Enforcement Report - Week of April 5, 2017

Class II Drugs Event

Event ID:
76662

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/06/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/30/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
GSK Consumer Healthcare
184 Liberty Corner Rd Ste 200
Warren NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Sensodyne Repair & Protect Whitening, (stannous fluoride 0.45% (0.15% w/v fluoride ion)), Net Wt. 3.4 oz, Distributed by Glaxo SmithKline Consumer Healthcare LP Moon Township PA 15108 --- NDC 0135-0575-01, UPC UPC: 3 10158 84060 2

Product Quantity:
56,840 cases

Reason for Recall:
Presence of Foreign Substance; low concentration of an additional flavoring ingredient, Patchouli oil resulting in complaints of off flavor/scent

Recall Number:
D-0624-2017

Code Information:
A6J231, expiration 08/2018; A6J261, expiration 08/2018; A6K171, expiration 08/2018; A6K241, expiration, 09/2018; A6M231, expiration 10/2018

Class II Drugs Event

Event ID:
76733

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/10/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/24/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Claris Lifesciences Inc
1445 US Highway 130
North Brunswick NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Ciprofloxacin in Dextrose (5%) Injection, USP, 400 mg in 200 mL 5% Dextrose, Rx only, Manufactured for: Claris Lifesciences Inc. North Brunswick NJ, 08902, By: Claris Injectable Ltd. Gujarat, India, NDC 36000-009-24

Product Quantity:
18,360 units (765 cartons x 24 bags)

Reason for Recall:
Lack of Assurance of Sterility: there is potential of a leak from the primary container which may result in a potential breach of sterility and contamination of the product.

Recall Number:
D-0613-2017

Code Information:
Lot #: A051288, Exp. Sep 2017

Product Description:
Fluconazole Injection, USP, 400 mg in 200 mL, Rx only, Manufactured for: Claris Lifesciences Inc. North Brunswick NJ, 08902, By: Claris Injectable Ltd. Gujarat, India, NDC 36000-003-06

Product Quantity:
18,096 units (3016 cartons x 6 bags)

Reason for Recall:
Lack of Assurance of Sterility: there is potential of a leak from the primary container which may result in a potential breach of sterility and contamination of the product.

Recall Number:
D-0614-2017

Code Information:
Lot #: A051052, Exp. Aug 2017

Product Description:
Levofloxacin Injection in 5% Dextrose, 750 mg in 150 mL 5% Dextrose, Rx only, Manufactured for: Claris Lifesciences Inc. North Brunswick NJ, 08902, By: Claris Injectable Ltd. Gujarat, India, NDC 36000-048-24

Product Quantity:
24,456 units (1019 cartons x 24 bags)

Reason for Recall:
Lack of Assurance of Sterility: there is potential of a leak from the primary container which may result in a potential breach of sterility and contamination of the product.

Recall Number:
D-0615-2017

Code Information:
Lot #: A060040, Exp. Dec 2017

Product Description:
Metronidazole Injection, USP, 500 mg/100 mL, Rx only, Manufactured for: Claris Lifesciences Inc. North Brunswick NJ, 08902, By: Claris Injectable Ltd. Gujarat, India, NDC 36000-001-24

Product Quantity:
72072 units

Reason for Recall:
Lack of Assurance of Sterility: there is potential of a leak from the primary container which may result in a potential breach of sterility and contamination of the product.

Recall Number:
D-0616-2017

Code Information:
Lot #: A060205; A060209, Exp.Jan 2018

Class II Drugs Event

Event ID:
76737

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/15/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/27/2017

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, 500 mg, a) 100 count (NDC 68382-033-01) and b) 500 count (NDC 68382-033-05) bottles, Rx only, manufactured by Cadila Healthcare Ltd, Ahmedabad, India, Distributed by: Zydus Pharmaceuticals, Pennington, NJ

Product Quantity:
32628 bottles

Reason for Recall:
Failed Dissolution Specifications; 9 month long term stability

Recall Number:
D-0617-2017

Code Information:
a) MR8221, MR8222 exp 7/31/2017; MR10260, exp 9/30/2017; MR10926, exp 10/31/2017; b) MR6187, exp 5/31/2017; MR7302, exp 6/30/2017; MR7768, MR7769, exp 7/31/2017; MR8247, exp 7/31/2017; MR8887, MR8892, MR8893 exp 8/31/2017; MR9014, MR10414 exp 9/30/2017; MR10928, exp 10/31/2017; MR11183, MR11185, MR11186, exp 11/30/2017

Class II Drugs Event

Event ID:
76750

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/20/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/28/2017

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Rd
Morgantown WV United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Atorvastatin Calcium Tablets, 10 mg*, packaged in a) 90-count bottles (NDC 0378-3950-77); b) 90-count bottles (NDC 0378-3950-09); c) 500-count bottles (NDC 0378-3950-05); d) 500-count bottles (NDC 0378-3950-07), Rx only, Mylan Pharmaceuticals Inc., Morgantown, WV 26505 U.S.A.

Product Quantity:
1,233,107 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products: potential of an elevated bioburden with identification of objectionable organisms.

Recall Number:
D-0618-2017

Code Information:
Lot #: a) 3076141, 3076142, Exp 05/18; 2007223, Exp 06/18; 2007335, Exp 07/18; 2007336, Exp 08/18; 2007446, 3084691, Exp 09/18; 3084692, Exp 01/18; b) 3073773, Exp 01/18; 2007445, Exp 09/18; c) 3076139, 3076140,

3076143, Exp 05/18; 3076144, 3076145, Exp 06/18; 2007445, Exp 09/18; d) 3070837, Exp 10/17; 3073773, Exp 01/18; 3076139, Exp 05/18; 3073774, Exp 01/18; 2007445, Exp 09/18

Product Description:
Atorvastatin Calcium Tablets, 20 mg*, packaged in a) 90-count bottles (NDC 0378-3951-09) and b) 500-count bottles (NDC 0378-3951-07); Rx only, Mylan Pharmaceuticals Inc., Morgantown, WV 26505 U.S.A.

Product Quantity:
299,112 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products: potential of an elevated bioburden with identification of objectionable organisms.

Recall Number:
D-0619-2017

Code Information:
Lot #: a) 3073776, Exp 01/18; 3073777, 3074909, Exp 02/18; 3075564, 3075565, Exp 03/18; 2007338, Exp 08/18; b) 3070838, Exp 10/17; 3073775, Exp 01/18; 3074908, 3074909, Exp 02/18; 3075564, Exp 03/18; 2007224, 3075887, Exp 06/18; 2007337, 2007338, Exp 08/18

Product Description:
Atorvastatin Calcium Tablets, 40 mg*, packaged in a) 90-count bottles (NDC 0378-3952-09) and b) 500-count bottles (NDC 0378-3952-07); Rx only, Mylan Pharmaceuticals Inc., Morgantown, WV 26505 U.S.A.

Product Quantity:
444,201 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products: potential of an elevated bioburden with identification of objectionable organisms.

Recall Number:
D-0620-2017

Code Information:
Lot #: a) 3073779, 3073780, Exp 02/18; 3074910, Exp 03/18; 3075568, Exp 04/18; 3075889, 3075890, Exp 06/18; 2007339, 2007340, Exp 08/18; 3079881, 3079882, Exp 10/18; b) 3070839, Exp 10/17; 3073778, 3073779, Exp 02/18; 3075566, 3075567, Exp 04/18; 3075890, 2007225, Exp 06/18; 2007340, Exp 08/18; 3079880, 3079881, Exp 10/18

Product Description:
Atorvastatin Calcium Tablets, 80 mg*, packaged in a) 90-count bottles (NDC 0378-3953-09) and b) 500-count bottles (NDC 0378-3953-07), Rx only, Mylan Pharmaceuticals Inc., Morgantown, WV 26505 U.S.A.

Product Quantity:
452,269 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products: potential of an elevated bioburden with identification of objectionable organisms.

Recall Number:
D-0621-2017

Code Information:
Lot #: a) 3073782, 3073783, Exp 02/18; 3074915, 3074916, 3074917, Exp 03/18; 3074918, 3075572, Exp 04/18; 3075573, 3075574, Exp 05/18; 2007226, 3075894, Exp 06/18; 2007344, 2007345, 2007346, Exp 08/18; 2007451, 2007452, 2007453, 2007454, Exp 09/18; b) 3070840, Exp 10/17; 3073781, 3074911, Exp 02/18; 3074912, 3074913, 3074914, Exp 03/18; 3075570, 3075571, Exp 04/18; 3075892, Exp 05/18; 3075893, Exp 06/18; 2007341, 2007342, 2007343, 2007347, Exp 08/18; 2007456, Exp 10/18

Class II Drugs Event

Event ID:
76802

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/21/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/28/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Institutional, Inc. (d.b.a. UDL Laboratories)
1718 Northrock Ct
Rockford IL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Atorvastatin Calcium Tablets, 10 mg*, 100-count Unit Dose Tablets (10 x 10) per carton, Rx only, Manufactured by: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 U.S.A.., NDC 51079-208-20

Product Quantity:
1,527 cartons

Reason for Recall:
Microbial Contamination of Non-Sterile Products: potential of an elevated bioburden with identification of objectionable organisms.

Recall Number:
D-0622-2017

Code Information:
Lot #: 3084288, Exp. 07/18

Class III Drugs Event

Event ID:
76412

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/07/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/29/2017

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