Enforcement Report - Week of June 26, 2019

Class II Drugs Event

Event ID:
82854

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/09/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/19/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
American Health Packaging
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide within the USA

Associated Products

Product Description:
Anastrozole Tablets, USP, 1mg, 30-count unit dose blisters per carton, Rx Only, Packaged and Distributed by: American Health Packaging, Columbus, Ohio 43217. NDC 60687-112-21.

Product Quantity:
15,386 cartons

Reason for Recall:
GMP Deviations: Potential cross contamination due to cleaning procedure failure.

Recall Number:
D-1394-2019

Code Information:
Lot #: 175289A, 175286B, 175290B, Exp. 08/31/2019; 179906A, Exp. 03/31/2020; 183252A, Exp. 09/30/2020; 184611A, Exp. 11/30/2020

Class II Drugs Event

Event ID:
83025

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/05/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/14/2019

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 in the USA

Associated Products

Product Description:
Allergy Relief D, Fexofenadine HCl 60 mg/ Pseudoephedrine HCl 120 mg, Extended Release Tablets, USP, 30-count box, Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895. Made in India. UPC 0 50428 39131 0

Product Quantity:
9528 30 count units

Reason for Recall:
Testing of Fexofenadine HCl and Pseudoephedrine Failed Impurities/Degradation Specifications: elevated substance results that were reported above or near the specification limit

Recall Number:
D-1387-2019

Code Information:
Lot: GKT0484B, EXP 04/2020

Product Description:
Allergy Relief D, Fexofenadine HCl 60 mg/ Pseudoephedrine HCl 120 mg, Extended Release Tablets, USP, 20-count box, Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895. Made in India. UPC 0 50428 43023 1

Product Quantity:
17,136 20-count units

Reason for Recall:
Testing of Fexofenadine HCl and Pseudoephedrine Failed Impurities/Degradation Specifications: elevated substance results that were reported above or near the specification limit

Recall Number:
D-1388-2019

Code Information:
Lot GKT0791, EXP 06/2020

Product Description:
Wal-Fex D Fexofenadine HCl 60 mg/ Pseudoephedrine HCl 120 mg/ Extended-Release Tablets, USP, Allergy & Congestion, 30-count box. Distributed by: Walgreen Co. 200 Wilmore Rd. Deerfield, IL 40015. Made in India. UPC 3 11917 19454 7

Product Quantity:
14,399 30-count units

Reason for Recall:
Testing of Fexofenadine HCl and Pseudoephedrine Failed Impurities/Degradation Specifications: elevated substance results that were reported above or near the specification limit

Recall Number:
D-1389-2019

Code Information:
Lot: GKS1014, EXP 09/2019; GKT0484A, EXP 04/2020

Product Description:
Wal-Fex D Fexofenadine HCl 60 mg/ Pseudoephedrine HCl 120 mg, Extended-Release Tablets, USP, Allergy & Congestion, 20-count box.Distributed by: Walgreen Co. 200 Wilmore Rd. Deerfield, IL 40015. Made in India UPC 3 11917 19453 0

Product Quantity:
17,904 20-count units

Reason for Recall:
Testing of Fexofenadine HCl and Pseudoephedrine Failed Impurities/Degradation Specifications: elevated substance results that were reported above or near the specification limit

Recall Number:
D-1390-2019

Code Information:
Lot GKT0406, EXP 3/2020

Class II Drugs Event

Event ID:
83101

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/10/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/20/2019

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Preferred Pharmaceuticals, Inc
1250 N Lakeview Ave Ste O
Anaheim CA United States

Distribution Pattern:
Distribution was made to CA and FL.

Associated Products

Product Description:
Robafen DM, Generic for Robitussin DM, In each teaspoonful (5mL): Dextromethorphan HBr, USP 10mg,/Guaifenesin, USP 100mg, 118mL (4oz) bottle, Manufactured for Preferred Pharmaceuticals, Inc., Anaheim, CA 92807 by Major Pharmaceuticals, Livonia, MI 48152, NDC 68788-0841-01

Product Quantity:
192 4 oz bottles

Reason for Recall:
CGMP Deviations: Potential product contamination with Burkholderia cepacia (B.cepacia) and Ralstonia pickettii (R. pickettii).

Recall Number:
D-1410-2019

Code Information:
Lot: J0218L, Batch: 10021812, Exp. 02/2020; Lot: L2718D, Batch numbers from consecutively from L2718D001 to L2718D096, Exp. 07/2020

Class II Drugs Event

Event ID:
83181

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/05/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/20/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
P & L Developments, LLC
200 Hicks St
Westbury NY United States

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Cetirizine HCL Oral Solution 1 mg/mL, Children's Allergy, Antihistamine, Dye Free, Gluten Free, Grape Flavor, 5 mg/5mL, 4 FL. oz. Bottle, Distributed by Dolgencorp, LLC, 100 mission ridge, Goodlettsville, TN 37072, NDC 55910-878-04, UPC 359726178051.

Product Quantity:
202,068 bottles

Reason for Recall:
cGMP Deviations: Firm was notified by their supplier of Cetirizine HCL Oral Solution, USP, 1mg/mL, 4oz, of the voluntary recall that they have initiated due to potential contamination with Burkholderia cepacia (B.cepacia) and Ralstonia pickettii (R. pickettii).

Recall Number:
D-1407-2019

Code Information:
Lot #s: C00138; A48440, Exp. 5/19; C02434; C04186, Exp. 6/19; C07864, Exp. 7/19; F13277; C08962; F13778, Exp. 10/19; C11746; F05899; F13777, Exp. 12/19; F09356; F10784; F13595, Exp. 2/20; F22355; F23239, Exp. 8/20.

Product Description:
Cetirizine Oral Solution 1 mg/mL, Children's Allergy, Antihistamine, Dye Free, Grape Flavor, 4 FL. oz. Bottle, Distributed by C.D.M.A. Inc., Novi, MI 48376, Quality Choice, NDC 63868-430-04, UPC 635515992474.

Product Quantity:
17,664 bottles

Reason for Recall:
cGMP Deviations: Firm was notified by their supplier of Cetirizine HCL Oral Solution, USP, 1mg/mL, 4oz, of the voluntary recall that they have initiated due to potential contamination with Burkholderia cepacia (B.cepacia) and Ralstonia pickettii (R. pickettii).

Recall Number:
D-1408-2019

Code Information:
Lot #s: C04866; C09863, Exp. 10/19; F01267, Exp. 12/19; F12609, Exp. 2/20; F25327, Exp. 8/20.

Product Description:
Cetirizine Oral Solution 1 mg/mL, Up & Up, Children's allergy relief, Antihistamine, Dye Free, Grape Flavor, 4 FL. oz. (118 mL) Bottle, Distributed by Target Corporation, Minneapolis, MN 55403, NDC 11673-178-04, UPC 359726178044.

Product Quantity:
124,512 bottles

Reason for Recall:
cGMP Deviations: Firm was notified by their supplier of Cetirizine HCL Oral Solution, USP, 1mg/mL, 4oz, of the voluntary recall that they have initiated due to potential contamination with Burkholderia cepacia (B.cepacia) and Ralstonia pickettii (R. pickettii).

Recall Number:
D-1409-2019

Code Information:
Lot #s: A98495; C03882; A49664, Exp. 5/19; C06541, Exp. 6/19; C05532; F00527, Exp. 10/19; F00528; F07279, Exp. 12/19; F07842; F10237, Exp. 2/20.

Class III Drugs Event

Event ID:
82983

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/20/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/14/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teligent Pharma, Inc.
105 Lincoln Avenue
Buena NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Betamethasone Dipropionate Ointment USP, 0.05%* (Augmented), a) 15 gram (NDC 52565-019-15) and b) 50 gram (NDC 52565-019-51) tubed, Rx Only, Manufactured by: Teligent Pharma, Inc. Buena, New Jersey 06310

Product Quantity:
9360 tubes

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-1391-2019

Code Information:
Lot 11852, exp date 08/2020

Class III Drugs Event

Event ID:
83073

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/07/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/17/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn Inc
1925 W Field Ct Ste 300
Lake Forest IL United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Myorisan (isotretinoin capsules, USP), 40 mg, packaged in cartons of 30 Capsules containing 3 x 10 Prescription Packs, Rx Only, Distributed by: VersaPharm Inc. - An Akorn Company, Lake Forest, IL 60045, NDC 61748-304-13

Product Quantity:
16,216 cartons

Reason for Recall:
Labeling: Label mix-up: Product secondary carton erroneously states 40mg instead of 30 mg, primary carton is label correctly.

Recall Number:
D-1392-2019

Code Information:
Lot#: V30M56A, Exp 9/20

Class III Drugs Event

Event ID:
83114

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/10/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/18/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ecolab Inc
1 Ecolab Pl
Saint Paul MN United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
QUIK-CARE Aerosol Foam Hand Sanitizer (62.5% Ethyl Alcohol), packaged in 7 oz cans, Ecolab, 370 Wabasha Street N, St. Paul, MN 55102-1390 USA, NDC 47593-490-82

Product Quantity:
183 cases

Reason for Recall:
Incorrect/undeclared excipients: Hand sanitizer was made using the wrong alcohol raw material.

Recall Number:
D-1393-2019

Code Information:
Lot #: C040591, Exp 4/21