Enforcement Report - Week of February 2, 2022

Class II Drugs Event

Event ID:
89172

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/06/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/24/2022

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Edge Pharma, LLC
856 Hercules Dr
Colchester VT United States

Distribution Pattern:
nationwide

Associated Products

Product Description:
ALUM Concentrate (Aluminum Potassium Sulfate Dodecahydrate in Sterile Water (PF) 30 g/300 ml, IV bag, Rx Only, Edge Pharma, LLC, 856 Hercules Dr, Colchester, VT 05446, NDC 05446-0637-03

Product Quantity:
30 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0394-2022

Code Information:
08-2021-25@2 12/08/2021 09-2021-08@1 12/23/2021 10-2021-20@3 02/01/2022

Product Description:
Lidocaine HCl Sterile Buffered Solution for Injection (PF) 1%, 10mL per syringe, Single Use Syringe for Infiltration and Nerve Block, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-0850-10

Product Quantity:
4465 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0395-2022

Code Information:
08-2021-27@3 12/09/2021 09-2021-24@1 01/06/2022 10-2021-14@2 01/31/2022

Product Description:
Lidocaine HCl/Epinephrine, Sterile Buffered Solution for Injection (PF) 1% / 1:100,000, 3 mL per syringe, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, (802) 992-1178, NDC 05446-1268-01

Product Quantity:
8140 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0396-2022

Code Information:
10-2021-25@4 12/08/2021 11-2021-08@6 12/22/2021

Product Description:
Ceftazidime, Sterile Ophthalmic Solution for Injection, Preservative Free (11.25 mg/0.5 mL (22.5 mg/mL), 0.5mL single use syringe for Intraocular Injection, Edge Pharma, LLC, 656 Hercules Dr., Colchester, VT 05446, NDC 05446-0733-01

Product Quantity:
168 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0397-2022

Code Information:
09-2021-01@6 12/14/2021 & 10-2021-27@4 01/01/2022

Product Description:
Cefuroxime, Sterile Ophthalmic Solution for Injection, Preservative Free, 3mg/0.3mL (10 mg/mL), 0.3 mL single use syringe for Intraocular Injection, Edge Pharma, LLC, 656 Hercules Dr., Colchester, VT 05446 NDC 05446-1003-01

Product Quantity:
1720 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0398-2022

Code Information:
08-2021-30@1 12/20/2021, 09-2021-21@5 01/03/2022 & 10-2021-18@5 02/07/2022

Product Description:
Dexamethasone sodium phosphate, sterile otic solution for injection Preservative free, 19.2 mg/0.8mL (24mg/mL), 0.8 mL per syringe Single Use Syringe For Otic Injection, Edge Pharma LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-0848-01

Product Quantity:
323 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0399-2022

Code Information:
09-2021-28@1 01/10/2022

Product Description:
Edetate Disodium (EDTA), Sterile Ophthalmic Solution (PF) 1.5%, 10 mL per dropper, Single Dose Droptainer for Topical Ophthalmic Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT, 05446, NDC 05446-1427-10

Product Quantity:
80 droppers

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-0400-2022

Code Information:
10-2021-20@1 02/10/2022

Product Description:
Edetate Disodium (EDTA), Sterile Ophthalmic Solution, (PF) 3%, 10mL per dropper, Single Dose Droptainer for Topical Ophthalmic Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT, 05446, NDC 05446-1428-10

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0401-2022

Code Information:
09-2021-22@1 01/04/2022

Product Description:
Epinephrine/Lidocaine HCl Sterile Ophthalmic Solution for Injection, Preservative Free, 0.025%/0.75%, 0.8 mL per syringe, Single Use Syringe, For Intraocular Injection, Edge Pharma, LLC, 856 Hercules Dr. Colchester, VT 05446, NDC 05446-0863-01

Product Quantity:
2568 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0402-2022

Code Information:
10-2021-18@4 12/08/2021& 11-2021-01@3 12/22/2021

Product Description:
Gemcitabine, Sterile Intravesical Solution, Preservative Free, 1g/50mL (20 mg/mL), 50 mL per syringe, Single Dose Syringe for Intravesical Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1566-50

Product Quantity:
627 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0403-2022

Code Information:
08-2021-18@1 12/14/2021, 08-2021-27@1 12/09/2021, 09-2021-01@4 12/14/2021, 09-2021-08@2 12/21/2021, 09-2021-14@6 01/05/2021, 09-2021-16@4 12/29/2021, 09-2021-17@4 12/30/2021, 09-2021-22@3 01/04/2022 & 10-2021-27@3 02/08/2022

Product Description:
Lidocaine HCL / Bupivacaine HCL (contains Hyaluronidase 15 units/mL), Sterile Ophthalmic Solution for Injection (PF), 2%/0.375%, 8 mL per syringe, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1548-18

Product Quantity:
1202 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0404-2022

Code Information:
10-2021-26@3 12/04/2021 11-2021-09@1 12/23/2021

Product Description:
Methacholine Challenge 5-Syringe Test Kit, Sterile Inhalation Solution, Preservative Free, 3 mL per syringe,(NDC 05446-1600-05), Kit includes; individual syringe: Methacholine Chloride,16 mg/mL (contains 48 mg) NDC 05446-1241-01; Methacholine Chloride 4 mg/mL (contains 12mg), NDC 05446-1246-01; Methacholine chloride 1mg/mL (contains 3 mg), NDC 05446-1247-01; Methacholine chloride 0.25mg/mL (contains 0.75mg), NDC 05446-1248-01; and Methacholine chloride 0.0625mg/mL NDC 05446-1249-01 Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446

Product Quantity:
1007 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0405-2022

Code Information:
09-2021-03@6 12/16/2021 & 10-2021-06@7 01/18/2022

Product Description:

Methotrexate, USP, Sterile Solution for Injection (PF), 125 mg/5mL (2mg/mL), 5 mL per syringe, Edge Pharma, LLC, 856 Hercules Dr, Colchester, VT 05446, NDC 05446-1505-05

Product Quantity:
457 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0406-2022

Code Information:
09-2021-10@2 12/23/2021, 10-2021-21@2 02/01/2022 & 11-2021-09@5 02/21/2022

Product Description:
Mitomycin-C, 40mg/40mL (1mg/mL), 40 mL per syringe, Single Dose Syringe for Intravesical Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1416-01

Product Quantity:
860 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0407-2022

Code Information:
08-2021-24@5 12/09/2021, 08-2021-27@2 12/21/2021, 08-2021-31@5 12/14/2021, 09-2021-02@2 12/15/2021, 09-2021-09@2 12/22/2021, 09-2021-15@3 12/29/2021, 09-2021-22@2 01/04/2022 & 10-2021-26@5 02/07/2022

Product Description:
Mitomycin-C Sterile Ophthalmic Solution, Preservative Free, 0.32mg/0.8 mL (0.4mg/mL) 0.8 mL per syringe, Single Use Syringe, For Topical Ophthalmic Use, Edge Pharma LLC, 856 Hercules Dr. Colchester, VT 05446, NDC 05446-1009-01

Product Quantity:
163 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0408-2022

Code Information:
11-2021-08@8 12/18/2021

Product Description:
Mitomycin-C, Sterile Ophthalmic Solution, Preservative Free, 0.16mg/0.8mL (0.2 mg/mL), 0.8 mL per syringe, Single Use Syringe, For Topical Ophthalmic Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1011-01

Product Quantity:
154 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0409-2022

Code Information:
11-2021-08@9 12/18/2021

Product Description:
Moxifloxacin, Sterile Ophthalmic Solution for Injection, Preservative Free, 0.8mg/0.8 mL (1mg/mL), 0.8 mL per syringe, Single Use Syringe, For Intraocular Injection, Edge Pharma, LL, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1050-01

Product Quantity:
860 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:

D-0410-2022

Code Information:
08-2021-26@2 12/09/2021 & 09-2021-23@1 01/05/2022

Product Description:
Neostigmine methylsulfate, 5 mg/5mL (1 mg/mL), 5 mL per syringe, Single Use Syringe for IV or IM Injection, Edge Pharma, LLC, 856 Hercules Dr. Colchester, VT 05446, NDC 05446-1549-05

Product Quantity:
160 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0411-2022

Code Information:
10-2021-07@1 01/19/2022

Product Description:
MVASI, (bevacizumab-awwb), Sterile Ophthalmic Solution for Injection, 3.25mg/0.13mL (25 mg/mL) 0.13 mL per syringe, Dose: 1.25mg/0.05mL, Single Use Syringe For Intraocular Injection, Edge Pharma, LLC, 856 Hercules Dr. Colchester, VT 05446, NDC 05446-1661-13

Product Quantity:
199 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0412-2022

Code Information:
11-2021-01@2 12/15/2021

Product Description:
Phenol, Sterile Solution for Injection (PF), 6%, 5 mL per vial, Single Use Vial for Perineural Injection, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1476-05, packaged in vials.

Product Quantity:
309 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0413-2022

Code Information:
09-2021-14@5 12/29/2021, 10/21/21 & 11-2021-04@2, 02/15/2022

Product Description:
Phenylephrine HCl / Tropicamide / Ciprofloxcin / Ketorolac Sterile Ophthalmic Solution, 10%/1%/0.3%/0.125%, 0.8 mL per syringe, Single Use Syringe, For Topical Ophthalmic Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1270-01

Product Quantity:
2463 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0414-2022

Code Information:
08-2021-31@8 12/21/2021 & 10-2021-13@1 01/19/2022

Product Description:
Phenylephrine HCl 0.5 mg/5mL, (0.1 mg/mL), 5 mL per syringe, Single Use Syringe for IV Injection, Edge Pharma, LLC, 856 Hercules Dr, Colchester, VT 05446, NDC 05446-1545-05

Product Quantity:

3747 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0415-2022

Code Information:
09-2021-09@4 12/22/2021 & 10-2021-14@1 01/26/2022

Product Description:
Phenylephrine HCl, 1mg/10mL (0.1mg/mL), 10 mL per syringe, Single Use Syringe for IV Injection, Edge Pharma, LLC, 856 Hercules Dr, Colchester, VT 05446 NDC 05446-1544-10

Product Quantity:
6535 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0416-2022

Code Information:
08-2021-26@3 12/16/2021, 09-2021-16@5 12/29/2021, 10-2021-07@2 01/19/2022 & 10-2021-22@1 02/03/2022.

Product Description:
Phenylephrine HCl, Sterile Solution for Injection, (PF), 800 mcg/10mL (80 mcg/mL), Single Use Syringe for IV Injection, Edge Pharma, LLC 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1652-01

Product Quantity:
5335 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0417-2022

Code Information:
08-2021-27@4 12/09/2021, 09-2021-17@1 12/30/2021, 10-2021-15@1 01/27/2022 & 10-2021-28@1 02/09/2022

Product Description:
PHENYLephrine, 0.9% Sodium Chloride Injection, USP, 20 mg/250mL, (0.08 mg/mL), Single use bag for IV injection (Preservative Free), Rx Only, Edge Pharma, LLC, 856 Hercules Dr, Colchester, VT NDC 05446-1667-01

Product Quantity:
3930 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0418-2022

Code Information:
08-2021-24@6 12/06/2021, 08-2021-31@7 12/12/2021, 09-2021-07@3 12/21/2021, 10-2021-20@2 02/02/2022 & 10-2021-28@2 02/10/2022.

Product Description:
Phenylephrine HCl/Lidocaine, Sterile Ophthalmic Solution for Injection, Preservative Free, 1.5%/1%, 0.8mL per syringe, Single Use Syringe For Intraocular Injection, Edge Pharma LLC, 856 Hercules Dr, Colchester, VT 05446, NDC 05446-1118-01

Product Quantity:
2750 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0419-2022

Code Information:
09-2021-16@1 12/29/2021

Product Description:
Phenylephrine HCl/Tropicamide, Sterile Ophthalmic Solution, 2.5%/1%, 15 mL per dropper, Multiple Dose Droptainer for Topical Ophthalmic Use, Edge Pharma, LLC, 856 Colchester, VT 05446, NDC 05446-0815-01

Product Quantity:
363 droptainers

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0420-2022

Code Information:
09-2021-15@1 12/28/2021

Product Description:
Phenylephrine HCl/Tropicamide/Cyclopentolate HCl/Ketorolac Sterile Ophthalmic Solution, 2.5%/0.25%/0.25%/0.125%, 0.5 mL syringe, Single Use Syringe, For Topical Ophthalmic Use, NDC 05446-0993-01

Product Quantity:
2562 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0421-2022

Code Information:
09-2021-15@2 12/28/2021 & 11-2021-02@3 02/14/2022

Product Description:
Phenylephrine HCl/Tropicamide/Cyclopentolate HCl/ Ketorolac Sterile Ophthalmic Solution, 10%/ 0.25%/ 0.25%/0.125%, 10 mL per dropper, Multiple Dose Droptainer for Topical Ophthalmic Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT, NDC 05446-0859-03

Product Quantity:
40 droptainers

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0422-2022

Code Information:
11-2021-02@2 12/16/2021

Product Description:
Betadine (povidone-iodine), Sterile Ophthalmic Solution, Preservative Free, 5% 0.5mL per syringe, Single Use Syringe, For Topical Ophthalmic Use, Edge Pharma, LLC, 656 Hercules Dr., Colchester, VT 05446, NDC 05446-1680-01

Product Quantity:
1773 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0423-2022

Code Information:
10-2021-25@5 12/09/2021

Product Description:
Vancomycin HCl, Sterile Ophthalmic Solution for Injection, Preservative Free, 8 mg/0.8mL (10 mg/mL) (vancomycin equivalent), 0.8 mL per syringe, Single Use Syringe, For Intraocular Injection, Edge Pharma LLC, 856 Hercules Dr., Colchester, VT, 05446, NDC 05446-0736-01

Product Quantity:
3360 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:

D-0424-2022

Code Information:
08-2021-31@2 12/12/2021 & 09-2021-20@4 01/02/2022

Product Description:
Vancomycin HCl in 0.9 % Sodium Chloride Injection, USP, 1,250 mg/250 mL, Single Use Bag for IV Injection (Preservative Free), 250 mL pre-filled bag, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1456-01

Product Quantity:
1795 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0425-2022

Code Information:
09-2021-13@3 12/27/2021 & 09-2021-30@5 01/13/2022

Product Description:
Vancomycin HCl in 0.9% Sodium Chloride Injection, 1,500 mg/500 mL, USP, Single Use Bag for IV Injection (Preservative Free), 500 mL pre-filled bag, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1458-01

Product Quantity:
1825 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0426-2022

Code Information:
08-2021-26@4 12/08/2021 & 09-2021-21@3 01/04/2022

Product Description:
Vancomycin HCl in 0.9% Sodium Chloride Injection, USP, 1,750mg/500mL, Single Use Bag for IV Injection (Preservative Free), 500 mL pre-filled bag, Rx Only, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446 NDC 05446-1459-01

Product Quantity:
749 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0427-2022

Code Information:
09-2021-09@6 12/23/2021 & 10-2021-13@5 01/27/2022

Product Description:
BLT Topical Cream, Benzocaine/Lidocaine/Tetracaine, 20%/8%/4%, 60gm per jar, Multiple Dose Container For Topical Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT, 05446, NDC 05446-1235-01

Product Quantity:
1173 jars

Reason for Recall:
CGMP Deviations

Recall Number:
D-0428-2022

Code Information:
06-2021-10@11 12-07-2021, 06-2021-10@9 12-07-2021, 06-2021-17@6 12-14-2021, 06-2021-17@7 12-14-2021, 06-2021-24@5 12-21-2021, 06-2021-24@8 12-21-2021, 07-2021-01@6 12-28-2021, 07-2021-01@7 12-28-2021, 07-2021-09@5 01-01-2022, 07-2021-09@6 01-05-2022, 07-2021-15@5 01-01-2022, 07-2021-15@6 01-01-2022, 07-2021-22@16 01-19-2022, 07-2021-22@8 01-01-2022, 07-2021-29@12 01-25-2022, 07-2021-29@24 01-25-2022, 08-2021-05@7 02-01-2022, 08-2021-05@8 02-01-2022, 08-2021-19@7 02-15-2022, 08-2021-19@8 02-15-2022, 08-2021-26@5 02-22-2022, 09-2021-01@10 02-28-2022, 09-2021-03@7 03-02-2022, 09-2021-09@7 03-08-2022, 09-2021-16@7 03-15-2022, 09-2021-17@7 03-16-2022, 09-2021-22@8 03-21-2021, 09-2021-23@2 03-22-2022, 09-2021-23@3 03-22-2022, 09-2021-30@10 03-29-2022, 09-2021-30@8 03-29-2022, 10-2021-07@10

04-05-2022, 10-2021-07@7 04-05-2022, 10-2021-08@1 04-06-2022, 10-2021-14@4 04-12-2022, 10-2021-14@5 04-12-2022, 10-2021-21@7 04-19-2022 & 10-2021-28@3 04-26-2022

Product Description:
Cantharidin Gel-Forming Suspension, 0.7%, 10 mL per vial, Multiple Dose Vial for Topical Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05546 NDC 05446-0572-03

Product Quantity:
1173 vials

Reason for Recall:
CGMP Deviations

Recall Number:
D-0429-2022

Code Information:
06-2021-11@6 12-08-2021, 07-2021-08@13 01-04-2022, 08-2021-06@6 02-02-2022, 08-2021-20@10 02-16-2022, 08-2021-26@6 02-22-2022, 08-2021-27@7 02-23-2022, 09-2021-02@5 03-01-2022, 09-2021-17@8 03-16-2022 & 09-2021-29@12 03-28-2022

Product Description:
Cantharidin PLUS, Cantharidin/Salicylic Acid Gel-Forming Suspension, 10 mL per vial, Multiple Dose Vials for Topical Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT, 05446, NDC 05446-0970-03

Product Quantity:
2204 vials

Reason for Recall:
CGMP Deviations

Recall Number:
D-0430-2022

Code Information:
06-2021-09@9 12-06-2021, 06-2021-16@11 12-13-2021, 06-2021-23@7 12-20-2021, 06-2021-30@11 12-27-2021, 07-2021-07@9 01-03-2022, 07-2021-13@6 01-09-2021, 07-2021-14@5 01-10-2022, 07-2021-21@8 01-17-2022, 07-2021-26@10 01-22-2022, 08-2021-04@5 01-31-2022, 08-2021-09@11 02-05-2022, 08-2021-10@6 02-06-2022, 08-2021-17@5 02-13-2022, 08-2021-25@4 02-21-2022, 09-2021-01@8 02-28-2022, 09-2021-08@8 03-07-2022, 09-2021-15@6 03-14-2022, 09-2021-21@8 03-20-2022, 09-2021-27@10 03-26-2022, 10-2021-06@8 04-04-2022, 10-2021-13@7 04-11-2022, 10-2021-20@7 04-18-2022, 10-2021-20@9 04-18-2021 & 10-2021-26@9, 04-24-2022

Product Description:
CSF Otic Insufflation Capsule, Sulfacetamide Sodium/ Ciprofloxacin/ Amphotericin B Otic Powder, 50mg / 30mg / 5mg, 5 count bottle, For Otic Use with Insufflator, Edge Pharma, LLC 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1633-05

Product Quantity:
1055 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0431-2022

Code Information:
10-2021-27@8 01-25-2022

Product Description:
CSF-HC Otic Insufflation Capsule, Sulfacetamide Sodium/Ciprofloxacin/Hydrocortisone/Amphotericin B Otic Powder, 50mg/ 30mg/ 25mg/ 5mg, 5 count bottle, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1634-01

Product Quantity:
440 cartons

Reason for Recall:
CGMP Deviations

Recall Number:
D-0432-2022

Code Information:
10-2021-05@9 01-01-2022 & 10-2021-28@4 01-26-2022

Product Description:
Dexamethasone sodium phosphate 0.4%, 120 mL per bottle, Multiple Dose Container For Topical Use, Edge Pharma, LLC, 856 Hercules

Dr., Colchester, VT 05446, NDC 05446-0622-01

Product Quantity:
56 cartons

Reason for Recall:
CGMP Deviations

Recall Number:
D-0433-2022

Code Information:
06-2021-23@6 12-20-2021, 09-2021-15@4 03-14-2022 & 10-2021-04@10 04-02-2022

Product Description:
Dibutyl Squaric Acid, Topical Solution (PF), Multiple Dose Vial, 2%, 10 mL per vial, Edge Pharma, LLC, 856 Hercules Dr, Colchester VT, 05446, NDC 05446-1047-03

Product Quantity:
63 vials

Reason for Recall:
CGMP Deviations

Recall Number:
D-0434-2022

Code Information:
09-2021-15@5 12-14-2021 & 10-2021-01@4 12-30-2021

Product Description:
Dibutyl Squaric Acid, Topical Solution (PF) Multiple Dose Vial, 1%, 10 mL per vial, Edge Parma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1156-03

Product Quantity:
20 vials

Reason for Recall:
CGMP Deviations

Recall Number:
D-0435-2022

Code Information:
08-2021-03@8 12-31-2021 & 09-2021-07@10 02-04-2022

Product Description:
LT Topical Cream, Lidocaine/Tetracaine, 23%/7%, 60gm per jar, Multiple Dose Container for Topical Use, Edge Pharma, LLC, 856 Hercules, VT, Colchester, VT 05446, NDC 05446-1647-01

Product Quantity:
74 jars

Reason for Recall:
CGMP Deviations

Recall Number:
D-0436-2022

Code Information:
08-2021-23@9 02-19-2022, 09-2021-07@13 03-06-2022 & 10-2021-22@5 04-20-2022.

Product Description:
LET Topical Gel, Lidocaine HCL / Epinepherine / Tetracaine HCl, 4%/0.05%/0.5%, 3 mL per syringe, Single Dose Syringe for Topical Use, Edge Pharma, LLC, 856 Hercules Dr. Colchester, VT, NDC 05446-0607-01

Product Quantity:
26917 syringes

Reason for Recall:
CGMP Deviations

Recall Number:
D-0437-2022

Code Information:
07-2021-12@6 12-09-2021, 07-2021-19@7 12-16-2021, 07-2021-26@5 12-23-2021, 08-2021-02@8 12-30-2021, 08-2021-09@10 01-06-2022, 08-2021-13@6 01-10-2022, 08-2021-18@4 01-15-2022, 08-2021-24@8 01-21-2022, 08-2021-30@5 01-27-2022, 09-2021-07@11 02-04-2022, 09-2021-13@5 02-10-2022 & 10-2021-04@9 03-03-2022.

Product Description:
Lidocaine HCl / Oxymetazoline HCl Nasal Solution, 4% / 0.05%, 240mL per bottle, Multiple Dose Container for Intranasal Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1256-01, packaged in bottles. no label

Product Quantity:
386 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0438-2022

Code Information:
06-2021-18@3 12-15-2021 07/07/21 - 07/22/21 06-2021-30@10 12-27-2021 07/20/21 - 08/17/21 07-2021-14@4 01-10-2022 08/05/21 - 08/20/21 07-2021-21@4 01-17-2022 08/23/21 - 09/16/21, 07-2021-28@9 01-24-2022 09/13/21 - 10/05/21 08-2021-12@8 02-08-2022 10/01/21 - 10/19/21 08-2021-24@9 02-20-2022 10/19/21 - 11/11/21 09-2021-09@10 03-08-2022 11/10/21 - 11/30/21 10-2021-05@6 04-03-2022 11/30/21

Product Description:
Profound Dental Gel, Lidocaine HCl/Prilocaine HCl/Tetracaine HCl, 10%/10%/4% Raspberry Marshmallow, 30 grams per jar, Multiple Dose Container For Topical Oral Use,Edge Pharma LLC, 856 Hercules Dr. Colchester, VT 05446, NDC 05446-0790-10

Product Quantity:
353 jars

Reason for Recall:
CGMP Deviations

Recall Number:
D-0439-2022

Code Information:
07-2021-20@7 01-16-2022, 08-2021-11@6 02-07-2022, 08-2021-31@11 02-01-2022, 09-2021-14@11 02-01-2022, 09-2021-21@6 02-01-2022 & 10-2021-12@4 04-10-2022.

Product Description:
Profound Dental Gel, Lidocaine HCl/Prilocaine HCl/Tetracaine HCl, 10% / 10% / 4%, Spearmint-Peppermint, Multiple Dose Container for Topical Oral Use, Edge Pharma, LLC, 856 Hercules Dr. Colchester, VT NDC 05446-0407-10

Product Quantity:
221 jars

Reason for Recall:
CGMP Deviations

Recall Number:
D-0440-2022

Code Information:
08-2021-16@12 02-01-2022 09/21/21 - 10/19/21 09-2021-13@8 02-01-2022 11/04/21 - 11/17/21 09-2021-29@8 03-01-2022 10/18/21 - 11/11/21 10-2021-26@7 04-24-2022 11/17/21 - 12/01/21

Product Description:
Profound-PE Dental Gel, Lidocaine HCl/ Prilocaine HCl/ Tetracaine HCl/ Phenylephrin HCl, 10% / 10% / 4% / 2% Raspberry-Marshmallow, Multiple Dose Container for Topical Oral Use, Edge Pharma, LLC, 856 Hercules Dr. Colchester, VT NDC 05446-1018-10

Product Quantity:
418 jars

Reason for Recall:
CGMP Deviations

Recall Number:
D-0441-2022

Code Information:
06-2021-29@15 12-26-2021, 07-2021-12@7 01-08-2022, 08-2021-03@7 01-30-2022, 08-2021-25@5 02-01-2022, 09-2021-10@4 02-01-2022, 09-2021-22@6 03-01-2022 & 10-2021-06@11 04-04-2022

Product Description:
Profound-PE Dental Gel, Lidocaine HCl/Prilocaine HCl/Tetracaine HCl/Phenylephrine, 10% / 10% / 4% / 2%, Spear-Peppermint, Multiple Dose Container for Topical Oral Use, 30 grams per jar, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT, 05446, NDC 05446-0408-10

Product Quantity:
175 jars

Reason for Recall:
CGMP Deviations

Recall Number:
D-0442-2022

Code Information:
07-2021-13@7 01-09-2022 08/24/21 - 10/06/21 07-2021-27@8 01-23-2022 10/06/21 - 11/02/21 08-2021-10@5 02-01-2022 10/28/21 - 12/01/21

Product Description:
Phenol, Topical Solution (PF) Multiple Dose Vial, 89%, 3 mL per vial, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT, NDC 05446-1211-03

Product Quantity:
1861 jars

Reason for Recall:
CGMP Deviations

Recall Number:
D-0443-2022

Code Information:
07-2021-12@9 01-08-2022 07/22/21 - 08/11/21 08-2021-11@10 02-07-2022 08/25/21 - 09/10/21 08-2021-12@12 02-08-2022 09/07/21 - 10/06/21 09-2021-22@5 03-21-2022 10/12/21 - 10/28/21 10-2021-07@8 04-05-2022 10/25/21 - 10/28/21 10-2021-08@4 04-06-2022 10/28/21 - 11/12/21 11-2021-01@7 04-30-2022 11/15/21 - 12/01/21

Product Description:
Lidocaine HCl/Phenylephrine HCl Nasal Solution, 4%/1%, 240 mL per bottle, Multiple Dose Container, Edge Pharma, LLC 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1045-03

Product Quantity:
231 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0444-2022

Code Information:
07-2021-02@7 12-29-2021, 07-2021-23@4 01-19-2022, 08-2021-11@7 02-07-2022, 08-2021-23@8 02-19-2022 & 09-2021-24@10 03-23-2022

Product Description:
Vitamin K (Vitamin K) Oral Solution (PF), 5 mg/mL, 1mL per syringe, single Dose Syringe for Oral Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1132-03

Product Quantity:
757 syringes

Reason for Recall:
CGMP Deviations

Recall Number:
D-0445-2022

Code Information:
10-2021-11@6 01-09-2022 10/27/21 - 11/16/21 11-2021-01@8 01-30-2022 11/16/21 - 12/01/21

Product Description:
Promethazine HCl Topical Ointment, 2.5% (25 mg/mL), 1.2 mL per syringe, Single Dose Syreinge for Topical Use Only, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1341-01

Product Quantity:
7788 syringes

Reason for Recall:
CGMP Deviations

Recall Number:
D-0446-2022

Code Information:
08-2021-02@9 12-15-2021, 08-2021-16@10 12-29-2021, 09-2021-08@6 01-21-2022, 09-2021-20@6 02-02-2022 & 10-2021-18@6 03-02-2022

Product Description:
Tetracaine HCl Nasal Solution, 4%, 240 mL per bottle, Multiple Dose Container for Intranasal Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT, 05446, NDC 05446-1195-03, packaged in bottles.

Product Quantity:
114 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0447-2022

Code Information:
06-2021-08@5 12-05-2021, 07-2021-07@7 01-03-2022, 07-2021-27@10 01-23-2022 & 10-2021-06@12 04-04-2022

Product Description:
Vancomycin HCl Oral Solution (PF) 125mg / 2.5mL (50 mg/mL), 2.5 mL per syringe, Single Dose Syringe for Oral Use Only, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1348-01

Product Quantity:
6925 syringes

Reason for Recall:
CGMP Deviations

Recall Number:
D-0448-2022

Code Information:
09-2021-10@3 12-09-2021, 09-2021-17@6 12-16-2021, 09-2021-24@8 12-23-2021, 09-2021-30@7 12-29-2021 & 10-2021-13@6 01-11-2022 .

Product Description:
Trypan Blue 0.03%, 0.5mL per syringe, Sterile Ophthalmic Solution for Injection Preservative Free, Single Use Syringe, For Intraocular Injection, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1348-01

Product Quantity:

Reason for Recall:
CGMP Deviations

Recall Number:
D-0449-2022

Code Information:
09-2021-10@3 12-09-2021, 09-2021-17@6 12-16-2021, 09-2021-24@8 12-23-2021, 09-2021-30@7 12-29-2021 & 10-2021-13@6 01-11-2022 .

Class II Drugs Event

Event ID:
89305

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/27/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/21/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
VIONA PHARMACEUTICALS INC
20 Commerce Dr Ste 340
Cranford NJ United States

Distribution Pattern:
Product was distributed to 17 wholesalers who further distributed the product to 85 locations.

Associated Products

Product Description:
Metformin Hydrochloride Extended-Release Tablets, USP 750 mg, 100 count HDPE bottles NDC# 72578-036-01

Product Quantity:
23,8416/100 count bottles

Reason for Recall:
CGMP Deviations- Detection of N-Nitrosodimethylamine (NDMA) levels in excess of the Acceptable Daily Intake Limit.

Recall Number:
D-0392-2022

Code Information:
M008130 06/2022, M008131 06/2022, M008132 06/2022, M008133 06/2022, M010080 07/2022, M010081 07/2022, M011029 08/2022, M011030 08/2022, M011031 08/2022, M011032 08/2022, M011304 08/2022, M013394 09/2022, M013395 09/2022, M013396 09/2022, M013966 09/2022, M013967 09/2022, M100831 12/2022, M100832 12/2022, M100833 01/2023, M100834 01/2023, M101267 01/2023, M102718 01/2023, M102719 01/2023

Class II Drugs Event

Event ID:
89323

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/29/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/24/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aurobindo Pharma USA Inc.
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Pioglitazone Tablets USP, 45 mg, 500 count bottles, Distributed by: Aurobindo Pharma USA, Inc., East Windsor, NJ -- NDC 57237-221-05

Product Quantity:
792 bottles

Reason for Recall:
Superpotent and Failed Tablet/Capsule Specifications

Recall Number:
D-0450-2022

Code Information:
Batch # PF4520028B & PF4520028A, Exp. Date 11/2022

Class II Drugs Event

Event ID:

Product Type:

89377

Status:
Ongoing

Recall Initiation Date:
12/20/2021

Center Classification Date:
01/25/2022

Recalling Firm:
American Health Packaging
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide in the USA

Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Metoprolol Succinate Extended-Release Tablets, USP 50 mg, 500-count bottle, Rx Only, Manufactured by: Alkem Laboratories Ltd., Mumbai - 400 013 INDIA. NDC 68001-501-03

Product Quantity:
6,637 500-count bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0451-2022

Code Information:
Lots# 21141983, 21141984 and 21141985, Exp 03/31/2023; Lots# 21142017, 21142018, 21142019, Exp 02/28/2023

Class II Drugs Event

Event ID:
89411

Status:
Ongoing

Recall Initiation Date:
01/12/2022

Center Classification Date:
01/21/2022

Recalling Firm:
Ascend Laboratories, LLC
339 Jefferson Rd Ste 101
Parsippany NJ United States

Distribution Pattern:
Nationwide in the USA

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Metoprolol Succinate Extended-Release Tablets, USP, 25 mg, Rx Only, 100 Tablets per bottle, Manufactured by: Alkem Laboratories Ltd., Mumbai - 400 013, India, Distributed by: Ascend Laboratories, LLC, Parsippany, NJ, 07054, NDC 67877-590-01.

Product Quantity:
9216 bottles

Reason for Recall:
Failed Dissolution Specifications.

Recall Number:

D-0393-2022

Code Information:
Lot #: 21143093, Exp. March 2023

Class II Drugs Event

Event ID:
89415

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/21/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/25/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Pharmaceuticals Inc
3711 Collins Ferry Rd
Morgantown WV United States

Distribution Pattern:
Recalled product was distributed nationwide within the United States.

Associated Products

Product Description:
Proctofoam HC (hydrocortisone acetate 1% and pramoxine hydrochloride 1%) topical aerosol, 10 g aerosol containers, Rx Only, Distributed by Meda Pharmaceuticals Inc, Somerset, New Jersey 08873-1120, NDC 0037-6822-10.

Product Quantity:
233,199/10 g aerosol containers

Reason for Recall:
cGMP deficiencies

Recall Number:
D-0452-2022

Code Information:
Lot #: 32925, Exp. date May 2023, 33010, Exp. date June 2023; 33119, 33123, Exp. date August 2023

Class III Drugs Event

Event ID:
89152

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/03/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/26/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dental Alliance Holdings LLC
812 Water Ave Ne
Albany OR United States

Distribution Pattern:
Distributed nationwide with the United States

Associated Products

Product Description:

CariFree CTx4 GEl 5000 1.1% Neutral Sodium Fluoride Mint, 2 oz (57 g) Rx only NDC: 61578-205-01 Manufactured by Oral BioTech Albany, Oregon 97321 Distributed in 12-pk/cases

Product Quantity:
6612 individual tubes for the 12 pack and 15 individual tubes for the 2 oz. of Lot 142017

Reason for Recall:
Subpotent Drug: Product contains less Sodium Fluoride than listed on product label.

Recall Number:
D-0453-2022

Code Information:
Lot #: 142017 Exp. Date 06/22

Product Description:
CTx7 Kit, contains one tube CariFree CTx4 Gel 5000, 1.1% Neutral Sodium Fluoride Mint, 2 oz (57 g) Rx only NDC: 61578-205-01 Manufactured by Oral BioTech Albany, Oregon 97321 and one bottle of CariFree CTx3 Rinse, Mint Anticavity Rinse, 16 fl oz. bottle.

Product Quantity:
3 single tubes of lot 192107 and 3 single tubes of 192108

Reason for Recall:
Subpotent Drug: Product contains less Sodium Fluoride than listed on product label.

Recall Number:
D-0454-2022

Code Information:
Lot #: 192107 and lot 192108 Exp. Date 06/22 (contains recalled CariFree CTx4 5000 gel tube lot 142017)

Product Description:
CTx21 Kit, contains three tubes of CariFree CTx4 Gel 5000, 1.1% Neutral Sodium Fluoride Mint, 2 oz (57 g) Rx only NDC: 61578-205-01 Manufactured by Oral BioTech Albany, Oregon 97321 and three bottles of CariFree CTx3 Rinse, Mint Anticavity Rinse, 16 fl oz. bottle.

Product Quantity:
180 single tube of lot 272109 and 180 single tube count of lot 272110

Reason for Recall:
Subpotent Drug: Product contains less Sodium Fluoride than listed on product label.

Recall Number:
D-0455-2022

Code Information:
Lot #: 272109, 272110 Exp. Date 06/22; (contains recalled CariFree CTx4 5000 gel tube lot 142017)

Product Description:
CTx26 Kit, contains three tubes of CariFree CTx4 Gel 5000, 1.1% Neutral Sodium Fluoride Mint, 2 oz (57 g) Rx only NDC: 61578-205-01 Manufactured by Oral BioTech Albany, Oregon 97321 and two bottles of CariFree CTx3 Rinse, Mint Anticavity Rinse, 16 fl oz. bottle an two boxes of 4fl.oz. Carifree CTx4 Treatment Rinse.

Product Quantity:
225 single tube of lot 31217 and 99 single tube of 312108

Reason for Recall:
Subpotent Drug: Product contains less Sodium Fluoride than listed on product label.

Recall Number:
D-0456-2022

Code Information:
Lot#: 312107, 312108 Exp. Date 06/22; (contains recalled CariFree CTx4 5000 gel tube lot 142017)

Product Description:
CTx36 Kit, contains three tubes of CariFree CTx4 Gel 5000, 1.1% Neutral Sodium Fluoride Mint, 2 oz (57 g) Rx only NDC: 61578-205-01 Manufactured by Oral BioTech Albany, Oregon 97321 and six boxes of 4fl.oz. Carifree CTx4 Treatment Rinse.

Product Quantity:
90 single tubes of 352110 and 315 single tubes of 352111

Reason for Recall:
Subpotent Drug: Product contains less Sodium Fluoride than listed on product label.

Recall Number:

D-0457-2022

Code Information:
Lot #: 352110, 352111 Exp. Date 06/22; (contains recalled CariFree CTx4 5000 gel tube lot 142017)

Product Description:
CariFree sample boxes, contains one tube of CariFree CTx4 Gel 5000, 1.1% Neutral Sodium Fluoride Mint, 2 oz (57 g) Rx only NDC: 61578-205-01 Manufactured by Oral BioTech Albany, Oregon 97321.

Product Quantity:
8 single tubes of lot 492106 and 50 single tubes of lot 492107

Reason for Recall:
Subpotent Drug: Product contains less Sodium Fluoride than listed on product label.

Recall Number:
D-0458-2022

Code Information:
Lot #: 492106, 492107 Exp. Date 06/22 (contains recalled CariFree CTx4 5000 gel tube lot 142017).

Product Description:
CTx12 5000 Kit which contains 3 boxes of CariFree CTx4 GEl 5000 gel tubes. 1.1% Neutral Sodium Fluoride Mint, 2 oz (57 g) Rx only NDC: 61578-205-01 Manufactured by Oral BioTech Albany, Oregon 97321.

Product Quantity:
360 individual tubes of lot 142017.

Reason for Recall:
Subpotent Drug: Product contains less Sodium Fluoride than listed on product label.

Recall Number:
D-0459-2022

Code Information:
Lot #: 142017, exp. Date 06/22