Enforcement Report - Week of February 12, 2020

Class II Drugs Event

Event ID:
84798

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/27/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/06/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
400 Interpace Pkwy
Parsippany NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Desmopressin Acetate Tablets, 0.1 mg, 100-count bottle, Rx Only, Manufactured by: Actavis Laboratories, Inc. Fort Lauderdale, FL 33314 USA, Distributed by: Actavis Pharma, Inc. Parisppany, NJ 07054 USA, NDC 0591-2464-01

Product Quantity:
22,868 bottles

Reason for Recall:
GMP Deviations: Product bottle may be absent of desiccant.

Recall Number:
D-0830-2020

Code Information:
Lot #: 1281203M, exp. date 03/2020 and 1290113M, exp. date 04/2020

Product Description:
Desmopressin Acetate Tablets, 0.2 mg, 100-count bottle, Rx Only, Manufactured by: Actavis Laboratories, Inc. Fort Lauderdale, FL 33314 USA, Distributed by: Actavis Pharma, Inc. Parisppany, NJ 07054 USA, NDC 0591-2465-01

Product Quantity:
69,012 bottles

Reason for Recall:
GMP Deviations: Product bottle may be absent of desiccant.

Recall Number:
D-0831-2020

Code Information:
Lot #: 1269726M, exp. date 01/2020; 1283269M, 1283270M, exp. date 03/2020; 1292992M,1292993A, exp. date 04/2020

Class II Drugs Event

Event ID:
84799

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/14/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/04/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Spectrum Laboratory Products
14422 S San Pedro St
Gardena CA United States

Distribution Pattern:
The recalled API was distributed to pharmacies in the following states: AZ, CA, FL, GA, NJ, PA, RI, SC, TX, UT, WY. The API was also distributed internationally to Canada and UAE.

Associated Products

Product Description:
Ranitidine Hydrochloride (powder), USP, Rx only, Spectrum Chemical Mfg Corp., a) 1 gram, b) 5 grams, c) 25 grams, d)100 grams, e) 500 grams, f) 1 Kilogram

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0825-2020

Code Information:
Lot #:11E0585, Exp. October 2023

Class II Drugs Event

Event ID:
84814

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/28/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/07/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Graviti Pharmaceuticals Private Limited
Survey No. 621 Isnapur Village Patancheru Mandal
Medak India

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Atorvastatin Calcium Tablets, USP, 10 mg*, 90-count bottle, Rx Only, Manufactured for: Biocon Pharma Inc., Iselin, NJ 08830-3009 USA; Manufactured By: Graviti Pharmaceuticals Pvt. Ltd., Telangana -502307, INDIA; NDC 70377-027-11.

Product Quantity:
29,056 bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules: Customer complaint that one 20 mg Atorvastatin Calcium Tablet was present in a bottle labeled as and containing eight-nine Atorvastatin Calcium Tablets, USP 10 mg.

Recall Number:
D-0832-2020

Code Information:
Lot #: ATA318099C, Exp 12/2020

Class II Drugs Event

Event ID:
84818

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/24/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/06/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ascend Laboratories LLC
339 Jefferson Rd Ste 101
Parsippany NJ United States

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Olmesartan Medoxomil Tablets 20 mg, Rx Only, 90 Tablets per Bottle, Manufactured by: Alkem Laboratories Ltd., Mumbai - 400 013 INDIA, Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054, NDC 67877-446-90.

Product Quantity:
192 Bottles

Reason for Recall:
cGMP Deviations; Olmesartan Medoxomil Tablets 20 mg was released in error with alternate API source prior to filing and approval of Prior Approval Supplement.

Recall Number:
D-0828-2020

Code Information:
Lot #: 19122552, Exp 7/31/2021

Class II Drugs Event

Event ID:
84820

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/10/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/04/2020

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
AZ, CA, FL, IL, IN, KY, ME, MS, OK, OR, PA, TN

Associated Products

Product Description:
ranitidine hydrochloride, USP ,150 mg tablets a) 14-count bottles (NDC 43063-844-14); b) 30-count bottles (NDC 43063-844-30); c) 60 -count bottles(NDC 43063-844-60); d) 90-count bottles (NDC 43063-844-90); e) 100-count bottles (NDC 43063-844-01), Rx Only, Distributed by: PD-Rx Pharmaceuticals Incorporated Oklahoma City, OK 73127

Product Quantity:

Reason for Recall:
CGMP Deviations: Received notice from supplier of potential -Nitrosodimethylamine (NDMA) amounts above established levels.

Recall Number:
D-0826-2020

Code Information:
a) H19E83 Exp. 11/30/2020, E19A82 Exp. 05/31/2020; b) H19B20 Exp. 11/30/2020, G19D77 Exp. 05/31/2020, C19D84 Exp. 05/31/2020, D19A77 Exp. 05/31/2020, D19E40 Exp. 05/31/2020; c) I19C45 Exp. 11/30/2020, E19E42 Exp. 11/30/2020, G19B41 Exp. 11/30/2020, H19C77 Exp. 11/30/2020, E19A34 Exp. 05/31/2020; d) H19B61 Exp. 11/30/2020, H19C82 Exp. 11/30/2020, C19A18 Exp. 05/31/2020, C19B13 Exp. 05/31/2020, D19B77 Exp. 05/31/2020, E19B76 Exp. 05/31/2020; e) I19B41 Exp. 11/30/2020, D19D51 Exp. 05/31/2020, F19C33 Exp. 05/31/2020

Class III Drugs Event

Event ID:
84750

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/22/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/05/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ascend Laboratories LLC
339 Jefferson Rd Ste 101
Parsippany NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Minocycline Hydrochloride Extended-Release Tablets, USP, 105 mg*, 30-count bottle, Rx Only, Manufactured by: Alkem Laboratories Ltd., Mumbai - 400 013 India, Distributed by: Ascend Laboratories, LLC, Parsippany, NJ 07054, NDC 67877-438-30.

Product Quantity:
4728 bottles

Reason for Recall:
Failed Dissolution Specifications: low out of specification results for dissolution testing.

Recall Number:
D-0827-2020

Code Information:
Lot #: 19140414, Exp 12/2020

Class III Drugs Event

Event ID:
84754

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/24/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/11/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Macleods Pharma Usa Inc
666 Plainsboro Rd Bldg 200 Ste 230
Plainsboro NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Pioglitazone and Metformin Hydrochloride Tablets, USP 15 mg/500 mg, Rx Only, 60-count bottle, Manufactured for Macleods Pharma USA, Inc. Plainsboro, NJ 08536, Manufactured by: Macleods Pharmaceuticals Ltd. Baddi, Himachal Pradesh, India, NDA 33342-176-09

Product Quantity:
4694 30x60-count bottles

Reason for Recall:
Subpotent Drug: Out of specification assay result, below specification, for two lots of Pioglitazone And Metformin Hydrochloride Tablets.

Recall Number:
D-0838-2020

Code Information:
Lot# BPA5903A, EXP 05/2021; BPA5819A, EXP 11/2020

Class III Drugs Event

Event ID:
84836

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/29/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/06/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
UNICHEM PHARMACEUTICALS USA INC
1 Tower Center Blvd Ste 2200
East Brunswick NJ United States

Distribution Pattern:
Distributed Nationwide in the US

Associated Products

Product Description:
Clonidine Hydrochloride Tablets, USP 0.1mg, Rx Only, 100-count bottle, Manufactured by: Unichem Laboratories Ltd. Pilerne Ind. Estate, Pilerne Bardez, Goa 403 511 India. Manufactured for: Unichem Pharmaceuticals (USA), Inc. East Brunswick, NJ 08816. NDC 29300-135-01

Product Quantity:
19161600 units

Reason for Recall:
Failed Impurities/Degredation Specifications: This recall is initiated as a precautionary measure due to potential migration of Benzophenone at very low level into product from container label.

Recall Number:
D-0829-2020

Code Information:
Lot Numbers: GCLL18108, GCLL18109, GCLL18110 - EXP 10/31/2020; GCLL19003 EXP 12/31/2020