Enforcement Report - Week of December 4, 2019

Class II Drugs Event

Event ID:
84189

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/01/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/25/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
New Vitalis Pharmacy LLC dba New Vitalis Pharmacy
4139 Cadillac Ct Ste 201
Louisville KY United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Testosterone Cypionate 180 mg/mL/Testosterone Propionate 20mg/mL Oil Injection Solution, 10 mL per vial, New Vitalis Pharmacy

Product Quantity:
2981.62 mL

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0523-2020

Code Information:
Lot, expiry: AL-07232019@99, exp 9-23-2019; AL-07312019@99, exp 9-30-2019; AL-08132019@99, exp 10-13-2019; AL-08272019@901, exp 10-27-2019; AL-08282019@909, exp 10-28-2019; Al-09032019@903, exp 11-3-2019

Class II Drugs Event

Event ID:
84218

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/06/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/26/2019

Initial Firm Notification of Consignee or Public:
Press Release

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

Distribution Pattern:
nationwide

Associated Products

Product Description:
DG Health Acid Reducer Ranitidine Tablets 150 mg, 8-count carton, Distributed by: Dolgencorp LLC 100 Mission Ridge Goodletville TN 37072 NDC 55910-092-79

Product Quantity:
69,696 bottles

Reason for Recall:
CGMP Deviations: N-nitrosodimethylamine (NDMA) has been detected in Ranitidine tablets, capsules and syrups.

Recall Number:
D-0526-2020

Code Information:
Lot # NBSB19001DA3; Exp FEB 2021

Product Description:
Aurobindo Ranitidine Caspules 150 mg, 60-count bottle, Rx Only Distributed by: Aurobindo Pharma USA, Inc. 279 Princeton-Hightstown Road East Windsor, NJ 08520 NDC 59651-144-60

Product Quantity:
45,456 bottles

Reason for Recall:
CGMP Deviations: N-nitrosodimethylamine (NDMA) has been detected in Ranitidine tablets, capsules and syrups.

Recall Number:
D-0527-2020

Code Information:
RA1518001-A Jul 2020 RA1518002-A Jul 2020 RA1518005-B Aug 2020 RA1518006-A Aug 2020 RA1519003-A May 2021

Product Description:
Aurobindo Ranitidine Capsules 300 mg, 30-count bottle, Rx Only Distributed by: Aurobindo Pharma USA, Inc. 279 Princeton-Hightstown Road East Windsor, NJ 08520 NDC 59651-145-30

Product Quantity:
134,160 bottles

Reason for Recall:
CGMP Deviations: N-nitrosodimethylamine (NDMA) has been detected in Ranitidine tablets, capsules and syrups.

Recall Number:
D-0528-2020

Code Information:
RA3018001-A Jul 2020 RA3018002-A Jul-2020 RA3018003-A Jul 2020 RA3018004-A Aug 2020 RA3018005-A Aug 2020 RA3018006-A Aug 2020 RA3018007-A Sep 2020 RA3018008-A Sep 2020 RA3018009-A Sep 2020 RA3018010-A Oct 2020 RA3019001-A Jan 2021 RA3019002-A Jan 2021 RA3019003-A May 2021

Product Description:
Ranitidine Syrup (Ranitidine Oral Solution, USP), 15 mg/mL (75 mg/5mL) 474 mL bottle, Rx only Distributed by: Aurobindo Pharma USA Inc. 279 Princeton-Hightstown Road East Windsor, NJ 08520 Made in India NDC 65862-431-74

Product Quantity:
19320 bottles

Reason for Recall:
CGMP Deviations: N-nitrosodimethylamine (NDMA) has been detected in Ranitidine tablets, capsules and syrups.

Recall Number:
D-0529-2020

Code Information:
UI1519001-A UI1519002-A UI1519003-A UI1519004-A

Product Description:
Aurobindo Ranitidine Capsules 150 mg, 500 count bottle, Rx Only Distributed by: Aurobindo Pharma USA, Inc. 279 Princeton-Hightstown Road East Windsor, NJ 08520 NDC 59651-144-05

Product Quantity:
26,736 bottles

Reason for Recall:
CGMP Deviations: N-nitrosodimethylamine (NDMA) has been detected in Ranitidine tablets, capsules and syrups.

Recall Number:
D-0530-2020

Code Information:
RA1518002-B Jul 2020 RA1518003-A Jul 2020 RA1518004-A Aug 2020 RA1518005-A Aug 2020 RA1518007-A Sep 2020 RA1518008-A Sep 2020 RA1518009-A Sep 2020 RA1518010-A Oct 2020 RA1518011-A Nov 2020 RA1518012-A Nov 2020 RA1518013-A Nov 2020 RA1518014-A Nov 2020 RA1518015-A Nov 2020 RA1519003-B May 2021 RA1519004-A May 2021

Class II Drugs Event

Event ID:
84287

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/14/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/26/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AVKARE Inc.
615 N 1st St
Pulaski TN United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
AVKARE Ranitidine Tablets, USP 150 mg Rx Only Manufactured for: AvKARE, Inc. Pulaski, TN 38478 Manufactured by: Amneal Pharmaceuticals of NY Hauppauge, NY 11788 a) 1000 tablets NDC 42291-724-10; b) 180 tablets NDC 42291-724-18; c) 60 tablets NDC 42291-724-60

Product Quantity:
631,138 bottles

Reason for Recall:
CGMP Deviations: Impurity N-nitrosodimethylamine (NDMA) found in API

Recall Number:
D-0524-2020

Code Information:
Lots: a) HK16617A Exp. 11/30/2019, HL03917A Exp. 11/30/2019, HL04017A Exp. 11/30/2019, HM06017A Exp. 11/30/2019, HM06117A Exp. 11/30/2019, HB03518A Exp. 03/31/2020, HB03618A Exp. 03/31/2020, HC14018A Exp. 04/30/2020, HC14118A Exp. 04/30/2020, HC14218A Exp. 04/30/2020, HC14318A Exp. 04/30/2020, HC14418A Exp. 04/30/2020, HC14518A Exp. 05/31/2020, HH04518A Exp. 08/31/2020, HH04618A Exp. 08/31/2020, HH04718A Exp. 08/31/2020, HH04818A Exp. 08/31/2020, HH04918A Exp. 08/31/2020, HK02718A Exp. 10/31/2020, HK06918A Exp. 10/31/2020, HL07418A Exp. 11/30/2020, HL07518A Exp. 11/30/2020, HA00419A Exp. 12/31/2020, HA00519A Exp. 12/31/2020, HA02719A Exp. 12/31/2020, HA02819A Exp. 12/31/2020, HA2719A Exp. 12/31/2020, HC05019A Exp. 03/31/2021, HC05119A Exp. 03/31/2021, HC05911A Exp. 03/31/2021, HE03319A Exp. 04/30/2021, HE03419A Exp. 04/30/2021, HE05419A Exp. 04/30/2021, HG02319A Exp. 06/30/2021, HG02419A Exp. 06/30/2021, HG02619A Exp. 06/30/2021; b) 21570 Exp. 03/31/2020, 21571 Exp. 03/31/2020, 22190 Exp. 03/31/2020, 22192 Exp. 05/31/2020, 22497 Exp. 05/31/2020, 22620 Exp. 05/31/2020, 22999 Exp. 09/30/2020, 23000 Exp. 09/30/2020, 24158 Exp. 03/31/2021, 24159 Exp. 04/30/2021; c) 21241 Exp. 03/31/2020, 21680 Exp. 03/31/2020, 22193 Exp. 03/31/2020, 22657 Exp. 03/31/2020, 23001 Exp. 09/30/2020, 23002 Exp. 09/30/2020, 24157 Exp. 04/30/2021

Product Description:
AVKARE Ranitidine Tablets, USP 300 mg Rx Only NDC Manufactured for: AvKARE, Inc. Pulaski, TN 38478 a) 250 tablets NDC 42291-725-25; b) 30 tablets NDC 42291-725-30

Product Quantity:
104,797 bottles

Reason for Recall:
CGMP Deviations: Impurity N-nitrosodimethylamine (NDMA) found in API

Recall Number:
D-0525-2020

Code Information:
Lots: a) 21307 Exp. 02/29/2020, 21309 Exp. 02/29/2020, 21528 Exp. 02/29/2020, 21527 Exp. 02/29/2020, 22247 Exp. 06/30/2020, 23214 Exp. 09/30/2020, 23243 Exp. 09/30/2020, 23244 Exp. 11/30/2020, 24198 Exp. 01/31/2021, 24199 Exp. 01/31/2021, 24289 Exp. 01/31/2021; b) 22291 Exp. 06/30/2020, 23215 Exp. 09/30/2020, 23776 Exp. 01/31/2021

Class II Drugs Event

Event ID:
84359

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/21/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/27/2019

Initial Firm Notification of Consignee or Public:
Telephone

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

Distribution Pattern:
CA, FL, IL

Associated Products

Product Description:
Ibuprofen Oral Suspension USP, 100 mg/5mL, 4 fl.oz. 118 mL, Rx only, Preferred Pharmaceuticals, Inc., Anaheim, CA. Mfg: Taro Pharm.; Hawthorne, NY; NDC 68788-7268-01

Product Quantity:

Reason for Recall:
Presence of foreign substance: Ibuprofen Oral Suspension USP may have small particles of an inert plastic material introduced during manufacturing.

Recall Number:
D-0531-2020

Code Information:
Lot #: I1718U, Exp. 3/2020; K0818L, Exp. 9/2020; L2718E, Exp. 9/2020; A2219E, Exp. 9/2020; C1519S, Exp. 12/2020; C2819Y, Exp. 12/2020; E2019V, Exp. 11/2020

Class III Drugs Event

Event ID:
84240

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/11/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/22/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AuroMedics Pharma LLC

279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Distributed Nationwide in the US

Associated Products

Product Description:
Amiodarone Hydrochloride Injection, USP, 150 mg per 3 mL (50 mg / mL), 3 mL Single Dose Vial, Rx only, Distributed by AuroMedics Pharma LLC E. Windsor, NJ. 08520, Made in India. NDC 55150-180-03

Product Quantity:
28,810 vials

Reason for Recall:
Crystallization: Presence of visible particulate matter.

Recall Number:
D-0520-2020

Code Information:
Lot# CAH180009, exp. date Feb 2020

Product Description:
Amiodarone Hydrochloride Injection, USP, 450 mg per 9 mL (50 mg / mL), 9 mL Single Dose Vial, Rx only, Distributed by AuroMedics Pharma LLC E. Windsor, NJ. 08520, Made in India. NDC 55150-181-09

Product Quantity:
29,830 vials

Reason for Recall:
Crystallization: Presence of visible particulate matter.

Recall Number:
D-0521-2020

Code Information:
Lot# CAH180001, exp. date Jan 2020; CAH180003, exp. date Feb 2020; CAH180011, CAH180012, exp. date Jun 2020

Product Description:
Amiodarone Hydrochloride Injection, USP, 900 mg per 18 mL (50 mg / mL), 18 mL Multiple Dose Vial, Rx only, Distributed by AuroMedics Pharma LLC E. Windsor, NJ. 08520, Made in India. NDC 55150-182-18

Product Quantity:
138,720 vials

Reason for Recall:
Crystallization: Presence of visible particulate matter.

Recall Number:
D-0522-2020

Code Information:
Lot#: CAH180013, CAH180014, exp. date Jul 2020

Not Yet Classified Drugs Event

Event ID:
84188

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/30/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Avantor Performance Materials Inc
7001 Martin Luther King Jr Blvd
Paris KY United States

Distribution Pattern:
Nationwide in the USA, Canada, India, and Singapore

Associated Products

Product Description:
Potassium Phosphate, Monobasic, Crystal, NF, Multi-Compendial, Bulk Pharmaceutical Chemical, packaged in a) 500G glass bottles, product number 3248-01, NDC 10106-3248-1; b) 2.5KG glass bottles, product number 3248-05, NDC 10106-3248-2; c) 12KG pails, product number 3248-07, NDC 10106-3248-3; d) 1KT bottles and drums, product number 3248-X2; e) 1KT bottles and drums, product number 3248-X3; f) 12KG pails, product number 7390-19; Avantor Performance Materials, LLC, 100 Matsonford, Road, Suite 200, Radnor, PA 19087.

Product Quantity:
a) 36 bottles; b) 85 bottles; c) 43 pails; d) 28 bottles and drums; e) 100 bottles and drums; f) 4 pails

Reason for Recall:
Failed Stability Specifications: Product exceeds compendia and firm's specifications for iron content.

Recall Number:

Code Information:
Batch: a) 0000226380; b) 0000224662, 0000224663, and 0000227641; c) 0000227640; d) 0000224809; e) 0000224818 and 0000225900; f) 0000224661; Retest Date 12/7/2023

Not Yet Classified Drugs Event

Event ID:
84241

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/11/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

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 in the USA

Associated Products

Product Description:
Lidocaine HCl Injection, USP, 2% 100 mg/5 mL (20 mg/mL), Preservative-Free, packaged in 10 x 5 mL Single Dose Vials per carton, Rx only, Distributed by: AuroMedics Pharma LLC, 279 Princeton-Hightstown Rd., E. Windsor, NJ 08520, NDC 55150-165-05.

Product Quantity:
111,850 vials

Reason for Recall:
Presence of Foreign Substance: Foreign material found inside the vial.

Recall Number:

Code Information:
Batch #: CLC190049, Exp 02/2022