Enforcement Report - Week of April 27, 2022

Class I Drugs Event

Event ID:
88960

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/26/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/22/2022

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
VIRGIN SCENT INC
16325 S Avalon Blvd
Gardena CA United States

Distribution Pattern:
Nationwide in the U.S.A

Associated Products

Product Description:
artnaturals hand sanitizer, SCENT FREE HAND SANITIZER (ethyl alcohol 62.5%), 8 fl oz (236 ml) bottles, Dist. By artnaturals, Gardena, CA 90248, UPC: 8 16820 02820 5

Product Quantity:
47,832 bottles

Reason for Recall:
Chemical Contamination: presence of benzene, acetaldehyde, and acetal.

Recall Number:
D-0782-2022

Code Information:
Lot: G20127E, G20128A, EXP 5/1/2022;

Class I Drugs Event

Event ID:
89949

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/29/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/25/2022

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

Recalling Firm:
Pink Toyz
9180 Gazette Ave
Chatsworth CA United States

Distribution Pattern:
Nationwide in the USA via walmart.com online marketplace

Associated Products

Product Description:
Pink Pussycat SENSUAL ENHANCEMENT capsule, 3000mg, 1-count blister card, Manufactured for: Pink Pussycat Products - Chatsworth, CA 91311, UPC 8 91875 00462 6.

Product Quantity:
120 blister cards

Reason for Recall:
Marketed Without An Approved NDA/ANDA: FDA analysis found the product to contain undeclared sildenafil, an ingredient found in FDA approved products for the treatment of male sexual enhancement, making this an unapproved drug.

Recall Number:
D-0785-2022

Code Information:
Lot: 2009066, Exp: 09/2023

Class II Drugs Event

Event ID:
88960

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/26/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/22/2022

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
VIRGIN SCENT INC
16325 S Avalon Blvd
Gardena CA United States

Distribution Pattern:
Nationwide in the U.S.A

Associated Products

Product Description:
artnaturals hand sanitizer, SCENT FREE HAND SANITIZER (ethyl alcohol 62.5%), 8 fl oz (236 ml) bottles, Dist. By artnaturals, Gardena, CA 90248, UPC: 8 16820 02820 5

Product Quantity:
570,268 Bottles

Reason for Recall:
CGMP Deviations: Other lots recalled because they were manufactured using common ingredients as the contaminated lot

Recall Number:
D-0783-2022

Code Information:
Lot: G20109D, G2019E, G20125E, G20125F, G20125D, G20125A, G20126C, G20126A, G20126D, G20126B, G20126E, G20127C, G20127B, G20127D, G20127A, G20127F, G20127A, G20128B, G20128C, G20128D, G20128E, G20128F, G20129B, G20129A, G20129C, G20129D, G20129E, G20130B, G20130A, G20130C, G20132A, G20132B, G20133A, EXP 5/1/2022; G20133A, EXP 8/1/2022

Product Description:
artnaturals Hand Sanitizer

Product Quantity:
46,368 Bottles

Reason for Recall:
CGMP Deviations: Other lots recalled because they were manufactured using common ingredients as the contaminated lot

Recall Number:
D-0784-2022

Code Information:
Lot: G20154A, G20155A, EXP 6/1/2022;

Class II Drugs Event

Event ID:
89910

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/07/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/15/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Pharmaceuticals Inc
3711 Collins Ferry Rd
Morgantown WV United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Rifampin for Injection, USP, 600 mg/vial, One Vial per carton, Rx only, Manufactured for: Mylan Institutional LLC, Morgantown, WV 26505 U.S.A., NDC 67457-445-60

Product Quantity:
33,893 vials

Reason for Recall:
Failed Impurities/Degradation Specifications: High out of specification results obtained for related compound during stability testing.

Recall Number:
D-0774-2022

Code Information:
Lot #: 7008990, exp. date Dec-2022; 7009025, exp. date Feb-2023; 7009085, 7009086, exp. date Apr-2023

Class II Drugs Event

Event ID:
89945

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/24/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/15/2022

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

Recalling Firm:
Preferred Pharmaceuticals, Inc.

1250 N Lakeview Ave Ste O
Anaheim CA United States

Distribution Pattern:
Nationwide within the USA.

Associated Products

Product Description:
Diclofenac Sodium Topical Solution 1.5% w/w, Generic for Pennsaid, 150 ml bottle, Rx Only, Mfg: Sola Pharmaceutical, Preferred Pharmaceuticals, Inc., The Physicians Solutions, NDC 68788-7918-01

Product Quantity:
528 bottles

Reason for Recall:
CGMP Deviations: all products within expiry are being recalled because the manufacturing firm, Teligent Pharma, Inc. is discontinuing its stability study program.

Recall Number:
D-0773-2022

Code Information:
Lots: E1220B, Exp.: 01/31/2023; F0220M, Exp.: 3/31/2023; F2320A, Exp.: 3/31/2023; F3020M, Exp.: 3/31/2023; G0920Q, Exp.: 3/31/2023; C0821M, Exp.: 1/31/2024; J1920, Exp.: 5/31/2023; E2421j, Exp.: 4/30/2024

Class II Drugs Event

Event ID:
89954

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/05/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/21/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
North American Custom Laboratories, LLC dba FarmaKeio Superior Custom Compounding
1736 N Greenville Ave
Richardson TX United States

Distribution Pattern:
Nationwide within United States

Associated Products

Product Description:
ARA-290 (Cibinetide Acetate) 6 mg/mL (4 mL) Injection, 4 mL vials, Rx only, Farmakeio 1736 N Greenville Ave Richardson, TX 75081 USA

Product Quantity:
28 vials

Reason for Recall:
Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile.

Recall Number:
D-0775-2022

Code Information:
Lot #: 32618 BUD: 4/4/2022; 34525 BUD: 5/24/2022

Product Description:
BPC-157 2 mg/mL (5 mL) Injection, 5 mL vials, Rx Only, Farmakeio 1736 N Greenville Ave Richardson, TX 75081

Product Quantity:
778 vials

Reason for Recall:
Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile.

Recall Number:
D-0776-2022

Code Information:
Lot #: 32242 BUD: 4/19/2022; 33911 BUD: 6/8/2022

Product Description:
Ipamorelin Acetate/Sermorelin Acetate (1 mg/1 mg)/mL (10 mL) Injection, 10 mL vials, Rx Only, Farmakeio 1736 N Greenville Ave Richardson, TX 75081

Product Quantity:
189 vials

Reason for Recall:
Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile.

Recall Number:
D-0777-2022

Code Information:
Lot #: 32961 BUD: 5/12/2022

Product Description:
LL-37 2 mg/mL (5 mL) Injection, 5 mL vials, Rx only, Farmakeio 1736 N Greenville Ave Richardson, TX 75081 USA

Product Quantity:
25 vials

Reason for Recall:
Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile.

Recall Number:
D-0778-2022

Code Information:
Lot #: 33444 BUD: 4/26/2022

Product Description:
Melanotan II 1 mg/mL (10 mL) Injection, 10mL vials, Rx only, Farmakeio 1736 N Greenville Ave Richardson, TX 75081 USA

Product Quantity:
35 vials

Reason for Recall:
Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile.

Recall Number:
D-0779-2022

Code Information:
Lot #: 32610 BUD: 4/4/2022; 35126 BUD: 6/7/2022

Product Description:
PT-141 (Bremelanotide Acetate) 10 mg/mL (2 mL) Injection, 2mL vials, Rx Only, Farmakeio 1736 N Greenville Ave Richardson, TX 75081

Product Quantity:
43 vials

Reason for Recall:
Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile.

Recall Number:
D-0780-2022

Code Information:
Lot #: 32616 BUD: 4/4/2022; 34527 BUD: 5/24/2022

Product Description:
Sermorelin Acetate 1 mg/mL (6 mL) Injection, 6 mL vials, Rx only, Farmakeio 1736 N Greenville Ave Richardson, TX 75081

Product Quantity:
76 vials

Reason for Recall:
Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile.

Recall Number:
D-0781-2022

Code Information:
Lot #: 32963 BUD: 4/12/2022; 34824 BUD: 5/30/2022; 35130 BUD: 6/7/2022