Enforcement Report - Week of August 11, 2021

Class II Drugs Event

Event ID:
88077

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/09/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/30/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pfizer Inc.
235 East 42nd Street
New York NY United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Chantix (varenicline) tablets, 0.5mg*, 56 Tablets, Rx Only, Distributed by Pfizer Labs, Division of Pfizer Inc., NY, NY 10017, Made in Ireland. NDC 0069-0468-56

Product Quantity:
59,232 bottles

Reason for Recall:
CGMP Deviations: Presence of the N-nitroso-varenicline impurity above FDA s acceptable interim acceptable intake limit

Recall Number:
D-0699-2021

Code Information:
Lots 00019213, Exp 31 Jan 2022 & EC6994, Exp May 31, 2023

Product Description:
Chantix (varenicline)Tablets, Contains: 1 Starting Week (0.5 mg* x 11 tablets), 3 Continuing Weeks (1 mg x 42 tablets), Rx Only, Distributed by Pfizer Labs, Division of Pfizer Inc, NY, NY 10017, Made in Ireland, NDC 0069-0471-03.

Product Quantity:
350,985 cartons

Reason for Recall:
CGMP Deviations: Presence of the N-nitroso-varenicline impurity above FDAs acceptable interim acceptable intake limit

Recall Number:
D-0700-2021

Code Information:
Lots 00020231, Exp 30 Sept 2021; 00020232, Exp 30 Nov 2021; 00020357, Exp 31 Dec 2021; 00020358, Exp 31, Jan 2022; 00020716, Exp 31, Jan 2022 ; ET1600, Exp 31, Jan 2023; ET1607, Exp 31, Jan 2023 & ET1609, Exp 31, Jan 2023.

Product Description:
Chantix (varenicline) tablets, 1 mg, 56 Tablets, Rx Only, Distributed by Pfizer Labs, Division of Pfizer Inc., NY, NY 10017, Made in Ireland. NDC 0069-0469-56

Product Quantity:
69,6396 bottles

Reason for Recall:
CGMP Deviations: Presence of the N-nitroso-varenicline impurity above FDAs acceptable interim acceptable intake limit

Recall Number:
D-0701-2021

Code Information:
Lots EC9843, Exp 31, Mar 2023; EA6080, Exp. 31, Mar 2023.

Class II Drugs Event

Event ID:
88222

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/30/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/30/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Cascade Kelly Holdings LLC
81200 Kallunki Rd
Clatskanie OR United States

Distribution Pattern:
Distributed to the firm's affiliated facilities and donated third party recipients located in the following states: CT, MA, ME, ND, NY, OR, PA, TX, VT.

Associated Products

Product Description:
Global Hand Sanitizer with moisturizer, Alcohol-based Antiseptic 80%, Non-sterile Topical Solution, 4 fl. oz./119 mL, Alcohol 80% v/v, Manufactured by: Cascade Kelly Holdings LLC, NDC 80253-001-01

Product Quantity:

Reason for Recall:
CGMP Deviations: Does not meet monograph for denaturant.

Recall Number:
D-0697-2021

Code Information:
All distributed lots within expiry

Product Description:
Global Hand Sanitizer with moisturizer, Alcohol-based Antiseptic 80%, Non-sterile Topical Solution, 8 fl. oz./236 mL, Alcohol 80% v/v, Manufactured by: Cascade Kelly Holdings LLC, NDC 80253-001-02

Product Quantity:

Reason for Recall:
CGMP Deviations: Does not meet monograph for denaturant.

Recall Number:
D-0698-2021

Code Information:
All distributed lots within expiry

Class II Drugs Event

Event ID:
88394

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/30/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/04/2021

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
BayCare Integrated Service Center, LLC /dba BayCare Central Pharmacy

7802 E Telecom Pkwy
Temple Terrace FL United States

Distribution Pattern:
FL

Associated Products

Product Description:
Succinylcholine Chloride 100 mg/5 mL (20 mg/mL), 5 mL Syringes, Rx only, For IV Use only, BayCare Central Pharmacy, 7802 E. Telecom Parkway, Temple Terrace, FL 33837

Product Quantity:
253 syringes

Reason for Recall:
Lack of sterility assurance

Recall Number:
D-0702-2021

Code Information:
Lot: SUCC10020210624 Exp. 09/22/2021

Not Yet Classified Drugs Event

Event ID:
88280

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/14/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Qikmoov LLC
14831 Piuma Ave
Norwalk CA United States

Distribution Pattern:
Distribution Nationwide in the USA via the internet and to the following countries Brazil, Canada, Germany, France, Hong Kong, Italy, Sweden, Switzerland, Thailand, and United Kingdom.

Associated Products

Product Description:
(Vietnamese Labeling) HAVYCO Vy&Tea 15/KLT 3.0G (15 tea sachets per box).Manufactured by Havyco No. 45, Group 1, National Highway 14, Son Hiep Hamlet, Tho Son Commune, Bu Dang District, Binh Phuoc Province, Vietnam

Product Quantity:

Reason for Recall:
Marketed Without An Approved NDA/ANDA: FDA analysis detected the presence of sibutramine.

Recall Number:

Code Information:
Best By Date: 9/2021