Enforcement Report - Week of July 15, 2020

Class II Drugs Event

Event ID:
85938

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/29/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/08/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
EMD Serono, Inc.
1 Technology Pl
Rockland MA United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Cetrotide (cetrorelix acetate for Injection) 0.25 mg, Sterile - for subcutaneous use only, Rx Only, Manufactured for: EMD Serono, Inc., Rockland, MD 02370, NDC: 44087-1225-1

Product Quantity:
30,756 vials

Reason for Recall:
Defective Container: Market complaints of missing rubber stoppers from drug vial. Missing rubber stoppers could lead to lack of sterility assurance.

Recall Number:
D-1379-2020

Code Information:
Lot # 8J025A; 8J025B, Exp 09/30/2020

Class III Drugs Event

Event ID:
85826

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/04/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/07/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SOMERSET THERAPEUTICS LLC
300 Franklin Square Dr
Somerset NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Brimonidine Tartrate Opthalmic Solution 0.2%, 5 mL bottle, Rx only, Manufactured for: Somerset Therapeutics, LLC Hollywood, FL 33024. Made in India. NDC 70069-231-01

Product Quantity:
383,437 bottles

Reason for Recall:
Failed Impurities/Degradation Specification: There is a slow leaching process from the product label on the bottle which may impact the product over the shelf life.

Recall Number:
D-1373-2020

Code Information:
Lots # BRM11W9001, BRM11W9002, BRM11W9003, EXP Nov 2020; BRM11W9004, BRM11W9005, BRM11W9006, EXP Dec 2020; BRM11W9007, BRM11W9008, BRM11W9009, EXP Mar 2021; BRM11W9010, BRM11W9011, BRM11W9012, BRM11W9013, EXP Apr 2021; BRM11W9014, BRM11W9015, EXP May 2021

Product Description:
Brimonidine Tartrate Opthalmic Solution 0.2%, 10 mL bottle, Rx only, Manufactured for: Somerset Therapeutics, LLC Hollywood, FL 33024. Made in India. NDC 70069-232-01

Product Quantity:
48,852 bottles

Reason for Recall:
Failed Impurities/Degradation Specification: There is a slow leaching process from the product label on the bottle which may impact the product over the shelf life.

Recall Number:
D-1374-2020

Code Information:
Lots # BRM12W9001, EXP 2020; BRM12W9002, BRM12W9003, EXP Dec. 2020; BRM12W9004, EXP Apr. 2021

Product Description:
Brimonidine Tartrate Opthalmic Solution 0.2%, 15 mL bottle, Rx only, Manufactured for: Somerset Therapeutics, LLC Hollywood, FL 33024. Made in India. NDC 70069-233-01

Product Quantity:
22,788 bottles

Reason for Recall:
Failed Impurities/Degradation Specification: There is a slow leaching process from the product label on the bottle which may impact the product over the shelf life.

Recall Number:
D-1375-2020

Code Information:
Lot #s BRM13W9001, BRM13W9002, BRM13W9003, EXP Dec. 2020: BRM13W9004, EXP Apr. 2021.

Class III Drugs Event

Event ID:
85888

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/23/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/08/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
VistaPharm, Inc.

7265 Ulmerton Rd
Largo FL United States

Distribution Pattern:
United States including Puerto Rico

Associated Products

Product Description:
Nystatin Oral Suspension, USP 500,000 units/5mL Cup, Delivers 5 mL, Rx Only, Manufactured by: VistaPharm, Largo, FL 33771, a) NDC 66689-037-50 (individual cup NDC: 66689-037-01); b) 66689-037-99.

Product Quantity:
380,700 cups

Reason for Recall:
Failed impurities/degradation products; Presence of an impurity peak that exceeds the approved specification.

Recall Number:
D-1377-2020

Code Information:
Lot #: a) 619800, Exp. 12/31/2020; 626200, Exp. 01/31/2021; b) 619800X,Exp. 12/31/2020; 626200X, Exp. 01/31/2021.

Product Description:
Nystatin Oral Suspension, USP 100,000 units per mL, Bubblegum Flavored, 16 fl. oz. bottle (480 mL), Shake Well Before Using, Rx Only, Manufactured by: VistaPharm, Inc., Largo, FL 33771, NDC 66689-008-16.

Product Quantity:
14,760 bottles

Reason for Recall:
Failed impurities/degradation products; Presence of an impurity peak that exceeds the approved specification.

Recall Number:
D-1378-2020

Code Information:
Lot # 639000, Exp. 10/31/2021

Class III Drugs Event

Event ID:
85906

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/23/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/09/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Biogen MA Inc.
5000 Davis Dr
Research Triangle Park NC United States

Distribution Pattern:
Product was distributed to wholesalers/distributors in KY, OH & MS.

Associated Products

Product Description:
Tecfidera (dimethyl fumarate) delayed-release capsules, 240 mg, 60-count bottle, Rx only, Manufactured by: Biogen Inc., Cambridge, MA 02142, NDC 64406-006-02

Product Quantity:
3,922 bottles

Reason for Recall:
cGMP deviations: one lot of the product was distributed to US Markets despite being rejected during in-process control.

Recall Number:
D-1381-2020

Code Information:
Lot # SH0274, Exp 2/2022