Enforcement Report - Week of June 22, 2022

Class II Drugs Event

Event ID:
89947

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/04/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/14/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hand Sanitizer LLC
850 Kaliste Saloom Rd Ste 212
Lafayette LA United States

Distribution Pattern:
Firm failed to provide distribution pattern information.

Associated Products

Product Description:
HAND SANITIZER SAY GOODBYE TO GERMS Alcohol Antiseptic 80% Topical Non-Sterile Solution, 12 FL OZ (254 mL) bottles, Distributed by: Hand Cleansing Gel 850 Kaliste Saloom Rd. Suite 212 Lafayette, LA 70508 UPC 8 60003 62626 9

Product Quantity:
24,020 bottles

Reason for Recall:
CGMP Deviations: FDA analysis found product to contain acetaldehyde and acetal above specification limits.

Recall Number:
D-1149-2022

Code Information:
Batch# 100620-128201, 100620-128202, 100620-128203, 100620-128204, 100620-128205, 100620-128206, 100620-128207, 100620-128208, 100620-128209, 100620-128210, 100620-128211, 100620-128212

Class II Drugs Event

Event ID:
90151

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/06/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/10/2022

Initial Firm Notification of Consignee or Public:

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton NJ United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
medroxyPROGESTERone Acetate Injectable Suspension, USP, 1 mL Prefilled Syringe, 150 mg/mL, Rx only, Manufactured by: Sun Pharmaceutical Industries, Ltd., Halol-Baroda Highway, Halol-389 350, Gujarat, India Distributed by: Afaxys Pharma, LLC, Charleston, SC, 29403, USA, Product of Italy, NDC 50102-591-40.

Product Quantity:
79339 syringes

Reason for Recall:
Lack of assurance of sterility

Recall Number:
D-1143-2022

Code Information:
Lots#: JKX4312A & JKX4313A, Exp 09/2022; JKX4827A, Exp 09/2023; HAC1290A & HAC2082B, Exp 06/2023;

Product Description:
medroxyPROGESTERone Acetate Injectable Suspension, USP, 1 mL Prefilled Syringe, 150 mg/mL, Rx only, Manufactured for: Northstar Rx LLC, Memphis, TN 38141, Manufactured by: Sun Pharmaceutical Industries Ltd., Halol-Baroda Highway, Halol-389 350, Gujarat, India, NDC 16714-999-01.

Product Quantity:
57997 syringes

Reason for Recall:
Lack of assurance of sterility

Recall Number:
D-1144-2022

Code Information:
Lot#: HAC1289A, Exo 06/2023; JKX2679A, Exp 06/2022; JKX3762A, Exp 08/2022; HAC0164A, Exp 06/2023.

Product Description:
medroxyPROGESTERone Acetate Injectable Suspension, USP, 1 mL Prefilled Syringe, 150 mg/mL, Rx only, Manufactured by Sun Pharmaceutical Industries Ltd., Halol-Baroda Highway, Halol-389 350, Gujarat, India, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, NDC 62756-091-40.

Product Quantity:
4625 syringes

Reason for Recall:
Lack of assurance of sterility

Recall Number:
D-1145-2022

Code Information:
Lot #: HAC1951A, Exp 06/2023

Product Description:
medroxyPROGESTERone Acetate Injectable Suspension, USP, 1 mL Single-Dose Vial, 150 mg/mL, Rx only, Manufactured for: Northstart Rx LLC, Memphis, TN, 38141, Manufactured by: Sun Pharmaceutical Industries Ltd., Halol Baroda Highway, Halol-389 350, Gujarat India , NDC 16714-981-01.

Product Quantity:
180813 syringes

Reason for Recall:
Lack of assurance of sterility

Recall Number:
D-1146-2022

Code Information:
Lot: HAC2075A, Exp 06/2023; HAC2076A, Exp 07/2023; HAC2077A, HAC2078A, Exp 08/2023; HAC3803A, Exp 09/2023; HAC0551A, Exp

02/2023; HAC0562A, HAC1183A, Exp 03/2023; HAC1807A, Exp 06/2023; JKX6017A, JKX6018A Exp 12/2022; HAC0163A, Exp 01/2023; HAC1184A, Exp 04/2023; HAC0162A, Exp 12/2022.

Product Description:
medroxyPROGESTERone Acetate Injectable Suspension, USP, 25 x 1 mL Single-Dose Vial, 150 mg/mL, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Ltd., Halol Baroda Highway, Halol-389 350, Gujarat India , NDC 16714-090-40 packaged in 25 count carton.

Product Quantity:
26892 vials

Reason for Recall:
Lack of assurance of sterility

Recall Number:
D-1147-2022

Code Information:
Lot#: HAC2074A, Exp Date 06/2023; HAC0163B, Exp Date 01/2023 & HAC1741A, Exp Date 04/2023

Class II Drugs Event

Event ID:
90152

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/10/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/14/2022

Initial Firm Notification of Consignee or Public:

Recalling Firm:
AMS Packaging Inc
161 Helen St
South Plainfield NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Premium Nature Instant Hand Sanitizer, (ethyl alcohol 65%), 8 oz/ 236 ML plastic bottles; Premium Nature, South Plainfield, NJ. UPC 819192028668

Product Quantity:
unknown

Reason for Recall:
Subpotent Drug: FDA analysis has revealed some bottles of these products were sub potent for ethanol.

Recall Number:
D-1148-2022

Code Information:
all lots

Class II Drugs Event

Event ID:
90202

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/13/2022

Center Classification Date:
06/10/2022

Recalling Firm:
Washington Homeopathic Products, Inc.
260 J R Hawvermale Way
Berkeley Springs WV United States

Distribution Pattern:
Product was distributed USA nationwide.

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Anthracinum, Potency: 6C, 7C, 8C, 9C, 12C, 14C, 30C, 200C, 11X, 14X, 30X Liquid Pellets, OTC, Washington Homeopathic Products, 260 JR Hawvermale Way Berkeley Springs, WV 25411

Product Quantity:
219 glass amber bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-1125-2022

Code Information:
Lot # 18415, 19369, 21577, 20308, 20331

Product Description:
Bacillinum Pulmo, Potency: 30C, 200C, Liquid Pellets, Rx only, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411

Product Quantity:
5 glass amber bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-1126-2022

Code Information:
Lot # 20308, 20331

Product Description:
Candida Albicans, Potency: 9C, 10C, 12C, 13C, 14C 15C 16C, 19C, 24C, 25C, 26C, 30C, 200C, 14X, 15X, 16X, 20X, 288X, 30X, Liquid Pellets, OTC, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411

Product Quantity:
1,047 glass amber bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-1127-2022

Code Information:
Lot # 17759, 18479, 18133

Product Description:
Candida Parapsilosis, Potency: 14X, 15X, 16X, 20X, 28X, 30X, 9C, 10C, 13C, 15C, 25C, 30C, 13X, 27X, 30X, Liquid Pellets, OTC, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411

Product Quantity:
134 glass amber bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-1128-2022

Code Information:
Lot # 22315, 26502

Product Description:
Colibacillinum, Potency: 12C, 14C, 15C, 18C, 20C, 30C, Liquid Pellets, OTC, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411

Product Quantity:
206 glass amber bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-1129-2022

Code Information:
Lot # 21881

Product Description:
Diphtherinum, Potency: 14C, 30C, 200C, Liquid Pellets, Rx only, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411,

Product Quantity:
7 glass amber bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-1130-2022

Code Information:
Lot # 20332, 20333

Product Description:
Influenzinum, Potency: 9X, 10X, 12X, 15X, 25X, 30X, 200C, 12C, 30C 1M, Liquid Pellets, OTC, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411

Product Quantity:
6,406 glass amber bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-1131-2022

Code Information:
Lot # 28960, 28962, 28961, 27415, 27464

Product Description:
Medorrhinum, Potency:12C, 30C, 200C, 1M, Liquid Pellets, Rx only, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411

Product Quantity:
49 glass amber bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-1132-2022

Code Information:
Lot# 20211, 20543, 22709

Product Description:
Morbillinum, Potency:7C, 8C, 9C, 10C 12C, 13C, 15C, 20C, 21C, 30C, 200 C,Liquid Pellets, OTC, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411

Product Quantity:
72 glass amber bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-1133-2022

Code Information:
Lot# 20307, 20309

Product Description:
Pertussinum, Potency: 19C, 30C, 200C, 1M, Liquid Pellets, OTC, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411

Product Quantity:
375 glass amber bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-1134-2022

Code Information:
Lot# 18829, 20142, 25410

Product Description:
Proteus, Potency: 7C, 8C, 9C, 12C, 15C, 16C, 20C, 30C, 200C, OTC, Liquid Pellets, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411

Product Quantity:
109 glass amber bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-1135-2022

Code Information:
Lot# 22747, 22771

Product Description:
Pyrogenium, Potency: 15X, 16X, 17X, 19X, 21X, 22X, 25X, 30X, 1M, 200C, 30C, OTC, Liquid Pellets, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411

Product Quantity:
6,782 glass amber bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-1136-2022

Code Information:
Lot# 17931-1, 26684, 17528-1, 30755, 30406, 30515, 29079, 29221, 26953, 23757

Product Description:
Streptococcinum, Potency: 8C, 9C, 30C, 200C, Liquid Pellets, Rx only, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411

Product Quantity:
5 glass amber bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-1137-2022

Code Information:
Lot# 21902, 21927

Product Description:
Syphilinum, Potency: 9C, 30C, 200C, 10X, 12X, Liquid Pellets, Rx only, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411

Product Quantity:
15 glass amber bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-1138-2022

Code Information:
Lot# 20390, 20441, 20389

Product Description:
Tuberculinum, Potency: 1X, 12X, 24X, 30X, 1M, Liquid Pellets, Rx only, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411

Product Quantity:
15 glass amber bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-1139-2022

Code Information:
Lot# 20388, 22728

Product Description:
Tuberculinum Bovinum, Potency: 12C, 30C, 200C, Liquid Pellets, Rx only, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411

Product Quantity:
4 glass amber bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-1140-2022

Code Information:
Lot# 19148, 21028

Product Description:
Vaccinotoxinum, Potency: 32X, 11C, 30C, Liquid Pellets, Rx only, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411

Product Quantity:
2 glass amber bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-1141-2022

Code Information:
Lot# 2512K, 20280

Class II Drugs Event

Event ID:
90298

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/11/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/10/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
A.P. Nonweiler
3321 County Road A
Oshkosh WI United States

Distribution Pattern:
Distributed in States of WI and VA

Associated Products

Product Description:
Alcohol Antiseptic 80%, Topical Solution, Hand Sanitizer, Non-Sterile Solution, Packaged as (a) 250 U.S. gallons per tote, Product Code 9999D361-250: (b) 1 U.S. gallon, Product Code 9999D361-001: A.P. Nonweiler Co., Inc., 3321 County Road A, Oshkosh, WI 54901.

Product Quantity:
833 gallons

Reason for Recall:
CGMP Deviations: FDA analysis found product to contain acetaldehyde and acetal above specification limits.

Recall Number:
D-1142-2022

Code Information:
Lot: 54931, No Expiration date.

Class II Drugs Event

Event ID:
90415

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/10/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/15/2022

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:
Product was distributed to 10 wholesalers/distributors and one mail order account who may have further distributed the product nationwide.

Associated Products

Product Description:
Zileuton Extended-Release Tablets, 600 mg, 120-count bottle, Rx only, Manufactured for Lupin Pharmaceuticals, Inc., Baltimore, MD 21202 by

Lupin Limited, Nagpur-441108, India, NDC 68180-169-16

Product Quantity:
3,216 bottles

Reason for Recall:
Failed Dissolution Specifications: Out of specification test results observed in dissolution testing during long term stability study.

Recall Number:
D-1150-2022

Code Information:
Lots: M100070, M100239, Exp. 06/22, M100312, Exp.09/22, M100366, Exp.10/22

Not Yet Classified Drugs Event

Event ID:
90359

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/24/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

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

Recalling Firm:
Wal Mart Stores, Inc
702 Sw 8th St
Bentonville AR United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Artri King Reforzado con Ortiga Omega 3 Tablets, ORIGINAL, 100-count bottles, Melchor Ocampo No. 55 Local D, Delegacion Xochimilco, C.P. 16800, Mexico, D.F., UPC 7 501031 111190.

Product Quantity:
1308 bottles total

Reason for Recall:
Marketed Without An Unapproved NDA/ANDA: Product lot found to be tainted with undeclared diclofenac, an FDA approved nonsteroidal anti-inflammatory drug (NSAID) for the treatment of pain and inflammation.

Recall Number:

Code Information:
Lot: LTARTKNGOMG30720, Exp Diciembre 2026

Product Description:
Artri Ajo King Reforzado con Ortiga y Omega 3 Tablets, ORIGINAL, 100-count bottles, UPC 7 501031 12705.

Product Quantity:
1308 bottles total

Reason for Recall:
Marketed Without An Unapproved NDA/ANDA: All lots were found to be unapproved drugs based on labeling claims.

Recall Number:

Code Information:
All product lots.

Product Description:
Artri King Reforzado con Ortiga Omega 3 Tablets, ORIGINAL, a) 100-count bottles labeled with UPC 7 501031 111190 and UPC 6 09002 40885, and b) 2 pack of 100-count bottles per carton UPC 3 72426 01434

Product Quantity:
1308 bottles total

Reason for Recall:
Marketed Without An Unapproved NDA/ANDA: All lots were found to be unapproved drugs based on labeling claims.

Recall Number:

Code Information:
All product lots.