Enforcement Report - Week of February 10, 2021

Class II Drugs Event

Event ID:
87067

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/30/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/04/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AuroMedics Pharma LLC
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Acetaminophen Injection 1,000 mg per 100 mL (10 mg/mL), 100 mL Single Dose Vial, For Intravenous Use Only, Distributed by: AuroMedics Pharma LLC 279 Princeton-Hightstown Rd. E. Windsor, NJ 08520 Made in India NDC 55150-307-01

Product Quantity:
3094 cartons

Reason for Recall:
Discoloration and failed pH specifications

Recall Number:
D-0248-2021

Code Information:
CAT200002 exp 9/2022; CAT200004 exp 9/2022; CAT200005 exp 9/2022; CAT200008 exp 9/2022; CAT200009 exp 9/2022; CAT200013 exp 10/2022; CAT200014 exp 10/2022; CAT200015 exp 10/2022; CAT200016 exp 10/2022; CAT200017 exp 10/2022; CAT200018 exp 10/2022

Class II Drugs Event

Event ID:
87152

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/08/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/01/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Dr
Hawthorne NY United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Nortriptyline HCl Capsules, USP equivalent to 10mg base Mfd. by: Taro Pharmaceutical Industries Ltd. Haifa Bay, Israel 2624761 Dist. by: Taro Pharmaceuticals U.S.A., Inc. Hawthorne, NY 10532 NDC 51672-4001-1

Product Quantity:
44,256 bottles

Reason for Recall:
CGMP deviations.

Recall Number:
D-0246-2021

Code Information:
AC05096, AC05098, and AC05099; Exp 10/31/2022

Class II Drugs Event

Event ID:
87210

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/25/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/04/2021

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

Recalling Firm:
Nostrum Laboratories Inc
1800 N Topping Ave
Kansas City MO United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Metformin Hydrochloride Extended-Release Tablets, USP, 750 mg, 100 Tablets per bottle, Rx Only, Manufactured by: Nostrum Laboratories, Inc., Kansas City, MO 64120. NDC: 29033-056-01

Product Quantity:
7071 bottles

Reason for Recall:
CGMP Deviations: detection of N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level.

Recall Number:
D-0249-2021

Code Information:
Lot MET200601, 07/2022

Class III Drugs Event

Event ID:
87195

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/21/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/03/2021

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

Associated Products

Product Description:
Oseltamivir Phosphate for Oral Suspension, 6 mg/mL, 60 mL (usable volume after constitution), Rx only, Manufactured for:Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, Manufactured by: Lupin Limited Aurangabad, Maharashtra, India. NDC: 68180-678-01

Product Quantity:
46,479 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications; Out-of-specification test results observed for Impurity C at 9 month long-term stability time point.

Recall Number:
D-0247-2021

Code Information:
Lot # A906423, exp. date Nov 2021.