

Enforcement Report - Week of July 20, 2022

Class I Drugs Event

Event ID:

90481

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

06/17/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

07/08/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Bryant Ranch Prepack, Inc.
1919 N Victory Pl
Burbank CA United States

Distribution Pattern:

Distributed to one wholesaler in AL for further distribution in the US.

Associated Products

Product Description:

Morphine Sulfate extended-Release Tablets, USP; 30 mg, 100-count bottles, Rx only, manufactured by: Ohm Laboratories Inc., New Brunswick NJ 08901 USA; Relabeled by: Bryant Ranch Prepack, Inc., Burbank, CA, 91504 USA, NDC: 63629-1088-01.

Product Quantity:**Reason for Recall:**

Labeling: Label Mix-up: bottles labeled as Morphine Sulfate 60 mg Extended-Release tablets contain Morphine Sulfate 30 mg Extended-Release tablets and bottles labeled as Morphine Sulfate 30 mg Extended-Release tablets may contain Morphine Sulfate 60 mg Extended-Release tablets.

Recall Number:

D-1187-2022

Code Information:

Lot #: 179642, Exp. Date 11/30/2023.

Product Description:

Morphine Sulfate extended-Release Tablets, USP; 60 mg, 100-count bottles, Rx only, manufactured by: Ohm Laboratories Inc., NJ; Relabeled by: Bryant Ranch Prepack, Inc, CA, NDC 63629-1089-01

Product Quantity:**Reason for Recall:**

Labeling: Label Mix-up: bottles labeled as Morphine Sulfate 60 mg Extended-Release tablets contain Morphine Sulfate 30 mg Extended-Release tablets and bottles labeled as Morphine Sulfate 30 mg Extended-Release tablets may contain Morphine Sulfate 60 mg Extended-Release tablets.

Recall Number:

D-1188-2022

Code Information:

Lot #: 179643, Exp. Date 08/31/2023.

Class II Drugs Event

Event ID:

89909

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

Recall Initiation Date:

03/07/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

07/14/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

TMC Acquisition LLC dba Tailor Made Compounding
200 Moore Dr
Nicholasville KY United States

Distribution Pattern:

Nationwide USA and Puerto Rico

Associated Products

Product Description:

Alpha Lipoic Acid 25mg/mL, 30mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

29 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1192-2022

Code Information:

Batch #: 12082102A2, Exp 3/8/2022; 02212201A1, Exp 5/22/2022.

Product Description:

Alprostadil/Papaverine/Phentolamine 60mcg/30mg/3mg/mL, 3mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

32 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1193-2022

Code Information:

Batch #: 01042221A2, Exp 3/5/2022; 02192216A1, Exp 4/20/2022.

Product Description:

Anastrozole/Testosterone Cypionate/Propionate 1mg/160mg/40mg/mL, 10 mL-vial, Room Temperature, Tailor Made Compounding

Product Quantity:

39

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1194-2022

Code Information:

Batch #: 10182113A1, Exp 4/16/2022.

Product Description:

Ascorbic Acid 500mg/mL, a) 25 mL-vial, b) 50 mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

657 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1195-2022

Code Information:

Batch #: a) 02282223A1, Exp 8/27/2022; 10112101A2, Exp 4/9/2022; 11032108A1, Exp 4/30/2022; 11222101A2, Exp 5/21/2022; b) 01042234B, Exp 7/3/2022; 01242211A2, Exp 7/23/2022; 02282222A1, Exp 8/27/2022; 10112101A2, Exp 4/9/2022; 10182101A1, Exp 4/16/2022; 11162112A1, Exp 5/15/2022; 12062105A2, Exp 6/4/2022; 12142143A2, Exp 6/12/2022; 12202102A2, Exp 6/18/2022.

Product Description:

BCAAs (Leucine/Iso-Leucine/Valine) 10mg/10mg/5mg/mL, 30mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

180 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1196-2022

Code Information:

Batch #: 11022106A1, Exp 4/30/2022; 11192106A2, Exp 5/18/2022; 12022105A1, Exp 5/31/2022; 12132108A1, Exp 6/11/2022; 12292117A1, Exp 6/27/2022.

Product Description:

Biotin 5mg/mL, 5mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

39

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1197-2022

Code Information:

Batch #: 12032113A2, Exp 6/1/2022; 01102206A1, Exp 7/9/2022.

Product Description:

Calcium Chloride Preservative Free, 100mg/mL, a) 5 mL-vial, b) 30 mL-vial, Room Temperature, Tailor Made Compounding

Product Quantity:

138 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1198-2022

Code Information:

Batch #: a) 12072101A2, Exp 3/7/2022; 01042216A1, Exp 4/4/2022; 02142220A1, Exp 5/15/2022; b) 12032129A2, Exp 3/3/2022; 02142220A1, Exp 5/15/2022; 03032213A1, Exp 6/1/2022; 03102214B, Exp 6/8/2022.

Product Description:

Dexpanthenol 250mg/mL, 30mL-vial, Room Temperature, Tailor Made Compounding

Product Quantity:

19 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1199-2022

Code Information:

Batch #: 01032232A1, Exp 7/2/2022; 01242229A2, Exp 7/23/2022.

Product Description:

Dexpanthenol Preservative Free 250mg/mL, 2mL-vial, Room Temperature, Tailor Made Compounding

Product Quantity:

84 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1200-2022

Code Information:

Batch#: 01032234A2, Exp 7/2/2022; 02072212A1, Exp 8/6/2022.

Product Description:

Estradiol Cypionate 10mg/mL, a) 1mL-vial, b) 2 mL-vial, Room Temperature, Tailor Made Compounding

Product Quantity:

349 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1201-2022

Code Information:

Batch #: a) 01052210A1, Exp 4/5/2022; 10202101A1, Exp 4/18/2022; 01052210A1 7/4/2022; b)10202102A1, Exp 4/18/2022; 12022126A1, Exp 5/31/2022; 01052210A1, Exp 7/4/2022.

Product Description:

Folic Acid 5mg/mL, 30mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

45

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1202-2022

Code Information:

Batch#: 10132102A2, Exp 3/22/2022; 01062221B, Exp 4/30/2022; 11302103A1, Exp 4/30/2022; 03032227A1, Exp 8/29/2022.

Product Description:

GAC (Glutamine/Arginine/L-Carnitine) 25mg/100mg/250mg/mL, 30mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

90 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1203-2022

Code Information:

Batch #: 10122110A2, Exp 3/20/2022; 12062110A2, Exp 4/30/2022; 02012202A2, 02192207A1, Exp 7/31/2022.

Product Description:

GOAL (Glutamine/Ornithine/Arginine/Lysine 25mg/75mg/150mg/250mg/ml) 30 mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

60 Vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1204-2022

Code Information:

Batch #: 10122105A2, Exp 3/20/2022; 01182216A1, Exp 5/31/2022; 02192207A1, Exp 7/31/2022; 03072206A1, Exp 9/3/2022.

Product Description:

Glutathione 200mg/mL Preservative Free, Injectable, 30mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

40 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1205-2022

Code Information:

Batch #: 12062113A2, Exp 3/6/2022; 01052209B, Exp 4/5/2022; 01312223A1, Exp 5/1/2022.

Product Description:

Glycyrrhizic Acid 8mg/mL, 10mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

101 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1206-2022

Code Information:

Batch #: 12172114A2, Exp 3/17/2022; 01142211A1, Exp 4/14/2022.

Product Description:

Gonadorelin 100mcg/mL, 10mL per vial, Refrigerate, Tailor Made Compounding

Product Quantity:

294 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1207-2022

Code Information:

Batch #: 01062225B, Exp 4/6/2022; 01142207A1, Exp 4/14/2022; 02012228A1, Exp 5/2/2022; 02032203A1, Exp 5/4/2022; 03012211A1, Exp 5/30/2022; 03082240A1, Exp 6/6/2022.

Product Description:

Hydroxocobalamin 25mg/mL, 10mL-vial, Room Temperature, Tailor Made Compounding

Product Quantity:

63 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1208-2022

Code Information:

Batch#: 12222104A2, Exp 3/22/2022; 01032224A2, Exp 4/3/2022; 01282217A2, Exp 4/28/2022; 02192211A1; Exp 5/20/2022.

Product Description:

Hydroxocobalamin Preservative Free 5mg/mL, 1mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

26 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1209-2022

Code Information:

Batch #: 01032236A2, Exp 4/3/2022; 03072232A1, Exp 6/5/2022

Product Description:

Inositol/Choline B12 + Carnitine 40mg/40mg/1mg/100mg/mL, 30mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

25 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1210-2022

Code Information:

Batch#: 01212203A2, Exp 4/21/2022; 02232213A1, Exp 5/24/2022.

Product Description:

Levocarnitine 500mg/mL, 30mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

12 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1211-2022

Code Information:

Batch #: 12022124A2, Exp 3/2/2022; 03032223A1, Exp 6/1/2022.

Product Description:

Melanotan I 200mcg/mL (2mg/ml), a) 1.5mL-vial, b) 5 mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

182 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1212-2022

Code Information:

Batch #: a) 01072212A1, Exp 4/7/2022; 03032220A1, Exp 6/1/2022; b) 12162120A2, Exp 3/16/2022; 01142205A1, Exp 4/14/2022; 02012226A1, Exp 5/2/2022; 03032220A1, Exp 6/1/2022.

Product Description:

Methionine/Inositol/Choline B12 + Carnitine 10mg/40mg/40mg/1mg/100mg/mL, a) 4mL-vial, b) 10 mL-vial, c) 30mL- vial, Refrigerate, Tailor Made Compounding

Product Quantity:

924 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1213-2022

Code Information:

Batch#: a) 01172233A1, Exp 4/17/2022; 01282213A1, Exp 4/28/2022; 02192221A1, Exp 5/20/2022; b)12032118A2, Exp 3/3/2022; 12282120A2, Exp 3/28/2022 01172233A1, Exp 4/17/2022, 01282213A1, Exp 4/28/2022, 02212242A1, Exp 5/22/2022, 03042202A1, Exp 6/2/2022; c) 02192219A1, Exp 5/20/2022; 03062201A1, Exp 6/4/2022.

Product Description:

Methionine/Inositol/Choline B12 25mg/50mg/50mg/1mg/mL, a)10 mL-vial, b) 30 mL-vial, Room Temperature, Tailor Made Compounding

Product Quantity:

232 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1214-2022

Code Information:

Batch#: a) 12092105A2, exp 3/9/2022; 01042219A2, Exp 4/4/2022; 01202210A2, exp 4/20/2022; 01282207A1, exp 4/28/2022; 03032217A1, Exp 6/1/2022; 12092105A2; b) 01282207A1, Exp 4/28/2022; 03032241A1, Exp 6/1/2022

Product Description:

Methylcobalamin 10mg/mL, a) 1 mL-vial, b) 10mL-vial, c) 30 mL-vial, Room Temperature, Tailor Made Compounding

Product Quantity:

652 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1215-2022

Code Information:

Batch#: a)11092114A2, Exp 4/30/2022; 12172113A2, Exp 6/15/2022; 03072227A1, Exp 9/3/2022; b)10122101A2, Exp 4/10/2022; 12022116A1, Exp 5/31/2022; 12292115A1, Exp 6/27/2022; 02222207A1, Exp 8/21/2022; c)10112103A2, Exp 4/9/2022; 11192112A2, Exp 5/18/2022; 12142114A2, Exp 6/12/2022; 12202103A1, Exp 6/18/2022; 12282119A2, Exp 6/26/2022; 01192222A1, Exp 7/18/2022; 02232201A1, Exp 8/22/2022.

Product Description:

Methylcobalamin 1mg/mL, a) 10 mL-vial, b) 30 mL-vial, Room Temperature, Tailor Made Compounding

Product Quantity:

191 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1216-2022

Code Information:

Batch #: a) 10282106A1, Exp 4/26/2022; 11022118A1, Exp 4/30/2022; 12292115A1, Exp 6/27/2022; b)12082113A2, Exp 6/2/2022; 12292115A1, Exp 6/27/2022; 03072230A1, Exp 9/3/2022.

Product Description:

Methylcobalamin Preservative Free, 10mg/mL, 1mL-vial, Room Temperature, Tailor Made Compounding

Product Quantity:

4 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1217-2022

Code Information:

Batch#: 03012234A1, Exp 8/28/2022.

Product Description:

Methylene Blue Hypotonic Solution, 10mg/mL, a) 2 mL-vial, b) 10mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

464 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1218-2022

Code Information:

Batch #: a)11032122A2, Exp 4/30/2022; 01142226A1, Exp 7/13/2022; b)10272101A1, Exp 4/25/2022; 11292137A1, Exp 5/28/2022; 12142120A2, Exp 6/12/2022; 01042235B, Exp 7/3/2022; 01142226A1, Exp 7/13/2022; 03012240A1, Exp 8/28/2022; 03042223A1, Exp 8/31/2022.

Product Description:

NAD+ 200mg/mL, 10mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

1,856 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1219-2022

Code Information:

Batch#: 10072110A2, 10142102A2, Exp 3/22/2022; 01112205A1, 11112123A1, Exp 4/30/2022; 11222114A1, 11172107A1, 11182120A2, Exp 5/7/2022; 01102207A1, 01122211A1, Exp 5/11/2022; 12162119A1, 12162121A1, Exp 5/24/2022; 02022223A2, Exp 6/30/2022; 03012204A1, Exp 8/23/2022; 03082249B, Exp 9/4/2022; 03092226B, 03092236B, Exp 9/5/2022.

Product Description:

Nandrolone Decanoate 200mg/mL, a) 5 mL-vial, b) 10mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

243 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1220-2022

Code Information:

Batch#: a) 10272107A1, Exp 4/25/2022; 12072130A1, Exp 6/5/2022; b) 01032230A1, Exp 7/2/2022.

Product Description:

Pentosan Polysulfate Sodium 250mg/mL, 5mL-vial, Room Temperature, Tailor Made Compounding

Product Quantity:

220 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1221-2022

Code Information:

Batch#: 11292109A2, Exp 5/28/2022, 01242202A1, Exp 6/18/2022; 03022214A1, Exp 8/29/2022.

Product Description:

Procaine HCL 2% (20mg/mL), 30 mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

58 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1222-2022

Code Information:

Batch#: 10112102A2, Exp 4/9/2022; 11302101A1, Exp 5/29/2022; 01242201A1, Exp 5/31/2022.

Product Description:

PT-141 10mg/mL a) 1mL-vial, b) 2 mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

392 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1223-2022

Code Information:

Batch#: a) 01042226A2, Exp 4/4/2022; 01242228A2, Exp 4/24/2022; 02212208A1, Exp 5/22/2022; b) 01192230A2, Exp 4/19/2022; 02212217A1, Exp 5/22/2022.

Product Description:

Semaglutide/Cyanocobalamin 2mg/0.4mg/ml, 1mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

5,842 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1224-2022

Code Information:

Batch#: 12032123A2, Exp 3/3/2022; 12102101A2, Exp 3/10/2022; 12202105A2, Exp 3/20/2022; 12292106A2, Exp 3/29/2022; 01062218B, Exp 4/6/2022; 01192228A2, Exp 4/19/2022; 01312214A2, Exp 5/1/2022; 02012211A1, Exp 5/2/2022; 02182201A1, 02182203A1, Exp 5/19/2022; 02242205A1, 02242206A1, Exp 5/25/2022; 03072209A1, Exp 6/5/2022; 03092203A1, 03092206A1, Exp 6/7/2022.

Product Description:

Semaglutide/Cyanocobalamin 5mg/0.2mg/ml, 2ml-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

9,993 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1225-2022

Code Information:

Batch#: 12092115A2, Exp 3/9/2022; 12162116A2, Exp 3/16/2022; 12212106A2, Exp 3/21/2022; 01062219B, Exp 4/6/2022; 01072205A1, 01072208A1, Exp 4/7/2022; 01102203A1, Exp 4/10/2022; 01132207A1, Exp 4/13/2022; 01192216A1, Exp 4/19/2022; 01202204A2, Exp 4/20/2022; 01272223A2, Exp 4/27/2022; 01312219A2, Exp 5/1/2022; 02032204A2, Exp 5/4/2022; 02072203A1, Exp 5/8/2022; 02182216A1, 02182224A1, Exp 5/19/2022; 02232202A1, 02232210A1, Exp 5/24/2022; 02242202A1, 02242203A1, 02242235A1, 02242238A1, Exp 5/25/2022; 03072217A1, 03072223A1, Exp 6/5/2022; 03082223A1, 03082229A1, Exp 6/6/2022; 03092207A1, 03092219A1, Exp 6/7/2022.

Product Description:

Sermorelin 2000mcg/mL, 7.5mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

1,208 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1226-2022

Code Information:

Batch#: 10122103A2, Exp 3/22/2022; 11092108A2, Exp 4/30/2022; 11192115A2, Exp 5/7/2022; 12022107A2, Exp 5/22/2022; 12132107A2, Exp 5/24/2022; 01182201A2, Exp 6/30/2022; 02142212A1, Exp 8/13/2022; 03022217A1, Exp 8/29/2022.

Product Description:

Sermorelin/Glycine 2000mcg/5mg/mL, 4mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

1,562 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1227-2022

Code Information:

Batch#: 11102107A2, Exp 4/9/2022; 11232104A1, Exp 5/7/2022; 02212229A1, 11292103A2, Exp 5/22/2022; 12132105A2, Exp 5/24/2022; 02282207A1, Exp 5/29/2022; 03082209A1, Exp 6/6/2022; 03112231B, Exp 6/9/2022; 01042212A1, Exp 6/27/2022.

Product Description:

Sermorelin/Glycine 2000mcg/5mg/mL, 7.5mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

2,870 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1228-2022

Code Information:

Batch #: 10122102A2, Exp 3/22/2022; 10252101A2, Exp 3/24/2022; 11092106A2, Exp 4/8/2022; 11232102A1, Exp 5/7/2022; 11162106A1, Exp 5/15/2022; 12032114A1, 02212224A1, Exp 5/22/2022; 12142111A1, 12202109A2, Exp 5/24/2022; 03032244A1, Exp 6/1/2022; 03082209A1, Exp 6/6/2022; 12292116A2, Exp 6/27/2022; 01182204A1, 01262232A1, 01262233A1, Exp 6/30/2022.

Product Description:

Teriparatide 226mcg/ml Injectable, 4 Pre-filled Syringes, 0.25 mL-Syringe, Refrigerate, Tailor Made Compounding

Product Quantity:

12 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1229-2022

Code Information:

Batch#: 01132208A1, Exp 4/13/2022; 02252205A1, Exp 5/26/2022.

Product Description:

Testosterone Cypionate (GSO) 100mg/ml a) 1mL-vial , b) 2mL-vial, Room temperature, Tailor Made Compounding

Product Quantity:

273 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1230-2022

Code Information:

Batch#: a) 12212109A2, Exp 6/19/2022; 01312217A1, Exp 7/30/2022; b) 10202108A1, Exp 4/18/2022; 12012125A, Exp 5/30/2022 ;02182230A1, Exp 8/17/2022; 10202108A1; 03022222A1, Exp 8/29/2022.

Product Description:

Testosterone Cypionate (GSO) 200mg/ml a) 2 mL-vial, b) 4 mL-vial, c) 5 mL-vial, d) 10 mL-vial, Room temperature, Tailor Made Compounding

Product Quantity:

4,219 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1231-2022

Code Information:

Batch#: a) 12212105A2, Exp 6/19/2022; 02182229A1, Exp 8/17/2022; b) 12012121A2, Exp 5/30/2022; 12212104A2, Exp 6/19/2022; 01242216A2,

Exp 7/23/2022; 02182236A1, Exp 8/17/2022; c) 12072133A1, Exp 6/5/2022; 01192225A1, Exp 7/18/2022; 02182228A1, Exp 8/17/2022; d) 10142105A, Exp 4/12/2022; 10272105A1, Exp 4/25/2022; 11102101A1, 11032120A2, Exp 4/30/2022; 11222116A2, Exp 5/21/2022; 12012121A2, Exp 5/30/2022; 12072132A1, Exp 6/5/2022; 12152110A1, Exp 6/13/2022; 12162118A1, Exp 6/14/2022; 12212103A2, Exp 6/19/2022; 01052206A1, Exp 7/4/2022; 01142229A1, Exp 7/13/2022; 01212207A2 Exp, 7/20/2022; 02042201A1, Exp 8/3/2022; 02182226A1, Exp 8/17/2022; 02252224A1, 02252226A1, Exp 8/24/2022.

Product Description:

Testosterone Cypionate/Anastrozole 200mg/0.5mg/mL, 10mL-vial, Room temperature, Tailor Made Compounding

Product Quantity:

41 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1232-2022

Code Information:

Batch#: 11232117A1, Exp 5/22/2022; 01312215A1, Exp 7/30/2022

Product Description:

Testosterone Cypionate/Anastrozole 200mg/1mg/mL, a) 4 mL-vial, b) 10mL-vial, Room temperature, Tailor Made Compounding

Product Quantity:

106 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1233-2022

Code Information:

Batch#: a) 10142123A2, Exp 4/12/2022, 02042202A1, Exp 8/3/2022; b) 10142121A2, Exp 4/12/2022; 10202105A1, Exp 4/18/2022; 11102102A1, Exp 4/30/2022; 02042202A1, Exp 8/3/2022.

Product Description:

Testosterone Cypionate/Enanthate 100/100mg/ml, a) 2 mL-vial, b) 4 mL-vial c) 10 mL-vial, Room temperature, Tailor Made Compounding

Product Quantity:

58 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1234-2022

Code Information:

Batch#: Expiry: a) 01142227A1, Exp 7/13/2022; b) 12012126A2, Exp 5/30/2022; 02042203A1, Exp 8/3/2022; c) 01052207A1, Exp 7/4/2022.

Product Description:

Testosterone Cypionate/Enanthate/Propionate 80/80/40mg, a) 5 mL-vial, b) 10 mL-vial, Room temperature, Tailor Made Compounding

Product Quantity:

246 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1235-2022

Code Information:

Batch#: a) 10202107A1, Exp 4/18/2022; b) 10142120A2, Exp 4/12/2022; 10272102A1, Exp 4/25/2022 ; 11032117A2, 11102104A2, Exp 4/30/2022; 01252212A2 , Exp 7/24/2022; 02182227A1, Exp 8/17/2022 .

Product Description:

Testosterone Cypionate/Propionate 180/20mg/ml, a) 5 mL-vial, b) 10 mL-vial, Room temperature, Tailor Made Compounding

Product Quantity:

176 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1236-2022

Code Information:

Batch#: a)11042102A1, Exp 4/30/2022; 12072135A1, Exp 6/5/2022, 01142228A1, Exp 7/13/2022; 02182231A1, Exp 8/17/2022; b)11042102A1, Exp 4/30/2022; 01142228A1, Exp 7/13/2022.

Product Description:

Testosterone Enanthate (GSO) 100mg/ml, 2 mL-vial, Room temperature, Tailor Made Compounding

Product Quantity:

93 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1237-2022

Code Information:

Batch#: 11102106A1, Exp 4/30/2022; 01142230A1, Exp 7/13/2022.

Product Description:

Testosterone Enanthate (GSO) 200mg/ml, a) 5 mL-vial, b) 10 mL-vial, Room temperature, Tailor Made Compounding

Product Quantity:

414 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1238-2022

Code Information:

Batch#: a)10142117A2, Exp 4/12/2022; 10272108A1, Exp 4/25/2022; 11302113A2, Exp 5/29/2022; 02252220A1, Exp 8/24/2022; b)10142108A2, Exp 4/12/2022; 12072134A1, Exp 6/5/2022.

Product Description:

Testosterone Propionate 100mg/ml, 10mL-vial, Room temperature, Tailor Made Compounding

Product Quantity:

64 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1239-2022

Code Information:

Batch#: 12012123A2, Exp 5/30/2022; 01312212A1, Exp 7/30/2022.

Product Description:

Vitamin B-Complex, a) 10 mL-vial, b) 30 mL-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

75 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1240-2022

Code Information:

Batch#: a) 01252201A2, Exp 3/26/2022; b) 01252201A2, Exp 3/26/2022; 02032213A2, Exp 4/4/2022; 03042209A1, Exp 5/3/2022.

Product Description:

Vitamin B-Complex Preservative Free, 3ml-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

6 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1241-2022

Code Information:

Batch#: 03112233B, Exp 5/10/2022

Product Description:

Vitamin D3 50,000IU/mL, 10mL-vial, Room Temperature, Tailor Made Compounding

Product Quantity:

15 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1242-2022

Code Information:

Batch#: 02252201A1, Exp 4/15/2022.

Product Description:

Glutathione 200mg/ml, a) 10ml-vial, b) 30ml-vial, Refrigerate, Tailor Made Compounding

Product Quantity:

485 Vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1243-2022

Code Information:

Batch#: a) 01122204A1, Exp 4/12/2022; 02192214A1, Exp 5/20/2022; b) 12142122A2, Exp. 3/14/2022; 12282118A2, Exp 3/28/2022; 01112203A1, Exp 4/11/2022; 01122208A1, Exp 4/12/2022; 01202211A2, Exp 4/20/2022; 02032205A1, Exp 5/4/2022; 02192212A1, Exp 5/20/2022; 03042201A1, Exp 6/2/2022.

Class II Drugs Event

Event ID:

90451

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

06/21/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

07/11/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton NJ United States

Distribution Pattern:

USA Nationwide

Associated Products

Product Description:

Testosterone Cypionate Injection, USP, 200mg/mL, CIII, Rx only, 1mL Single-dose vial, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceuticals Industries Ltd., Halol- Baroda Highway, Halol-Baroda, Highway, Halol- 389 350, Gujarat, India, NDC 62756-015-40.

Product Quantity:

50860 vials

Reason for Recall:

cGMP - Water leakage

Recall Number:

D-1190-2022

Code Information:

HAC4337A

Class II Drugs Event

Event ID:

90455

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

06/16/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

07/08/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Jubilant Draximage Inc
16751 Rte Transcanadienne
Kirkland Canada

Distribution Pattern:

Product was distributed to retailers nationwide.

Associated Products

Product Description:

Draximage MAA (Kit for the preparation of Technetium Tc 99m Albumin Aggregate) 2.5 mg per vial, 30 glass vials per carton, Rx Only, Manufactured for Jubilant Draximage Inc. Kirkland, Canada, NDC 65174-270-30.

Product Quantity:

519 cartons/30 vials each

Reason for Recall:

Lack of Assurance of Sterility: Out-of-specification test results obtained for Endotoxin testing.

Recall Number:

D-1189-2022

Code Information:

Lot # 1H005, exp. date Nov 30, 2023

Class II Drugs Event

Event ID:

90509

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

06/24/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

07/14/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Vi-Jon, LLC

1 Swan Dr

Smyrna TN United States

Distribution Pattern:

USA Nationwide

Associated Products

Product Description:

Hydrogen Peroxide Topical Solution, USP, 32 fl. oz. (1 QT) 946 mL, Distributed by: CVS Pharmacy, Inc. One CVS Drive Woonsocket, RI 02895, NDC 59779-871-45, UPC 0-50428-40950-3

Product Quantity:

36,840 bottles

Reason for Recall:

Labeling: Label Mix-Up-The primary label on the front of the bottles have Hydrogen Peroxide affixed to the front and back of the containers. However, the product inside the bottle is 70% Isopropyl Alcohol.

Recall Number:

D-1191-2022

Code Information:

Lot: 0562272, Exp 02/2025

Not Yet Classified Drugs Event

Event ID:

90427

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

06/10/2022

Voluntary / Mandated:

Voluntary: Firm initiated

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

Letter

Recalling Firm:

Latin Foods Market

205 E Alma Ave F1

San Jose CA United States

Distribution Pattern:

Nationwide in the USA

Associated Products

Product Description:

Arti King Refozado con Ortiga y Omega 3 Tablets, 100-count bottles, Hecho en Mexico por: "PLANTAS MEDICINALES DE MEXICO", Melchor Ocampo No. 55 Local D, Delegacion Xochimilco, C.P. 16800 Mexico, UPC 7 501031 111138

Product Quantity:

unknown

Reason for Recall:

Marketed Without An Approved NDA/ANDA: Product contains undeclared diclofenac and dexamethasone.

Recall Number:

Code Information:

Lot 334 21, Exp: 30 Nov, 2025