Enforcement Report - Week of August 16, 2017

Class II Drugs Event

Event ID:
77760

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/11/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/09/2017

Initial Firm Notification of Consignee or Public:
Visit

Recalling Firm:
AtHome Medical, Inc.
200 The American Rd
Morris Plains NJ United States

Distribution Pattern:
NJ

Associated Products

Product Description:
Oxygen Refrigerated Liquid USP UN 1073, Rx only, At Home Medical 200 American Road, Morris Plains, NJ 07950,973-538-0485.

Product Quantity:
80 lbs

Reason for Recall:
GMP Deviations: The firm does not include an SOP for testing for out of specifications.

Recall Number:
D-1060-2017

Code Information:
B-06324027 (AHM #E040645) Lot #: 051017V1, Exp. Date: 5/11/17

Class II Drugs Event

Event ID:
77780

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/14/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/09/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Cantrell Drug Company
7321 Cantrell Rd
Little Rock AR United States

Distribution Pattern:
Nationwide within the US

Associated Products

Product Description:
Ephedrine Sulfate in 0.9% Sodium Chloride 10 mL, 50 mg/10 mL (5 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207 877-666-5222, NDC 52533-019-12

Product Quantity:
24638 syringes

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1061-2017

Code Information:
Lot #: 9906, 9915 BUD: 7/28/2017; 9950, 9984, 10001,10010, BUD: 8/4/2017; 10064, BUD: 8/17/2017; 10341, 10452 BUD: 9/23/2017,

Product Description:
Ephedrine Sulfate in 0.9% Sodium Chloride 5 mL, 25 mg/5 mL (5 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207 877-666-5222, NDC 52533-019-15

Product Quantity:
25529 syringes

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1062-2017

Code Information:
Lot #: 9910, 9928, BUD: 7/28/2017; 9962, 9993, BUD: 8/4/2017; 10333, 10481, 10538, BUD: 9/23/2017

Product Description:
Ephedrine Sulfate Injection Solution 1 mL, 50 mg/1 mL (50 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207 877-666-5222, NDC 52533-258-45

Product Quantity:
7656 syringes

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1063-2017

Code Information:
Lot #: 10099, BUD: 7/27/2017; 10127, BUD: 8/1/2017; 10208, BUD: 8/10/2017; 10254, BUD: 8/15/2017; 10278, BUD: 8/17/2017; 10303, BUD: 8/21/2017; 10371, BUD: 9/3/2017; 10457, BUD: 9/17/2017

Product Description:
Ephedrine Sulfate in 0.9% Sodium Chloride 5 mL, 50 mg/5 mL (10 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207 877-666-5222, NDC 52533-118-15

Product Quantity:
49666 syringes

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1064-2017

Code Information:
Lot #: 9904, 9914, 9939, BUD: 7/28/2017; 9952, 9969, 10004, BUD: 8/4/2017; 10043, 10088, 10115, BUD: 8/17/2017; 10269, BUD: 9/8/2017;10431, BUD: 9/23/2017; 10554, BUD: 10/27/2017

Product Description:
Glycopyrrolate Injection Solution, 5 mL 1 mg/5 mL (0.2 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207 877-666-5222; NDC 52533-028-15

Product Quantity:
75840 syringes

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1065-2017

Code Information:
Lot #: 9783, BUD: 7/27/2017; 9801, BUD: 7/29/2017; 9807, BUD: 7/30/2017; 9847, BUD: 8/4/2017; 9954, BUD: 8/20/2017; 10022, BUD: 9/1/2017; 10052, BUD: 9/6/2017; 10063, BUD: 9/7/2017; 10086, BUD: 9/9/2017; 10108, BUD: 9/13/2017; 10156, BUD: 9/20/2017; 10180, BUD: 9/22/2017; 10245, BUD: 9/29/2017; 10264, BUD: 9/30/2017; 10322, BUD: 10/8/2017; 10339, BUD: 10/13/2017; 10368, BUD: 10/18/2017; 10406, BUD: 10/25/2017; 10419, BUD: 10/26/2017; 10435, BUD: 10/28/2017; 10455, BUD: 11/1/2017; 10489, BUD: 11/5/2017; 10497, BUD: 11/6/2017; 10516, BUD: 11/9/2017; 10527, BUD: 11/10/2017; 10577, BUD: 11/19/2017

Product Description:
Glycopyrrolate Injection Solution, 2 mL 0.4 mg/2 mL (0.2 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207 877-666-5222; NDC 52533-028-16

Product Quantity:
21080 syringes

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1066-2017

Code Information:
Lot #: 9781, BUD: 7/26/2017; 9784, BUD: 7/27/2017; 9822, BUD: 8/2/2017; 9852, BUD: 8/5/2017; 10061, BUD: 9/7/2017; 10105, BUD: 9/13/2017; 10150, BUD: 9/17/2017; 10178, BUD: 9/22/2017; 10185, BUD: 9/23/2017; 10501, BUD: 11/8/2017

Product Description:
Glycopyrrolate Injection Solution, 1 mL 0.2 mg/1 mL (0.2 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207 877-666-5222; NDC 52533-028-45

Product Quantity:
5245 syringes

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1067-2017

Code Information:
Lot #: 9868, BUD: 8/9/2017; 9872, BUD: 8/10/2017; 10318, BUD: 10/7/2017

Product Description:
Succinylcholine Chloride Injection Solution 10 mL, 200 mg/10 mL (20 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222, NDC 52533-067-12

Product Quantity:
57430 syringes

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1068-2017

Code Information:
Lot #: 10078, BUD: 7/24/2017; 10111, BUD: 7/27/2017; 10125, BUD: 7/31/2017; 10143, BUD: 8/2/2017; 10166, BUD: 8/6/2017; 10191, BUD: 8/2/2017; 10195, BUD: 7/31/2017; 10221, BUD: 8/13/2017; 10297, BUD: 8/20/2017; 10376, BUD: 9/3/2017; 10398, BUD: 9/6/2017; 10432, BUD: 9/12/2017; 10447,10472, BUD: 9/14/2017; 10547, BUD: 9/27/2017; 10571, BUD: 10/3/2017

Product Description:
Succinylcholine Chloride Injection Solution 5 mL, 100 mg/5 mL (20 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222, NDC 52533-067-15

Product Quantity:
18015 syringes

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1069-2017

Code Information:
Lot #: 10076, BUD: 7/24/2017; 10106, BUD: 7/27/2017; 10145, BUD: 8/2/2017; 10220, BUD: 8/13/2017; 10298, BUD: 8/20/2017; 10400, BUD: 9/6/2017; 10446, BUD: 9/14/2017; 10548, BUD: 9/27/2017

Product Description:
Norepinephrine Bitartrate 8 mg Added to 0.9% Sodium Chloride 250 mL (32 mcg per mL) Single-Dose Bag, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222, NDC 52533-217-18

Product Quantity:
8928 bags

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1070-2017

Code Information:
Lot #: 10095, BUD: 7/27/2017; 10119, BUD: 7/31/2017; 10135, BUD: 8/2/2017; 10162, BUD: 8/6/2017; 10168, BUD: 8/7/2017; 10186, BUD: 8/9/2017; 10247, BUD: 8/15/2017; 10301, BUD: 8/21/2017; 10325, BUD: 8/24/2017; 10390, BUD: 9/5/2017; 10465, BUD: 9/18/2017; 10487, BUD: 9/20/2017; 10542, BUD: 9/27/2017

Product Description:
Norepinephrine Bitartrate 16 mg Added to 0.9% Sodium Chloride 250 mL (64 mcg per mL) Single-Dose Bag, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222, NDC 52533-288-18

Product Quantity:
1718 bags

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1071-2017

Code Information:
Lot 3:: 10374, BUD: 8/4/2017; 10429, BUD: 8/13/2017; 10532, BUD: 8/27/2017

Product Description:
Norepinephrine Bitartrate 4 mg Added to 0.9% Sodium Chloride 250 mL (16 mcg per mL) Single-Dose Bag, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222, NDC 52533-134-18

Product Quantity:
3039 bags

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1072-2017

Code Information:
Lot #: 10069, BUD: 7/24/2017; 10090, BUD: 7/26/2017; 10121, BUD: 7/31/2017; 10142, BUD: 8/3/2017; 10183, BUD: 8/8/2017; 10360, BUD: 8/31/2017; 10443, BUD: 9/14/2017

Product Description:
Diltiazem HCl 125 mg in 5% Dextrose 125 mL Single-Dose- Bag, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222; NDC 52533-103-13

Product Quantity:
2761 bags

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1073-2017

Code Information:
Lot #: 10084, BUD: 7/25/2017; 10137, BUD: 8/2/2017; 10252, BUD: 8/15/2017; 10271, BUD: 8/17/2017; 10350, BUD: 8/30/2017; 10491, BUD: 9/21/2017

Product Description:
Phenylephrine HCL in 0.9% Sodium Chloride 10 mL, 1 mg/10 mL (100 mcg/mL) Single-Dose Syringe, Rx Only,

Product Quantity:
46078 syringes

Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222, NDC 52533-171-12

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1074-2017

Code Information:
Lot #: 9556, BUD: 7/26/2017; 9566, BUD: 7/30/2017; 9584, BUD; 8/1/2017; 9613, BUD: 8/6/2017; 9656, BUD: 8/14/2017; 9798, BUD: 9/11/2017; 981 2, BUD: 8/31/2017; 9819, BUD: 9/16/2017; 9836, BUD: 9/17/2017; 9944, BUD: 10/3/2017; 10158, 10493, 10565, BUD: 10/30/2017

Product Description:
Sodium Bicarbonate 8.4% Injection Solution 50 mL, 50 mEq (1mEq/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222

Product Quantity:
40081 syringes

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1075-2017

Code Information:
Lot#: 10349, BUD: 7/30/2017; 10356, BUD: 7/31/2017; 10377, BUD: 8/4/2017; 10386, BUD: 8/5/2017; 10394, BUD: 8/6/2017; 10404, BUD: 8/8/2017; 10423 BUD: 8/12/2017; 10468, BUD: 8/18/2017; 10473, BUD: 8/19/2017; 10482, BUD: 8/20/2017; 10514, BUD: 8/25/2017; 10524, BUD: 8/26/2017; 1 0569, BUD: 9/3/2017

Product Description:
Adenosine in 0.9% Sodium Chloride 30mL, 90 mg/30 mL (3 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222; NDC 52533-236-03

Product Quantity:
6210 syringes

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1076-2017

Code Information:
Lot #: 9814, 9831 BUD: 9/12/2017; 10059, BUD: 10/18/2017

Product Description:
Neostigmine Methylsulfate Injection Solution 5 mL, 5 mg/5 mL (1 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222, NDC 52533-046-15

Product Quantity:
120856 syringes

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1078-2017

Code Information:
Lot #: 10081, BUD: 7/25/2017; 10096, BUD: 7/27/2017; 10112, BUD: 7/30/2017; 10117, BUD: 7/31/2017; 10152, BUD: 8/3/2017; 10159, BUD: 8/6/201 7; 10170, BUD: 8/7/2017; 10174, BUD: 8/8/2017; 10193, BUD: 8/9/2017; 10202, BUD: 8/10/2017; 10212, BUD: 8/13/2017; 10242, BUD: 8/15/2017; 1 0276, BUD: 8/17/2017; 10294, BUD: 8/20/2017; 10320, BUD: 8/23/2017; 10328, BUD: 8/24/2017; 10334, BUD: 8/28/2017; 10342, BUD: 8/29/2017; 1 0364, BUD: 9/3/2017; 10392, BUD: 9/6/2017; 10420, BUD: 9/11/2017; 10427, BUD: 9/12/2017; 10440, BUD: 9/14/2017; 10463, BUD: 9/18/2017; 104 95, BUD: 9/22/2017; 10499, BUD: 9/24/2017; 10512, BUD: 9/25/2017; 10556, BUD: 10/1/2017; 10567, BUD: 10/3/2017; 10583, BUD: 10/6/2017

Product Description:
Rocuronium Bromide Injection Solution 5 mL, 50 mg/5 mL (10 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222, NDC 52533-064-15

Product Quantity:
28779 syringes

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1079-2017

Code Information:
Lot #: 9598, BUD: 8/2/2017; 9609, BUD: 8/5/2017; 9621, BUD: 8/7/2017; 9681, BUD: 8/19/2017; 9765, BUD: 9/5/2017; 10102, BUD: 10/24/2017; 103 47, BUD: 11/26/2017; 10357, BUD: 11/26/2017; 10387, BUD: 12/3/2017; 10478, 10505, 10585, BUD: 12/16/2017

Class II Drugs Event

Event ID:
77834

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/17/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/09/2017

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:
X-Gen Pharmaceuticals Inc.
300 Daniel Zenker Dr
Horseheads NY United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Nystatin Topical Powder, USP, 100,000 USP units per gram, 15 grams per bottle, Rx only, Vensun, NDC 42543-052-61

Product Quantity:
9,816 bottles

Reason for Recall:
Presence of Foreign Substance: potential presence of plastic particles.

Recall Number:
D-1059-2017

Code Information:
Lot #: 23701.158A, EXP 10/31/18

Class II Drugs Event

Event ID:
77836

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/26/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/09/2017

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
HOSPIRA INC, LAKE FOREST
275 NORTH FOREST DRIVE
LAKE FOREST IL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Hydromorphone Hydrochloride Injection, USP, 500 mg/50 mL (10 mg/mL), 50 mL Single Dose Vial. Mfd For: Teva Parenteral Medicines, Inc., Irvine, CA 92618 USA. NDC: 0703-0018-01

Product Quantity:
14,300 vials

Reason for Recall:
Presence of Particulate Matter: Silicone oil

Recall Number:
D-1080-2017

Code Information:
Lot #: 560053F, Exp. 01AUG2017

Product Description:
Hydromorphone Hydrochloride Injection, USP, 500 mg/50 mL (10 mg/mL), 50 mL Single Dose Vial per Carton, 100 vials per case. Hospira, Inc., Lake Forest, IL 60045 USA, NDC: 0409-2634-50

Product Quantity:
9,009 vials

Reason for Recall:
Presence of Particulate Matter: Silicone oil

Recall Number:
D-1081-2017

Code Information:
Lot #: 56260DD, Exp. 01AUG2017

Product Description:
Hydromorphone Hydrochloride Injection, USP, 50 mg/5 mL (10 mg/mL), 5 mL Single Dose Vial.(10 vials per carton NDC 0703-0113-01) and 180 vials per case (NDC 0703-0113-03) Mfd By: Hospira, Inc., Lake Forest, IL 60045 USA, Mfd For: Teva Parenteral Medicines, Inc., Irvine, CA 92618 USA.

Product Quantity:
56,340 vials

Reason for Recall:
Presence of Particulate Matter: Silicone oil

Recall Number:
D-1082-2017

Code Information:
Lot #: 560103F, Exp. 01AUG2017

Class III Drugs Event

Event ID:
77881

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/02/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/08/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
1090 Horsham Rd
North Wales PA United States

Distribution Pattern:
Product distributed to OH, IL, PA, MI, VA and CT

Associated Products

Product Description:
Glipzide Extended-Release Tablets (anti-diabetic agent), 5 mg, packaged in 30-unit dose blister pack per carton, Rx only, Mfd for: Watson Laboratories, Inc., Corona, CA 92880, Mfd by: Patheon Pharmaceuticals, Inc., Cincinnati, OH 43215, NDC 0591-0844-15

Product Quantity:
2,880 cartons (30 unit dose blister pack per carton)

Reason for Recall:
Failed Moisture Limits: out of specification test results for water content obtained during stability testing.

Recall Number:
D-1058-2017

Code Information:
Lot # 3138405A, Exp 8/2017