Enforcement Report - Week of August 19, 2020

Class I Drugs Event

Event ID:
85987

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/23/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Itech 361 LLC
240 Derby Rd
Sunland Park NM United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
All Clean Hand Sanitizer, Fresh Scent, 1 Liter bottles, Ethyl Alcohol 70.00%, Produced by Eskbiochem SA de CV Ave Mexico Japon 50 Celaya, Gto. Mexico 38010, Distributed by All Clean Natural LTD, UPC Code 6 28055 37013 0

Product Quantity:
18,760 bottles

Reason for Recall:
Chemical Contamination: Product contains undeclared methanol.

Recall Number:

Code Information:
All Lots

Class II Drugs Event

Event ID:
86017

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/14/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/10/2020

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide United States

Associated Products

Product Description:
Lidocaine Patch 5%, packaged in 30-count cartons, Rx only, Manufactured by: Actavis Laboratories UT, Inc., Salt Lake City, UT 84108, USA, Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054 USA, NDC 0591-3525-30

Product Quantity:
28,596 cartons

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp date on the individual transdermal pouches but not in the carton.

Recall Number:
D-1492-2020

Code Information:
Carton Lot # 1383513B, Patch Lot # 1383513, Exp date 03/2022

Class II Drugs Event

Event ID:
86108

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/21/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/13/2020

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide within the U.S.

Associated Products

Product Description:
Mibelas 24 Fe (norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets) chewable,1 mg/0.02 mg/75 mg, Rx Only, Provides 24 days of active therapy, Pouch Contains one wallet of 28 tablets, NDC: 68180-911-11, Carton contains 3 wallets of 28 tablets each, NDC: 68180-911-13, Distributed by: Lupin Pharmaceuticals, Inc., MD, 21200, Manufactured by: Lupin Limited, India.

Product Quantity:
560,922 Pouches

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of specification result observed in related substance test.

Recall Number:
D-1502-2020

Code Information:
Lot #s: L900017, L900070, Exp. 12/31/2020; L900589, Exp. 03/31/2021; L901085, Exp. 04/30/2021; L901008, Exp. 06/30/2021; L901641, L901735, Exp.10/31/2021.

Class II Drugs Event

Event ID:
86170

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/04/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/12/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
PAI Holdings, LLC. dba Pharmaceutical Associates Inc
1700 Perimeter Rd
Greenville SC United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Nystatin Oral Suspension, USP 100,000 units per mL, Cherry/Peppermint Flavor, 16 fl. oz. (473 mL), Rx only, Pharmaceutical Associates, Inc. Greenville, SC 29605, NDC 0121-0610-16

Product Quantity:
7416 bottles

Reason for Recall:
Subpotent drug: Out of specification for assay at the 15-month test interval.

Recall Number:
D-1494-2020

Code Information:
Lot: B973, Exp 11/20

Class II Drugs Event

Event ID:
86171

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/04/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/13/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Eosera, Inc.
5000 South Fwy Ste 106
Fort Worth TX United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Ear Pain MD Pain Relief Drops For Kids (lidocaine HCl Monohydrate 4%) 0.5 FL OZ (15 mL) bottles, Eosera, Inc. 5000 South Freeway Fort Worth, TX 76115, NDC 72429-0070-8

Product Quantity:
45,673 bottles

Reason for Recall:
cGMP Deviations.

Recall Number:
D-1498-2020

Code Information:
Lots: P203093 Exp. DEC 21; P203026 Exp. JUN 21; P193084, P193044, Exp. APR 21; P193073, P193072, P193071, P193070 Exp. FEB 21; P192050 Exp. MAY 21; P193042 Exp. MAR 21; P193013 Exp. JAN 21; P193012 Exp. DEC 20

Product Description:
Ear Pain MD Pain Relief Drops with 4% Lidocaine (lidocaine HCl Monohydrate 4%) 0.5 FL OZ (15 mL) bottles, Eosera, Inc. 5000 South Freeway Fort Worth, TX 76115, NDC 72429-0072-2

Product Quantity:
125,874 bottles

Reason for Recall:
cGMP Deviations.

Recall Number:
D-1499-2020

Code Information:
Lot #: P203076, P203075 Exp. NOV 21; P203061, P203057 Exp. AUG 21; P203047, P203044, P203040, JUL 21; P203033, P203030, P203016, P203015, P203002, P203001, P193053 Exp. JUN 21; P203024, P193097 Exp. MAY 21; P203017 Exp. JUL 20; P193091, P193089, P193088, P193087 Exp. APR 21; P193068, P193067 Exp. FEB 21; P193064, P193063, P193062, P193059, P193014 Exp. JAN 21; P193057, P193056, P193055, P193011, P193010, P193009, P193008, P193007, P193006, P192005, P193003, P193002, P193001, Exp. DEC 20; P183018, P183017 Exp. SEP 20

Product Description:
Ear Itch MD Anti-Itch Spray (pramoxine HCL 1%) 0.5 FL OZ (15 mL) bottles, Eosera, Inc. 5000 South Freeway Fort Worth, TX 76115, NDC 72429-0071-5, UPC 851722007125

Product Quantity:
43,424 bottles

Reason for Recall:
cGMP Deviations.

Recall Number:
D-1500-2020

Code Information:
Lot #: F203071 Exp. SEP 21; F203059 Exp. OCT 21; F193095, F193094 Exp. MAY 21; F193093 Exp. APR 21; F193082 Exp. MAR 21; F193069 Exp. FEB 21; F193061 Exp. JAN 21; F193058, F193054 Exp. DEC 20; F193032, F193030, F193029, F193028, F193027, F193026, F193025, F193024 Exp. AUG 20

Product Description:
Day & Night Pack Ear Itch MD Anti-Itch Spray (pramoxine HCL 1%), 0.5 FL OZ (15 mL) bottles/Ear Itch MD Nighttime Intensive Soothing Spray (pramoxine HCL 1%), 0.5 FL OZ (15 mL) bottles, Eosera, Inc. 5000 South Freeway Fort Worth, TX 76115, NDC 72429-0071-5

Product Quantity:
15229 bottles

Reason for Recall:
cGMP Deviations.

Recall Number:
D-1501-2020

Code Information:
Lot #: TP203073 Exp. SEP 21; TP203055 Exp. OCT 21; TP203012, TP203009, TP203006 Exp. JUN 21

Class II Drugs Event

Event ID:
86194

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/29/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/12/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SCA Pharmaceuticals

755 Rainbow Rd Ste B
Windsor CT United States

Distribution Pattern:
Product was distributed nationwide within the United States.

Associated Products

Product Description:
Heparin Sodium 5,000 units in 0.9% Sodium Chloride 1000 mL bag (5 units/mL), Rx only, SCA Pharmaceuticals 755 Rainbow Rd. Windsor, CT 06095, NDC 70004-0650-46

Product Quantity:
3,932 bags

Reason for Recall:
Subpotent Drug: Out-of-Specification potency results at the 30-day stability timepoint.

Recall Number:
D-1495-2020

Code Information:
Lot #: 1220018755, Exp. Date 7/30/2020; 1220018861, 1220018850, Exp. Date 8/4/2020; 1220018899, Exp. Date 8/5/2020; 1220019027, Exp. Date 8/11/2020; 1220019075, Exp. Date 8/12/2020; 1220019243, Exp. Date 8/20/2020; 1220019439, 1220019279, 1220019392, Exp. Date 8/24/2020; 1220019488, Exp. Date 8/26/2020

Class III Drugs Event

Event ID:
86079

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/22/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/07/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
West-Ward Columbus Inc
1809 Wilson Rd
Columbus OH United States

Distribution Pattern:
OH and MS

Associated Products

Product Description:
Leucovorin Calcium Tablets USP, 10 mg, Rx only, 24 Tablets per bottle, Distr. by: West-Ward Pharmaceuticals Corp. Eatontown, NJ 07724, NDC 0054-4497-10

Product Quantity:
2300 bottles

Reason for Recall:
Failed Tablet/Capsule Specifications: Tablets are imprinted with the incorrect identification code.

Recall Number:
D-1490-2020

Code Information:
Lot: #064046A, Exp. 03/2022

Class III Drugs Event

Event ID:
86101

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/20/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/12/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Dr
Hawthorne NY United States

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Clobetasol Propionate Cream USP, 0.05%, a) 15 g tube, NDC: 60429-902-15; b) 45 g tube, NDC: 60429-902-45, Rx Only, For External Use Only, Not for Ophthalmic Use, Mfd by: Taro Pharmaceuticals Inc. Brampton, Ontario, Canada L6T 1C1, Marketed by: Golden State Medical Supply, Inc. Camarillo, CA 93012.

Product Quantity:
7632 tubes

Reason for Recall:
Failed Content Uniformity: bulk lot used to make these two lots was found to have failed content uniformity.

Recall Number:
D-1496-2020

Code Information:
a) AB28353, Exp 12/31/2021; b) AB40178, Exp 12/31/2021

Class III Drugs Event

Event ID:
86129

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/24/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/13/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Golden State Medical Supply Inc.
5187 Camino Ruiz
Camarillo CA United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Clobetasol Propionate Cream, USP, 0.05%, packaged in a)15g Tubes (NDC 60429-902-15) and b) 45g Tubes (NDC 60429-902-45), Rx Only, Mfd. by: Taro Pharmaceuticals Inc. Brampton, Ontario, Canada, Marketed by: Golden State Medical Supply Inc. Camarillo, CA 93012.

Product Quantity:

Reason for Recall:
Failed Content Uniformity: bulk lot used to make these two lots was found to have failed content uniformity.

Recall Number:
D-1497-2020

Code Information:
Lot #: a) AB28535, Exp. Date: Dec. 2021 b) AB40178, Exp. Date: Dec. 2021