Enforcement Report - Week of April 3, 2019

Class II Drugs Event

Event ID:
82344

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/06/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/27/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ecolab Inc
Level 7 370 N
Saint Paul MN United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Gel Hand Sanitizer (Ethyl Alcohol 70%), packaged in a) 37 mL (1.25 fl oz) bottles (NDC 47593-487-49), b) 118 mL (4 fl oz) bottles (NDC 47593-487-33), and c) 540 mL (18 fl oz) bottles (NDC47593-487-31) Ecolab, 370 Wabasha Street N, St. Paul, MN 55102.

Product Quantity:
a) 22 units b) 314 units c) 3511 units

Reason for Recall:
Chemical Contamination: low levels of various substituted benzene (aromatic) compounds identified in the product after complaints of malodor.

Recall Number:
D-1060-2019

Code Information:
Lot #: a) HS091281, Exp. AUG 2020, b) HS091781, Exp. AUG 2020 and c) HS082881, HS083081, and HS090781, Exp. AUG 2020

Product Description:
Advanced Gel Hand Sanitizer (Ethyl alcohol 62%), packaged in a) 37 mL (1.25 fl oz) bottles (NDC 47593-488-49) and b) 540 mL (18 fl oz) bottles (NDC 47593-488-31) Ecolab, 370 Wabasha Street N, St. Paul, MN 55102.

Product Quantity:
a) 118 units, b) 3,783 units

Reason for Recall:
Chemical Contamination: low levels of various substituted benzene (aromatic) compounds identified in the product after complaints of malodor.

Recall Number:
D-1061-2019

Code Information:
Lot #: a) HS092781, Exp. SEP 2020; b) HS091381, HS091781, and HS091881, Exp. SEP 2020

Product Description:
Moisturizing Gel Hand Sanitizer (Ethyl Alcohol 62%), 118 mL (4 fl oz) bottles, Ecolab, 370 Wabasha Street N, St. Paul, MN 55102. NDC 47593-489-33

Product Quantity:
30 units

Reason for Recall:
Chemical Contamination: low levels of various substituted benzene (aromatic) compounds identified in the product after complaints of malodor.

Recall Number:
D-1062-2019

Code Information:
Lot #: HS092781, Exp. SEP 2020

Product Description:
Quick-Care Foam Hand Sanitizer (Ethyl alcohol 62%), 45 mL (1.5 fl oz) bottles, Ecolab, 370 Wabasha Street N, St. Paul, MN 55102. NDC 47593-491-85

Product Quantity:
67 units

Reason for Recall:
Chemical Contamination: low levels of various substituted benzene (aromatic) compounds identified in the product after complaints of malodor.

Recall Number:
D-1063-2019

Code Information:
Lot #: HS103181, Exp. OCT 2020

Product Description:
Express Gel Hand Sanitizer (Ethyl Alcohol 70%), 37 mL (1.25 fl oz) bottles, Ecolab, 370 Wabasha Street N, St. Paul, MN 55102. NDC 47593-502-49

Product Quantity:
105 units

Reason for Recall:
Chemical Contamination: low levels of various substituted benzene (aromatic) compounds identified in the product after complaints of malodor.

Recall Number:
D-1064-2019

Code Information:
Lot #: HS092681, Exp. SEP 2020

Class II Drugs Event

Event ID:
82356

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/22/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/25/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
111 S Calvert St Fl 21ST
Baltimore MD United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Fayosim (levonorgestrel and ethinyl estradiol) tablets USP, (0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg) and ethinyl estradiol tablets USP, (0.01 mg), packaged in 1 Extended-Cycle Wallet of 91 Tablets packed in a pouch(NDC 68180-860-11); one pouch per carton (NDC 68180-860-12), Rx only, Distributed by: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202; Manufactured by: Lupin Limited, Pithampur (M.P.) - 454775, INDIA.

Product Quantity:
12,464 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: Out-of-specification results observed in related substance test (Any Other Individual Impurity and Total impurities) in Ethinyl Estradiol Tablets USP 0.01mg at 12 month long term stability study.

Recall Number:
D-1057-2019

Code Information:
Lot #: L800016, Exp 12/2019; L800721, Exp 05/2020

Class II Drugs Event

Event ID:
82424

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/19/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/22/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Allergan Sales, LLC
8301 Mars Dr
Waco TX United States

Distribution Pattern:
TN only

Associated Products

Product Description:
Combigan (brimonidine tartrate/timolol maleate ophthalmic solution) 0.2%/0.5% 5 mL bottles, Rx only, Allergan, Inc. Irvine, CA 92612 U.S.A. NDC 0023-9211-05

Product Quantity:
72 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-1056-2019

Code Information:
Lot#: 99946 Exp. January 16, 2021

Class III Drugs Event

Event ID:
82401

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/18/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/25/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ingenus Pharmaceuticals Llc
4190 Millenia Blvd
Orlando FL United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico.

Associated Products

Product Description:
Diclofenac Sodium Topical Solution, 1.5% w/w, 5 FL. OZ. (150 mL) bottle, Rx Only, Manufactured for: Ingenus Pharmaceuticals, LLC, Orlando, FL 32839-6408, NDC 50742-308-05.

Product Quantity:
29,435 bottles

Reason for Recall:
Defective Container: firm discovered samples stored horizontally as well as product quality complaints from customers for bottles leaking.

Recall Number:
D-1058-2019

Code Information:
Lot #: 31804, Exp 11/2019; 31911, 31917, Exp 02/2020; 32067, 32072, 32084, Exp 06/2020; 32248, Exp 10/2020

Not Yet Classified Drugs Event

Event ID:
82419

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/14/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Ata International Inc
8241 E Loftwood Ln
Orange CA United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Blue Fusion Capsules, 1- count blister pack, Distributed by: DNS Distribution 5225 Canyon Crest Dr. Ste 71-640, Riverside, CA 92507, UPC 7 48252 66460 0

Product Quantity:
Unknown

Reason for Recall:
Marketed Without An Approved NDA/ANDA: FDA analysis found this product to contain undeclared ingredients: Sildenafil, Tadalafil, desmethyl carbodenafil, dithiodesmethyl carbodenafil, scutellarin, and daidzein.

Recall Number:

Code Information:
All lots