Enforcement Report - Week of November 20, 2019

Class II Drugs Event

Event ID:
83871

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/24/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/12/2019

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Apotex Inc.
150 Signet Drive
North York Canada

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Walgreens Maximum Strength Wal-Zan 150 Ranitidine Tablets, USP 150 mg/Acid Reducer Distributed By: Walgreen Co., 200 Wilmot RD., Deerfield, IL 60015 a) 200 Tablets NDC 0363-1030-07; b) 24 Tablets NDC 0363-1030-02; c) 95 Tablets NDC 0363-1030-09; d) 65 Tablets NDC 0363-1030-06

Product Quantity:
259,647 bottles

Reason for Recall:
GGMP Deviations: Possible contamination with impurity N-nitrosodimethylamine (NDMA).

Recall Number:
D-0314-2020

Code Information:
All lots remaining within expiry.

Product Description:
Walgreens Regular Strength Wal-Zan 75 Ranitidine Tablets, USP 75 mg/Acid Reducer 30 Tablets NDC 0363-1029-03 Distributed By: Walgreen Co., 200 Wilmot RD., Deerfield, IL 60015

Product Quantity:
42,873 bottles

Reason for Recall:
GGMP Deviations: Possible contamination with impurity N-nitrosodimethylamine (NDMA).

Recall Number:
D-0315-2020

Code Information:
All lots remaining within expiry.

Product Description:
Equate Maximum Strength Ranitidine Tablets, USP 150 mg Acid Reducer 130 Tablets Distributed by Wal-Mart Stores, Inc. Bentonville, AR 72716 a) Twin Pack NDC: 49035-100-07; b) Single Pack NDC: 49035-100-00

Product Quantity:
1,132,453 bottles

Reason for Recall:
GGMP Deviations: Possible contamination with impurity N-nitrosodimethylamine (NDMA).

Recall Number:
D-0316-2020

Code Information:
All lots remaining within expiry.

Product Description:
Rite Aid Pharmacy Maximum Strength Ranitidine Tablets, USP 150 mg Cool Mint Acid Reducer 24 Tablets Sugar Free NDC 11822-6107-4 Distributed By: Rite Aid 30 Hunter Lane, Camp Hill, PA 17011

Product Quantity:
31,968 bottles

Reason for Recall:
GGMP Deviations: Possible contamination with impurity N-nitrosodimethylamine (NDMA).

Recall Number:
D-0317-2020

Code Information:
All lots remaining within expiry.

Product Description:
Equate Maximum Strength Ranitidine Tablets, USP 150 mg Acid Reducer Cool Mint Tablets Sugar Free 65 Tablets NDC: 49035-117-06 Distributed By: Wal-Mart Stores, Inc. Bentonville, AR 72716

Product Quantity:
162,344 bottles

Reason for Recall:
GGMP Deviations: Possible contamination with impurity N-nitrosodimethylamine (NDMA).

Recall Number:
D-0318-2020

Code Information:
All lots remaining within expiry.

Product Description:
Rite Aid Pharmacy Maximum Strength Ranitidine Tablets, USP 150 mg-acid reducer Distributed By: Rite Aid 30 Hunter Lane Camp Hill, PA 17011 a) 50 tablets NDC 11822-6052-1; b) 65 tablets NDC 11822-6052-2; c) 95 tablets NDC 11822-4727-3; d) 24 tablets NDC 11822-6051-8

Product Quantity:
215,387 bottles

Reason for Recall:
GGMP Deviations: Possible contamination with impurity N-nitrosodimethylamine (NDMA).

Recall Number:
D-0319-2020

Code Information:
All lots remaining within expiry.

Class II Drugs Event

Event ID:
84055

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/15/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/14/2019

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
8046255 Canada Inc. DBA Viatrexx

1360 Louis-Marchand St
Beloeil Canada

Distribution Pattern:
Distributed to physicians Nationwide throughout the United States and Puerto Rico.

Associated Products

Product Description:
Viatrexx-Connectissue, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0090, NDC 73069-100-41.

Product Quantity:
24 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0326-2020

Code Information:
Lot Numbers: 19-S00001, Exp. May: 2020

Product Description:
Viatrexx-MuSkel-Neural, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC4020, NDC 73069-347-41.

Product Quantity:
61 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0327-2020

Code Information:
Lot Numbers: 19-S00002, Exp. May: 2020

Product Description:
Viatrexx-Ouch, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0500, NDC 73069-402-41.

Product Quantity:
19 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0328-2020

Code Information:
Lot Numbers: 19-S00003, Exp. May: 2020

Product Description:
Viatrexx-Ithurts, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0290, NDC 73069-270-41.

Product Quantity:
12 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0329-2020

Code Information:
Lot Numbers: 19-S00004, Exp. May: 2020

Product Description:
Viatrexx-Adipose, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0008, NDC 73069-024-41.

Product Quantity:
4 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0330-2020

Code Information:
Lot Numbers: 19-S00005, Exp. May: 2020

Product Description:
Viatrexx-Systemic Detox, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0665, NDC 73069-500-41.

Product Quantity:
5 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0331-2020

Code Information:
Lot Numbers: 19-S00007, Exp. May: 2020

Product Description:
Viatrexx-Articula, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0031, NDC 73069-037-41.

Product Quantity:
69 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0332-2020

Code Information:
Lot Numbers: 19-S00008, Exp. May: 2020

Product Description:
Viatrexx-Neuro 3, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0463, NDC 73069-373-41.

Product Quantity:
7 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0333-2020

Code Information:
Lot Numbers: 19-S00010, Exp. May: 2020

Product Description:
Viatrexx-Infla, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0279, NDC 73069-249-41.

Product Quantity:
54 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0334-2020

Code Information:
Lot Numbers: 19-S00012, Exp. May: 2020

Product Description:
Viatrexx-Collagen, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0085, NDC 73069-095-41.

Product Quantity:
22 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0335-2020

Code Information:
Lot Numbers: 19-S00014, Exp. May: 2020

Product Description:
Viatrexx-Prolo, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0558, NDC 73069-443-41.

Product Quantity:
42 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0336-2020

Code Information:
Lot Numbers: 19-S00016, Exp. May: 2020

Product Description:
Viatrexx-Lymph 1, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0370, NDC 73069-310-41.

Product Quantity:
3 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0337-2020

Code Information:
Lot Numbers: 19-S00017, Exp. May: 2020

Product Description:
Viatrexx-Mesenchyme, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0092, NDC 73069-102-41.

Product Quantity:
7 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0338-2020

Code Information:
Lot Numbers: 19-S00018, Exp. May: 2020

Product Description:
Viatrexx-GI, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0211, NDC 73069-189-41.

Product Quantity:
3 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0339-2020

Code Information:
Lot Numbers: 19-S00019, Exp. May: 2020

Product Description:
Viatrexx-Arthros, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0030, NDC 73069-035-41.

Product Quantity:
6 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0340-2020

Code Information:
Lot Numbers: 19-S00021, Exp. May: 2020

Product Description:
Viatrexx-Immunexx, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0270, NDC 73069-244-41.

Product Quantity:
18 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0341-2020

Code Information:
Lot Numbers: 19-S00023, Exp. May: 2020

Product Description:
Viatrexx-Relief +, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0615, NDC 73069-450-41.

Product Quantity:
1 vial

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0342-2020

Code Information:
Lot Numbers: 19-S00024, Exp. May: 2020

Product Description:
Viatrexx-Intra-Cell, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0280, NDC 73069-250-41.

Product Quantity:
8 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0343-2020

Code Information:
Lot Numbers: 19-S00025, Exp. May: 2020

Product Description:
Viatrexx-Facial, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0184, NDC 73069-164-41.

Product Quantity:
13 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0344-2020

Code Information:
Lot Numbers: 19-S00026, Exp. May: 2020

Product Description:
Viatrexx-Hair, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0251, NDC 73069-206-41.

Product Quantity:
3 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0345-2020

Code Information:
Lot Numbers: 19-S00009, Exp. May: 2020

Product Description:
Viatrexx-Neuro, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0460, NDC 73069-375-41.

Product Quantity:
13 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0346-2020

Code Information:
Lot Numbers: 19-S00020, Exp. May: 2020

Product Description:
Viatrexx-Male+, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0400, NDC 73069-320-41.

Product Quantity:
2 vials

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0347-2020

Code Information:
Lot Numbers: 19-S00022, Exp. May: 2020

Product Description:
Viatrexx-ANS/CNS, 10 mL Sterile multi-dose vial, Rx only, Viatrexx Bio Incorporated, Newark, DE, USA, 19713, Item: VSPC0025, NDC 73069-039-41.

Product Quantity:
1 vial

Reason for Recall:
Lack of Assurance of Sterility: products manufactured in a manner than cannot guarantee its sterility.

Recall Number:
D-0348-2020

Code Information:
Lot Numbers: 19-S00027, Exp. May: 2020

Class II Drugs Event

Event ID:
84147

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/25/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/10/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Novitium Pharma LLC
70 Lake Dr
East Windsor NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Novitium Pharma Ranitidine Capsules 150 mg 60 capsules Rx Only Manufactured by: Novitium Pharma LLC 70 Lake Drive, East Windsor, New Jersey 08520 NDC 70954-001-20

Product Quantity:
19560 bottles

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0310-2020

Code Information:
all lots within expiry.

Product Description:
Novitium Pharma Ranitidine Capsules 150 mg 500 capsules Rx Only Manufactured by: Novitium Pharma LLC 70 Lake Drive, East Windsor, New Jersey 08520 NDC 70954-001-40

Product Quantity:
2718 bottles

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0311-2020

Code Information:
all lots within expiry.

Product Description:
Novitium Pharma Ranitidine Capsules 300 mg 30 capsules Rx Only Manufactured by: Novitium Pharma LLC 70 Lake Drive, East Windsor, New Jersey 08520 NDC 70954-002-10

Product Quantity:
12312 bottles

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0312-2020

Code Information:
all lots within expiry.

Product Description:
Novitium Pharma Ranitidine Capsules 300 mg 100 capsules Rx Only Manufactured by: Novitium Pharma LLC 70 Lake Drive, East Windsor, New Jersey 08520 NDC 70954-002-40

Product Quantity:
6660 bottles

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0313-2020

Code Information:
all lots within expiry.

Class II Drugs Event

Event ID:
84149

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/28/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/10/2019

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Lannett Company, Inc.
9000 State Rd
Philadelphia PA United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Lannett Ranitidine Syrup (Ranitidine Oral Solution, USP), 15mg/mL Rx Only Distributed by: Lannett Company, Inc. Philadelphia, PA 19154 NDC 54838-550-80

Product Quantity:
683,149 bottles

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0309-2020

Code Information:
1503A 10/2019 1504A 10/2019 1505A 10/2019 1523A 10/2019 1524A 10/2019 1525A 11/2019 1561A 12/2019 1562A 12/2019 1563A 12/2019 1589A 12/2019 1590A 12/2019 1591A 12/2019 1614A 01/2020 1615A 01/2020 1617A 01/2020 1644A 02/2020 1775A 06/2020 1646A 02/2020 1647A 02/2020 1668A 03/2020 1669A 03/2020 1670A 03/2020 1708A 03/2020 1709A 04/2020 1710A 04/2020 1729A 04/2020 1730A 04/2020 1731A 04/2020 1757A 05/2020 1758A 05/2020 1759A 05/2020 1773A 06/2020 1774A 06/2020 1989A 12/2020 1794A 06/2020 1795A 06/2020 1796A 06/2020 1817A 06/2020 1818A 07/2020 1819A 07/2020 1840A 08/2020 1840B 08/2020 1841A 08/2020 1842A 08/2020 1863A 08/2020 1864A 09/2020 1865A 09/2020 1899A 10/2020 1900A 10/2020 1901A 10/2020 1910A 10/2020 1911A 10/2020 1912A 10/2020 1918A 10/2020 1919A 10/2020 1920A 10/2020 1925A 10/2020 1926A 10/2020 1927A 10/2020 1977A 12/2020 1978A 12/2020 1979A 12/2020 1990A 12/2020 1991A 12/2020 1998A 01/2021 1999A 01/2021 2000A 01/2021 2019A 01/2021 2020A 01/2021 2065A 03/2021 2066A 03/2021 2067A 03/2021 2071A 03/2021 2072A 03/2021 2073A 03/2021 2076A 03/2021 2077A 03/2021 2078A 03/2021 2126A 05/2021 2127A 05/2021 2128A 05/2021 2164A 06/2021 2165A 06/2021 2166A 06/2021 2179A 06/2021 2180A 07/2021 2181A 07/2021 2214A 08/2021 2215A 08/2021 2216A 08/2021

Class II Drugs Event

Event ID:
84233

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/06/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/10/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Golden State Medical Supply Inc.
5187 Camino Ruiz
Camarillo CA United States

Distribution Pattern:
AZ, IA, MA, MO

Associated Products

Product Description:
GSMS: Ranitidine Capsules 150 mg, Rx only, 500 count bottles (NDC 51407-097-05) Manufactured by Novitium Pharma LLC, 70 Lake Drive, East Windsor, New Jersey 08520; Packaged by GSMS, Incorporated, Carmillo, CA 93012 USA.

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0307-2020

Code Information:
Lot Codes: GS023970, Exp. 10/31/2020; GS026108, Exp. 10/31/2020;GS026099, Exp. 10/31/2020; GS026838, Exp. 10/31/2020; GS025702, Exp. 10/31/2020; GS027272, Exp. 10/31/2020; GS027273, Exp. 05/31/2021.

Product Description:
GSMS: Ranitidine Capsules 300 mg, Rx only, 100 count bottles (NDC 51407-097-05) Manufactured by Novitium Pharma LLC, 70 Lake Drive, East Windsor, New Jersey 08520; Packaged by GSMS, Incorporated, Carmillo, CA 93012 USA.

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0308-2020

Code Information:
Lot Codes: GS023971, Exp. 10/31/2020; GS025527, Exp. 10/31/2020; GS025526, Exp. 10/31/2020; GS026114, Exp. 10/31/2020; GS025813, Exp. 10/31/2020; GS026189, Exp. 10/31/2021; GS027555, Exp. 7/31/2021; GS026190, Exp. 5/31/2021; GS026220, Exp. 05/31/2021; GS026584, Exp. 05/31/2021; GS027139, Exp. 05/31/2021; GS027554, Exp. 05/31/2021.

Class III Drugs Event

Event ID:
83964

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/01/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/13/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sato Pharmaceutical Inc.
20695 S Western Ave Ste 240
Torrance CA United States

Distribution Pattern:
Nationwide within the United States, Guam and Saipan

Associated Products

Product Description:
Zentrip (meclizine Hydrochloride), 25 mg strips, 8-strips per box, Distributed by Sato Pharmaceutical INC. 20695 S. Western Ave., Suite 240 Torrence, CA 90501, NDC 49873-803-01. UPC 4987301603

Product Quantity:
21,864 units

Reason for Recall:
Subpotent Drug

Recall Number:
D-0322-2020

Code Information:
Lot #: TXWW, TXTW, Exp. date Dec 2019; AXPS, AXLS, AXBS AXNS, Exp. date Oct 2021; AXZL, AXAL, AXTL, AXWL, Exp. date Jun 2021.

Product Description:
Motion Sickness (meclizine hydrochloride) 25 mg tablets, 12-count box, Distributed by Sato Pharmaceutical INC. 20695 S. Western Ave., Suite 240 Torrence, CA 90501, NDC 59779-534-01. UPC 050428345535

Product Quantity:
210,744 units

Reason for Recall:
Subpotent Drug

Recall Number:
D-0323-2020

Code Information:
Lot #: TXWP, TXTP, Exp. date Jul 2020; AXTZ, Exp. date Mar 2021; AXNP, Exp. date Jul 2021; AXBC, Exp. date Oct 2021; ZXWW, Exp. date Dec 2021

Product Description:
WAL-DRAM 2 (meclizine Hydrochloride) 25 mg tablets, packaged in a) 12 count (NDC 0363-1407-01, UPC 3 11917-18328 2) and b) 18-count boxes (NDC 0363-1407-02, UPC 3 11917-20318 8) Distributed by Sato Pharmaceutical INC. 20695 S. Western Ave., Suite 240 Torrence, CA 90501,

Product Quantity:
a) 112,104 units b) 24,696 units

Reason for Recall:
Subpotent Drug

Recall Number:
D-0324-2020

Code Information:
Lot #: a) AXWA, Exp. date Feb 2021; AXAB, Exp. date May 2021; AXLK, Exp. date Nov 2021; b) AXZP, Exp. date Jul 2021

Product Description:
Motion Sickness Strips (meclizine hydrochloride) 25 mg strips, 8-count box, Distributed by Sato Pharmaceutical INC. 20695 S. Western Ave., Suite 240 Torrence, CA 90501, NDC 69842-288-01. UPC 5042849946

Product Quantity:
39,504 units

Reason for Recall:
Subpotent Drug

Recall Number:
D-0325-2020

Code Information:
Lot #: AXTK, AXAK, AXZK, AXNK, AXBK, AXLK, AXPK, AXCK, Exp. Date Nov 2021

Class III Drugs Event

Event ID:
84073

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/16/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/13/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amneal Pharmaceuticals, Inc.
50 Horseblock Rd
Brookhaven NY United States

Distribution Pattern:
Recalled product was distributed to retailers and wholesalers who may have further distribute the product.

Associated Products

Product Description:
Isotretinoin Capsules, USP 10 mg. Rx Only, 3 Prescription Blister Packs of 10- Capsules Each (30 Capsules)-. Distributed by: Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807. NDC 69238-1174-3

Product Quantity:
2460 cartons/3 blister cards/10 capsules each

Reason for Recall:
Failed Impurities/Degradation Specifications: Tretinoin levels slightly above specification limits.

Recall Number:
D-0321-2020

Code Information:
Batch Numbers: BL10917, BL11017, BL11117, Exp. date 11/2019

Not Yet Classified Drugs Event

Event ID:
84184

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/01/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
KVK-Tech, Inc.
110 Terry Dr
Newtown PA United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Hydrocodone Bitartrate and Homatropine Methlybromide Oral Solution 5 mg/1.5 mg per 5 mL, 473 mL bottles, Rx only, Mfd. by: KVK-Tech, Inc. Newtown PA 18940; NDC 10702-150-16

Product Quantity:
1534 bottles

Reason for Recall:
Presence of Foreign Substance: Black particles were found in the lots during retain sample inspection

Recall Number:

Code Information:
Lot #: 14375A, Exp. date 2019-DEC; 14398A, Exp. date 2020-JAN