Enforcement Report - Week of April 21, 2021

Class II Drugs Event

Event ID:
87602

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/26/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/12/2021

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 in the USA and Puerto Rico

Associated Products

Product Description:
Cefprozil for Oral Suspension USP, 250mg/5mL, packaged as a) 50 mL (when mixed) bottles (NDC 68180-402-01); b) 75 mL (when mixed) bottles (NDC 68180-402-02); and c) 100 mL (when mixed) bottles (NDC 68180-402-03); Rx only, Manufactured for: Lupin Pharmaceutical, Inc., Baltimore, MD 21202; Manufactured by: Lupin Limited, Mandideep 462 046, India.

Product Quantity:
a) 6,816 bottles; b) 3,960 bottles and c) 7,038 bottles

Reason for Recall:
Superpotent Drug

Recall Number:
D-0332-2021

Code Information:
Lot Numbers: a) F801122, exp. date June 2021; b) F801123, exp. date June 2021; c) F801124, exp. date June 2021

Class II Drugs Event

Event ID:
87650

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/31/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/13/2021

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Riomet (metformin hydrochloride oral solution) 500 mg/5 mL Cherry Flavor, 16 fl. oz., 473 mL bottles Rx Only, Manufactured by: Mikart, LLC, Atlanta, GA 30318, Distributed by: Sun Pharmaceutical Industries Inc., Cranbury, NJ 08512, NDC 10631-206-02.

Product Quantity:
13,834 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Product

Recall Number:
D-0334-2021

Code Information:
Lot #: J190386A, X190354A, Exp. 3/2021, J190393A, Exp. 5/2021, A200035A, Exp. 6/2021, B200064A, Exp. 8/2021; H200236A, Exp. 1/2022

Class II Drugs Event

Event ID:
87667

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/01/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/12/2021

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Itraconazole Capsules, 100 mg, 30-count bottles, Rx only, Manufactured by: Jubilant Generics Ltd., Roorkee - 247661, India; Marketed by: Jubilant Cadista Pharmaceuticals, Inc., Salisbury, MD 21801, NDC 59746-282-30.

Product Quantity:
Lot #IT119008B - (4,128 Bottles); Lot #IT20001A - (3,984 Bottles); Lot #IT20002B - (4.080 Bottles)

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0333-2021

Code Information:
Lot #s: IT119008B, Exp 05/2021; IT120001A, IT120002A, Exp 12/2021

Class III Drugs Event

Event ID:
87548

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/19/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/12/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Asclemed USA Inc. dba Enovachem Pharmaceuticals
379 Van Ness Ave Ste 1403
Torrance CA United States

Distribution Pattern:
Distributed to three physicians in the following states: CA, LA (Enovachem). DocRx distributed recalled product to one Distributor located in AL.

Associated Products

Product Description:
Distributed by: DocRx, Methylprednisolone Tablets, USP 4 mg, Rx, 21 Count Blister, NDC: 69306-004-21, Relabeled by: Enovachem Pharmaceuticals 379 Van Ness Ave. Suite 1403-1406, Torrance, CA 90501, Manufactured by: Jubilant Cadista Pharmaceuticals Inc. Source NDC: 59746-001-03, DocRx, Mobile, AL 36608

Product Quantity:

Reason for Recall:
Labeling: Illegible label: Manufacturer received complaint of mis-alignment print of the printed dosing instructions on the blister card.

Recall Number:
D-0330-2021

Code Information:
Lot #: 20K0043P, Exp. 8/31/2022; 20L0026P, Exp. 9/30/2022

Class III Drugs Event

Event ID:
87607

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/22/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/12/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Macleods Pharma Usa Inc
666 Plainsboro Rd Bldg 200 Ste 230
Plainsboro NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Candesartan Cilexetil Tablets, USP, 4 mg, 30-count bottles, Rx only, Manufactured for: Macleods Pharma USA, Inc., Plainsboro, NJ 08536, Manufactured by: Macleods Pharmaceuticals Ltd., Daman (U.T.), India, NDC 33342-114-10

Product Quantity:
8015 packs

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0329-2021

Code Information:
Lots # : ECD5908C, Exp 7/2021; ECD5909A, ECD5910A, ECD5911A, ECD5912A, Exp. 09/2021.

Class III Drugs Event

Event ID:
87631

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/29/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/12/2021

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Lidocaine Ointment USP, 5%, NET WT 35.44 g (1 1/4 Oz) tube, Rx Only, Teligent Pharma Inc., Buena, New Jersey, 08310, NDC 52565-008-14.

Product Quantity:
62,040 tubes

Reason for Recall:
Failed Stability Specifications: product did not meet viscosity results.

Recall Number:
D-0331-2021

Code Information:
Lot 13269, Exp March 2021

Not Yet Classified Drugs Event

Event ID:
87537

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/22/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Novo Nordisk Inc
800 Scudders Mill Rd
Plainsboro NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Fiasp FlexTouch (insulin aspart injection) 100 units/mL (U-100), 3 mL pen, Rx only, Manufactured by: Novo Nordisk, Inc., Bagsvaerd, Denmark NDC 0169-3204-90

Product Quantity:

Reason for Recall:
Temperature Abuse: Product samples were stored at temperatures below 0 degrees Celsius which is not in accordance with storage requirements.

Recall Number:

Code Information:
KP51207 exp 30.06.2022; KP52618 exp 31.10.2022

Product Description:
Fiasp PenFill (insulin aspart injection) 100 units/mL (U-100), 3 mL PenFill cartridges, Rx Only, Manufactured by: Novo Nordisk, Bagsvaerd, Denmark NDC 0169-3205-91

Product Quantity:

Reason for Recall:
Temperature Abuse: Product samples were stored at temperatures below 0 degrees Celsius which is not in accordance with storage requirements.

Recall Number:

Code Information:
Lots KS6BF84, Exp 30.06.2022

Product Description:
Fiasp (insulin aspart injection),100 units/mL (U-100), 10 mL multiple dose vials, Rx Only, Manufactured by: Novo Nordisk, Bagsvaerd, Denmark NDC 0169-3201-90

Product Quantity:

Reason for Recall:
Temperature Abuse: Product samples were stored at temperatures below 0 degrees Celsius which is not in accordance with storage requirements.

Recall Number:

Code Information:
KS6BX63 exp 31.10.2022; KS6AK76 exp 31.05.2022; KS6BR92 exp 30.09.2022

Product Description:
Levemir FlexTouch (insulin detemir) injection, 100 units/mL (U-100), 3 mL prefilled pen, Rx Only, Manufactured by: Novo Nordisk, Bagsvaerd, Denmark NDC 0169-6438-90

Product Quantity:

Reason for Recall:
Temperature Abuse: Product samples were stored at temperatures below 0 degrees Celsius which is not in accordance with storage requirements.

Recall Number:

Code Information:
JP52336 exp 31.10.2021; KP51933 exp 31.07.2022

Product Description:
NovoLog FlexPen (insulin aspart) injection, 100 units/mL (U-100), 3 mL single patient use FlexPen, Rx Only, Manufactured by: Novo Nordisk, Bagsvaerd, Denmark NDC 0169-6339-90

Product Quantity:

Reason for Recall:
Temperature Abuse: Product samples were stored at temperatures below 0 degrees Celsius which is not in accordance with storage requirements.

Recall Number:

Code Information:
Lot KS6BS11, Exp 30.11.2021

Product Description:
NovoLog Vial (insulin aspart) injection, 100 units/mL (U-100), 10 mL multiple dose vial, Rx Only, Manufactured by: Novo Nordisk, Bagsvaerd, Denmark NDC 0169-7501-90

Product Quantity:

Reason for Recall:
Temperature Abuse: Product samples were stored at temperatures below 0 degrees Celsius which is not in accordance with storage requirements.

Recall Number:

Code Information:
JZFC826 exp 30.06.2021; KZFM305 exp 31.08.2022

Product Description:
Ozempic (semaglutide) injection, 2 mg/1.5 mL (1.34 mg/mL) prefilled pen, Rx only, Manufactured by: Novo Nordisk, Bagsvaerd, Denmark NDC 0169-4132-90

Product Quantity:

Reason for Recall:
Temperature Abuse: Product samples were stored at temperatures below 0 degrees Celsius which is not in accordance with storage requirements.

Recall Number:

Code Information:
KP50867, exp 31.10.2022, KP53021, exp 30.04.2023, KP52338, exp 28.02.2023, JP54354, exp 31.08.2022, KP50676, exp 31.10.2022,

KP51434, exp 30.11.2022, KP51491, exp 30.11.2022, KP51781, exp 31.01.2023, KP52249, exp 31.01.2023, KP52270, exp 31.01.2023, KP52722, exp 31.01.2023, KP52973, exp 31.01.2023, KP53031, exp 31.01.2023, KP53221, exp 12.04.2023, KP53369, exp 31.01.2023

Product Description:
Saxenda (liraglutide) Injection 6 mg/mL, 3 mL prefilled singe use pen, Rx only, Manufactured by: Novo Nordisk, Bagsvaerd, Denmark NDC 0169-2800-90 (pen), NDC 0169-2800-97 (kit)

Product Quantity:

Reason for Recall:
Temperature Abuse: Product samples were stored at temperatures below 0 degrees Celsius which is not in accordance with storage requirements.

Recall Number:

Code Information:
K1620A1 (Kit); KZFH714 (Pen) exp 31.05.2022; B2020A (Kit); JZFF482 (Pen) exp 30.11.2021; I2320A (Kit); KZFH714 (Pen) exp 31.05.2022; H1020A (Kit); KZFH714 (Pen) exp 31.05.2022; J0520A(Kit); KZFH714 (Pen) exp 31.05.2022

Product Description:
Tresiba FlexTouch (insulin degludec injection) 100 units/mL, 3 mL Single Use prefilled pen, Rx only, Manufactured by: Novo Nordisk, Bagsvaerd, Denmark NDC 0169-2660-90

Product Quantity:

Reason for Recall:
Temperature Abuse: Product samples were stored at temperatures below 0 degrees Celsius which is not in accordance with storage requirements.

Recall Number:

Code Information:
JP53136 exp 30.06.2021; KP50575 exp 31.01.2022; KP50976 exp 31.01.2022; KP51813 exp 30.04.2022; KP52035 exp 30.04.2022; KP52117 exp 30.04.2022; KP52440 exp 30.06.2022; KP52461 exp 30.04.2022; KP52616 exp 30.06.2022

Product Description:
Tresiba FlexTouch (insulin degludec injection) 100 units/mL, 10 mL multiple dose vial, Rx only, Manufactured by: Novo Nordisk, Bagsvaerd, Denmark NDC 0169-2662-90

Product Quantity:

Reason for Recall:
Temperature Abuse: Product samples were stored at temperatures below 0 degrees Celsius which is not in accordance with storage requirements.

Recall Number:

Code Information:
JZFE233 exp 30.11.2021

Product Description:
Tresiba FlexTouch (insulin degludec injection) 200 units/mL, 3mL prefilled pen, Rx only, Manufactured by: Novo Nordisk, Bagsvaerd, Denmark NDC 0169-2550-90 (pen) 0169-2550-97 (Kit)

Product Quantity:

Reason for Recall:
Temperature Abuse: Product samples were stored at temperatures below 0 degrees Celsius which is not in accordance with storage requirements.

Recall Number:

Code Information:
JP54181 exp 30.09.2021; KP51059 exp 30.11.2021; KP51865 exp 30.11.2021; KP54179 exp 30.11.2022; KP52829 exp 31.07.2022

Product Description:
Victoza (liraglutide) injection, 18 mg/3 mL (6 mg/mL), 3 mL pre-filled multi-dose Pen, Rx only, Manufactured by: Novo Nordisk, Bagesvaerd, Denmark NDC 0169-4060-90 (Pen), 0169-4060-99 (kit) 0169-4060-99 (kit)

Product Quantity:

Reason for Recall:
Temperature Abuse: Product samples were stored at temperatures below 0 degrees Celsius which is not in accordance with storage requirements.

Recall Number:

Code Information:
I2419A (Kit); JS68K86 (Pen) exp 31.05.2021

Product Description:
Xultophy 100/3.6 (insulin degludec and liraglutide injection), 100/units/mL and 3.6 mg/mL, Single Use Pen, Rx only, NDC 0169-2911-90 (Pen) NDC 0169-2911-97 (kit)

Product Quantity:
3 pens

Reason for Recall:
Temperature Abuse: Product samples were stored at temperatures below 0 degrees Celsius which is not in accordance with storage requirements.

Recall Number:

Code Information:
JP54291, exp 20-06-2021

Not Yet Classified Drugs Event

Event ID:
87633

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/29/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Spartan Chemical Co Inc
1110 Spartan Dr
Maumee OH United States

Distribution Pattern:
Nationwide USA and Puerto Rico; Mexico

Associated Products

Product Description:
Lite'n Foamy Lemon Blossom Hand Sanitizer (benzalkonium chloride 0.1%), Net Contents: 18 oz/ 532 ml per foam pump container, For Institutional and Industrial Use Only, Spartan Chemical Company, Inc., 1110 Spartan Drive, Maumee, OH 43537 USA. NDC: 64009-331-82

Product Quantity:
19,044 containers

Reason for Recall:
Microbial Contamination of Non-Sterile Products; lot tested positive for Bulkholderia multivorans

Recall Number:

Code Information:
Lot 538305, exp 1/14/2023

Product Description:
FoamyiQ Lemon Blossom Hand Sanitizer (benzalkonium chloride 0.1%), Net Contents: 42.27 oz/1250 ml per foam pump cartridge, For Institutional and Industrial Use Only, Spartan Chemical Company, Inc., 1110 Spartan Drive, Maumee, OH 43537 USA. NDC: 64009-202-06

Product Quantity:
26,328 cartridges

Reason for Recall:
CGMP Deviations

Recall Number:

Code Information:
Lot, expiry: Lot 526756, exp 9/22/2022; Lot 527499, exp 9/28/2022; Lot 527501, exp 9/30/2022

Product Description:
Antiseptic Hand Cleaner (Chloroxylenol, 1.0%), Net Contents: 1 US Gallon/ 3.79 Liters per gallon container, For Institutional and Industrial Use Only, Spartan Chemical Company, Inc., 1110 Spartan Drive, Maumee, OH 43537 USA. NDC: 64009-336-85

Product Quantity:
400 containers

Reason for Recall:
CGMP Deviations

Recall Number:

Code Information:
Lot, expiry: Lot 538885, exp 1/25/2023

Product Description:
Lite n Foamy E2 Sanitizing Handwash (Benzalkonium Chloride, 0.13%), Net Contents: 1 US Gallon/ 3.79 Liters per gallon container, For Institutional and Industrial Use Only, Spartan Chemical Company, Inc., 1110 Spartan Drive, Maumee, OH 43537 USA. NDC: 64009-333-95

Product Quantity:
2,152 containers

Reason for Recall:
CGMP Deviations

Recall Number:

Code Information:
Lot, expiry: Lot 538882, exp 1/22/2023

Product Description:
Lite n Foamy Eucalyptus Mint Sanitizing Handwash (Benzalkonium Chloride, 0.13%), Net Contents: 18 oz/ 532 ml per foam pump container, For Institutional and Industrial Use Only, Spartan Chemical Company, Inc., 1110 Spartan Drive, Maumee, OH 43537 USA. NDC: 64009-332-72

Product Quantity:
1,200 cases

Reason for Recall:
CGMP Deviations

Recall Number:

Code Information:
Lot, expiry: Lot 538307, exp 1/20/2023

Product Description:
Lite n Foamy Healthcare Personnel Handwash (Chloroxylenol, 1.0%), Net Contents: 18 oz/ 532 ml per foam pump container, For Institutional and Industrial Use Only, Spartan Chemical Company, Inc., 1110 Spartan Drive, Maumee, OH 43537 USA. NDC: 64009-335-82

Product Quantity:
960 containers

Reason for Recall:
CGMP Deviations

Recall Number:

Code Information:
Lot, expiry: Lot 538310, exp 1/21/2023