

# Enforcement Report - Week of December 11, 2019

## Class II Drugs Event

**Event ID:**

84122

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**
**Recall Initiation Date:**

10/22/2019

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

12/01/2019

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Sanofi-Aventis U.S. LLC  
55 Corporate Dr  
Bridgewater NJ United States

**Distribution Pattern:**

Nationwide

## Associated Products

**Product Description:**

Cool Mint Tablets Maximum Strength Zantac 150 mg Sanofi Distributed by: Chattem, Inc., a Sanofi Company P.O. Box 2219, Chattanooga, TN 37409-0219. NDC's: 0597-0120-06, 0597-0120-08, 0597-0120-09, 0597-0120-24, 0597-0120-38, 0597-0120-50, 0597-0120-76, 0597-0120-78, 0597-0120-80, 0597-0120-82, 0597-0120-87.

**Product Quantity:**
**Reason for Recall:**

CGMP Deviations: Presence of NDMA impurity detected in product.

**Recall Number:**

D-0534-2020

**Code Information:**

all lots

**Product Description:**

Regular Strength Zantac 75 mg, Distributed by: Chattem, Inc., a Sanofi Company P.O. Box 2219, Chattanooga, TN 37409-0219 NDC's 41167-0300-0, 41167-0300-1, 41167-0300-3, 41167-0300-5, 41167-0300-6, 41167-0300-7, 41167-0300-8

**Product Quantity:**
**Reason for Recall:**

CGMP Deviations: Presence of NDMA impurity detected in product.

**Recall Number:**

D-0535-2020

**Code Information:**

all lots

**Product Description:**

Maximum Strength Zantac 150 mg Distributed by: Chattem, Inc., a Sanofi Company P.O. Box 2219, Chattanooga, TN 37409-0219. NDC's 41167-0310-1 41167-0310-2 41167-0310-3 41167-0310-4 41167-0310-6 41167-0310-7 41167-0310-8

**Product Quantity:**
**Reason for Recall:**

CGMP Deviations: Presence of NDMA impurity detected in product.

**Recall Number:**

D-0536-2020

**Code Information:**

all lots

**Product Description:**

Regular Strength Zantac 150 mg Distributed by: Chattem, Inc., a Sanofi Company P.O. Box 2219, Chattanooga, TN 37409-0219, NDC 05269-220-25.

**Product Quantity:****Reason for Recall:**

CGMP Deviations: Presence of NDMA impurity detected in product.

**Recall Number:**

D-0537-2020

**Code Information:**

all lots

**Product Description:**

Cool Mint Maximum Strength Zantac 150 mg, Distributed by: Chattem, Inc., a Sanofi Company P.O. Box 2219, Chattanooga, TN 37409-0219  
NDC's: 41167-0320-1 41167-0320-2 41167-0320-3 41167-0320-4 41167-0320-5 41167-0320-6 41167-0320-7

**Product Quantity:****Reason for Recall:**

CGMP Deviations: Presence of NDMA impurity detected in product.

**Recall Number:**

D-0538-2020

**Code Information:**

all lots

**Product Description:**

Maximum Strength Zantac 150 mg, Distributed by: Chattem, Inc., a Sanofi Company P.O. Box 2219, Chattanooga, TN 37409-0219. NDC's: 0597-0121-01, 0597-0121-06, 0597-0121-08, 0597-0121-09, 0597-0121-11, 0597-0121-24, 0597-0121-38, 0597-0121-50, 0597-0121-64, 0597-0121-66, 0597-0121-68, 0597-0121-78, 0597-0121-80, 0597-0121-82, 0597-0121-85, 0597-0121-90, 0597-0121-94.

**Product Quantity:****Reason for Recall:**

CGMP Deviations: Presence of NDMA impurity detected in product.

**Recall Number:**

D-0539-2020

**Code Information:**

all lots

**Product Description:**

Regular Strength Zantac 75 mg, Distributed by: Chattem, Inc., a Sanofi Company P.O. Box 2219, Chattanooga, TN 37409-0219. NDC 50269-222-25.

**Product Quantity:****Reason for Recall:**

CGMP Deviations: Presence of NDMA impurity detected in product.

**Recall Number:**

D-0540-2020

**Code Information:**

all lots

**Product Description:**

Regular Strength Zantac 150 mg, Distributed by: Chattem, Inc., a Sanofi Company P.O. Box 2219, Chattanooga, TN 37409-0219. NDC 67751-151-01.

**Product Quantity:****Reason for Recall:**

CGMP Deviations: Presence of NDMA impurity detected in product.

**Recall Number:**

D-0541-2020

**Code Information:**

all lots

**Product Description:**

Regular Strength Zantac 75 mg, Distributed by: Chattem, Inc., a Sanofi Company P.O. Box 2219, Chattanooga, TN 37409-0219. NDC's 67751-152-01 67751-152-02

**Product Quantity:****Reason for Recall:**

CGMP Deviations: Presence of NDMA impurity detected in product.

**Recall Number:**

D-0542-2020

**Code Information:**

all lots

**Product Description:**

Regular Strength Zantac 75 mg, Distributed by: Chattem, Inc., a Sanofi Company P.O. Box 2219, Chattanooga, TN 37409-0219. NDC 68151-2584-0.

**Product Quantity:****Reason for Recall:**

CGMP Deviations: Presence of NDMA impurity detected in product.

**Recall Number:**

D-0543-2020

**Code Information:**

all lots

**Product Description:**

Zantac 150 mg, Distributed by: Chattem, Inc., a Sanofi Company P.O. Box 2219, Chattanooga, TN 37409-0219. NDC's 66715-9736-2 66715-9736-3 66715-9736-8

**Product Quantity:****Reason for Recall:**

CGMP Deviations: Presence of NDMA impurity detected in product.

**Recall Number:**

D-0544-2020

**Code Information:**

all lots

**Product Description:**

Zantac 75 mg, Distributed by: Chattem, Inc., a Sanofi Company P.O. Box 2219, Chattanooga, TN 37409-0219, NDC's 0597-0122-01 0597-0122-08 0597-0122-13 0597-0122-37 0597-0122-40 0597-0122-54 0597-0122-61 0597-0122-81 0597-0122-96

**Product Quantity:****Reason for Recall:**

CGMP Deviations: Presence of NDMA impurity detected in product.

**Recall Number:**

D-0545-2020

**Code Information:**

all lots

## Class II Drugs Event

**Event ID:**

84179

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

10/31/2019

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

11/29/2019

**Initial Firm Notification of Consignee or Public:**

Press Release

**Recalling Firm:**

Fagron, Inc  
2400 Pilot Knob Rd  
Saint Paul MN United States

**Distribution Pattern:**

Nationwide

## Associated Products

**Product Description:**

LETS GEL KIT Convenience Pack (To prepare 100 mL LETS GEL), Contains: LETS Powders for Gel: Lidocaine Hydrochloride - 4 g, Ephinephrine Bitartrate - 180 mg, Tetracaine Hydrochloride - 500 mg, Sodium Metabisulfite - 75 mg, SuturaGel Methlcellulose Base; RX Only, For Prescription Compounding, Fagron, Inc., 2400 Pilot Knob Rd, St. Paul, MN 55120. NDC: 51552-1539-1

**Product Quantity:**

11,912 kits

**Reason for Recall:**

Microbial contamination of non-sterile product.

**Recall Number:**

D-0533-2020

**Code Information:**

Lot, expiry: 18F25-U03-044296, 11/8/2019; 18F25-U04-044297, 11/8/2019; 18H22-U06-045284, 1/24/2020; 18I24-U05-045853, 11/8/2019; 18K06-U03-047041, 1/24/2020; 18K06-U04-047042, 1/24/2020; 18K27-U11-047460, 3/16/2020; 18K28-U10-047519, 3/16/2020; 19A06-U02-048182, 3/16/2020; 19A06-U03-048183, 3/16/2020; 19A16-U13-048363, 3/16/2020; 19A21-U02-048503, 3/16/2020; 19B10-U02-048787, 3/16/2020; 19B14-U05-048781, 3/16/2020; 19C05-U01-049199, 3/16/2020; 19C05-U02-049200, 3/16/2020; 19C11-U07-049451, 3/16/2020; 19C25-U02-048758, 3/16/2020; 19D07-U01-049884, 3/16/2020; 19D07-U02-049885, 3/16/2020; 19E09-U01-050298, 3/16/2020; 19E23-U01-050763, 9/11/2020; 19F16-U12-000052, 9/11/2020; 19F16-U13-000053, 10/24/2020; 19G07-U01-000357, 10/24/2020; 19G07-U02-000358, 10/24/2020; 19G21-U01-000930, 10/24/2020; 19G21-U02-000931, 12/17/2020; 19H01-U01-001172, 12/17/2020; 19H01-U02-001174, 12/17/2020; 19I03-U01-002019, 2/4/2021; 19I03-U02-002020, 2/4/2021; 19I03-U03-002021, 12/17/2020

## Class II Drugs Event

**Event ID:**

84244

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

11/12/2019

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

12/09/2019

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

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

**Distribution Pattern:**

Product was distributed to major wholesalers/distributors who may have further distribute the product throughout the United States.

## Associated Products

**Product Description:**

Fluphenazine Decanoate Injection USP 125mg/5mL, (5 mL Multiple Dose Vial), Rx only, For IM or SC Use, Mfd in India for: AuroMedics Pharma,

LLC, E. Windsor, NJ

**Product Quantity:**

59,500 vials

**Reason for Recall:**

Discoloration; Hazy solution found in one vial instead of a clear solution.

**Recall Number:**

D-0609-2020

**Code Information:**

Lot CFD190004, exp. date August 2020

## Class II Drugs Event

**Event ID:**

84263

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

11/12/2019

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

12/03/2019

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

QuVa Pharma, Inc.  
1075 W Park One Dr Ste 100  
Sugar Land TX United States

**Distribution Pattern:**

Nationwide.

## Associated Products

**Product Description:**

fentaNYL 500 mcg/250 mL (2 mcg/mL) Bupivacaine HCl 0.1% 250 mg/250 mL (1 mg/mL) in 0.9% Sodium Chloride 250 mL Bag, Rx only, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1160-37

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0546-2020

**Code Information:**

Lots: 10029297 Exp. 11/14/2019 10029199 Exp. 11/17/2019, 10029737 Exp. 11/17/2019, 10029763 Exp. 11/17/2019, 10029785 Exp. 11/18/2019, 10029789 Exp. 11/18/2019, , 10029790 Exp. 11/18/2019, 10029894 Exp. 11/20/2019, 10029950 Exp. 11/21/2019, 10030006 Exp. 11/24/2019, , 10030007 Exp. 11/27/2019, 10030336 Exp. 11/27/2019, , 10030941 Exp. 12/3/2019, 10030886 Exp. 12/2/2019, 10030453 Exp. 11/26/2019, 10030887 Exp. 12/4/2019, 10030990 Exp. 12/4/2019, 10030991 Exp. 12/4/2019,, 10030942 Exp. 12/3/2019, 10030886 Exp. 12/2/2019, 10030909 Exp. 12/2/2019, 10030431 Exp. 11/26/2019, 10030432 Exp. 11/26/2019, 10030454 Exp. 11/26/2019, 10031056 Exp. 12/5/2019, 10031057 Exp. 12/5/2019, 10030990 Exp. 12/4/2019, 10030886 Exp. 12/2/2019,, 10030454 Exp. 11/26/2019, 10031056 Exp. 12/5/2019, 10031058 Exp. 12/5/2019, 10031087 Exp. 12/6/2019, 10031153 Exp. 12/8/2019, 10031087 Exp. 12/6/2019, 10031088 Exp. 12/6/2019, 10031376 Exp. 12/6/2019, 10031178 Exp. 12/9/2019, 10031179 Exp. 12/9/2019, 10031152 Exp. 12/8/2019, 10031153 Exp. 12/8/2019, 10031376 Exp. 12/6/2019, 10031236 Exp. 12/10/2019, 10031179 Exp. 12/9/2019, 10031152 Exp. 12/8/2019, 10031236 Exp. 12/10/2019, 10031237 Exp. 12/10/2019, 10031732 Exp. 12/22/2019, 10031616 Exp. 12/19/2019, 10031617 Exp. 12/22/2019, 10031731 Exp. 12/22/2019, 10031732 Exp. 12/22/2019, 10031616 Exp. 12/19/2019, 10031617 Exp. 12/22/2019, 10031950 Exp. 12/26/2019, 10031979 Exp. 12/29/2019, 10031980 Exp. 12/30/2019, 10032308 Exp. 12/31/2019, 10032309 Exp. 12/31/2019, 10032415 Exp. 1/2/2020, 10032416 Exp. 1/2/2020, 10032804 Exp. 1/5/2020, 10032805 Exp. 1/5/2020, 10032582 Exp. 1/6/2020, 10032808 Exp. 1/6/2020, 10032809 Exp. 1/6/2020, 10032810 Exp. 1/6/2020, 10032559 Exp. 1/6/2020, 10032582 Exp. 1/6/2020, 10032809 Exp. 1/6/2020, 10032810 Exp. 1/6/2020, 10032811 Exp. 1/6/2020, 10032805 Exp. 1/5/2020, 10032805 Exp. 1/5/2020, 10032534 Exp. 1/14/2020, 10032534 Exp. 1/14/2020, 10032534 Exp. 1/14/2020, 10032534 Exp. 1/14/2020, 10032534 Exp. 1/14/2020, 10032534 Exp. 1/14/2020, 10031951 Exp. 12/26/2019, 10031951 Exp. 12/26/2019, 10031951 Exp. 12/26/2019, 10031951 Exp. 12/26/2019, 10033008 Exp.

1/15/2020, 10033008 Exp. 1/15/2020, 10032038 Exp. 1/19/2020, 10032038 Exp. 1/19/2020, 10032039 Exp. 1/19/2020, 10033008 Exp. 1/15/2020, 10032039 Exp. 1/19/2020

**Product Description:**

fentaNYL 500 mcg/250 mL (2 mcg/mL) 0.125% BUPivacaine HCl 312.5 mg/250 mL (1.25 mg/mL) in 0.9% Sodium Chloride 250 mL Bag, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1105-37

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0547-2020

**Code Information:**

Lots: 10029289 Exp. 11/14/2019 10029841 Exp. 11/19/2019, 10029861 Exp. 11/19/2019, 10029863 Exp. 11/19/2019, 10030008 Exp. 11/24/2019, 10029946 Exp. 11/21/2019, 10030009 Exp. 11/24/2019, 10030010 Exp. 11/24/2019, 10030483 Exp. 11/27/2019, 10030482 Exp. 11/27/2019, , 10030958 Exp. 12/3/2019, , 10030908 Exp. 12/2/2019, 10030430 Exp. 11/26/2019, 10030989 Exp. 12/4/2019, 10030959 Exp. 12/3/2019, 10030907 Exp. 12/2/2019, 10030908 Exp. 12/2/2019, 10031283 Exp. 12/11/2019, 10031345 Exp. 12/12/2019, 10031346 Exp. 12/12/2019, 10031477 Exp. 12/16/2019, 10031433 Exp. 12/15/2019, 10031434 Exp. 12/15/2019, 10031478 Exp. 12/16/2019, 10031568 Exp. 12/18/2019, 10031615 Exp. 12/19/2019, 10031479 Exp. 12/18/2019, 10031568 Exp. 12/18/2019, 10031569 Exp. 12/18/2019, 10031570 Exp. 12/18/2019, 10031642 Exp. 12/20/2019, 10031591 Exp. 12/19/2019, 10031813 Exp. 12/23/2019, 10031814 Exp. 12/23/2019, 10032008 Exp. 12/27/2019, 10032009 Exp. 12/27/2019, 10031759 Exp. 12/26/2019, 10031946 Exp. 12/26/2019, 10031846 Exp. 12/24/2019, 10032250 Exp. 12/30/2019, 10031845 Exp. 12/24/2019, 10031846 Exp. 12/24/2019, 10032366 Exp. 1/1/2020, 10032391 Exp. 1/1/2020, , 10032333 Exp. 12/31/2019, 10032445 Exp. 1/2/2020, 10031760 Exp. 1/7/2020, 10031975 Exp. 12/29/2019, 10031760 Exp. 1/7/2020, 10032533 Exp. 1/7/2020, 10031975 Exp. 12/29/2019, 10031976 Exp. 12/29/2019, 10031977 Exp. 12/29/2019, 10031760 Exp. 1/7/2020, 10032533 Exp. 1/7/2020, 10031976 Exp. 12/29/2019, 10031977 Exp. 12/29/2019, 10032664 Exp. 1/8/2020, 10032665 Exp. 1/8/2020, 10032533 Exp. 1/7/2020, , 10032614 Exp. 1/7/2020, 10032615 Exp. 1/7/2020

**Product Description:**

fentaNYL 200 mcg/100 mL (2 mcg/mL) ROPivacaine HCl 0.2% 200 mg/100 mL (2 mg/mL) in 0.9% Sodium Chloride 100 mL CADD, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478NDC 70092-1259-75

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0548-2020

**Code Information:**

Lots: 10029829 Exp. 11/18/2019, 10029883 Exp. 11/19/2019, 10029829 Exp. 11/18/2019, 10029883 Exp. 11/19/2019, 10030056 Exp. 11/24/2019, 10029883 Exp. 11/19/2019, 10030867 Exp. 11/27/2019, 10030056 Exp. 11/24/2019, 10031005 Exp. 12/4/2019, 10030950 Exp. 12/3/2019, 10031005 Exp. 12/4/2019, 10031103 Exp. 12/6/2019, 10031006 Exp. 12/4/2019, 10031142 Exp. 12/8/2019, 10031274 Exp. 12/10/2019, 10031710 Exp. 12/12/2019, 10031628 Exp. 12/19/2019, 10031777 Exp. 12/22/2019, 10031683 Exp. 12/22/2019, 10032050 Exp. 12/29/2019, 10032051 Exp. 12/29/2019, 10032435 Exp. 1/2/2020, 10032468 Exp. 1/2/2020, 10032545 Exp. 1/5/2020, 10032676 Exp. 1/8/2020, 10032677 Exp. 1/8/2020, 10032595 Exp. 1/6/2020, 10032545 Exp. 1/5/2020, 10032596 Exp. 1/6/2020

**Product Description:**

fentaNYL 500 mcg/250 mL (2 mcg/mL) BUPivacaine HCl 0.0625% 156.25 mg/250 mL (0.625 mg/mL) in 0.9% Sodium Chloride in 250 mL Bag, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1269-37

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0549-2020

**Code Information:**

Lots: 10029288 Exp. 11/14/2019, 10029762 Exp. 11/14/2019, 10029788 Exp. 11/18/2019, 10029838 Exp. 11/19/2019, 10029948 Exp. 11/21/2019, 10029949 Exp. 11/21/2019, 10030337 Exp. 11/24/2019, 10029838 Exp. 11/19/2019, 10030539 Exp. 11/28/2019, 10030943 Exp. 12/3/2019, 10030964 Exp. 12/3/2019, 10030963 Exp. 12/3/2019, 10030964 Exp. 12/3/2019, 10030888 Exp. 12/2/2019, 10030963 Exp. 12/3/2019, 10031129 Exp. 12/8/2019, 10031284 Exp. 12/11/2019, 10031414 Exp. 12/15/2019, 10031435 Exp. 12/16/2019, 10031735 Exp. 12/22/2019, 10032253 Exp. 12/30/2019, 10030455 Exp. 11/26/2019, 10032535 Exp. 1/6/2020, 10032280 Exp. 12/31/2019, 10030455 Exp. 11/26/2019, 10032535 Exp. 1/6/2020, 10033009 Exp. 1/15/2020, 10032585 Exp. 1/14/2020, 10033009 Exp. 1/15/2020

**Product Description:**

fentaNYL 200 mcg/100 mL (2 mcg/mL) BUPivacaine HCl 0.125% 125 mg/100 mL (1.25 mg/mL) in 0.9% Sodium Chloride Preservative Free, 100

mL in 150 Bag, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1104-36

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0550-2020

**Code Information:**

Lots: 1002929 Exp. 11/14/2019, 10029839 Exp. 11/19/2019, 10029840 Exp. 11/19/2019, 10029806 Exp. 11/18/2019, 10029860 Exp. 11/18/2019, 10030370 Exp. 11/25/2019, 10030002 Exp. 11/24/2019, 10030001 Exp. 11/25/2019, 10030003 Exp. 11/24/2019, 10030013 Exp. 11/24/2019, 10030014 Exp. 11/24/2019, 10030001 Exp. 11/25/2019, 10030013 Exp. 11/24/2019, 10030001 Exp. 11/25/2019, 10030538 Exp. 11/28/2019, 10030906 Exp. 11/28/2019, 10030905 Exp. 11/28/2019, 10030429 Exp. 11/26/2019, 10031151 Exp. 12/8/2019, 10031039 Exp. 12/5/2019, 10031282 Exp. 12/11/2019, 10031412 Exp. 12/15/2019, 10031432 Exp. 12/16/2019, 10031460 Exp. 12/16/2019, 10031461 Exp. 12/16/2019, 10031462 Exp. 12/16/2019, 10031567 Exp. 12/18/2019, 10031613 Exp. 12/19/2019, 10031614 Exp. 12/19/2019, 10031567 Exp. 12/18/2019, 10031695 Exp. 12/22/2019, 10031667 Exp. 12/20/2019, 10031788 Exp. 12/23/2019, 10031789 Exp. 12/23/2019, 10031790 Exp. 12/23/2019, 10031812 Exp. 12/23/2019, 10031475 Exp. 12/20/2019, 10031476 Exp. 12/20/2019, 10031641 Exp. 12/20/2019, 10031667 Exp. 12/20/2019, 10031668 Exp. 12/20/2019, 10031566 Exp. 12/18/2019, 10031200 Exp. 12/10/2019, 10032006 Exp. 12/27/2019, 10032007 Exp. 12/27/2019, 10032037 Exp. 12/27/2019, 10032249 Exp. 12/30/2019, 10032276 Exp. 12/30/2019, 10031916 Exp. 12/25/2019, 10031917 Exp. 12/25/2019, 10031843 Exp. 12/24/2019, 10031844 Exp. 12/24/2019, 10031866 Exp. 12/24/2019, 10031867 Exp. 12/24/2019, 10032248 Exp. 12/30/2019, 10032276 Exp. 12/30/2019, 10031811 Exp. 12/25/2019, 10031916 Exp. 12/25/2019, 10031868 Exp. 12/24/2019, 10032306 Exp. 12/31/2019, 10032307 Exp. 12/31/2019, 10032332 Exp. 12/31/2019, 10032364 Exp. 1/1/2020, 10032365 Exp. 1/1/2020, 10032389 Exp. 1/1/2020, 10032390 Exp. 1/2/2020, 10032331 Exp. 12/31/2019 10032556 Exp. 1/6/2020, 10031974 Exp. 12/29/2019, 10032556 Exp. 1/6/2020 10032557 Exp. 1/6/2020 10032277 Exp. 12/30/2019, 10031974 Exp. 12/29/2019, 10032612 Exp. 1/7/2020, 10032613 Exp. 1/7/2020, 10032635 Exp. 1/7/2020, 10032636 Exp. 1/7/2020, 10032556 Exp. 1/6/2020, 10032557 Exp. 1/6/2020, 10032849 Exp. 1/12/2020, 10032532 Exp. 1/14/2020, 10033351 Exp. 1/16/2020, 10031040 Exp. 12/5/2019

**Product Description:**

fentaNYL 1500 mcg/30 mL (50 mcg/mL) 30 mL in 35 mL Syringe Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1099-49

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0551-2020

**Code Information:**

Lots: 10029934 Exp. 11/19/2019, 10029820 Exp. 11/18/2019, 10029872 Exp. 11/19/2019, 10029873 Exp. 11/19/2019, 10030868 Exp. 11/28/2019, 10030567 Exp. 11/28/2019, 10030892 Exp. 12/2/2019, 10030567 Exp. 11/28/2019, 10030568 Exp. 11/28/2019, 10030892 Exp. 12/2/2019, 10031210 Exp. 12/9/2019, 10031211 Exp. 12/9/2019, 10031209 Exp. 12/12/2019, 10031439 Exp. 12/15/2019, 10031700 Exp. 12/22/2019, 10031438 Exp. 12/15/2019, 10031766 Exp. 12/26/2019, 10032225 Exp. 12/29/2019, 10032260 Exp. 12/30/2019, 10032343 Exp. 12/31/2019,

**Product Description:**

fentaNYL 500 mcg/250 mL (2 mcg/mL) ROPivacaine HCl 0.2% 500 mg/250 mL (2 mg/mL) in 0.9% Sodium Chloride 250 mL Bag Rx, Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1225-37

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0552-2020

**Code Information:**

Lots: 10029346 Exp. 11/15/2019, 10029347 Exp. 11/15/2019, 10029982 Exp. 11/22/2019, 10029347 Exp. 11/15/2019, 10029982 Exp. 11/22/2019, 10030017 Exp. 11/24/2019, 10029982 11/22/2019, 10030017 Exp. 11/24/2019, 10030401 Exp. 11/25/2019, 10030017 Exp. 11/24/2019, 10031092 Exp. 12/6/2019, 10030401 Exp. 11/25/2019, 10031092 12/6/2019, 10031349 Exp. 12/12/2019, 10032011 Exp. 12/27/2019, 10032012 Exp. 12/27/2019, 10032505 Exp. 1/5/2020, 10032447 Exp. 1/2/2020, 10032932 Exp. 1/13/2020,

**Product Description:**

fentaNYL 2500 mcg/250 mL (10 mcg/mL) in 0.9% Sodium Chloride 250 mL Bag Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1093-37

**Product Quantity:**

**Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0553-2020

**Code Information:**

Lots: 10029202 Exp. 11/17/2019, 10029753 Exp. 11/17/2019, 10029756 Exp. 11/17/2019, 10029792 Exp. 11/18/2019, 10029793 Exp. 11/18/2019, 10029808 Exp. 11/18/2019, 10029809 Exp. 11/18/2019, 10029810 Exp. 11/18/2019, 10029757 Exp. 11/17/2019, 10029758 Exp. 11/17/2019, 10029809 Exp. 11/18/2019, 10029810 Exp. 11/18/2019, 10029920 Exp. 11/19/2019, 10029897 Exp. 11/20/2019, 10029793 Exp. 11/18/2019, 10029920 Exp. 11/19/2019, 10030394 Exp. 11/25/2019, 10030395 Exp. 11/25/2019, 10030479 Exp. 11/27/2019, 10030480 Exp. 11/27/2019, 10030481 Exp. 11/27/2019, 10030449 Exp. 11/26/2019, 10030450 Exp. 11/26/2019, 10030451 Exp. 11/26/2019, 10030883 Exp. 12/2/2019, 10030885 Exp. 12/2/2019, 10030507 Exp. 11/27/2019, 10030508 Exp. 11/27/2019, 10030936 Exp. 12/3/2019, 10030937 Exp. 12/3/2019, 10030956 Exp. 12/3/2019, 10030903 Exp. 11/30/2019, 10030904 Exp. 11/30/2019, 10030988 Exp. 12/4/2019, 10030938 Exp. 12/3/2019, 10030955 Exp. 12/3/2019, 10030884 Exp. 11/30/2019, 10030902 Exp. 11/30/2019, 10030986 Exp. 12/4/2019, 10030987 Exp. 12/4/2019, 10031009 Exp. 12/4/2019, 10031127 Exp. 12/8/2019, 10031128 Exp. 12/8/2019, 10031150 Exp. 12/8/2019, 10031009 Exp. 12/4/2019, 10030506 Exp. 11/27/2019, 10030448 Exp. 11/26/2019, 10031176 Exp. 12/9/2019, 10031385 Exp. 12/9/2019, 10031127 Exp. 12/8/2019, 10031128 Exp. 12/8/2019, 10031149 Exp. 12/8/2019, 10031234 Exp. 12/10/2019, 10031235 Exp. 12/10/2019, 10031259 Exp. 12/10/2019, 10031261 Exp. 12/10/2019, 10031177 Exp. 12/9/2019, 10031384 Exp. 12/9/2019, 10030426 Exp. 11/26/2019, 10030427 Exp. 11/26/2019, 10031260 Exp. 12/10/2019, 10030957 Exp. 12/3/2019, 10031389 Exp. 12/11/2019, 10030957 Exp. 12/3/2019, 10030904 Exp. 11/30/2019, 10031502 Exp. 12/17/2019, 10031474 Exp. 12/16/2019, 10031503 Exp. 12/17/2019, 10031589 Exp. 12/19/2019, 10031611 Exp. 12/19/2019, 10031565 Exp. 12/18/2019, 10031502 Exp. 12/17/2019, 10031563 Exp. 12/17/2019, 10031693 Exp. 12/22/2019, 10031694 Exp. 12/22/2019, 10031730 Exp. 12/22/2019, 10031588 Exp. 12/19/2019, 10031589 Exp. 12/19/2019, 10031610 Exp. 12/19/2019, 10031564 Exp. 12/18/2019, 10031565 Exp. 12/18/2019, 10031785 Exp. 12/23/2019, 10031693 Exp. 12/22/2019, 10031694 Exp. 12/22/2019, 10031729 Exp. 12/22/2019, 10031640 Exp. 12/20/2019, 10031564 Exp. 12/18/2019, 10031786 Exp. 12/23/2019, 10031810 Exp. 12/23/2019, 10031893 Exp. 12/25/2019, 10031894 Exp. 12/25/2019, 10032247 Exp. 12/30/2019, 10032218 Exp. 12/29/2019, 10031914 Exp. 12/25/2019, 10031915 Exp. 12/25/2019, 10031841 Exp. 12/24/2019, 10031864 Exp. 12/24/2019, 10032217 Exp. 12/29/2019, 10031914 Exp. 12/25/2019, 10031841 Exp. 12/24/2019, 10031842 Exp. 12/24/2019, 10032362 Exp. 1/1/2020, 10032363 Exp. 1/1/2020, 10032387 Exp. 1/1/2020, 10032304 Exp. 12/31/2019, 10032388 Exp. 1/1/2020, 10032554 Exp. 1/6/2020, 10032503 Exp. 1/5/2020, 10032504 Exp. 1/5/2020, 10032554 Exp. 1/6/2020, 10032555 Exp. 1/6/2020, 10032580 Exp. 1/6/2020, 10032581 Exp. 1/6/2020, 10032504 Exp. 1/5/2020, 10032529 Exp. 1/5/2020, 10032530 Exp. 1/5/2020, 10032554 Exp. 1/6/2020, 10032555 Exp. 1/6/2020, 10032581 Exp. 1/6/2020, 10032504 Exp. 1/5/2020, 10032529 Exp. 1/5/2020, 10032530 Exp. 1/5/2020

**Product Description:**

fentaNYL 400 mcg/200 mL (2 mcg/mL) ROPivacaine HCl 0.2% 400 mg/200 mL (2 mg/mL) in 0.9% Sodium Chloride 200 mL CADD Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1440-76

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0554-2020

**Code Information:**

Lots: 10029307 Exp. 11/14/2019, 10029939 Exp. 11/20/2019, 10029884 Exp. 11/19/2019, 10029915 Exp. 11/20/2019, 10030385 Exp. 11/25/2019, 10030386 Exp. 11/25/2019, 10030923 Exp. 12/11/2019, 10031320 Exp. 12/11/2019, 10031025 Exp. 12/12/2019, 10031024 Exp. 12/12/2019, 10032678 Exp. 1/8/2020, 10032993 Exp. 1/14/2020

**Product Description:**

fentaNYL 1000 mcg/100 mL (10 mcg/mL) in 0.9% Sodium Chloride Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1092-36

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0555-2020

**Code Information:**

Lots: 10029286 Exp. 11/14/2019 10029287 Exp. 11/14/2019 10029761 Exp. 11/14/2019 10029764 Exp. 11/14/2019 10029754 Exp. 11/17/2019 10029787 Exp. 11/17/2019 10029862 Exp. 11/18/2019 10029892 Exp. 11/20/2019 10029893 Exp. 11/20/2019 10030011 Exp. 11/24/2019 10030012 Exp. 11/24/2019 10030018 Exp. 11/24/2019 10029947 Exp. 11/21/2019 10029951 Exp. 11/21/2019 10030011 Exp. 11/24/2019 10030012 Exp. 11/24/2019 10030018 Exp. 11/24/2019 10030346 Exp. 11/24/2019 10030345 Exp. 11/24/2019 10030880 Exp. 12/2/2019 10030882 Exp. 12/2/2019 10030983 Exp. 12/4/2019 10030985 Exp. 12/4/2019 10030933 Exp. 12/3/2019 10030934 Exp. 12/3/2019 10030935 Exp. 12/3/2019 10030881 Exp. 12/2/2019 10030982 Exp. 12/4/2019 10030983 Exp. 12/4/2019 10030984 Exp. 12/4/2019 10030985 Exp. 12/4/2019 10031035 Exp. 12/5/2019 10031036 Exp. 12/5/2019 10031037 Exp. 12/5/2019 10031038 Exp. 12/5/2019 10031175 Exp. 12/9/2019 10031198 Exp. 12/10/2019 10031199



Exp. 12/10/2019 10031232 Exp. 12/10/2019 10031242 Exp. 12/10/2019 10031386 Exp. 12/10/2019 10031174 Exp. 12/9/2019 10030424 Exp. 11/26/2019 10030425 Exp. 11/26/2019 10031233 Exp. 12/10/2019 10031459 Exp. 12/16/2019 10031526 Exp. 12/16/2019 10031410 Exp. 12/15/2019 10031431 Exp. 12/15/2019 10031458 Exp. 12/16/2019 10031459 Exp. 12/16/2019 10031525 Exp. 12/16/2019 10031526 Exp. 12/16/2019 10031608 Exp. 12/19/2019 10031664 Exp. 12/20/2019 10031608 Exp. 12/19/2019 10031609 Exp. 12/19/2019 10031663 Exp. 12/20/2019 10031411 Exp. 12/15/2019 10031840 Exp. 12/24/2019 10031863 Exp. 12/24/2019 10031754 Exp. 12/26/2019 10031755 Exp. 12/26/2019 10031943 Exp. 12/26/2019 10031945 Exp. 12/26/2019 10032002 Exp. 12/27/2019 10032003 Exp. 12/27/2019 10032005 Exp. 12/27/2019 10032031 Exp. 12/27/2019 10032033 Exp. 12/27/2019 10032035 Exp. 12/27/2019 10031754 Exp. 12/26/2019 10031755 Exp. 12/26/2019 10031756 Exp. 12/26/2019 10031940 Exp. 12/26/2019 10031941 Exp. 12/26/2019 10031943 Exp. 12/26/2019 10031944 Exp. 12/26/2019 10031945 Exp. 12/26/2019 10032005 Exp. 12/27/2019 10032032 Exp. 12/27/2019 10032035 Exp. 12/27/2019 10031754 Exp. 12/26/2019 10031942 Exp. 12/26/2019 10031970 Exp. 12/29/2019 10031971 Exp. 12/29/2019 10031972 Exp. 12/29/2019 10031973 Exp. 12/29/2019 10032273 Exp. 12/30/2019 10032274 Exp. 12/30/2019 10032329 Exp. 12/31/2019 10032330 Exp. 12/31/2019 10032812 Exp. 1/6/2020 10032502 Exp. 1/5/2020 10032004 Exp. 12/27/2019 10032028 Exp. 12/27/2019 10032029 Exp. 12/27/2019 10032034 Exp. 12/27/2019 10032813 Exp. 1/6/2020 10032502 Exp. 1/5/2020 10032029 Exp. 12/27/2019 10032030 Exp. 12/27/2019 10032034 Exp. 12/27/2019 10032813 Exp. 1/6/2020 10033353 Exp. 1/17/2020 10033352 Exp. 1/16/2020 10031753 Exp. 12/26/2019

**Product Description:**

fentaNYL 100 mcg/2 mL (50 mcg/mL) Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1097-43

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0556-2020

**Code Information:**

Lots: 10029772 Exp. 11/17/2019, 10030627 Exp. 11/22/2019, 10030626 Exp. 11/21/2019, 10030408 Exp. 11/25/2019, 10030512 Exp. 11/27/2019, 10030408 Exp. 11/25/2019, 10031107 Exp. 12/5/2019, 10031268 Exp. 12/10/2019, 10031437 Exp. 12/15/2019, 10031821 Exp. 12/23/2019, 10032285 Exp. 12/30/2019

**Product Description:**

fentaNYL 200 mcg/100 mL (2 mcg/mL) 0.125% Bupivacaine HCl 125 mg/100 mL (1.25 mg/mL) in 0.9% Sodium Chloride, 100 mL CADD Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1202-75

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0557-2020

**Code Information:**

Lots: 10029306 Exp. 11/14/2019, 10029881 Exp. 11/18/2019, 10029748 Exp. 11/17/2019, 10029881 Exp. 11/18/2019, 10029882 Exp. 11/18/2019, 10029854 Exp. 11/19/2019, 10029882 Exp. 11/18/2019, 10030947 Exp. 12/3/2019, 10030894 Exp. 12/2/2019, 10030442 Exp. 11/26/2019, 10031295 Exp. 12/11/2019, 10031319 Exp. 12/11/2019, 10031518 Exp. 12/17/2019, 10031553 Exp. 12/17/2019, 10031468 Exp. 12/16/2019, 10032703 Exp. 1/8/2020, 10032594 Exp. 1/6/2020, 10032543 Exp. 1/5/2020, 10031906 Exp. 12/25/2019, 10031882 Exp. 12/24/2019, 10031802 Exp. 12/23/2019, 10032594 Exp. 1/6/2020, 10032543 Exp. 1/5/2020, 10031906 Exp. 12/25/2019, 10031802 Exp. 12/23/2019, 10031775 Exp. 12/22/2019, 10031582 Exp. 12/18/2019, 10032673 Exp. 1/8/2020, 10032021 Exp. 12/27/2019, 10031582 Exp. 12/18/2019, 10032021 Exp. 12/27/2019, 10031960 Exp. 12/26/2019, 10031906 Exp. 12/25/2019, 10031582 Exp. 12/18/2019, 10032405 Exp. 1/1/2020, 10032021 Exp. 12/27/2019, 10031960 Exp. 12/26/2019, 10032380 Exp. 1/1/2020, 10032673 Exp. 1/8/2020

**Product Description:**

fentaNYL 2750 mcg/55 mL (50 mcg/mL) 55 mL Syringe, Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1100-50

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0558-2020

**Code Information:**

Lots: 10029773 Exp. 11/17/2019, 10029821 Exp. 11/18/2019, 10030351 Exp. 11/21/2019, 10031014 Exp. 12/2/2019, 10030351 Exp. 11/21/2019, 10030912 Exp. 12/2/2019, 10030569 Exp. 11/28/2019, 10030966 Exp. 12/3/2019, 10031796 Exp. 12/23/2019, 10031509 Exp. 12/17/2019, 10031067 Exp. 12/5/2019, 10031156 Exp. 12/16/2019

<p><b>Product Description:</b> fentaNYL 200 mcg/100 mL (2 mcg/mL) BUPivacaine HCl 0.1% 100 mg/100 mL (1 mg/mL) in 0.9% Sodium Chloride 100 mL CADD Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1255-75</p> <p><b>Product Quantity:</b></p> <p><b>Reason for Recall:</b> Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules</p> <p><b>Recall Number:</b> D-0559-2020</p> <p><b>Code Information:</b> Lots: 10029914 Exp. 11/20/2019, 10030342 Exp. 11/24/2019, 10030948 Exp. 12/3/2019, 10030895 Exp. 12/2/2019, 10030949 Exp. 12/3/2019, 10030895 Exp. 12/2/2019, 10031377 Exp. 12/6/2019, 10031141 Exp. 12/9/2019, 10031423 Exp. 12/15/2019, 10031627 Exp. 12/19/2019, 10031709 Exp. 12/22/2019, 10031907 Exp. 12/25/2019, 10032022 Exp. 12/27/2019, 10031858 Exp. 12/24/2019, 10032381 Exp. 1/1/2020, 10032296 Exp. 12/31/2019, 10032268 Exp. 12/30/2019, 10032467 Exp. 1/2/2020, 10032674 Exp. 1/8/2020, 10032569 Exp. 1/6/2020, 10032570 Exp. 1/6/2020, 10032516 Exp. 1/5/2020, 10032517 Exp. 1/5/2020, 10032674 Exp. 1/8/2020, 10032570 Exp. 1/6/2020, 10032675 Exp. 1/8/2020, 10033019 Exp. 1/15/2020,</p>
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<p><b>Product Description:</b> fentaNYL 250 mcg/5 mL (50 mcg/mL), 5 mL Syringe, Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1098-44</p> <p><b>Product Quantity:</b></p> <p><b>Reason for Recall:</b> Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules</p> <p><b>Recall Number:</b> D-0560-2020</p> <p><b>Code Information:</b> Lots: 10030458 Exp. 11/26/2019, 10031113 Exp. 12/5/2019, 10031305 Exp. 12/11/2019, 10031417 Exp. 12/15/2019, 10031765 Exp. 12/26/2019, 10032259 Exp. 12/30/2019</p>
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<p><b>Product Description:</b> fentaNYL 200 mcg/100 mL (2 mcg/mL) ROPivacaine HCl 0.2% 200 mg/100 mL (2 mg/mL) in 0.9% Sodium Chloride , 100 mL bag, Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1108-36</p> <p><b>Product Quantity:</b></p> <p><b>Reason for Recall:</b> Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules</p> <p><b>Recall Number:</b> D-0561-2020</p> <p><b>Code Information:</b> Lots: 10029291 Exp. 11/14/2019 10029292 Exp. 11/14/2019 10029977 Exp. 11/20/2019 10030041 Exp. 11/21/2019 10029977 Exp. 11/20/2019 10029978 Exp. 11/21/2019 10029979 Exp. 11/21/2019 10030041 Exp. 11/21/2019 10030043 Exp. 11/21/2019 10030396 Exp. 11/25/2019 10030960 Exp. 12/2/2019 10030961 Exp. 12/4/2019 10030962 Exp. 12/4/2019 10031010 Exp. 12/4/2019 10031011 Exp. 12/4/2019 10031012 Exp. 12/4/2019 10030960 Exp. 12/2/2019 10031086 Exp. 12/6/2019 10030960 Exp. 12/2/2019 10031263 Exp. 12/10/2019 10031262 Exp. 12/10/2019 10031413 Exp. 12/15/2019 10031463 Exp. 12/16/2019 10031696 Exp. 12/22/2019 10031947 Exp. 12/26/2019 10031948 Exp. 12/31/2019 10032414 Exp. 1/2/2020 10031978 Exp. 1/1/2020 10031948 Exp. 12/31/2019 10032412 Exp. 1/2/2020 10032413 Exp. 1/2/2020 10032687 Exp. 1/8/2020 10032723 Exp. 1/9/2020 10033037 Exp. 1/23/2020 10032929 Exp. 1/26/2020</p>
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<p><b>Product Description:</b> fentaNYL 400 mcg/200 mL (2 mcg/mL) 0.1% ROPivacaine HCl 200 mg/200 mL (1 mg/mL) in 0.9% Sodium Chloride , 200 mL bag, Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1207-37</p> <p><b>Product Quantity:</b></p> <p><b>Reason for Recall:</b> Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules</p> <p><b>Recall Number:</b> D-0562-2020</p> <p><b>Code Information:</b> Lots: 10029343 Exp. 11/15/2019, 10029344 Exp. 11/15/2019, 10029345 Exp. 11/15/2019, 10029895 Exp. 11/20/2019, 10029918 Exp. 11/20/2019,</p>
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10029919 Exp. 11/20/2019, 10029895 Exp. 11/20/2019, 10030398 Exp. 11/25/2019, 10030399 Exp. 11/25/2019, 10030400 Exp. 11/25/2019, 10031089 Exp. 12/6/2019, 10031059 Exp. 12/5/2019, 10031060 Exp. 12/5/2019, 10031061 Exp. 12/5/2019, 10031326 Exp. 12/12/2019, 10031327 Exp. 12/12/2019, 10031507 Exp. 12/17/2019, 10031480 Exp. 12/19/2019, 10031618 Exp. 12/19/2019, 10031619 Exp. 12/19/2019, 10031672 Exp. 12/20/2019, 10031618 Exp. 12/19/2019, 10031504 Exp. 12/18/2019, 10031733 Exp. 12/22/2019, 10031734 Exp. 12/22/2019, 10031672 Exp. 12/20/2019, 10031815 Exp. 12/23/2019, 10031505 Exp. 12/18/2019, 10031506 Exp. 12/17/2019, 10031328 Exp. 12/12/2019, 10031816 Exp. 12/23/2019, 10031897 Exp. 12/25/2019, 10031919 Exp. 12/25/2019, 10031847 Exp. 12/24/2019, 10031791 Exp. 12/23/2019, 10031792 Exp. 12/23/2019, 10031793 Exp. 12/23/2019, 10031817 Exp. 12/23/2019, 10032279 Exp. 12/31/2019, 10031847 Exp. 12/24/2019, 10032279 Exp. 12/31/2019, 10032334 Exp. 12/31/2019, 10032368 Exp. 1/1/2020, 10032392 Exp. 1/1/2020, 10032278 Exp. 12/31/2019, 10032251 Exp. 12/30/2019, 10032252 Exp. 12/30/2019, 10032930 Exp. 1/13/2020, 10032850 Exp. 1/12/2020, 10032584 Exp. 1/6/2020, 10032850 Exp. 1/12/2020, 10032900 Exp. 1/13/2020, 10032583 Exp. 1/7/2020, 10032901 Exp. 1/13/2020, 10032931 Exp. 1/16/2020, 10032900 Exp. 1/13/2020

**Product Description:**

fentaNYL 2000 mcg/100 mL (20 mcg/mL) in 0.9% Sodium Chloride, 100 mL Bag, Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1094-36

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0563-2020

**Code Information:**

Lots: 10029201 Exp. 11/17/2019, 10029983 Exp. 11/22/2019, 10029987 Exp. 11/22/2019, 10030428 Exp. 11/26/2019, 10030879 Exp. 11/28/2019, 10031240 Exp. 12/10/2019, 10031241 Exp. 12/10/2019, 10031344 Exp. 12/12/2019, 10031343 Exp. 12/12/2019, 10031394 Exp. 12/12/2019, 10031612 Exp. 12/19/2019, 10031665 Exp. 12/20/2019, 10031666 Exp. 12/20/2019, 10031590 Exp. 12/18/2019, 10031787 Exp. 12/23/2019, 10032036 Exp. 12/27/2019, 10032305 Exp. 12/31/2019, 10032444 Exp. 1/2/2020, 10033172 Exp. 1/12/2020

**Product Description:**

fentaNYL 400 mcg/200 mL (2 mcg/mL) ROPivacaine HCl 0.1% 200 mg/200 mL (1 mg/mL) in 0.9% Sodium Chloride 200 mL CADD, Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1441-76

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0564-2020

**Code Information:**

Lots: 10029361 Exp. 11/15/2019, 10029362 Exp. 11/15/2019, 10029334 Exp. 11/14/2019, 10029855 Exp. 11/19/2019, 10029856 Exp. 11/19/2019, 10030387 Exp. 11/25/2019, 10030388 Exp. 11/25/2019, 10031026 Exp. 12/12/2019, 10031078 Exp. 12/12/2019, 10031469 Exp. 12/16/2019, 10031493 Exp. 12/16/2019, 10031519 Exp. 12/17/2019, 10031804 Exp. 12/23/2019, 10031105 Exp. 12/12/2019, 10031830 Exp. 12/23/2019, 10031884 Exp. 12/24/2019, 10032704 Exp. 1/8/2020, 10032888 Exp. 1/12/2020, 10032889 Exp. 1/12/2020, 10032913 Exp. 1/13/2020, 10032939 Exp. 1/13/2020, 10032940 Exp. 1/13/2020

**Product Description:**

fentaNYL 200 mcg/100 mL (2 mcg/mL) BUPivacaine HCl 0.1% 100 mg/100 mL (1 mg/mL) in 0.9% Sodium Chloride Preservative Free 100 mL in 150 mL Bag, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1103-36

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0565-2020

**Code Information:**

Lots: 10029200 Exp. 11/18/2019, 10030347 Exp. 11/24/2019, 10031325 Exp. 12/16/2019, 10030939 Exp. 12/3/2019, 10031865 Exp. 12/24/2019, 10031758 Exp. 12/26/2019, 10031757 Exp. 12/26/2019, 10032275 Exp. 12/30/2019

**Product Description:**

fentaNYL 1000 mcg/20 mL (50 mcg/mL) 20 mL in 20 mL Syringe Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1415-47

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0566-2020

**Code Information:**

Lots: 10030359 Exp. 11/21/2019, 10030549 Exp. 11/28/2019, 10031169 Exp. 12/8/2019, 10031491 Exp. 12/16/2019, 10031879 Exp. 12/24/2019, 10032317 Exp. 12/31/2019, 10032265 Exp. 12/30/2019

**Product Description:**

fentaNYL 1250 mcg/250 mL (5 mcg/mL) in 0.9% Sodium Chloride 250 mL Bag Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1444-05

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0567-2020

**Code Information:**

Lots: 10029186 Exp. 11/18/2019, 10029791 Exp. 11/18/2019, 10030403 Exp. 11/25/2019, 10030456 Exp. 11/27/2019, 10030910 Exp. 12/2/2019, 10030403 Exp. 11/25/2019, 10031154 Exp. 12/8/2019, 10031238 Exp. 12/10/2019, 10031182 Exp. 12/9/2019, 10031130 Exp. 12/8/2019, 10031483 Exp. 12/16/2019, 10031482 Exp. 12/16/2019, 10031621 Exp. 12/19/2019, 10031592 Exp. 12/19/2019, 10031921 Exp. 12/25/2019, 10031869 Exp. 12/24/2019, 10032219 Exp. 12/29/2019, 10032393 Exp. 1/1/2020, 10032369 Exp. 1/1/2020, 10032561 Exp. 1/6/2020, 10032586 Exp. 1/6/2020, 10031898 Exp. 12/26/2019

**Product Description:**

fentaNYL 800 mcg/200 mL (4 mcg/mL) BUPivacaine HCl 0.1667% 333.4 mg/200 mL (1.667 mg/mL) in 0.9% Sodium Chloride 200 mL in 250 mL CADD Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1436-76

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0568-2020

**Code Information:**

Lots: 10029972 Exp. 11/21/2019, 10030562 Exp. 11/28/2019, 10031447 Exp. 12/15/2019, 10031341 Exp. 12/15/2019, 10031630 Exp. 12/19/2019, 10031748 Exp. 12/22/2019, 10032817 Exp. 1/8/2020, 10033208 Exp. 1/19/2020, 10032887 Exp. 1/12/2020

**Product Description:**

fentaNYL 2500 mcg/50 mL (50 mcg/mL) 50 mL bag, Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1436-76

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0569-2020

**Code Information:**

Lots: 10030890 Exp. 12/2/2019, 10031264 Exp. 12/10/2019, 10031093 Exp. 12/6/2019, 10032337 Exp. 12/31/2019

**Product Description:**

fentaNYL 1500 mcg/30 mL (50 mcg/mL) 30 mL PCA Vial Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1180-79

**Product Quantity:****Reason for Recall:**

Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules

**Recall Number:**

D-0570-2020

**Code Information:**

Lots: 10030060 Exp. 11/21/2019, 10030574 Exp. 11/28/2019, 10031353 Exp. 12/12/2019, 10031677 Exp. 12/20/2019, 10031622 Exp. 12/19/2019, 10031419 Exp. 12/15/2019, 10031769 Exp. 12/26/2019, 10031826 Exp. 12/23/2019, 10032287 Exp. 12/30/2019

<p><b>Product Description:</b> fentaNYL 1000 mcg/100 mL (10 mcg/mL) in 0.9% Sodium Chloride 100 mL CADD Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1250-75</p> <p><b>Product Quantity:</b></p> <p><b>Reason for Recall:</b> Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules</p> <p><b>Recall Number:</b> D-0571-2020</p> <p><b>Code Information:</b> Lots: 10030341 11/24/2019, 10031102 12/6/2019, 10031555 Exp. 12/18/2019, 10031554 Exp. 12/18/2019, 10031803 Exp. 12/23/2019, 10031776 Exp. 12/22/2019, 10032266 Exp. 12/30/2019, 10032267 Exp. 12/30/2019, 10032321 Exp. 12/31/2019, 10032320 Exp. 12/31/2019, 10032544 Exp. 1/5/2020, 10032515 Exp. 1/5/2020</p>
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<p><b>Product Description:</b> fentaNYL 550 mcg/55 mL (10 mcg/mL) in 0.9% Sodium Chloride 55 mL Syringe Preservative Free, Rx, QuVA Pharma 1075 West Park One Drive, Suite 100 Sugar Land, TX 77478 NDC 70092-1274-50</p> <p><b>Product Quantity:</b></p> <p><b>Reason for Recall:</b> Presence of Particulate matter: manufacturer recalled fentanyl API due to potential for glass particules</p> <p><b>Recall Number:</b> D-0572-2020</p> <p><b>Code Information:</b> Lot: 10031855 Exp. 12/24/2019</p>
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## Class II Drugs Event

<b>Event ID:</b> 84311	<b>Product Type:</b> Drugs
<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 11/21/2019	<b>Voluntary / Mandated:</b> Voluntary: Firm initiated
<b>Center Classification Date:</b> 12/10/2019	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> Pacira Pharmaceuticals, Inc. 10450 Science Center Dr San Diego CA United States	
<b>Distribution Pattern:</b> Distributed Nationwide in the USA	

## Associated Products

<p><b>Product Description:</b> EXPAREL, Bupivacaine Liposome Injectable Suspension, 1.3%, 266 mg/20 mL (13 mg/mL), Sterile, 20 mL vial, Rx only, Manufactured by: Pacira Pharmaceuticals, Inc. San Diego, CA 92121. NDC: 65250-266-20,</p> <p><b>Product Quantity:</b> 910 20 mL vials</p> <p><b>Reason for Recall:</b> Sub Potent Drug: Out of Specification (OOS)</p> <p><b>Recall Number:</b> D-0621-2020</p>
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**Code Information:**

Pacira Lot #: 19-5002, Patheon manufacturer Lot #: 098214; Exp. Date: Dec 2019