Enforcement Report - Week of July 22, 2020

Class II Drugs Event

Event ID:
85986

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/03/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/14/2020

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Granules Pharmaceuticals Inc
3701 Concorde Pkwy
Chantilly VA United States

Distribution Pattern:
US Nationwide

Associated Products

Product Description:
Metformin Hydrochloride Extended-Release Tablets USP, 750 mg, a) 100 ct. bottle (NDC 70010-492-01) and 500 ct. bottle (NDC 70010-492-05), Manufactured for: Granules Pharmaceutical Inc., Chantilly, VA, Manufactured by: Granules India Limited, Hyderabad - 500-081, India

Product Quantity:
a) 476,073 bottles; b) 2,100 bottles

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1386-2020

Code Information:
a) 100 count 4920003A/May-21 4920004A/Jun-21 4920005A/Jun-21 4920009A/Nov-21 4920010A/May-22 4920011A/Jun-22 4920012A/Jun-22 4920013A/Jul-22 4920014A/Jul-22 4920015A/Aug-22 4920016A/Jan-23 b) 500 count 4920005B/Jun-21

Class II Drugs Event

Event ID:
85998

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/07/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/14/2020

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:
Product was distributed throughout the United States.

Associated Products

Product Description:
Metformin Hydrochloride Extended-release Tablets USP 500 mg, 100 count bottles, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Manufactured by: Lupin Limited, Goa INDIA NDC 68180-338-01

Product Quantity:
64,344 bottles

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1382-2020

Code Information:
Batch# G808201 Aug-20 G808202 Aug-20 G808200 Aug-20 G900935 Dec-20 G901311 Dec-20 G900957 Dec-20 G900958 Dec-20 G901006 Dec-20 G904803 May-21 G904804 May-21 G906551 Jul-21 G906552 Jul-21 G907375 Aug-21 G908605 Oct-21 G908604 Oct-21 G002108 Jan-22 G002109 Jan-22 G002559 Feb-22 G002560 Feb-22

Product Description:
Metformin Hydrochloride Extended-Release Tablets USP 1000 mg, 90 count bottles, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Manufactured by: Lupin Limited, Goa INDIA NDC 68180-339-09

Product Quantity:
95,886 bottles

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1383-2020

Code Information:
Batch # G807093 Jul-20 G807147 Jul-20 G807208 Jul-20 G807479 Jul-20 G807480 Jul-20 G807830 Jul-20 G807092 Jul-20 G809471 Jul-20 G808155 Aug-20 G808074 Aug-20 G808115 Aug-20 G900231 Nov-20 G900232 Nov-20 G903277 Mar-21 G903278 Mar-21 G903279 Mar-21 G903280 Mar-21 G903281 Mar-21 G903818 Apr-21 G904048 Apr-21 G904164 Apr-21 G906548 Jul-21 G907239 Aug-21 G907255 Aug-21 G907256 Aug-21 G907263 Aug-21 G001802 Jan-22 G001804 Jan-22 G001803 Jan-22 G001805 Jan-22 G001806 Jan-22 G001807 Jan-22 G001808 Jan-22 G808154 Aug-20 G900227 Nov-20 G900228 Nov-20 G900229 Nov-20 G900230 Nov-20 G906549 Jul-21 G906550 Jul-21 G906547 Jul-21 G907279 Aug-21 G907364 Aug-21 G001809 Jan-22 G001801 Jan-22 G002563 Feb-22 G002564 Feb-22

Product Description:
Metformin Hydrochloride Extended-Release Tablets USP 500 mg, 60 count bottles, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Manufactured by: Lupin Limited, Goa INDIA NDC 68180-336-07

Product Quantity:
59,568 bottles

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1384-2020

Code Information:
Batch # G808293 Aug-20 G808284 Aug-20 G808285 Aug-20 G808343 Aug-20 G901201 Dec-20 G901202 Dec-20 G906915 Jul-21 G906913 Jul-21 G906914 Jul-21 G002135 Jan-22 G002849 Feb-22

Product Description:
Metformin Hydrochloride Extended-Release Tablets USP 1000 mg, 60 count bottles, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Manufactured by: Lupin Limited, Goa INDIA NDC 68180-337-07

Product Quantity:
273,060 bottles

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1385-2020

Code Information:
Batch # G807619 Jul-20 G807620 Jul-20 G807733 Jul-20 G807734 Jul-20 G807735 Jul-20 G807445 Jul-20 G807617 Jul-20 G807618 Jul-20 G808042 Jul-20 G808043 Jul-20 G807349 Jul-20 G807350 Jul-20 G807444 Jul-20 G807507 Jul-20 G807508 Jul-20 G807314 Jul-20 G807316 Jul-

20 G807325 Jul-20 G807348 Jul-20 G807616 Jul-20 G807312 Jul-20 G807313 Jul-20 G807315 Jul-20 G808374 Aug-20 G808427 Aug-20 G808373 Aug-20 G808426 Aug-20 G900057 Oct-20 G900058 Oct-20 G900059 Oct-20 G900060 Oct-20 G900061 Oct-20 G900062 Oct-20 G900106 Oct-20 G900140 Oct-20 G900141 Oct-20 G900152 Oct-20 G809596 Oct-20 G809598 Oct-20 G810182 Oct-20 G810183 Oct-20 G810184 Oct-20 G810185 Oct-20 G810186 Oct-20 G810187 Oct-20 G810188 Oct-20 G810189 Oct-20 G809554 Oct-20 G809556 Oct-20 G809557 Oct-20 G809558 Oct-20 G809559 Oct-20 G809548 Oct-20 G809549 Oct-20 G809550 Oct-20 G809551 Oct-20 G809552 Oct-20 G809553 Oct-20 G809555 Oct-20 G901004 Dec-20 G901005 Dec-20 G901053 Dec-20 G901002 Dec-20 G901003 Dec-20 G903182 Mar-21 G903183 Mar-21 G903236 Mar-21 G903237 Mar-21 G903238 Mar-21 G903155 Mar-21 G903156 Mar-21 G903157 Mar-21 G903158 Mar-21 G903159 Mar-21 G903178 Mar-21 G903179 Mar-21 G903180 Mar-21 G903181 Mar-21 G903239 Mar-21 G001837 Jan-22 G001860 Jan-22 G001861 Jan-22 G001905 Jan-22 G001933 Jan-22 G001934 Jan-22 G001763 Jan-22 G001764 Jan-22 G001765 Jan-22 G001766 Jan-22 G001767 Jan-22 G001795 Jan-22 G001836 Jan-22

Class II Drugs Event

Event ID:
86002

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/01/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/15/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Preferred Pharmaceuticals, Inc.
1250 N Lakeview Ave Ste O
Anaheim CA United States

Distribution Pattern:
Nationwide within the U.S.

Associated Products

Product Description:
Lidothol Patch, Lidocaine 4.5% & Menthol 5%, In each patch: lidocaine 4.5% topical anesthetic, menthol 5% topical analgesic, Pkg Size 15 patches per box, Insurance NDC: 53225-1025-01, Mfg: Terrain Pharmaceuticals; Reno, NV, Prod # (NDC): 68788-7405-01, Preferred Pharmaceuticals, Inc., The Physicians Solutions.

Product Quantity:

Reason for Recall:
CGMP Deviations: Contract Manufacturing Organization (CMO) misplaced/lost batch records and test results for the recalled batch.

Recall Number:
D-1390-2020

Code Information:
Lot Numbers: H0218Z, H1518J, I2018L, J2918C, L1018Q, A0419M, G0519G; Exp: 5/31/2021.

Class II Drugs Event

Event ID:
86006

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/29/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/14/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RemedyRepack Inc.

625 Kolter Dr Ste 4
Indiana PA United States

Distribution Pattern:
Product was distributed to MN.

Associated Products

Product Description:
Carbamazepine 200 mg Tablets, 100-unit dose tablets per box, Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC 70518-2489-00 for box; 70518-2489-01 per unit dose.

Product Quantity:
498 tablets

Reason for Recall:
FAILED DISSOLUTION SPECIFICATION: Low out-of-specification (OOS) dissolution results obtained during routine stability testing.

Recall Number:
D-1387-2020

Code Information:
Lot #: B0796217-020920, Exp. Date: 02/28/2021

Class II Drugs Event

Event ID:
86008

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/10/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/15/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Keryx Biopharmaceuticals, Inc.
1 Marina Park Dr Fl 12
Boston MA United States

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Auryxia (ferric citrate) tablets 210 mg, Rx Only, 200 tablets per bottle, Manufactured for and distributed by: Keryx Biopharmaceuticals, Inc., 245 First Street Suite 1400, Cambridge, MA 02142, NDC: 59922-631-01.

Product Quantity:
59,820 bottles

Reason for Recall:
cGMP deviations: Lots recalled were not manufactured in conformance with the FDA-approved manufacturing process for Auryxia.

Recall Number:
D-1389-2020

Code Information:
Lot #s: AK6003C, Exp. 10/31/2020; AK6004B, Exp. 11/30/2020; CBMKF, CBMKH, Exp. 08/31/2020; CCKSM, Exp. 09/30/2020; CBWKN, Exp. 11/30/2020; CCSTZ, CCWZB, Exp. 05/31/2021; CCYSF, CCYSG, CCWZC, Exp. 06/30/2021; CDCTB, CDCSZ, Exp. 07/31/2021.

Class III Drugs Event

Event ID:
86018

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/13/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/16/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fresenius Kabi USA, LLC
3 Corporate Dr
Lake Zurich IL United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Fosaprepitant for Injection, 150 mg / vial in a 10 mL Single-Dose vial, Rx only, Fresenius Kabi, Lake Zurich, IL 60047; NDC 63323-972-10

Product Quantity:
63,067 vials

Reason for Recall:
Labeling Error: Label Error on Declared Strength: Carton label and product insert incorrectly states the quantity of the excipient edetate disodium (EDTA) as 5.4 mg / vial, rather than the actual amount of 18.8 mg / vial.

Recall Number:
D-1391-2020

Code Information:
Lot #: 6122760, 6122761, exp 08/2021; 6122762, exp 09/2021; 6123883, exp 03/2022

Class III Drugs Event

Event ID:
86019

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/26/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/14/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn, Inc.
1925 W Field Ct Ste 300
Lake Forest IL United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
Proparacaine Hydrochloride Ophthalmic Solution, USP, 0.5%, 15 mL per dropper bottle, Sterile, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC 17478-263-12

Product Quantity:
33,343 bottles

Reason for Recall:
Chemical contamination; out of specification results obtained for equipment cleaning residue rinse sample

Recall Number:
D-1388-2020

Code Information:
Lot 9E52A, exp 04/2021