

# Enforcement Report - Week of June 8, 2022

## Class II Drugs Event

**Event ID:**

90128

**Product Type:**

Drugs

**Status:**

Ongoing

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

05/05/2022

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

05/27/2022

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

Letter

**Recalling Firm:**

Vi-Jon, LLC  
1 Swan Dr  
Smyrna TN United States

**Distribution Pattern:**

Nationwide in the USA

## Associated Products

**Product Description:**

Equate Tartar Control Plus (Eucalyptol 0.092%, Menthol 0.042%, Methyl salicylate 0.060%, Thymol 0.064%) Antiseptic Mouthrise Plus, Antigingivitis/Antiplaque, Blue Mint, 1.5 Liter (50.7 FL OZ) bottle, Distributed By: Wal-Mart Stores, Inc., Bentonville, AR 72716, UPC 6 81131 14800 9

**Product Quantity:**

75,064 bottles

**Reason for Recall:**

Superpotent Drug: product complaint for milky blue appearance and consistency, further investigation by the firm found the recalled lots out of specification for the four active ingredients.

**Recall Number:**

D-0970-2022

**Code Information:**

Lots: 0559696, 0563041, Exp. 02/2024

## Class II Drugs Event

**Event ID:**

90161

**Product Type:**

Drugs

**Status:**

Ongoing

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

05/05/2022

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

05/27/2022

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

Letter

**Recalling Firm:**

Direct Rx  
94 Worldwide Dr  
Dawsonville GA United States

**Distribution Pattern:**

AL, GA, FL, LA

## Associated Products

**Product Description:**

Losartan Pot./HCTZ 100/12.5 mg Packaged and Distributed By: Direct Rx Dawsonville, GA 30534 Mfg For: Lupin Pharmaceuticals, Inc. Baltimore, MD 21202 a) 30 Tabs NDC 72189-167-30; b) 90 Tabs NDC 72189-167-90

**Product Quantity:**

81 bottles

**Reason for Recall:**

CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

**Recall Number:**

D-0971-2022

**Code Information:**

a) 30-count bottles- Lot: 11MY2103 Exp. 11/30/22 Lot: 05JA2106 Exp. 6/30/22 b) 90-count bottles- Lot: 20MY2115 Exp. 11/30/22 Lot: 22JU2118 Exp. 12/31/22 Lot: 29JY2113 Exp. 12/31/22 Lot: 13SE2113 Exp. 2/28/23 Lot: 05JA2106 Exp. 6/30/22

## Class II Drugs Event

**Event ID:**

90211

**Product Type:**

Drugs

**Status:**

Ongoing

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

05/18/2022

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

05/27/2022

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

Letter

**Recalling Firm:**

Nephron Sterile Compounding Center LLC  
4500 12th Street Ext  
West Columbia SC United States

**Distribution Pattern:**

Nationwide in the USA

## Associated Products

**Product Description:**

8.4% Sodium Bicarbonate Injection, USP, 1 mEq/mL, 4.2 g/50 mL (84 mg/mL), 1 x 50 mL Pre-Filled Syringe, packaged in a) 10 x 1 syringe carton, b) 30 x 1 syringe carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-214-50

**Product Quantity:**

13612 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0950-2022

**Code Information:**

Lots: SB2001A, Exp. 1/2/2023; SB2005B, SB2005C, Exp. 3/8/2023; SB2006A, SB2006B, SB2006C, Exp. 3/16/2023

**Product Description:**

Calcium Gluconate Injection, USP 10%, 0.465 mEq Ca<sup>++</sup>/mL, 1 g/10 mL (100 mg/mL), 10 mL Pre-Filled Syringe, 5 x 10 Pre-filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-950-10

**Product Quantity:**

30180 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0951-2022

**Code Information:**

Lots: CG1003A, Exp. 12/3/2022; CG2001A, Exp. 2/10/2023

**Product Description:**

EPINEPHrine Injection, USP, 0.1 mg/10 mL (10 mcg/mL), 10 mL Pre-Filled Syringe, 5 x 10 mL Pre-filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-544-10

**Product Quantity:**

35850 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0952-2022

**Code Information:**

Lots: EN2005A, Exp. 7/25/2022; EN2009A, Exp. 8/20/2022; EN2010A, Exp. 9/13/2022

**Product Description:**

Epinephrine Injection, USP, 1 mg/10 mL (100 mcg/mL), 10 mL Pre-Filled Syringe, 5 x 10 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-925-10

**Product Quantity:**

134415 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0953-2022

**Code Information:**

Lots: EN1047A, Exp. 6/7/2022; EN2002A, Exp. 7/7/2022; EN2006A, Exp. 7/19/2022; EN2011A, Exp. 9/1/2022

**Product Description:**

Fentanyl Citrate in 0.9% Sodium Chloride Injection, USP, 2500 mcg/250 mL (10 mcg/mL), 150 mL IV Bag, 10 x 1 IV Bag, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-523-21

**Product Quantity:**

3532 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0954-2022

**Code Information:**

Lots: FN1088A, Exp. 6/21/2022; FN1089A, Exp. 6/26/2022

**Product Description:**

Glycopyrrolate Injection, USP, 1 mg/5 mL (0.2 mg/mL), Preservative Free, 5 mL Pre-Filled Syringe, 5 x 5 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-903-05

**Product Quantity:**

32,550 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0955-2022

**Code Information:**

Lot: GL2002B Exp. 8/13/2022

**Product Description:**

Glycopyrrolate Injection, USP, 0.6 mg/3 mL (0.2 mg/mL), Preservative Free, 3 mL Pre-Filled Syringe, 5 x 3 mL Pre-Filled Syringes, 6 x 5 Syringe

Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-903-03

**Product Quantity:**

6150 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0956-2022

**Code Information:**

Lot: GL2002A, Exp. 8/13/2022

**Product Description:**

Hydromorphone HCl Injection, USP, 50 mg/50 mL (1 mg/mL), 50 mL Pre-Filled Syringe, 5 x 50 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-559-50

**Product Quantity:**

2795 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0957-2022

**Code Information:**

Lot: HN2005A, Exp. 9/17/2022

**Product Description:**

Hydromorphone HCl Injection, USP, 6 mg/30 mL (0.2 mg/mL), 30 mL Pre-Filled Syringe, 5 x 30 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-529-30

**Product Quantity:**

6210 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0958-2022

**Code Information:**

Lot: HH2008A, Exp. 9/5/2022

**Product Description:**

Ketamine Hydrochloride Injection, USP, 30 mg/3 mL (10 mg/mL), 3 mL Pre-Filled Syringe, 5 x 3 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-982-33

**Product Quantity:**

30,290 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0959-2022

**Code Information:**

Lot: KH2008A, Exp. 8/8/2022

**Product Description:**

Ketamine Hydrochloride Injection, USP, 50 mg/5 mL (10 mg/mL), 5 mL Pre-Filled Syringe, 5 x 5 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-982-55

**Product Quantity:**

107530 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0960-2022

**Code Information:**

Lots: KH1086A, Exp. 6/24/2022; KH2002B, Exp. 7/5/2022; KH2008B, Exp. 8/8/2022; KH2012A, Exp. 8/23/2022

**Product Description:**

Labetalol HCl Injection, USP, 20 mg/4 mL (5 mg/mL), Preservative Free, 4 mL Pre-Filled Syringe, 5 x 4 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-946-04

**Product Quantity:**

115640 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0961-2022

**Code Information:**

Lots: LB1020A, LB1022A Exp. 5/21/2022; LB2003A, Exp. 8/5/2022; LB2007A, Exp. 9/20/2022

**Product Description:**

Lidocaine HCl Injection, USP, 2%, 100 mg/5 mL (20 mg/mL), Preservative Free, 5 mL Pre-Filled Syringe, 5 x 5 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-949-05

**Product Quantity:**

65590 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0962-2022

**Code Information:**

Lot: LI2001A, Exp. 6/8/2022

**Product Description:**

Neostigmine Methylsulfate Injection, USP, 5 mg/5 mL (1 mg/mL), Preservative Free, 5 mL Pre-Filled Syringe, 5 x 5 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only Nephron 503B outsourcing facility 4500 12th St. Extension West Columbia, SC 29172 NDC: 69374-902-05

**Product Quantity:**

64450 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0963-2022

**Code Information:**

Lots: NE2001A, Exp. 6/30/2022; NE2009B, Exp. 8/27/2022

**Product Description:**

Oxytocin 30 Units/500 mL (0.06 Units/mL) in 0.9% Sodium Chloride Injection, USP, 500 mL Single-Dose Container Bag, 10 x 1 IV Bag, Rx Only Nephron 503B outsourcing facility 4500 12th St. Extension West Columbia, SC 29172 NDC: 69374-543-50

**Product Quantity:**

3587 bags

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0964-2022

**Code Information:**

Lots: OX2008C, Exp. 5/27/2022; OX2010C, Exp. 6/17/2022; OX2011C, OX2011D, Exp. 6/24/2022

**Product Description:**

Phenylephrine HCl Injection, USP, 0.4 mg/10 mL (40 mcg/mL), 10 mL Pre-Filled Syringe, 5 x 10 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx

Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-955-10

**Product Quantity:**

57810 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0965-2022

**Code Information:**

Lots: PE1108A, Exp. 5/27/2022; PE2006A, Exp. 8/3/2022; PE2010A, Exp. 8/12/2022

**Product Description:**

Phenylephrine HCl Injection, USP, 0.8 mg/10 mL (80 mcg/mL), 10 mL Pre-Filled Syringes, 5 x 10 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-956-10

**Product Quantity:**

76860 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0966-2022

**Code Information:**

Lots: PE1107A, Exp. 5/22/2022; PE1123A, Exp. 6/21/2022; PE2007A, Exp. 8/4/2022; PE2012A, Exp. 8/28/2022

**Product Description:**

Phenylephrine HCl Injection, USP, 1 mg/10 mL (100 mcg/mL), 10 mL Pre-Filled Syringe, 5 x 10 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-957-10

**Product Quantity:**

585660 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0967-2022

**Code Information:**

Lots: PE1115B, PE1115C, Exp. 5/31/2022; PE1122A, Exp. 6/19/2022; PE2004B, PE2004C, Exp. 7/11/2022; PE2011A, PE2011C, Exp. 8/22/2022; PE2015A, PE2015B, PE2015C, Exp. 9/5/2022; PE2016A, PE2016B, PE2016C, Exp. 9/13/2022

**Product Description:**

Rocuronium Bromide Injection, 50 mg/5 mL (10 mg/mL), Preservative Free, 5 mL Pre-Filled Syringe, 5 x 5 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-924-05

**Product Quantity:**

604080 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0968-2022

**Code Information:**

Lots: RC1050A, Exp. 5/30/2022; RC1051B, Exp. 6/6/2022; RC1053A, Exp. 6/27/2022; RC2001A, Exp. 7/19/2022; RC2002A, Exp. 8/13/2022; RC2003A, Exp. 8/28/2022; RC2004A, Exp. 9/8/2022

**Product Description:**

Succinylcholine Chloride Injection, USP, 100 mg/5 mL (20 mg/mL), Preservative Free, 5 mL Pre-Filled Syringe, 5 x 5 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-920-05

**Product Quantity:**

181560 syringes

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0969-2022

**Code Information:**

Lots: SU2004A, Exp. 5/18/2022; SU2007A, Exp. 6/2/2022

## Class II Drugs Event

**Event ID:**

90229

**Product Type:**

Drugs

**Status:**

Ongoing

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

05/16/2022

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

05/28/2022

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

Strides Pharma Inc.  
2 Tower Center Blvd Ste 1102  
East Brunswick NJ United States

**Distribution Pattern:**

Nationwide

## Associated Products

**Product Description:**

Losartan Potassium Tablets, USP 25 mg, Rx only, Manufactured by: Vivimed Life Sciences Private Limited, Plot No., 101, 102, 107 & 108, SIDCO Pharmaceutical Complex, Alathur, Kanchipuram - 603 110, Tamilnadu, India, Distributed by: Strides Pharma Inc., East Brunswick, NJ 08816. 90 film coated tablets NDC 64380-933-05 1000 film coated tablets NDC 64380-933-08

**Product Quantity:**

200407 bottles

**Reason for Recall:**

CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

**Recall Number:**

D-0972-2022

**Code Information:**

NDC 64380-933-05 Lots 7901007A, Exp Date Jun-22; Lots 7901144A,7901178A & 7901179A, Exp Date Sep-22; Lots 7901246A & 7901247A, Exp Date Oct-22; Lot 7901343A, Exp Date Dec-22. NDC 64380-933-08 7901006A, Exp Date Jun-22; 7901145A,& 7901180A, Exp Date Sep-22 & 7901181A, Exp Date Oct-22.

**Product Description:**

Losartan Potassium Tablets, USP, 50 mg, Rx Only, Manufactured by: Vivimed Life Sciences Private Limited, Plot No., 101, 102, 107 & 108, SIDCO Pharmaceutical Complex, Alathur, Kanchipuram - 603 110, Tamilnadu, India, Distributed by: Strides Pharma Inc., East Brunswick, NJ 08816. 90 film coated tablets NDC 64380-934-05 1000 film coated tablets NDC 64380-934-08

**Product Quantity:**

381456 bottles

**Reason for Recall:**

CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

**Recall Number:**

D-0973-2022

**Code Information:**

NDC 64380-934-05 7901146A, 7901147A, 7901148A &7901149A, Exp. Date Sep-22 7901279A, Exp. Date Nov-22

7901280A,7901281A,7901282A,7901283A,7901284A, 7901359A, 7901360A & 7901361A, Exp. Date Dec 22; 7901362A, 7901406A, 7901407A, 7901408A & 7901409A, Exp Date Jan-23 64380-934-08 7901008A & 7901009A, Exp Date Jun-22; 7901150A & 7901151A, Exp Date Sep-22; 7901285B, 7901286B, 7901287A, 7901288A, 7901289A, 7901290A , 7901291A, 7901292A, 7901293A & 7901294A, Exp Date Nov-22

**Product Description:**

Losartan Potassium Tablets, USP, 100 mg, Rx Only, Manufactured by: Vivimed Life Sciences Private Limited, Plot No., 101, 102, 107 & 108, SIDCO Pharmaceutical Complex, Alathur, Kanchipuram - 603 110, Tamilnadu, India, Distributed by: Strides Pharma Inc., East Brunswick, NJ 08816. 90 film coated tablets NDC 64380-935-05 1000 film coated tablets NDC 64380-935-08

**Product Quantity:**

96966 bottles

**Reason for Recall:**

CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits

**Recall Number:**

D-0974-2022

**Code Information:**

64380-935-05 7901047B, 7901048B, 7901049B & 7901050B Exp Date Jul-22 7901185A, 7901186A, 7901187A & 7901188A, Exp Date Oct-22 7801250A, 7801251A & 7801252A Exp Date Nov-22 7901185A, 7901186A, 7901187A, 7901188A, Exp Date Oct 22 7901250A, 7901251A & 7901252A, Exp Date Nov 22 64380-935-08 7900813B May-22 7900814B May-22 7900908A May-22 7900935A May-22 7900936A May-22 7900937A May-22 7900938A May-22 7900939B May-22

## Class II Drugs Event

**Event ID:**

90270

**Product Type:**

Drugs

**Status:**

Ongoing

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

05/17/2022

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

05/31/2022

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

E-Mail

**Recalling Firm:**

Family Dollar Stores, Llc.  
500 Volvo Pkwy  
Chesapeake VA United States

**Distribution Pattern:**

USA Nationwide

## Associated Products

**Product Description:**

Only At Family Dollar AMBI Skincare Even & Clear Nourishing Daily Facial Moisturizer With Broad Spectrum SPF 30 Sunscreen, Net Wt. 1.7 FL. OZ. (50 mL)

**Product Quantity:**

Unknown

**Reason for Recall:**

cGMP deviations: product stored outside of labeled temperature requirements.

**Recall Number:**

D-0975-2022

**Code Information:**

SKUs 2096628.

**Product Description:**

AMBI Skincare Fade Cream Normal Skin, Net Wt. 2 OZ. (56g)

**Product Quantity:**



**Reason for Recall:**

cGMP deviations: product stored outside of labeled temperature requirements.

**Recall Number:**

D-0976-2022

**Code Information:**

SKUs 2024222

**Product Description:**

AMBI Skincare Fade Cream Oily Skin New & Improved, Net Wt. 2 OZ (56g)

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

cGMP deviations: product stored outside of labeled temperature requirements.

**Recall Number:**

D-0977-2022

**Code Information:**

SKUs 2024219

**Product Description:**

AMBI Skincare Even & Clear Exfoliating Wash Salicylic Acid Acne Treatment With Oat and Sea Whip, Net Wt. 5 OZ. (141 g)

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

cGMP deviations: product stored outside of labeled temperature requirements.

**Recall Number:**

D-0978-2022

**Code Information:**

SKUs 2097153

**Product Description:**

Luxury Hygiene Hand Sanitizer Moisturizing Formula with Vitamin E Advanced Aloe Vera, 8 FL. OZ. (236 mL), TSM Brands LLC 540 Equinox Ln Manalapan, NJ 07726, UPC 6 86275 96537 6

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

cGMP deviations: product stored outside of labeled temperature requirements.

**Recall Number:**

D-0979-2022

**Code Information:**

SKUs 2007625

**Product Description:**

Luxury Hygiene Hand Sanitizer Moisturizing Formula with Vitamin E, 8 FL. OZ. (236 mL), TSM Brands LLC 540 Equinox Ln Manalapan, NJ 07726, UPC 6 86275 96536 9

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

cGMP deviations: product stored outside of labeled temperature requirements.

**Recall Number:**

D-0980-2022

**Code Information:**

SKUs 2007626

**Product Description:**

Aveeno Daily Moisturizing Lotion Fragrance Free with Soothing Oat & Rich Emollients, Net Wt. 5 oz (141 g), Distributed by Johnson & Johnson Consumer, Inc. Skillman, NJ 08558, UPC 3 81137-001530 7

**Product Quantity:**

Unknown

**Reason for Recall:**

cGMP deviations: product stored outside of labeled temperature requirements.

**Recall Number:**

D-0981-2022

**Code Information:**

SKUs 2005444

## Not Yet Classified Drugs Event

**Event ID:**

90182

**Product Type:**

Drugs

**Status:**

Ongoing

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

05/11/2022

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:****Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**Teva Pharmaceuticals USA Inc  
400 Interpace Pkwy Bldg A  
Parsippany NJ United States**Distribution Pattern:**

Distributed Nationwide in the USA

## Associated Products

**Product Description:**

Teva Anagrelide Capsules, USP 0.5 mg, Rx Only, 100 Capsules, Manufactured in India For: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454. NDC 0172-5241-60.

**Product Quantity:**

4224 cartons

**Reason for Recall:**

Failed Dissolution Specifications- Stability testing revealed lower dissolution - taking longer to dissolve once ingested.

**Recall Number:****Code Information:**

Lot # GD01090, Exp 05/2022