

# Enforcement Report - Week of May 1, 2019

## Class II Drugs Event

**Event ID:**

82620

**Product Type:**

Drugs

**Status:**

Ongoing

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

04/12/2019

**Voluntary / Mandated:**

Voluntary: Firm Initiated

**Center Classification Date:**

04/23/2019

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

Letter

**Recalling Firm:**

CMC Enterprise Pharmacy  
4400 Golf Acres Dr  
Charlotte NC United States

**Distribution Pattern:**

NC

## Associated Products

**Product Description:**

Dexmedetomidine 400 mcg in NS 100 mL bag, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

5678 bags

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1209-2019

**Code Information:**

Lots: EA141908 Exp. 4/14/2019; EA171909 Exp. 4/17/2019; EA211906 Exp. 4/21/2019; EA251908 Exp. 4/25/2019; EB041905 Exp. 5/6/2019; EB071907 Exp. 5/8/2019; EB151909 Exp. 5/16/2019; EC041906 Exp. 6/2/2019; EC111907 Exp. 6/9/2019; EC181908 Exp. 6/16/2019; EC201907 Exp. 6/18/2019

**Product Description:**

Clindamycin 900 mg in NS 50 mL bag, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

1233 bags

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1210-2019

**Code Information:**

Lots: EA211905 Exp. 4/21/2019; EB061906 Exp. 5/7/2019; EB131907 Exp. 5/14/2019; EB221907 Exp. 5/23/2019; EC251909 Exp. 6/23/2019

**Product Description:**

Diltiazem 250 mg in NS 250 mL bag, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

1475 bags

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1211-2019

**Code Information:**

Lots: EA161906 Exp. 4/16/2019; EA181906 Exp. 4/18/2019; EA231907 Exp. 4/23/2019; EA241907 Exp. 4/24/2019; EB061907 Exp. 5/7/2019; EB201907 Exp. 5/21/2019; EC181909 Exp. 6/16/2019

**Product Description:**

Labetalol 20 mg/4 mL, 20 mg in 4 mL syringe, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

6667 syringes

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1212-2019

**Code Information:**

Lots: EA241908 Exp. 4/24/2019; EB011905 Exp. 5/2/2019; EB081909 Exp. 5/9/2019; EB151910 Exp. 5/16/2019; EB251909 Exp. 5/26/2019; EC061907 Exp. 6/4/2019; EC151906 Exp. 6/13/2019

**Product Description:**

Magnesium Sulfate 1 GM in NS 50 mL bag, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

2162 bags

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1213-2019

**Code Information:**

Lots: EK051810 Exp. 5/4/2019; EK281808 Exp. 5/27/2019; EL101810 Exp. 6/8/2019; EL141807 Exp. 6/12/2019; EA081910 Exp. 7/7/2019; EA161908 Exp. 7/15/2019; EA301908 Exp. 7/29/2019; EB111907 Exp. 8/10/2019; EC041907 Exp. 8/31/2019

**Product Description:**

Magnesium Sulfate 2 GM in NS 50 mL bag, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

6746 bags

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1214-2019

**Code Information:**

Lots: EK021807, EK021807A Exp. 5/1/2019; EK261807 Exp. 5/25/2019; EK271808 Exp. 5/26/2019; EK301811 Exp. 5/29/2019; EL261811 Exp. 6/24/2019; EL281808 Exp. 6/26/2019; EA031908 Exp. 7/2/2019; EA111908 Exp. 7/10/2019; EA181907 Exp. 7/17/2019; EA281908 Exp. 7/27/2019; EB071908 Exp. 8/6/2019; EB201909 Exp. 8/19/2019; EC151907 Exp. 9/11/2019.

**Product Description:**

Magnesium Sulfate 4 GM in NS 50 mL bag, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

3007 bags

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1215-2019

**Code Information:**

Lots: EK131812 Exp. 5/12/2019; EL051809 Exp. 6/3/2019; EL111808 Exp. 6/9/2019; EL141808 Exp. 6/12/2019; EA031909 Exp. 7/2/2019; EA141909 Exp. 7/13/2019; EA311910 Exp. 7/30/2019; EB061909 Exp. 8/5/2019; EC121909 Exp. 9/8/2019; EC251910 Exp. 9/21/2019

**Product Description:**

Magnesium Sulfate 6 GM in NS 50 mL bag, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

196 bags

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1216-2019

**Code Information:**

Lots: EA111909 Exp. 7/10/2019; EB061910 Exp. 8/5/2019; EB131909 Exp. 8/12/2019

**Product Description:**

NICARDipine 25 mg in NS 250 mL EXCEL bag, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

1783 bags

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1217-2019

**Code Information:**

Lots: EA161909 Exp. 4/16/2019; EA211907 Exp. 4/21/2019; EB041906 Exp. 5/5/2019; EB111908 Exp. 5/12/2019; EB181907 Exp. 5/19/2019; EB251910 Exp. 5/26/2019; EC111908 Exp. 6/9/2019; EC201909 Exp. 6/18/2019; EC261909 Exp. 6/24/2019; EC271919 Exp. 6/25/2019

**Product Description:**

Norepinephrine 16 mg in NS 250 mL bag, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

2567 bags

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1218-2019

**Code Information:**

Lots: EA151909 Exp. 4/15/2019; EA251907 Exp. 4/25/2019; EA301909 Exp. 4/30/2019; EA311911 Exp. 5/1/2019; EB131910 Exp. 5/14/2019; EB201910 Exp. 5/21/2019; EB271909 Exp. 5/28/2019; EC081910 Exp. 6/6/2019; EC131908 Exp. 6/11/2019

**Product Description:**

Oxytocin 30 units in NS 500 mL bag, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

3690 bags

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1219-2019

**Code Information:**

Lots: EA241909 Exp. 4/24/2019; EA281909 Exp. 4/28/2019; EA301910 Exp. 4/30/2019; EB111909 Exp. 5/12/2019; EB141909 Exp. 5/15/2019; EB221908 Exp. 5/23/2019; EC061908 Exp. 6/4/2019; EC131909 Exp. 6/11/2019; EC261910 Exp. 6/24/2019

**Product Description:**

Alteplase 1 mg/mL 1 mL in 10 mL syringe, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

97 syringes

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1220-2019

**Code Information:**

Lots: ED021901 Exp. 5/17/2019; ED031921 Exp. 5/18/2019

**Product Description:**

Lidocaine Buffered with J-Tip 0.25 mL, 1 mL syringe, 10:1, For Intradermal Use Only, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

705 syringes

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1221-2019

**Code Information:**

Lots: ED041901 Exp. 4/13/2019; ED051901 Exp. 4/14/2019; ED081901 Exp. 4/17/2019; ED01901 Exp. 4/18/2019; ED101901 Exp. 4/19/2019; ED111901 Exp. 4/20/2019

**Product Description:**

Lidocaine 1% - Sodium Bicarb 8.4% 10:1, 10 mL syringe, For Intradermal Use Only, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

40 syringes

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1222-2019

**Code Information:**

Lots: ED051902 Exp. 4/14/2019; ED101902 Exp. 4/19/2019

**Product Description:**

Lidocaine 1% - Sodium Bicarbonate 8.4% 1:1, 1 mL syringe, For Intradermal Use Only, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

1135 syringes

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1223-2019

**Code Information:**

Lots: ED041902 Exp. 4/13/2019; ED051903 Exp. 04/14/2019; ED081902 Exp. 4/17/2019; ED091902 Exp. 4/18/2019; ED101903 Exp. 4/19/2019; ED111902 Exp. 4/20/2019

**Product Description:**

CeFAZolin 1 GM a) in NS 100 mL bag; b) 100 mg/mL (10 mL) syringe, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

a) 150 bags; b)1369 syringes

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1224-2019

**Code Information:**

Lots: a) ED051904 Exp. 4/14/2019; ED081903 Exp. 4/17/2019; ED091903 Exp. 4/18/2019; ED111903 Exp. 4/20/2019; b) EB271904 Exp. 4/13/2019; EB281904 Exp. 4/14/2019; EC011903 Exp. 4/15/2019; EC051904 Exp. 4/19/2019; EC071904 Exp. 4/21/2019; EC081905 Exp. 4/22/2019; EC121905 Exp. 4/26/2019; EC131903 Exp. 4/27/2019; EC141903 Exp. 4/28/2019; EC151903 Exp. 4/29/2019; EC181904 Exp. 5/2/2019; EC191905 Exp. 5/3/2019; EC211904 Exp. 5/5/2019; EC221905 Exp. 5/6/2019; EC251904 Exp. 5/9/2019; EC271904 Exp. 5/11/2019;

EC281904 Exp. 5/12/2019; ED011904 Exp. 5/16/2019; ED021906 Exp. 5/17/2019; ED031904 Exp. 5/18/2019; ED041903 Exp. 5/19/2019; ED051905 Exp. 5/20/2019; ED081904 Exp. 5/23/2019; ED091904 Exp. 5/24/2019; ED101904 Exp. 5/25/2019; ED111904 Exp. 5/26/2019

**Product Description:**

CeFAZolin 2 GM a) in NS 100 mL bag; b) 100 mg/mL (20 mL) syringe, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

a) 1357 bags; b) 6895 syringes

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1225-2019

**Code Information:**

Lots: a) ED041904 Exp. 4/13/2019; ED051906 Exp. 4/14/2019; ED081905 Exp. 4/17/2019; ED091905 Exp. 4/18/2019; ED111905 Exp. 4/20/2019; b) EB271906 Exp. 4/13/2019; EB281906 Exp. 4/14/2019; EC051906 Exp. 4/19/2019; EC061905 Exp. 4/20/2019; EC071906 Exp. 4/21/2019; EC081907 Exp. 4/22/2019; EC111905 Exp. 4/25/2019; EC121907 Exp. 4/26/2019; EC131905 Exp. 4/27/2019; EC141905 Exp. 4/28/2019; EC151905 Exp. 4/29/2019; EC181906 Exp. 5/2/2019; EC191907 Exp. 5/3/2019; EC201905 Exp. 5/4/2019; EC211906 Exp. 5/5/2019; EC221907 Exp. 5/6/2019; EC251906 Exp. 5/9/2019; EC261906 Exp. 5/10/2019; EC271906 Exp. 5/11/2019; EC281906 Exp. 5/12/2019; EC011904 Exp. 5/16/2019; ED021908 Exp. 5/17/2019; ED031906 Exp. 05/18/2019; ED041905 Exp. 5/19/2019; ED051907 Exp. 5/20/2019; ED081906 Exp. 5/23/2019; ED091905 Exp. 5/24/2019; ED101906 Exp. 5/25/2019; ED111906 Exp. 5/26/2019

**Product Description:**

CeFAZolin 3 gm 100 mg/mL, 30 mL syringe, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

475 syringes

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1226-2019

**Code Information:**

Lots: EB281907 Exp. 4/14/2019; EC011905 Exp. 4/15/2019; EC071907 Exp. 4/21/2019; EC081908 Exp. 4/22/2019; EC131906 Exp. 4/27/2019; EC141906 Exp. 4/28/2019; EC151919 Exp. 4/29/2019; EC181907 Exp. 5/2/2019; EC201906 Exp. 5/4/2019; EC211907 Exp. 5/5/2019; EC221908 Exp. 5/6/2019; EC251907 Exp. 5/9/2019; EC261907 Exp. 5/10/2019; EC271907 Exp. 5/11/2019; EC281907 Exp. 5/12/2019; EC011907 Exp. 5/16/2019; ED021909 Exp. 5/17/2019; ED031907 Exp. 5/18/2019; ED041906 Exp. 5/19/2019; ED051908 Exp. 5/20/2019; ED081907 Exp. 5/23/2019; ED091907 Exp. 5/24/2019

**Product Description:**

CefTRIAxone 1 GM, 100 mg/mL, 10 mL syringe, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

15 syringes

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1227-2019

**Code Information:**

Lots: EB271907 Exp. 4/13/2019; ED041907 Exp. 5/19/2019

**Product Description:**

Chlorothiazide 100 mg, 3.57 mL syringe, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

60 syringes

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1228-2019

**Code Information:**

Lots: ED041908 Exp. 4/18/2019; ED051909 Exp. 4/19/2019; ED081908 Exp. 4/22/2019

**Product Description:**

Heparin Pork 30,000 Units in NS 1000 mL bag, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

87 bags

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1229-2019

**Code Information:**

Lots: ED091908 Exp. 4/18/2019; ED101908 Exp. 4/19/2019

**Product Description:**

Phenylephrine 0.8 mg/10 mL NS (0.08 mg/mL), (80 mcg/mL) syringe, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

1310 syringes

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1230-2019

**Code Information:**

Lots: ED041911 Exp. 4/13/2019; ED051910 Exp. 4/14/2019; ED081910 Exp. 4/17/2019; ED091909 Exp. 4/18/2019; ED101910 Exp. 4/19/2019; ED111908 Exp. 4/20/2019

**Product Description:**

Phenylephrine 20 mg NS 250 mL bag, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

390 bags

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1231-2019

**Code Information:**

Lots: ED051911 Exp. 4/14/2019; ED081911 Exp. 4/17/2019; ED091910 Exp. 4/18/2019; ED101911 Exp. 4/19/2019; ED111909 Exp. 4/20/2019

**Product Description:**

Phenylephrine 40 mg in 0.9% Sodium Chloride 250 mL bag, 160 mcg/mL, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

215 bags

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1232-2019

**Code Information:**

Lots: ED041912 Exp. 4/13/2019; ED051912 Exp. 4/14/2019; ED081912 Exp. 4/17/2019; ED091911 Exp. 4/18/2019; ED101912 Exp. 4/19/2019; ED111910 Exp. 4/20/2019

**Product Description:**

Sodium Bicarbonate 150 mEq in D5W 1000 mL bags, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

100 bags

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1233-2019

**Code Information:**

Lots: ED041913 Exp. 4/13/2019; ED051913 Exp. 4/14/2019; ED081913 Exp. 4/17/2019; ED091913, ED091912 Exp. 4/18/2019; ED101914, ED101913 Exp. 4/19/2019; ED111911 Exp. 4/20/2019

**Product Description:**

Sodium Citrate 4%, 40 mg/mL, 3 mL syringe, Flush Syringe, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

40 syringes

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1234-2019

**Code Information:**

Lots: ED031915 Exp. 4/17/2019; ED041919 Exp. 4/18/2019; ED091914 Exp. 4/23/2019; ED111912 Exp. 4/25/2019

**Product Description:**

Vancomycin 1000 mg in NS 250 mL bag, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

532 bags

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1235-2019

**Code Information:**

Lots: ED041918 Exp. 4/13/2019; ED051918 Exp. 4/14/2019; ED081918 Exp. 4/17/2019; ED091918 Exp. 4/18/2019; ED101918 Exp. 4/19/2019; ED111916 Exp. 4/20/2019

**Product Description:**

Vancomycin 1250 mg in NS 250 mL bag, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

737 bags

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1236-2019

**Code Information:**

Lots: ED041915 Exp. 4/13/2019; ED051915 Exp. 4/14/2019; ED081915 Exp. 4/17/2019; ED091915 Exp. 4/18/2019; ED101915 Exp. 4/19/2019; ED111913 Exp. 4/20/2019

**Product Description:**

Vancomycin 1500 mg in NS 250 mL bag, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.

**Product Quantity:**

715 bags

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-1237-2019

**Code Information:**

Lots: ED041916 Exp. 4/13/2019; ED051916 Exp. 4/14/2019; ED081916 Exp. 4/17/2019; ED091916 Exp. 4/18/2019; ED101916 Exp. 4/19/2019; ED111914 Exp. 4/20/2019

<p><b>Product Description:</b> Vancomycin 1750 mg in 0.9% Sodium Chloride 500 mL bag, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.</p> <p><b>Product Quantity:</b> 118 bags</p> <p><b>Reason for Recall:</b> Lack of sterility assurance.</p> <p><b>Recall Number:</b> D-1238-2019</p> <p><b>Code Information:</b> Lots: ED041918 Exp. 4/13/2019; ED051917 Exp. 4/14/2019; ED081917 Exp. 4/17/2019j; ED091917 Exp. 4/18/2019; ED1019117 Exp. 4/19/2019; ED111915 Exp. 4/20/2019</p>
--

<p><b>Product Description:</b> Vancomycin 2000 mg in 0.9% Sodium Chloride 500 mL bag, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.</p> <p><b>Product Quantity:</b> 532 bags</p> <p><b>Reason for Recall:</b> Lack of sterility assurance.</p> <p><b>Recall Number:</b> D-1239-2019</p> <p><b>Code Information:</b> Lots: ED041919 Exp. 4/13/2019; ED051919 Exp. 4/14/2019; ED041919 Exp. 4/17/2019; ED091919 Exp. 4/18/2019; ED101919 Exp. 4/19/2019; ED111917 Exp. 4/20/2019</p>
--

<p><b>Product Description:</b> DelNido Cardioplegia (Normosol-R pH 7.4 or Plasma-Lyte A pH 7.4 1000 mL bag) Mannitol 20%-16.3 mL, Potassium Chloride 2 meq/mL-13 mL, Sodium Bicarbonate 8.4%-Lidocaine 1%-1:1 Dilution-26 mL, Magnesium Sulfate 500 mg/mL-4 mL, Cardiac Perfusion Only - Not for IV Use, Made by: Enterprise Pharmacy, 4400 Golf Acres Drive, Bldg. J Suite E, Charlotte, NC, 28208.</p> <p><b>Product Quantity:</b> 110 bags</p> <p><b>Reason for Recall:</b> Lack of sterility assurance.</p> <p><b>Recall Number:</b> D-1240-2019</p> <p><b>Code Information:</b> Lots: ED041909 Exp. 4/13/2019; ED111907 Exp. 4/20/2019</p>
---

## Class III Drugs Event

**Event ID:**

82657

**Status:**

Ongoing

**Recall Initiation Date:**

04/23/2019

**Center Classification Date:**

04/24/2019

**Recalling Firm:**

Akorn Inc  
1925 W Field Ct Ste 300  
Lake Forest IL United States

**Product Type:**

Drugs

**Date Terminated:**

**Voluntary / Mandated:**

Voluntary: Firm Initiated

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

Letter



**Distribution Pattern:**

U.S.A. Nationwide

**Associated Products****Product Description:**

Fentanyl Citrate Injection, USP, 100 mcg/2 mL (50 mcg/mL), 25 Ampules per carton, (2 mL each), Rx only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045, NDC 17478-030-25

**Product Quantity:**

5,380 cartons (25 ampules per carton)

**Reason for Recall:**

Failed impurities/degradation specification: Out of Specification result for total impurity at 4.0% (Limit: NMT 3.0%) at 12 months stability testing.

**Recall Number:**

D-1241-2019

**Code Information:**

Lot #: 011198, Exp 01/22