

Enforcement Report - Week of March 11, 2020

Class II Drugs Event

Event ID:

84978

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

01/15/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

03/05/2020

Initial Firm Notification of Consignee or Public:

Press Release

Recalling Firm:

Fusion IV Pharmaceuticals, Inc. dba Axia Pharmaceutical
1990 Westwood Blvd Ste 135
Los Angeles CA United States

Distribution Pattern:

U.S.A. Nationwide and Puerto Rico, Barbados and Dominican Republic

Associated Products

Product Description:

Alprostadil/Papaverine Hydrochloride/Phentolamine Mesylate/Atropine Sulfate Injection, 18 mcg/1.8mg/0.2mg/0.02mg/mL, For Intracavernosal Use, Freeze, 2.5 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0547-2

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0932-2020

Code Information:

Lot #: 12042019+533247, Exp 1/17/2020

Product Description:

Alprostadil/Papaverine Hydrochloride/Phentolamine Mesylate/Atropine Sulfate Injection, 40 mcg/25 mg/0.5mg/0.01mg/ml, For Intracavernosal Use, Freeze, 2.5 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0549-2

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0933-2020

Code Information:

Lot #: 12042019+533225, Exp 1/17/2020

Product Description:

Alprostadil/Papaverine Hydrochloride/Phentolamine Mesylate/Atropine Sulfate Injection, 60 mcg/30 mg/2 mg/0.15mg/ml, For Intracavernosal Use, Freeze, 2.5 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0550-2

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0934-2020

Code Information:

Lot #: 12042019+53323, Exp 1/17/2020

Product Description:

Alprostadil (prostaglandin E1)150 MCG/ML Injectable, For Intracavernosal Use, Freeze, 2.5 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0538-2

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0935-2020

Code Information:

Lot #: 12042019+53331, Exp 1/17/2020

Product Description:

Alprostadil (prostaglandin E1) 80 MCG/ML Injectable, For Intracavernosal Use, Freeze, 2.5 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0543-2

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0936-2020

Code Information:

Lot #: 11112019+53208, Exp 4/29/2020

Product Description:

Alprostadil/Papaverine Hydrochloride/Phentolamine Mesylate Injection 20MCG/30MG/1MG/ML Injectable, For Intracavernosal Use, Freeze, 2.5 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0545-2

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0937-2020

Code Information:

Lot #: 11112019+53210, Exp 4/4/2020

Product Description:

Alprostadil/Papaverine Hydrochloride/Phentolamine Mesylate Injection 40MCG/30MG/2MG/ML Injectable, For Intracavernosal Use, Freeze, 2.5 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0546-2

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0938-2020

Code Information:

Lot #: 11112019+53214, Exp 3/5/2020

Product Description:

AscorbiX (Buffered C) Injection, Ascorbix (30ML) 500MG/ML Injectable, For IV, IM, SC Use, Refrigerate, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0226-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0939-2020

Code Information:

Lot #: 07112019+52635, Exp 1/17/2020; 09092019+52890, Exp 3/17/2020

Product Description:

AscorbiX (Buffered C) Injection, Ascorbix (50ML) 500MG/ML Injectable, For IV, IM, SC Use, Refrigerate, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0226-5

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0940-2020

Code Information:

Lot #: 08222019+52828, Exp 2/28/2020; 09092019+52889, Exp 3/17/2020; 09182019+52924, Exp 3/26/2020; 09262019+52971, Exp 4/3/2020; 10142019+53108, Exp 4/21/2020; 10212019+53136, Exp 4/28/2020; 10302019+53164, Exp 5/7/2020; 11252019+53278, Exp 6/2/2020; 11262019+53284, Exp 6/3/2020

Product Description:

B-COMPLEX 110 INJECTABLE, For IV, IM, SC Use, Refrigerate, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0212-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0941-2020

Code Information:

Lot #: 07022019+52584, 07022019+52579, Exp 3/29/2020; 08012019+52780, 08012019+52782, Exp 4/28/2020; 11262019+53288, Exp 8/23/2020

Product Description:

BETAMETHASONE ACETATE/BETAMETHASONE (PF) Injectable Suspension, Betamethasone Acetate/Betamethasone (PF) CMC [2ML] 6MG/ML INJ SUSP, For IM, IA, IT Use, Shake Well. Preservative Free. Discard Unused Portion, 2 mL Single-use Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0620-2

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0942-2020

Code Information:

Lot #: 10022019+53004, Exp 2/28/2020; 11252019+53282, Exp 6/12/2020

Product Description:

BETAMETHASONE ACETATE/BETAMETHASONE (PF) Injectable Suspension, Betamethasone Acetate/Betamethasone (PF) CMC [10ML] 7MG/ML INJ SUSP, For IM, IA Use, Shake Well, 10 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0621-1

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0943-2020

Code Information:

Lot #: 07092019+52610, Exp 2/6/2020; 07232019+52734, Exp 2/19/2020; 08282019+52853, 09042019+52878, 09102019+52903, Exp 3/2/2020; 09182019+52929, Exp 4/17/2020; 10092019+53082, Exp 2/28/2020, 10152019+53124; Exp 5/4/2020; 10222019+53142, Exp 2/28/2020; 10292019+53160, 11052019+53186, Exp 5/4/2020; 11202019+53257, Exp 6/19/2020; 11212019+53270, Exp 6/20/2020; 12042019+53317, Exp 7/3/2020; 12102019+53363, Exp 7/9/2020

Product Description:

BETAMETHASONE ACETATE/BETAMETHASONE (PF) Injectable Suspension, Betamethasone Acetate/Betamethasone (PF) CMC [5ML] 7MG/ML

INJ SUSP, For IM, IA Use, Shake Well. 10 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0621-5

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0944-2020

Code Information:

Lot #: 07232019+52738, Exp 2/20/2020

Product Description:

Biotin (Vitamin H) Injectable Suspension, BIOTIN 10 MG/ML INJ SUSP, For IM Use, Refrigerate, Shake Well, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0220-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0945-2020

Code Information:

Lot #: 11132019+53229, Exp 2/10/2020

Product Description:

Calcium Chloride Injection, For IM Use, Refrigerate, Shake Well, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0225-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0946-2020

Code Information:

Lot #: 10302019+53166, Exp 2/15/2020

Product Description:

Coenzyme Q10 Injection, COENZYME Q-10 20MG/ML OIL INJ SOLN, For IM Use, 10 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0411-1

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0947-2020

Code Information:

Lot #: 06032019+52353, Exp 7/29/2020; 07082019+52596, Exp 9/2/2020; 10012019+52986, Exp 8/12/2020; 12122019+53374, Exp 1/25/2021

Product Description:

Cyanocobalamin Injection, CYANOCOBALAMIN 2000 MCG/ML INJECTABLE, For IV, IM, SC Use, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0330-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0948-2020

Code Information:

Lot #: 07172019+52695, 07172019+52697, 07252019+52759, Exp 1/25/2020

Product Description:

Cyanocobalamin/Folinic Acid Injection, CYANOCOBALAMIN : FOLINIC ACID 2000 MCG/ML: 500MCG/ML INJECTABLE, For IV, IM, SC Use, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0333-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0949-2020

Code Information:

Lot #: 09252019+52967, Exp 4/4/2020

Product Description:

Deoxycholic Acid Sodium Injection, DEOXYCHOLIC ACID SODIUM 1.67% INJECTABLE, For SC Use, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0462-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0950-2020

Code Information:

Lot #: 10082019+53080, Exp 6/30/2020; 11192019+53251, Exp 8/24/2020

Product Description:

Dexamethasone (LA) Injectable Suspension, DEXAMETHASONE LA [10ML] 16MG INJ SUSP, For IM, IA Use, Shake Well, 10 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0630-1

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0951-2020

Code Information:

Lot #: 10022019+53002, Exp 10/1/2020

Product Description:

Dexpanthenol Injection, DEXPANTHENOL 250 MG/ML INJECTABLE, For IV, IM Use, Shake Well, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0214-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0952-2020

Code Information:

Lot #: 07242019+52740, Exp 1/20/2020; 11202019+53259, Exp 5/18/2020

Product Description:

Glutathione Injection, GLUTATHIONE 200MG/ML INJECTABLE For IV, IM Use, Refrigerate, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-1231-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0953-2020

Code Information:

Lot #: 10212019+53138, Exp 11/19/2020; 10302019+53172, Exp 1/28/2020; 11122019+53225, Exp 2/10/2020

Product Description:

Glycerin (PF) Injection, GLYCERIN 99% INJECTABLE, For IV Use, 10 mL Single-use Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0464-1

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0954-2020

Code Information:

Lot #: 08142019+52805, Exp 2/10/2020

Product Description:

Glycine Injection, GLYCINE USP 50MG/ML INJECTABLE, For IV, IM Use, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0344-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0955-2020

Code Information:

Lot #: 07012019+52572, Exp 4/6/2020; 10102019+53106, Exp 6/30/2020

Product Description:

Human Chorionic Gonadotropin (hCG) Injection, HCG [10ML] 1000 IU/ML INJECTABLE, For IM, SC Use, Refrigerate, 10 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0533-1

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0956-2020

Code Information:

Lot #: 07222019+52720, Exp 1/28/2020; 09182019+52923, Exp 3/26/2020; 10232019+53148, Exp 2/28/2020; 11142019+53243, Exp 5/22/2020

Product Description:

Hydroxocobalamin Injection, HYDROXOCOBALAMIN 5MG/ML INJECTABLE, For IV, IM Use, Refrigerate, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0339-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0957-2020

Code Information:

Lot #: 11042019+53179, Exp 2/18/2020

Product Description:

Hydroxyprogesterone Caproate Injection, HYDROXYPROGESTERONE CAPROATE [4ML] 250 MG/ML INJECTABLE, For IV, IM Use, Refrigerate, 4 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0532-5

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0958-2020

Code Information:

Lot #: 07302019+52772, Exp 2/25/2020

Product Description:

Arginine Hydrochloride Injection, L-ARGININE HCL 100MG/ML INJECTABLE, For IV, IM Use, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0341-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0959-2020

Code Information:

Lot #: 10242019+53154, Exp 1/22/2020

Product Description:

Polyoxyl Lauryl Ether (Polidocanol) Injection, LAURETH-9 (POLIDOCANOL) 5% INJECTABLE, For IV Use, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-060-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0960-2020

Code Information:

Lot #: 10152019+53126, Exp 4/6/2020

Product Description:

Levocarnitine Injection, LEVOCARNITINE 500 MG/ML INJECTABLE, For IV Use, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-9260-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0961-2020

Code Information:

Lot #: 08212019+52824, Exp 2/17/2020

Product Description:

Lidocaine HCL (PF) Injection, LIDOCAINE HCL 4% (PF) 40 MG/ML INJECTABLE, For ocular injection, Preservative free, discard unused portion, protect from light, 5 mL Single-use Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-1011-5

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0962-2020

Code Information:

Lot #: 07012019+52569, Exp 3/15/2020

Product Description:

Lysine Hydrochloride Injection, LYSINE HCL 100MG/ML INJECTABLE, For IV, IM Use, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0342-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0963-2020

Code Information:

Lot #: 10222019+53144, Exp 1/27/2020

Product Description:

Methionine/Inositol/Choline Injection, METHIONINE/INOSITOL/CHOLINE 25MG/50MG/50MG/ML INJECTABLE, For IM Use, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0215-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0965-2020

Code Information:

Lot #: 09052019+52881, Exp 4/7/2020; 09302019+52977, Exp 5/2/2020; 10072019+53049, Exp 5/9/2020

Product Description:

Methylcobalamin Injection, METHYLCOBALAMIN [CD] 10MG/100MG/ML INJECTABLE, For IV, IM, SC Use, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0338-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0966-2020

Code Information:

Lot #: 07292019+52764, Exp 1/25/2020; 07292019+52766, Exp 1/25/2020

Product Description:

Methylcobalamin Injection, METHYLCOBALAMIN 1 MG/ML INJECTABLE, For IV, IM, SC Use, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0331-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0967-2020

Code Information:

Lot #: 07232019+52730, Exp 1/19/2020; 07232019+52732, Exp 1/19/2020; 07242019+52748, Exp 1/20/2020; 11212019+53272, Exp 5/19/2020

Product Description:

Methylprednisolone Acetate/Bupivacaine Hydrochloride Injectable Suspension, METHYLPRED ACETATE/BUPIV [10ML] CMC 40MG/5MG/ML INJ SUSP, For IM, IA Use, Shake Well, 10 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0623-1

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0968-2020

Code Information:

Lot #: 09042019+52874, Exp 3/2/2020

Product Description:

Methylprednisolone Acetate/Bupivacaine Hydrochloride Injectable Suspension, METHYLPRED ACETATE/BUPIVACAINE HCL [10ML] CMC 80MG/5MG/ML INJ SUSP, For IM, IA Use, Shake Well, 10 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0624-1

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0969-2020

Code Information:

Lot #: 09042019+52876, Exp 3/2/2020

Product Description:

Methylprednisolone Acetate Injectable Suspension, METHYLPREDNISOLONE ACETATE (PF) CMC [2ML] 80 MG/ML INJ SUSP, For IM, IA Use, Shake Well, 10 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0639-2

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0970-2020

Code Information:

Lot #: 06102019+52398, Exp 2/24/2020

Product Description:

Methylprednisolone Acetate Injectable Suspension, METHYLPREDNISOLONE ACETATE [10ML] CMC 100 MG/ML INJ SUSP, For IM, IA Use, Shake Well, 10 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0619-1

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0971-2020

Code Information:

Lot #: 06122019+52423, Exp 7/9/2020; 06122019+52420, Exp 7/9/2020; 07182019+52703, Exp 8/14/2020

Product Description:

Methylprednisolone Acetate Injectable Suspension, METHYLPREDNISOLONE ACETATE [10ML] CMC 50 MG/ML INJ SUSP, For IM, IA Use, Shake Well, 10 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0636-1

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0972-2020

Code Information:

Lot #: 03202019+51817, Exp 4/16/2020; 09122019+52911, Exp 10/9/2020; 09132019+52918, Exp 8/12/2020

Product Description:

MIC-B12 Injection, MIC-B12 25MG/50MG/50MG/1MG/ML INJECTABLE, For IM Use, Refrigerate. Protect From Light, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0230-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0973-2020

Code Information:

Lot #: 07102019+52618, Exp 2/8/2020; 09052019+52880, Exp 4/5/2020; 10012019+52983, Exp 5/1/2020; 11052019+53188, Exp 6/5/2020; 12112019+53367, Exp 7/11/2020

Product Description:

MIC-PLEX Injection, Vitamin Complex, MIC-COMBO* 25MG/50MG/50MG/1MG/20MG/5MG/ML INJECTABLE, For IM Use, Protect From Light, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0233-3

Product Quantity:

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0974-2020

Code Information:

Lot #: 11212019+53263, Exp 2/16/2020; 11252019+53276, Exp 2/20/2020

Product Description:

MIC-PLUS Injection, Vitamin Complex, MIC-COMBO* 25MG/50MG/50MG/1MG/20MG/5MG/ML INJECTABLE, For IM Use, Refrigerate, Protect From Light, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0231-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0975-2020

Code Information:

Lot #: 06242019+52513, Exp 1/23/2020; 06242019+52515, Exp 1/23/2020; 07252019+52756, Exp 2/23/2020; 08212019+52823, Exp 3/21/2020; 10012019+52989, Exp 5/1/2020; 11062019+53194, Exp 6/6/2020

Product Description:

Mitomycin-C (PF) Irrigation Solution, MITOMYCIN-C (PF) 0.5 MG/ML PF SYRINGE, For Intravesicular Use, Freeze, Cytotoxic Agent, Preservative Free, Protect From Light, 80 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0812-8

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0976-2020

Code Information:

Lot #: 07082019+52606, Exp 4/3/2020; 07242019+52742, Exp 7/22/2020; 07242019+52745, Exp 7/22/2020; 09112019+52907, Exp 5/31/2020; 11142019+53235, Exp 11/12/2020

Product Description:

Nicotinamide Adenine Dinucleotide (PF) Injection, NICOTINAMIDE ADENINE DINUCLEOTIDE (PF) 50 MG/ML INJECTABLE, For IV, IM Use, Refrigerate, 10 mL Single Use Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0306-1

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0977-2020

Code Information:

Lot #: 08282019+52850, Exp 1/24/2020; 10102019+53094, Exp 2/28/2020; 10312019+53174, Exp 3/28/2020

Product Description:

Nicotinamide Adenine Dinucleotide (PF) Injection, NICOTINAMIDE ADENINE DINUCLEOTIDE (PF) 20 MG/ML INJECTABLE, For IV, IM Use, Refrigerate, 10 mL Single Use Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0336-1

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0978-2020

Code Information:

Lot #: 10082019+53069, Exp 2/28/2020

Product Description:

Iohexol (PF) Injection, OMNIPAQUE INJECTION [5ML] 300MG I/ML INJECTABLE, For IA Use, 5 mL Single Use Vial, Rx only, Axia Pharmaceutical

1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-1413-5

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0979-2020

Code Information:

Lot #: 10012019+52984, Exp 1/19/2020

Product Description:

Pyridoxine Hydrochloride Injection, PYRIDOXINE HCL 100 MG/ML INJECTABLE, For IV, IM Use, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0216-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0980-2020

Code Information:

Lot #: 09132019+52914, Exp 2/28/2020; 09162019+52920, Exp 3/2/2020; 09192019+52939; Exp 2/28/2020; 10292019+53162, Exp 4/14/2020; 12112019+53369, Exp 5/27/2020

Product Description:

Selenium Injection, SELENIUM 200MCG/ML INJECTABLE, For IV Use, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0227-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0981-2020

Code Information:

Lot #: 11052019+53182, Exp 4/7/2020

Product Description:

Super MIC Injection, SUPER MIC* INJECTABLE, Vitamin Complex, For IM Use, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0234-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0982-2020

Code Information:

Lot #: 11042019+53181, Exp 2/2/2020; 12122019+53376, Exp 3/11/2020

Product Description:

Testosterone Cypionate Injection, TESTOSTERONE CYP IN GRAPSEED OIL [10ML] 200 MG/ML INJECTABLE, For IM Use, 10 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0530-1

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0983-2020

Code Information:

Lot #: 03252019+51850, Exp 7/6/2020; 04252019+52098, Exp 6/29/2020; 04292019+52108, Exp 6/29/2020; 05012019+52132, Exp 10/22/2020; 05202019+52268, Exp 11/10/2020; 05222019+52290, Exp 11/10/2020; 05302019+52334, Exp 11/20/2020; 07082019+52594, Exp 12/29/2020;

07102019+52619, Exp 12/29/2020; 07292019+52762, Exp 8/12/2020; 07312019+52778, Exp 8/12/2020; 09102019+52898, Exp 1/16/2021; 09112019+52905, Exp 1/18/2021

Product Description:

Testosterone Cypionate Injection, TESTOSTERONE CYP IN GRAPSEED OIL [1ML] 200 MG/ML INJECTABLE, For IM Use, 1 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0530-2

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0984-2020

Code Information:

Lot #: 03062019+51706, Exp 6/28/2020

Product Description:

Testosterone Cypionate/Progesterone Injection, TESTOSTERONE CYP/PROGESTERONE [2ML] 200MG/2.5MG/ML INJECTABLE, For IM Use, 2 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0531-2

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0985-2020

Code Information:

Lot #: 03042019+51685, Exp 6/26/2020

Product Description:

Triamcinolone Acetonide/Bupivacaine Hydrochloride Injectable Suspension, TRIAMCINOLONE ACET/BUPIVACAINE HCL [10ML] 40MG/5MG/ML INJ SUSP, For IM, IA Use, 10 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0632-1

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0986-2020

Code Information:

Lot #: 05292019+52328, Exp 2/13/2020

Product Description:

Triamcinolone Acetonide (PF) Injectable Suspension, TRIAMCINOLONE ACETONIDE (PF) [2ML] 40MG/ML INJ SUSP, For IM, IA, IT Use, 2 mL Single Use Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0635-2

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0987-2020

Code Information:

Lot #: 08272019+52841, Exp 2/22/2020; 09242019+52953, Exp 3/22/2020; 11072019+53198, Exp 5/5/2020; 11112019+53206, Exp 5/9/2020; 11122019+53223, Exp 5/10/2020

Product Description:

Triamcinolone Acetonide (PF) Injectable Suspension, TRIAMCINOLONE ACETONIDE (PF) [10ML] 50MG/ML INJ SUSP, For IM, IA, IT Use, 2 mL Single Use Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC # 71283-0633-1

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0988-2020

Code Information:

Lot #: 06132019+52446, Exp 7/17/2020; 11142019+53240, Exp 12/18/2020

Product Description:

Triamcinolone Diacetate Injectable Suspension, TRIAMCINOLONE Diacetate [10ML] CMC 10MG/ML INJ SUSP, For IM, IA Use, 10 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0625-1

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0989-2020

Code Information:

Lot #: 10102019+53104, Exp 5/4/2020

Product Description:

Triamcinolone Diacetate Injectable Suspension, TRIAMCINOLONE DIACETATE (PF) [2ML] CMC 40 MG/ML INJ SUSP, For IM, IA, IT Use, 2 mL Single Use Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0628-2

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0990-2020

Code Information:

Lot #: 08272019+52845, Exp 2/23/2020; 09252019+52965, Exp 3/23/2020

Product Description:

Triamcinolone Diacetate Injectable Suspension, TRIAMCINOLONE DIACETATE [10ML] CMC 80 MG/ML INJ SUSP, For IM, IA, IT Use, 10 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0634-1

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0991-2020

Code Information:

Lot #: 07162019+52686, Exp 4/11/2020; 11062019+53192, Exp 8/2/2020

Product Description:

Cholecalciferol (Vitamin D3) Injection, VITAMIN D3 [P] 1,000 IU/ML INJECTABLE, For IM Use, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0210-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0992-2020

Code Information:

Lot #: 04082019+51930, Exp 4/8/2020; 09092019+52891, Exp 8/12/2020

Product Description:

Cholecalciferol (Vitamin D3) Injection, VITAMIN D3 [P] 100,000 IU/ML INJECTABLE, For IM Use, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0251-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0993-2020

Code Information:

Lot #: 04292019+52110, Exp 4/28/2020; 06252019+52525, Exp 6/24/2020; 09252019+52962, 10072019+53051, Exp 8/12/2020

Product Description:

Zinc Chloride Injection, ZINC CHLORIDE 10MG/ML INJECTABLE, For IV, IM Use, 30 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0224-3

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0994-2020

Code Information:

Lot #: 10302019+53170, Exp 2/9/2020

Class II Drugs Event

Event ID:

85015

Status:

Ongoing

Recall Initiation Date:

02/19/2020

Center Classification Date:

03/03/2020

Recalling Firm:Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore MD United States**Distribution Pattern:**

Product was distributed throughout the United States.

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Desoximetasone Topical Spray, 0.25%, 2.5 mg desoximetasone, 100 mL bottles, Rx only, Manufactured for: Lupin Pharmaceuticals, Baltimore, MD

Product Quantity:

876 bottles

Reason for Recall:

Failed Impurities/Degradation Specification; high out of specification results observed

Recall Number:

D-0866-2020

Code Information:

K800475 exp. date May 2020 K800477 exp. date June 2020

Class II Drugs Event

Event ID:

85017

Status:

Ongoing

Product Type:

Drugs

Date Terminated:

Recall Initiation Date:

02/20/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

03/02/2020

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Teva Pharmaceuticals USA
400 Interpace Pkwy
Parsippany NJ United States

Distribution Pattern:

Nationwide in the USA.

Associated Products

Product Description:

Mesalamine Delayed-Release Tablets, USP, 1.2 gram, 120-count bottle, Rx Only, Manufactured by: Actavis Laboratories FL, Inc., Fort Lauderdale, FL 33314; Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054; NDC 0591-2245-22.

Product Quantity:

3,695 bottles

Reason for Recall:

Failed Dissolution Specifications: Low out of specification dissolution result observed during stability testing.

Recall Number:

D-0862-2020

Code Information:

Lot #: 1342500A, Exp 10/2020

Class II Drugs Event

Event ID:

85067

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

02/27/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

03/05/2020

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Pfizer Inc.
235 E 42nd St
New York NY United States

Distribution Pattern:

Nationwide within the United States and Albania, Israel, Serbia, Macedonia, Afghanistan, Botswana/South Africa/Zimbabwe, India, Israel, Rwanda, Uruguay, Mongolia

Associated Products

Product Description:

Elelyso (taliglucerase alfa) for injection, 200 units/vials., Rx only, Distributed by Pfizer Labs, Division of Pfizer Inc, NY, NY 10017. NDC 0069-0106-01

Product Quantity:

24,714 vials

Reason for Recall:

Lack of Assurance of Sterility--Reports of loose metal ferrule crimps on vials for injection. The entire cap either lifted or dislodged while attempting to flip off the orange color plastic button.

Recall Number:

D-0995-2020

Code Information:

Lot #: X14209, Exp. Date 02/2020; AH4601, Exp. Date 03/2020; AH4603, X46389, X78365, AT2927, Exp. Date 04/2020; AH4602, Exp. Date 05/2020; AL8590, Exp. Date 10/2020

Class III Drugs Event

Event ID:

84938

Status:

Ongoing

Recall Initiation Date:

02/14/2020

Center Classification Date:

03/04/2020

Recalling Firm:

AAA Pharmaceutical, Inc.
681 Main St
Lumberton NJ United States

Distribution Pattern:

Ohio

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Discount Drug Mart, Allergy Relief, Fexofenadine Hydrochloride Tablets, 180 mg /Antihistamine, Indoor/Outdoor Allergies, 24 Hour, a) 30 tablets per bottle, NDC 53943-192-04, UPC Code 0-93351-03069-7; b) 45 tablets per bottle, NDC 53943-192-06, UPC Code 0-93351-03070-3, Distributed by: Drug Mart -Food Fair, 211 Commerce Drive, Medina, OH 44256.

Product Quantity:

3456 Bottles

Reason for Recall:

Labeling: Incorrect or Missing Lot and/or Expiration date.

Recall Number:

D-0868-2020

Code Information:

Lot #s: a) P138855, Exp. 05/30/2022; b) P138856, Exp. 05/30/2022

Class III Drugs Event

Event ID:

84978

Status:

Ongoing

Recall Initiation Date:

01/15/2020

Center Classification Date:

03/05/2020

Recalling Firm:

Fusion IV Pharmaceuticals, Inc. dba Axia Pharmaceutical
1990 Westwood Blvd Ste 135
Los Angeles CA United States

Distribution Pattern:

U.S.A. Nationwide and Puerto Rico, Barbados and Dominican Republic

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Press Release

Associated Products

Product Description:

Magnesium Chloride Injection, MAGNESIUM CHLORIDE 20% INJECTABLE, For IV Use, 50 mL Multi-dose Vial, Rx only, Axia Pharmaceutical 1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025; NDC 71283-0225-5

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0964-2020

Code Information:

Lot #: 10292019+53156, Exp 4/26/2020; 11182019+53247, Exp 5/16/2020