Enforcement Report - Week of December 2, 2020

Class I Drugs Event

Event ID:
86656

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/27/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/23/2020

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

Recalling Firm:
Sunstar Americas, Inc.
301 E Central Rd
Schaumburg IL United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Paroex (chlorhexidine gluconate) Oral Rinse, USP 0.12%, Alcohol Free, Rx only, packaged in: a) 1 pint (473 mL) NDC 52376-021-02; b) 4 fl oz (118 mL) NDC 52376-021-04, Sunstar Americas, Inc.

Product Quantity:
a) 116,662 bottles; b) 13,296 bottles

Reason for Recall:
Microbial Contamination of Non-sterile Products: contamination with Burkholderia lata.

Recall Number:
D-0103-2021

Code Information:
Lot #: a) C170FY, C170FZ, C170GA, C170GB, C170GC, C177GP, C177GQ, C177GR, Exp 6/30/2022; C191KS, C191KT, C191KU, C191KW, C191KX, C191KY, C198LJ, C198LK, C198LL, C198LM, C205BH, C205BJ, C205BK, C205BL, C205BM, C205BN, Exp 7/31/2022; C219DK, C219DL, C219DM, C219DN, C219DP, C219DQ, C219DR, C219DS, Exp 8/31/2022; C240GM, C240GP, C240GQ, C240GR, Exp 9/30/2022; b) C191KR, Exp 7/31/2020

Class II Drugs Event

Event ID:
86497

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/24/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/23/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AA PRODUCTS INC
8424 Amparan Rd
Laredo TX United States

Distribution Pattern:
Texas

Associated Products

Product Description:
SYP Health Hand Sanitizer Alcohol Gel (ethyl alcohol) 70%, Net Wt. 16.91 FL OZ (500 mL) bottles,Biotecnologia, Educacion y Genetica, S.A. de C.V. Av. Quetra, UPC 9 780201 378624 .

Product Quantity:
1392 bottles

Reason for Recall:
CGMP Deviations: product manufactured at the same facility that produced product that FDA sampled and found to be subpotent for ethanol and contained methanol.

Recall Number:
D-0102-2021

Code Information:
EXP MAY/2021

Class II Drugs Event

Event ID:
86698

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/06/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/24/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Jubilant Cadista Pharmaceuticals, Inc.
207 Kiley Dr
Salisbury MD United States

Distribution Pattern:
Product was distributed nationwide.

Associated Products

Product Description:
clomiPRAMINE Hydrochloride Capsules USP, 50 mg, 30-count bottle, Rx Only, Manufactured by: Jubilant Cadista Pharmaceuticals Inc., Salisbury, MD NDC 59746-711-30

Product Quantity:
4,416 bottles

Reason for Recall:
Failed Tablet/Capsule Specification

Recall Number:
D-0104-2021

Code Information:
Lot# 20P0141, exp. date 02/2022

Class II Drugs Event

Event ID:
86740

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/10/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/25/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
EYWA PHARMA INC
2 Research Way Floor 3
Princeton NJ United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Levetiracetam Tablets, USP 500 mg, packaged in 120-count bottle, Rx only, Manufactured by: VKT Pharma Private Limited Srikakulam, India - 532 409, Manufactured for: Eywa Pharma Inc. 2 Research Way, Floor 3 Princeton, NJ 08540, NDC 71930-063-52

Product Quantity:
5451 bottles

Reason for Recall:
Presence of foreign tablet/capsule: A 1000 mg Levetiracetam Tablet was found in 500 gram bottle of Levetiracetam Tablets.

Recall Number:
D-0109-2021

Code Information:
Lot #: LEV5019021A, Exp 10/2021

Class II Drugs Event

Event ID:
86834

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/18/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/25/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fusion Health and Vitality LLC
1360 Union Hill Rd 11B
Alpharetta GA United States

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Immune Boost with natural strawberry flavor, 8,000 IU, Supports a Healthy and Balanced Immune System, 60 mL bottle, Manufactured by: Fusion Health and Vitality, LLC. 1360 Union Hill Road, Suite 11B Alpharetta, GA 30004.

Product Quantity:
5000 bottles

Reason for Recall:
Marketed without an Approved NDA/ANDA: Product marketed with drug claims.

Recall Number:
D-0107-2021

Code Information:
Lot #s: 200407, 200413, 200420, 200602, 200608.

Class III Drugs Event

Event ID:
86659

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/23/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/25/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Heritage Pharmaceuticals Inc
1 Tower Center Blvd Ste 1700
East Brunswick NJ United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Felodipine Extended Release Tablets, USP 10 mg,100-count bottle, Rx only, Distributed by: Heritage Pharmaceuticals Inc. East Brunswick, NJ 08816 Made in India, NDC 23155-050-01

Product Quantity:
7176 bottles

Reason for Recall:
Failed impurities/ degradation specifications: Out of specification impurity results were observed during routine testing of stability samples for the impurity Felodipine Related compound A

Recall Number:
D-0108-2021

Code Information:
Lot #: 18029979, Exp 1/2021

Class III Drugs Event

Event ID:
86705

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/03/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/25/2020

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Triamcinolone Acetonide Lotion USP, 0.025%, 60 mL (60 grams) bottle, Rx Only, Teligent Pharma, Inc. Buena, New Jersey 08310, NDC 52565-010-59

Product Quantity:
4008 units

Reason for Recall:
Subpotent Drug: One lot of Triamcinolone Acetonide Lotion, 0.025% 60 mL.does not meet assay results.

Recall Number:
D-0110-2021

Code Information:
Lot #: 14481 Exp 10/31/2021

Class III Drugs Event

Event ID:
86765

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/17/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/24/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fresenius Kabi USA, LLC
3 Corporate Dr
Lake Zurich IL United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
DOXOrubicin Hydrochloride Injection, USP, 10 mg / 5 mL (2 mg / mL), 5 mL fill in a 6 mL vial, Single Dose Vial, Rx only, Sterile, Fresenius Kabi, Lake Zurich, IL 60047. NDC: 63323-883-05

Product Quantity:
16,986 vials

Reason for Recall:
Cross Contamination with Other Products: trace amounts of octreotide found during testing

Recall Number:
D-0105-2021

Code Information:
Batch: 6120525, exp 11/2020