEq/mL) 4.2 grams (84 mg/mL), Rx Only, Mfd by Hospira, INC, Lake Forest, IL 60045 USA, NDC: 0409-6625-02

Product Quantity:
91,483,150 50 mL single dose vials

Reason for Recall:
Lack of Sterility Assurance

Recall Number:
D-1047-2017

Code Information:
Lot: 72109EV Exp. 12/01/2018, Lot: 72110EV Exp. 12/01/2018, Lot: 72112EV Exp. 12/01/2018, Lot: 72113EV Exp. 12/01/2018, Lot: 72114EV Exp. 12/01/2018, Lot: 73068EV Exp. 01/01/2019, Lot: 73071EV Exp. 01/01/2019, Lot: 73072EV Exp. 01/01/2019, Lot: 73224EV Exp. 01/01/2019, Lot: 73225EV Exp. 01/01/2019, Lot: 73230EV Exp. 01/01/2019, Lot: 73231EV Exp. 01/01/2019, Lot: 73232EV Exp. 01/01/2019, Lot: 73233EV Exp. 01/01/2019, Lot: 73234EV Exp. 01/01/2019, Lot: 73235EV Exp. 01/01/2019, Lot: 73236EV Exp. 01/01/2019, Lot: 73298EV Exp. 01/01/2019, Lot: 74058EV Exp. 02/01/2019, Lot: 74104EV Exp. 02/01/2019, Lot: 74105EV Exp. 02/01/2019, Lot: 74106EV Exp. 02/01/2019, Lot; 74107EV Exp. 02/01/2019, Lot: 74197EV Exp. 02/01/2019, Lot: 74198EV Exp. 02/01/2019, Lot: 74199EV Exp. 02/01/2019, Lot: 74200EV Exp. 02/01/2019, Lot: 74201EV Exp. 02/01/2019, Lot: 75171EV Exp. 03/01/2019, Lot: 75172EV Exp. 03/01/2019, Lot: 75173EV Exp. 03/01/2019, Lot: 75174EV Exp. 03/01/2019, Lot: 75175EV Exp. 03/01/2019, Lot: 75176EV Exp. 03/01/2019, Lot: 75177EV Exp. 03/01/2019, Lot: 75178EV Exp. 03/01/2019. Lot: 75293 Exp. 03/01/2019, Lot: 75418EV Exp. 03/01/2019, Lot: 75419EV Exp. 03/01/2019

Product Description:
Succinylcholine Chloride Injection, USP 200 mg (20 mg/mL) Quelicin Multiple-dose vial, 10 mL, For I.V. or I.M. use. a.) one vial (NDC: 0409-6629-02), b.) 25 vial carton (NDC: 0409-6629-25).

Product Quantity:
15,034,600 10 mL multiple dose use vials

Reason for Recall:
Lack of Sterility Assurance

Recall Number:
D-1048-2017

Code Information:
a.) one vial Lot: 74393EV Exp. 05/01/2018 Lot: 75157EV Exp. 06/01/2018 Lot: 75367EV, Exp. 06/01/2018 b.) 25 vial carton Lot: 75158EV; Exp. 06/01/2018

Product Description:
Neut Sodium Bicarbonate 4% (2.4 mEq) Additive Solution 5 mL , a.) Single-dose vial (NDC 0409-6609-02), b.) 25 vial carton (NDC 0409-6609-25), Rx Only, Mfd by Hospira, INC, Lake Forest, IL 60045 USA

Product Quantity:
21,436,700 5mL single dose vials

Reason for Recall:
Lack of Sterility Assurance

Recall Number:
D-1049-2017

Code Information:
a.) one vial: Lot: 72226EV Exp. 12/01/2018 Lot: 72236EV Exp. 12/01/2018 Lot: 75382EV Exp. 03/01/2019 Lot: 75383EV Exp. 03/01/2019 b.) 25 vial carton: Lot: 7538EV; Exp 03/01/2019

Class II Drugs Event

Event ID:
77576

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/16/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/03/2017

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

Recalling Firm:
Time-Cap Laboratories, Inc.
7 Michael Ave
Farmingdale NY United States

Distribution Pattern:
Nationwide U.S.A.

Associated Products

Product Description:
Ibuprofen Tablets, USP 600 mg, 500-count bottle (Capsule Shaped), Rx only, Manufactured for: Time Cap Labs, Inc., 7 Michael Avenue Farmingdale, NJ 11735, USA, Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83 Verna Indl. Estate, Verna, Goa-403 722, India, NDC 49483-603-50

Product Quantity:
1,980 bottles

Reason for Recall:
Presence of foreign tablets/capsules: Ibuprofen Tablets USP, 600 mg bottles were found to contain some Ibuprofen Tablets USP 800 mg.

Recall Number:
D-1055-2017

Code Information:
Lot #: HN7003

Class II Drugs Event

Event ID:
77601

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/19/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/31/2017

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Apace KY LLC
12954 Fountain Run Rd
Fountain Run KY United States

Distribution Pattern:
KY

Associated Products

Product Description:
Amantadine HCl Capsules, USP, 100 mg, Rx Only, 50 Capsules (5x10) Unit Dose Cartons, Manufactured for: AvKARE Inc, Pulaski, TN 38478 --- NDC: 50268-0069-15

Product Quantity:
1,483 cartons

Reason for Recall:
Labeling; Label Mix up; cartons labeled as Amantadine HCl 100 mg Capsules contain unit dose blister cards of Cyclobenzaprine HCl Tablet, USP 5 mg

Recall Number:
D-1035-2017

Code Information:
Lot: 16710, exp 07/2018

Product Description:
Cyclobenzaprine HCl Tablets, USP, 5 mg, 50 Tablets (5x10) Unit Dose Cartons, Rx Only, Manufactured for: AvKARE Inc, Pulaski, TN 38478 --- NDC: 50268-0190-15

Product Quantity:

Reason for Recall:
Labeling; Label Mix up; cartons labeled as Amantadine HCl 100 mg Capsules contain unit dose blister cards of Cyclobenzaprine HCl Tablet, USP 5 mg

Recall Number:
D-1036-2017

Code Information:
Lot: 16710, exp 07/2018

Class II Drugs Event

Event ID:
77638

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/26/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/01/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
VistaPharm, Inc.
7265 Ulmerton Rd
Largo FL United States

Distribution Pattern:
CA, IL, LA, NH, OH, PA, SC

Associated Products

Product Description:
Lactulose Solution, USP, 10 g/15 mL, dose cups delivers 15 mL packaged in 50-unit dose cups per case, Manufactured by VistaPharm, Inc., Largo, FL 33771, NDC 66689-038-50

Product Quantity:
6150 cases

Reason for Recall:
Microbial contamination of non-sterile product: product failed Total Yeast/Mold Count specification.

Recall Number:
D-1052-2017

Code Information:
Lot #: 468300, Exp 09/2018; 474400, Exp 11/2018

Product Description:
Lactulose Solution, USP, 20 g/30 mL, dose cups delivers 30 mL packaged 50-unit dose cups per case, Manufactured by VistaPharm, Inc., Largo, FL 33771, NDC 66689-038-01

Product Quantity:
9945 cases

Reason for Recall:
Microbial contamination of non-sterile product: product failed Total Yeast/Mold Count specification.

Recall Number:
D-1053-2017

Code Information:
Lot #: 458300, Exp 09/2018; 462600, Exp 07/2018; 471000, Exp 10/2018; 474300, Exp 11/2018

Class II Drugs Event

Event ID:
77674

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/10/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/31/2017

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

Associated Products

Product Description:
Divalproex Sodium Delayed Release Tablets, USP, 125 mg, 100-count bottle Rx only, Manufactured by Cadila Healthcare Ltd, Ahmedabad, India, Distributed by: Zydus Pharmaceuticals, Pennington, NJ 07054, NDC 68382-031-01

Product Quantity:
108,096 HDPE bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-1041-2017

Code Information:
MR6317 Exp.05/17 MR6318 Exp. 05/17 MR6319 Exp. 05/17 MR5361 Exp. 06/17 MR9007 Exp. 08/17 MR10000 Exp. 08/17 MR10923 Exp. 10/17 MR10924 Exp. 10/17 MR10925 Exp. 10/17 MR11554 Exp. 11/17 MR11555 Exp. 11/17 MS1359 Exp. 12/17

Product Description:
Divalproex Sodium Delayed Release Tablets, USP, 250 mg 100-count bottle (NDC 68382-032-01), b.) 500-count bottle (NDC 68382-032-05),Rx only, Manufactured by Cadila Healthcare Ltd, Ahmedabad, India, Distributed by: Zydus Pharmaceuticals, Pennington, NJ 07054

Product Quantity:
115,122 HDPE bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-1042-2017

Code Information:
MR5990 May-17 MR5991 May-17 MR7294 Jun-17 MR7295 Jun-17 MR7296 Jun-17 MR7297 Jun-17 MR7298 Jun-17 MR7603 Jun-17 MR7604 Jun-17 MR7605 Jun-17 MR7606 Jul-17 MR7607 Jul-17 MR8575 Aug-17 MR8576 Aug-17 MR8577 Aug-17 MR8882 Aug-17 MR8883 Aug-17 MR8884 Aug-17 MR8885 Aug-17 MR8886 Aug-17 MR9417 Aug-17 MR9418 Aug-17 MR9419 Aug-17 MR9499 Aug-17 MR9500 Aug-17 MR9501 Sep-17 MR9502 Sep-17 MR9601 Sep-17 MR9602 Sep-17 MR9805 Sep-17 MR9806 Sep-17 MR9807 Sep-17 MR9808 Sep-17 MR10536 Oct-17 MR10537 Oct-17 MR10538 Oct-17 MR10539 Oct-17 MR10540 Oct-17 MR10916 Oct-17 MR10918 Oct-17 MR10919 Nov-17 MR10920 Nov-17 MR10921 Nov-17 MR11366 Nov-17 MR11367 Nov-17 MR11368 Nov-17 MR11369 Nov-17 MR11370 Nov-17 MR11671 Nov-17 MR11672 Nov-17 MR11682 Nov-17 MR11682 Nov-17 MS1360 Dec-17 MS1361 Dec-17 MS1362 Dec-17 MS1363 Dec-17 MS1364 Dec-17 M600386 Feb-18 M600387 Feb-18 M600388 Feb-18 M602270 Mar-18 M602272 Apr-18

Product Description:
Divalproex Sodium Delayed Release Tablets, USP, 500 mg, a.) 100-count bottle (NDC 68382-033-01) b.) 500-count bottle (NDC 68382-033-05), Rx only, manufactured by Cadila Healthcare Ltd, Ahmedabad, India, Distributed by: Zydus Pharmaceuticals, Pennington, NJ 07054

Product Quantity:
108,726 HDPE bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-1043-2017

Code Information:
M603084 May-18 M603085 May-18 M603679 May-18 MR10030 Sep-17 MR10040 Sep-17 MR10103 Sep-17 MR10104 Sep-17 MR10259 Sep-17 MR10262 Sep-17 MR10263 Sep-17 MR10413 Sep-17 MR10415 Sep-17 MR10416 Oct-17 MR10695 Oct-17 MR10696 Oct-17 MR10697 Oct-17 MR10698 Oct-17 MR10699 Oct-17 MR10927 Oct-17 MR10929 Oct-17 MR10930 Nov-17 MR11182 Nov-17 MR11184 Nov-17 MR11187 Oct-17 MR11188 Oct-17 MR11189 Nov-17 MR11190 Nov-17 MR11361 Nov-17 MR11362 Nov-17 MR11363 Nov-17 MR11364 Nov-17 MR11365 Nov-17 MR11673 Nov-17 MR11674 Nov-17 MR11675 Nov-17 MR11676 Nov-17 MR11677 Nov-17 MR11872 Nov-17 MR11873 Nov-17 MR11874 Nov-17 MR11875 Nov-17 MR11876 Nov-17 MR11877 Nov-17 MR11878 Nov-17 MR5992 May-17 MR6188 May-17 MR6189 May-17 MR6313 May-17 MR6314 Jun-17 MR6315 Jun-17 MR6316 Jun-17 MR6620 Jun-17 MR6621 Jun-17 MR6622 Jun-17 MR7031 Jun-17 MR7032 Jun-17 MR7033 Jun-17 MR7034 Jun-17 MR7035 Jun-17 MR7299 Jun-17 MR7300 Jun-17 MR7301 Jun-17 MR7303 Jun-17 MR7767 Jul-17 MR8223 Jul-17 MR8224 Jul-17 MR8225 Jul-17 MR8248 Jul-17 MR8249 Jul-17 MR8578 Aug-17 MR8579 Aug-17 MR8580 Aug-17 MR8581 Aug-17 MR8888 Aug-17 MR8889 Aug-17 MR8890 Aug-17 MR8891 Aug-17 MR8894 Aug-17 MR9012 Aug-17 MR9013 Sep-17 MR9015 Sep-17 MR9016 Sep-17 MR9414 Aug-17 MR9415 Aug-17 MR9416 Sep-17 MS1246 Dec-17 MS1247 Dec-17 MS1248 Dec-17 MS1249 Dec-17 MS1250 Dec-17 MS1251 Dec-17 MS1252 Dec-17 MS1355 Dec-17 MS1356 Dec-17 MS1357 Jan-18 MS1358 Dec-17 MS2490 Feb-18 MS2491 Feb-18 MS2492 Feb-18

Class II Drugs Event

Event ID:
77732

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/05/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/31/2017

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Precision Dose Inc.
722 Progressive Ln
South Beloit IL United States

Distribution Pattern:
OH and CT

Associated Products

Product Description:
Carbamazepine Oral Suspension, USP. 100 mg/5 mL, 5 mL Unit Dose Cups, Rx Only, Pkg: Precision Dose, Inc., S. Beloit, IL 61080, NDC 68094-301-59.

Product Quantity:
480 (5mL) unit dose cups

Reason for Recall:
Labeling Error: Label mix-up. Products' unit dose cups are correctly labeled, but the product carton lists incorrect volume and NDC.

Recall Number:
D-1037-2017

Code Information:
Lot #: 500326, Exp. 6/30/2018

Class II Drugs Event

Event ID:
77757

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/12/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/31/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fusion IV Pharmaceuticals, Inc. dba Axia Pharmaceutical
1990 Westwood Blvd Ste 135
Los Angeles CA United States

Distribution Pattern:
There were only one customer in California

Associated Products

Product Description:
Testosterone Cypionate + Progesterone, 200 mg/ 2.5 mg/mL ,10 mL amber glass vials, Rx Only, Compounded by AXIA Pharmaceutical, Los Angeles, CA 90025

Product Quantity:
120 vials

Reason for Recall:
CGMP Deviations

Recall Number:
D-1040-2017

Code Information:
Lot # 03022017+44906; BUD 08/29/17

Class II Drugs Event

Event ID:
77771

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/17/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/03/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Vi-Jon, Inc.

Distribution Pattern:
GA, PA, NJ

1 Swan Dr
Smyrna TN United States

Associated Products

Product Description:
Magnesium Citrate Oral Solution, packaged in a 10 fl. oz. (296 mL) glass bottle, OTC, labeled as: a) GoodSense Magnesium Citrate Oral Solution Saline Laxative Very Low Sodium, UPC# 846036007381, NDC 50804-686-38, Distributed by: Geiss, Desitin &Dunn, Inc., Peachtree City, GA 30269; b) Premier Value Magnesium Citrate Oral Solution saline laxative very low sodium, UPC# 840986010255, NDC 68016-826-38, Distributed by: Chain Drug Consortium, Boca Raton, FL 33431; c) Swan Very Low Sodium Citroma Magnesium Citrate, UPC# 308690686383, NDC 0869-686-38, Distributed by: Vi-Jon, Smyrna, TN, 37167 ; d) ShopRite Magnesium Citrate Oral Solution Saline Laxative Low Sodium, UPC# 041190211487, NDC 41190-686-38, Distributed by: Wakefern Food Corporation, Jamesburg, NJ 08831

Product Quantity:
101,244 bottles

Reason for Recall:
Microbial contamination of non-sterile products: product was found to contain mold, identified as Rhinocladiella similis.

Recall Number:
D-1054-2017

Code Information:
Lot#: a) 0341906, Exp 12/2018; b) 0341906 Exp 12/2018; c) 0341906, Exp 12/2018; 0343709, Exp 1/2019 d) 0343709 Exp 1/2019

Class II Drugs Event

Event ID:
77835

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/24/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/03/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
1090 Horsham Rd
North Wales PA United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Famotidine Tablets USP, 20 mg, 100 count bottles, Rx only, Manufactured For: TEVA PHARMACEUTICALS USA, Sellersville, PA --- NDC 0172-5728-60

Product Quantity:
28,188 bottles

Reason for Recall:
Failed Tablet/Capsule Specification; out of specification for tablet weight

Recall Number:
D-1056-2017

Code Information:
Lot # 3429066, exp 06/2018

Class II Drugs Event

Event ID:
77847

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/28/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/03/2017

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
PD-Rx Pharmaceuticals, Inc.
727 N Ann Arbor Ave
Oklahoma City OK United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Famotidine USP 20 mg, 30 tablets bottle, Rx, PKG By; PD Rx Pharmaceuticals Incorporated Oklahoma City, OK 73127 --- NDC 55289-765-30

Product Quantity:
100 bottles

Reason for Recall:
Failed Tablet/Capsule Specification: out of specification for tablet weight.

Recall Number:
D-1057-2017

Code Information:
Lot: A17F55 Exp. 06/30/2018

Class III Drugs Event

Event ID:
77734

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/11/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/31/2017

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 in the USA

Associated Products

Product Description:
Pravastatin Sodium Tablets, USP, 10 mg, packaged in a) 90-count bottles (NDC 55111-229-90) and b) 500-count bottles (NDC 55111-229-05), Rx only, Manufactured by: Dr. Reddy's Laboratories Limited, Bachupally - 500 090 INDIA; Distributed by: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540 USA.

Product Quantity:
544 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: high out of specification results for related impurity for lot C700220.

Recall Number:
D-1038-2017

Code Information:
Lot #: a) C700220, Exp 06/18; b) C700220, Exp 06/18

Class III Drugs Event

Event ID:
77832

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/25/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/31/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
1090 Horsham Rd
North Wales PA United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Albuterol Sulfate Inhalation Solution, 0.021% (0.63 mg/3mL), packaged in 5 pouches of 5 x 3mL Sterile Unit-Dose Vials For Inhalation per carton, Rx only, Mfd. for: Watson Laboratories, Inc., Corona, CA 92880; Mfd. by: Cipla Ltd., Verna, Goa INDIA, NDC 0591-3467-53.

Product Quantity:
401,750 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: high out of specification results for related compound D.

Recall Number:
D-1039-2017

Code Information:
Lot #s: GA60206, GA60207, Exp 08/17; GA60283, GA60284, Exp 09/17; GA60378, GA60379, GA60478, Exp 10/17; GA60491, Exp 11/17; GA60615, GA60616, Exp 12/17; GA60719, GA60720, GA60721, GA60749, GA60750, GA60751, Exp 01/18; GA70001, GA70031, GA70046, GA70047, GA70074, GA70075, Exp 06/18