Enforcement Report - Week of February 28, 2018

Class II Drugs Event

Event ID:
78828

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/27/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/20/2018

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Pharmedium Services, LLC
150 N Field Dr Ste 350
Lake Forest IL United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
HYDROmorphone HCl in Sodium Chloride 0.9% in all doses, all strengths, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0428-2018

Code Information:
All lots remaining within expiry.

Product Description:
Bupivacaine HCl in 0.9% Sodium Chloride in all doses, all strengths, and packaging.

Product Quantity:
297 bags

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0429-2018

Code Information:
All lots remaining within expiry.

Product Description:
Fentanyl Citrate and Ropivacaine HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0430-2018

Code Information:
All lots remaining within expiry.

Product Description:
Fentanyl Citrate and Bupivacaine HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0431-2018

Code Information:
All lots remaining within expiry.

Product Description:
Ephedrine Sulfate in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0432-2018

Code Information:
All lots remaining within expiry.

Product Description:
HYDROmorphone HCl Injection in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0433-2018

Code Information:
All lots remaining within expiry.

Product Description:
Midazolam HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0434-2018

Code Information:
All lots remaining within expiry.

Product Description:
Midazolam HCl in 5% Dextrose in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0435-2018

Code Information:
All lots remaining within expiry.

Product Description:
Morphine Sulfate in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0436-2018

Code Information:
All lots remaining within expiry.

Product Description:
Morphine Sulfate in 5% Dextrose in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0437-2018

Code Information:
All lots remaining within expiry.

Product Description:
Lidocaine HCl in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0438-2018

Code Information:
All lots remaining within expiry.

Product Description:
Fentanyl Citrate in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0439-2018

Code Information:
All lots remaining within expiry.

Product Description:
Potassium Chloride in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0440-2018

Code Information:
All lots remaining within expiry.

Product Description:
Ketamine HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0441-2018

Code Information:
All lots remaining within expiry.

Product Description:
Succinylcholine Chloride in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0442-2018

Code Information:
All lots remaining within expiry.

Product Description:
Adenosine Injection in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0443-2018

Code Information:
All lots remaining within expiry.

Product Description:
Dexamethasone Sodium Phosphate in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0444-2018

Code Information:
All lots remaining within expiry.

Product Description:
Phenylephrine HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0445-2018

Code Information:
All lots remaining within expiry.

Product Description:
Potassium Chloride in 5% Dextrose in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0446-2018

Code Information:
All lots remaining within expiry.

Product Description:
Labetalol HCl in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0447-2018

Code Information:
All lots remaining within expiry.

Product Description:
Methadone HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0448-2018

Code Information:
All lots remaining within expiry.

Product Description:
Midazolam HCl Injection in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0449-2018

Code Information:
All lots remaining within expiry.

Product Description:
Fentanyl Citrate Injection in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0450-2018

Code Information:
All lots remaining within expiry.

Product Description:
Ephedrine Sulfate Injection in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0451-2018

Code Information:
All lots remaining within expiry.

Product Description:
Ketamine HCl Injection in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0452-2018

Code Information:
All lots remaining within expiry.

Product Description:
Ropivacaine HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0453-2018

Code Information:
All lots remaining within expiry.

Product Description:
Glycopyrrolate in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0454-2018

Code Information:
All lots remaining within expiry.

Product Description:
Lidocaine HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0455-2018

Code Information:
All lots remaining within expiry.

Product Description:
Atropine Sulfate Injection in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0456-2018

Code Information:
All lots remaining within expiry.

Product Description:
HYDROmorphone HCl in 5% Dextrose in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0457-2018

Code Information:
All lots remaining within expiry.

Product Description:
Ropivacaine HCl Injection in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0458-2018

Code Information:
All lots remaining within expiry.

Product Description:
Nicardipine HCl in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0459-2018

Code Information:
All lots remaining within expiry.

Product Description:
Labetalol HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0460-2018

Code Information:
All lots remaining within expiry.

Product Description:
Neostigmine Methylsulfate Injection in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0461-2018

Code Information:
All lots remaining within expiry.

Product Description:
Vecuronium Bromide in Sterile Water for Injection in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0462-2018

Code Information:
All lots remaining within expiry.

Product Description:
Dexamethasone Sodium Phosphate added to 0.9% Sodium Chloride in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0463-2018

Code Information:
All lots remaining within expiry.

Product Description:
Esmolol HCl in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0464-2018

Code Information:
All lots remaining within expiry.

Product Description:
Meperidine HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0465-2018

Code Information:
All lots remaining within expiry.

Product Description:
Methadone HCl Injection in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0466-2018

Code Information:
All lots remaining within expiry.

Product Description:
Rocuronium Bromide in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0467-2018

Code Information:
All lots remaining within expiry.

Product Description:
Dexamethasone Sodium Phosphate added to 5% Dextrose in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0468-2018

Code Information:
All lots remaining within expiry.

Product Description:
Nicardipine HCl in 0.9% Sodium Chloride in all strengths, all doses, and all packaging.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0469-2018

Code Information:
All lots remaining within expiry.

Class II Drugs Event

Event ID:
79149

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/09/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/22/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
American Pharmaceutical Ingredients LLC
6650 Highland Rd Ste 302
Waterford MI United States

Distribution Pattern:
Nationwide within USA.

Associated Products

Product Description:
Amitriptyline HCl USP for prescription compounding , packaged in a) 25 g (NDC 58597-8003-4); b) 100 g (NDC 58597-8003-6); c) 500 g (NDC 58597-8003-7), d) 1000 g (NDC 58597-8003-8), RX only, packed by American Pharmaceutical Ingredients, 6650 Highland Road, Waterford, MI 48327.

Product Quantity:
15000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0474-2018

Code Information:
Lot #: a) 031915-1, Exp. 12/31/2019; b) 031915-2, Exp. 12/31/2019; c) 031915-2, Exp. 12/31/2019; d) 031915-1, Exp. 12/31/2019.

Product Description:
Anastrozole USP for prescription compounding, packaged in a) 1g (NDC 58597-8080-1), b) 5g (NDC 58597-8080-2), c) 25g (NDC 58597-8080-4), RX only, packed by American Pharmaceutical Ingredients, 6650 Highland Road, Waterford, MI 48327.

Product Quantity:
684 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0475-2018

Code Information:
Lot #: a) 011116-1, Exp. 07/31/2020; b) 011116-1, 011116-2, Exp. 07/31/2020; c) 011116-1, Exp. 07/31/2020

Product Description:
Baclofen USP (Micronized) for prescription compounding, packaged in a) 25g (NDC 58597-8004-4); b)100g (NDC 58597-8004-6); c) 500g (NDC 58597-8004-7); d) 1000g (NDC 58597-8004-8), RX only, packed by American Pharmaceutical Ingredients, 6650 Highland Road, Waterford, MI 48327.

Product Quantity:
55500 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0476-2018

Code Information:
Lot #: a) 021816-2, 021816-3, Exp. 08/24/2018; 70616-1, Exp. 01/31/2019; b) 021816-1, Exp. 08/24/2018; 070616-1, Exp. 01/31/2019; c) 021816-1, Exp. 08/24/2018; 070616-1, Exp. 01/31/2019; d) 021816-1, Exp. 08/24/2018; 070616-1, exp. 01/31/2019.

Product Description:
Calcipotriene BP (Monohydrate) for prescription compounding, packaged in a) 250mg (NDC 58597-8630-1); b) 500mg (NDC 58597-8630-2); c) 1g (NDC 58597-8630-3), Rx only, packed by American Pharmaceutical Ingredients, 6650 Highland Road, Waterford, MI 48327.

Product Quantity:
10 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0477-2018

Code Information:
Lot #: a) 050715-2, Exp. 04/30/2019; b) 050715-2, Exp. 04/30/2019; c) 050715-1, Exp. 04/30/2019.

Product Description:
Celecoxib USP for prescription compounding, packaged in a) 25g (NDC 58597-8635-4); b) 100g (NDC 58597-8635-5); c) 1000g (NDC 58597-8635-7), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
48525 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0478-2018

Code Information:
Lot #: a) 080515-2, Exp. 06/05/2019; b) 080515-1, Exp. 06/05/2019; c) 080515-1, Exp. 06/05/2019;

Product Description:
Clindamycin Phosphate USP for prescription compounding, packaged in a) 10g (NDC 58597-8198-3); b) 100g (NDC 58597-8198-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
1300 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0479-2018

Code Information:
Lot #: a) 042315-1, Exp. 03/12/2018; b) 042315-1, Exp. 03/12/2018

Product Description:
Clonidine HCl USP for prescription compounding, packaged in a) 5g (NDC 58597-8010-2); b) 10g (NDC 58597-8010-3); c) 25g (NDC 58597-8010-4); d)100g (NDC 58597-8010-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
5000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0480-2018

Code Information:
Lot #: a) 070915-1, Exp. 12/31/2019; b) 070915-1, Exp. 12/31/2019; c) 070915-1, Exp. 12/31/2019; d) 070915-1, Exp. 12/31/2019

Product Description:
Cyclobenzaprine HCl USP for prescription compounding, packaged in a) 25g (NDC 58597-8011-4), b)100g (NDC 58597-8011-6); c) 500 g (NDC 58597-8011-7); d)1000g (NDC 58597-8011-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
123900 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0481-2018

Code Information:
Lot #: a) 081715-1, Exp. 2/29/2020; b) 010615-1, Exp. 6/30/2019; 051616-1, Exp.11/30/2020; 081715-1, Exp. 2/29/2020; CBP1307004BVP-4102015, Exp. 4/30/2018; c) 010615-1, Exp. 6/30/2019; 081715-1, Exp. 2/29/2020 d) 010615-1, Exp. 6/30/2019; 051616-1, Exp.11/30/2020; 081715-1, Exp. 2/29/2020; 081715-2, Exp. 2/29/2020;

Product Description:
Cyclosporine USP, for prescription compounding, packaged in a) 5g (NDC 58597-8210-2); b) 10g (NDC 58597-8210-3); c) 100g, NDC 58597-8210-6; d) 500g (NDC 58597-8210-7), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
13335 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0482-2018

Code Information:
Lot #: a) 062515-2, Exp. 02/28/2019; b) 062515-1, Exp. 02/28/2019; 062515-2, Exp. 02/28/2019; 052317B-2, Exp. 01/31/2021; c) 052317B-1, Exp. 01/31/2021; 052317B-1, Exp. 01/31/2021; 062515-1, exp. 02/28/2019; d) 052317B-1, Exp. 01/31/2021; 062515-3, exp. 02/28/2019.

Product Description:
Desoximetasone USP (Micronized) for prescription compounding, 5g, RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327, NDC 58597-8634-2.

Product Quantity:

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0483-2018

Code Information:
Lot #: 071015-1, Exp. 3/7/2018

Product Description:
Diclofenac Sodium USP for prescription compounding, packaged in a) 25g (NDC 58597-8012-4); b)100g (NDC 58597-8012-6); c) 500 g (NDC 58597-8012-7); d) 1000g (NDC 58597-8012-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
116850 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0484-2018

Code Information:
Lot #: a) 082715-1, Exp. 06/24/2018; 061715-1, Exp. 6/6/2018; 072516-2, Exp. 07/04/2019; b) 082715-1, Exp. 06/24/2018; 061715-1, Exp. 6/6/2018; 072516-2, Exp. 07/04/2019; c) 061715-1, Exp. 6/6/2018; 072516-2, Exp. 07/04/2019; 082715-1, Exp. 06/24/2018; d) 072516-1, Exp. 07/04/2019; 082715-1, Exp. 06/24/2018;

Product Description:
Diphenhydramine HCl USP f (or prescription compounding , packaged in a) 25g (NDC 58597-8081-4); b) 100g (NDC 58597-8081-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
8300 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0485-2018

Code Information:
Lot #: a) 031715-1, Exp. 12/31/2019; b) 031715-1, Exp. 12/31/2019

Product Description:
Doxycycline Hyclate USP for prescription compounding, packaged in a) 25g (NDC 58597-8082-4); b) 100g (NDC 58597-8082-6); c) 500g (NDC 58597-8082-7); d) 1000g (NDC 58597-8082-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
75000

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0486-2018

Code Information:
Lot #: a) 082815-1, Exp. 06/04/2019; b) 082417-1, Exp. 03/04/2020; 082815-1, Exp. 06/04/2019; c) 082815-1, Exp. 06/04/2019; d) 082815-1, Exp. 06/04/2019

Product Description:
Duloxetine HCl USP for prescription compounding, packaged in a)100g (NDC 58597-8632-6); b)1000 g (NDC 58597-8632-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
10000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0487-2018

Code Information:
Lot #: a) 061115-2, Exp. 05/31/2019; b) 061115-1, Exp. 5/31/2019;

Product Description:
Estradiol USP (Micronized) (Yam) for prescription compounding, packaged in a) 1g (NDC 58597-8047-1); b) 5g (NDC 58597-8047-3); c) 10g (NDC 58597-8047-4); d) 25g (NDC 58597-8047-5); e) 100 g (NDC 58597-8047-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
2000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0488-2018

Code Information:
Lot #: a) 111516-1, Exp. 09/19/2018; b) 011917A-1, Exp. 09/22/2018; c) 111516-1, Exp. 09/19/2018; d) 011917A-1, Exp. 09/22/2018; 111516-1, Exp.

09/19/2018; e) 011917A-1, Exp. 09/22/2018; 111516-1, Exp. 09/19/2018

Product Description:
Estradiol Hemihydrate USP (Micronized) (Soy) for prescription compounding, packaged in a) 5g (NDC 58597-8001-3); b) 25g (NDC 58597-8001-5); c)100 g (NDC 58597-8001-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
4910 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0489-2018

Code Information:
Lot: #:a) 083017-1, Exp. 7/22/2022; b) 083017-1, Exp. 7/22/2022; c) 083017-1, Exp. 7/22/2022.

Product Description:
Estriol USP (Micronized) (Yam) for prescription compounding, packaged in a) 5g (NDC 58597-8048-2), b) 25g (NDC 58597-8048-4), c) 100g (NDC 58597-8048-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327.

Product Quantity:
3675 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0490-2018

Code Information:
Lot #: a) 111516-1, Exp. 9/19/2018; 011817-1, Exp. 9/10/2018; 111616-1, Exp. 5/18/2018; 052317A-1, Exp. 5/27/2019; b) 011817-1, Exp. 9/10/2018; 111616-1, Exp. 5/18/2018; 052317A-1, Exp. 5/27/2019; c) 011817-1, Exp. 9/10/2018; 052317A-1, Exp. 5/27/2019; 111616-1, Exp. 5/18/2018;

Product Description:
Estrone USP for prescription compounding, packaged in a) 5 g (NDC 58597-8049-3); b) 100mg (NDC 58597-8049-1); c) 25 g (NDC 58597-8049-4), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
5000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0491-2018

Code Information:
Lot #: a) 052915-2, Exp. 05/05/2017; b) 052915-2, Exp. 05/05/2017; c) 052915-1, Exp. 05/05/2017.

Product Description:
Fluconazole USP for prescription compounding, packaged in a) 25g (NDC 58597-8268-4); b) 100g (NDC 58597-8268-6); c)1000g (NDC 58597-8268-8) RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
106200 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0492-2018

Code Information:
Lot #: a) 051115-1, Exp. 4/30/2020; 081017-1, exp 11/30/2021; 122216-1,122216-2, Exp. 12/31/2020; b) 041017-1, Exp. 11/30/2021; 051115-1, Exp. 4/30/2020; 081017-1, exp 11/30/2021; c) 041017-1, 041017-2, Exp. 11/30/2021; 122216-1, 122216-2, exp. 12/31/2020

Product Description:
Flurbiprofen USP for prescription compounding, packaged in a) 25g (NDC 58597-8075-4); b)100g (NDC 58597-8075-6) ; c) 500g (NDC 58597-8075-7); d) 1000g (NDC 58597-8075-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
193000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0493-2018

Code Information:
Lot #: a) 062915-2, Exp. 04/30/2020; b) 022416-1, Exp. 11/30/2020; 062915-2, exp. 04/30/2020; 081215-2, Exp. 06/30/2020; c) 022416-1, Exp. 11/30/2020; 062915-1, Exp. 04/30/2020; 081215-1, Exp. 06/30/2020; d) 022416-1, Exp. 11/30/2020; 062915-1, Exp. 04/30/2020; 081215-1, Exp. 06/30/2020; 110415-1, Exp. 09/30/20120

Product Description:
Gabapentin USP for prescription compounding, packaged in a) 25g (NDC 58597-8014-4); b) 100g (NDC 58597-8014-6); c) 500g (NDC 58597-8014-7); d) 1000g (NDC 58597-8014-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
606950

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0494-2018

Code Information:
Lot #: a) 031116-7, exp. 03/31/2019; 112816-1, Exp. 03/01/2020 b) 011717-2, 051617-1, Exp. 04/30/2020; 031116-1, 031116-2, 031116-7, exp. 03/31/2019; 051215-1, exp. 03/05/2018; 063015-1, Exp. 05/19/2018; 092315-1, Exp. 07/17/2018; 111615-6, Exp. 08/27/2018; 112816-1, Exp. 03/01/2020; c) 011717-7, 011717-2, 051617-1, 082117B-1, Exp. 04/30/2020; ; 031116-2, 031116-4, 031116-5, 031116-7, Exp.. 03/31/2019; 051215-1, Exp. 03/05/2018; 092315-2, Exp. 07/17/2018; 111615-4, 111615-5, Exp. 08/27/2018; 112816-1, 112816-2, Exp. 03/01/2020; d) 011717-7, 051617-1, 082117B-1, Exp. 04/30/2020; 031116-1, 031116-2, 031116-3, 031116-4, 031116-6, 031116-7, Exp. 03/31/2019; 051215-1, 051215-3, Exp. 03/05/2018; 063015-2, Exp. 05/19/2018; 111615-1, 111615-2, 111615-3, Exp. 08/27/2018; 112816-2, Exp. 03/01/2020

Product Description:
Hydroxyprogesterone Caproate USP for prescription compounding, packaged in a) 25g (NDC 58597-8051-4); b) 100g (NDC 58597-8051-6); c) 500g (NDC 58597-8051-7), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
26500 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0495-2018

Code Information:
Lot #: a) 081015-1, Exp 07/23/2018; b) 081015-1, Exp 07/23/2018; 111116-1, Exp. 10/05/2019; c) 081015-1, Exp. 07/23/2018; 111116-1, Exp. 10/05/2019

Product Description:
Imiquimod USP for prescription compounding, packaged in a) 1g (NDC 58597-8317-1); b) 10g (NDC 58597-8317-3); c) 25g (NDC 58597-8317-4) RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
1638 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0496-2018

Code Information:
Lot #: a) 012016-2, Exp. 11/30/2020; b) 012016-1, Exp. 11/30/2020; c) 012016-1, Exp. 11/30/2020; 012016-2, Exp.11/30/2020;

Product Description:
Itraconazole USP (Micronized) for prescription compounding, packaged in a) 10g (NDC 58597-8133-3); b) 25g (NDC 58597-8133-4); c)100g (NDC 58597-8133-6); d) 1000g (NDC 58597-8133-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
52000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0497-2018

Code Information:
Lot #: a) 061515-1, Exp. 04/30/2020; b) 080316-1, Exp. 06/30/2021; 052317C-1, Exp 02/28/2022; 061515-1, Exp. 04/30/2020; c) 061515-1, Exp. 04/30/2020; 080316-1, Exp. 06/30/2021; 091216-1, Exp. 07/31/2021; d) 061515-1, 061515-2, exp. 04/30/2020; 080316-1, Exp. 06/30/2021; 091216-1, Exp. 07/31/2021

Product Description:
Ketamine HCl USP for prescription compounding, packaged in a) 25g (NDC 58597-8333-4); b) 100g (NDC 58597-8333-6); c) 500g (NDC 58597-8333-7); d) 1000g (NDC 58597-8333-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
191000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0498-2018

Code Information:
Lot #: a) 102015-3, Exp. 07/31/2020; 081616-3R, Exp. 02/28/2021; b) 081616-3, 081616-3R, Exp. 02/28/2021; 102015-2, Exp. 07/31/2020; c) 081616-1R, Exp. 02/28/2021; 081616-1, Exp. 02/29/2021; 102015-1, 102015-2, Exp. 07/31/2020; d) 102015-1, Exp. 07/31/2020; 081616-1, Exp. 02/29/2021; 081616-1R, 081616-2R, Exp. 02/28/2021.

Product Description:
Ketoconazole USP for prescription compounding, packaged in a) 25g (NDC 58597-8053-4); b) 100g (NDC 58597-8053-6); c) 500g (NDC 58597-8053-7) RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
4600 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0499-2018

Code Information:
Lot #: a) 091115-1, Exp. 07/31/2020; 091115-2, Exp. 07/31/2020; b) 091115-1, Exp. 07/31/2020; c) 091115-1, Exp. 07/31/2020.

Product Description:
Ketoprofen USP (Micronized) for prescription compounding, packaged in a) 25g (NDC 58597-8336-4); b) 100g (NDC 58597-8336-6); c) 500g (NDC 58597-8336-7); d) 1000g (NDC 58597-8336-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
225300 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0500-2018

Code Information:
Lot #: a) 051916-1, Exp. 04/30/2019; 061015-1, Exp. 03/03/2018; 041216-2, Exp. 03/27/2019; b) 051916-1, Exp. 04/30/2019; 052517-1, Exp. 02/28/2022; 061015-1, Exp. 03/03/2018; c) 041216-1, Exp. 03/27/2019; 051916-3, Exp. 04/30/2019; 052517-1, Exp. 02/28/2022; 061015-1, Exp. 03/03/2018; d) 041216-1, 041216-3, Exp. 03/27/2019; 051916-2, 051916-3, 051916-4, Exp. 04/30/2019; 061015-1, Exp. 03/03/2018;

Product Description:
Leucovorin Calcium USP for prescription compounding, packaged a) 100mg, (NDC 58597-8084-1); b) 1g (NDC 58597-8084-3); c) 5g (NDC 58597-8084-4); d) 25 g (NDC 58597-8084-5), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
240 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0501-2018

Code Information:
Lot #: a) 092415-1, Exp. 05/21/2018; b) 092415-1, Exp. 05/21/2018; 122915-1, Exp. 05/15/2018; c) 092415-1, Exp. 05/21/2018; 122915-1, Exp. 05/15/2018 d) 092415-1, Exp. 05/21/2018;

Product Description:
Levetiracetam USP for prescription compounding, packaged in a) 500g (NDC 58597-8353-7); b) 1000g (NDC 58597-8353-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
36100 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0502-2018

Code Information:
Lot #: a) 072616-1, Exp. 06/29/2019; b) 060115-1, Exp. 01/23/2018; 072616-1, Exp. 06/29/2019;

Product Description:
Levocetirizine Dihydrochloride for prescription compounding, packaged in a) 25g (NDC 58597-8355-6); b) 100g (NDC 58597-8355-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
5800 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0503-2018

Code Information:
Lot #: a) 073115-1, Exp. 6/30/2020; b) 073115-1, Exp. 6/30/2020;

Product Description:
Levofloxacin Hemihydrate USP for prescription compounding, packaged in a) 100g (NDC 58597-8085-6); b) 1000g (NDC 58597-8085-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
10000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0504-2018

Code Information:
Lot #: a) 072915-1, Exp. 07/05/2019; b) 072915-1, Exp. 07/05/2019

Product Description:
Levothyroxine Sodium USP for prescription compounding, packaged in a) 1g (NDC 58597-8638-1); b) 5 g (NDC 58597-8638-2), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
75 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0505-2018

Code Information:
Lot #: a) 090517B-2, Exp. 11/17/2019; b) 090517B-2, Exp. 11/17/2019

Product Description:
Lidocaine HCl USP for prescription compounding, packaged in a) 100g (NDC 58597-8020-6); b) 500g (NDC 58597-8020-7); c) 1000g (NDC 58597-8020-8) RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
166000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0506-2018

Code Information:
Lot #: a) 021115-1, Exp. 01/15/2020; 080415-1, Exp. 03/22/2020; b) 020116-2, Exp. 12/13/2020; 021115-1, Exp. 01/15/2020; 080415-1, Exp. 03/22/2020; c) 020116-1, 020116-2, Exp. 12/13/2020; 021115-1, exp. 01/15/2020; 080415-1, Exp. 03/22/2020; 082416-1, 082416-2 Exp. 01/31/2021.

Product Description:
Lidocaine USP for prescription compounding, packaged in a) 25g (NDC 58597-8019-4); b) 100g (NDC 58597-8019-6); c) 500g (NDC 58597-8019-7); d) 1000 (NDC 58597-8019-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
74000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0507-2018

Code Information:
Lots #: a) 110215-2, Exp. 09/30/2020; b) 110215-1, Exp. 09/30/2020; 082516-1, Exp. 05/31/2021; c) 110215-1, Exp. 09/30/2020; 082516-1, Exp. 05/31/2021; d) 110215-1, Exp. 09/30/2020; 082516-1, Exp. 05/31/2021.

Product Description:
Lincomycin HCl USP for prescription compounding, packaged in a)100g (NDC 58597-8359-6); b) 500g (NDC 58597-8359-7); c) 1000g (NDC 58597-8359-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
22900 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0508-2018

Code Information:
Lot #: a) 110515-2, Exp. 09/30/2018; b) 110515-1, Exp. 09/30/2018; c) 110515-1, Exp. 09/30/2018.

Product Description:
Liothyronine Sodium USP for prescription compounding ,1g, RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327, NDC 58597-8021-2.

Product Quantity:
73 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0509-2018

Code Information:
Lot #: 090517A-1, Exp. 09/13/2018

Product Description:
Medroxyprogesterone Acetate USP (Micronized) for prescription compounding 1000 g, RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Water ford, MI 48327, NDC 58597-8055-8

Product Quantity:
12000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0510-2018

Code Information:
Lot #: 081415-2, Exp. 05/03/2018

Product Description:
Naltrexone HCl USP (Dihydrate) for prescription compounding, packaged in a) 1g (NDC 58597-8407-1); b) 5g (NDC 58597-8407-2); c) 25g (NDC 58597-8407-4); d) 100g (NDC 58597-8407-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
7000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0511-2018

Code Information:
Lot #: a) 120916-1, Exp. 10/31/2019; b) 120916-1, Exp. 10/31/2019 c) 120916-1, Exp. 10/31/2019; d) 120916-1, Exp. 10/31/2019.

Product Description:
Nandrolone Decanoate USP for prescription compounding, packaged in a) 25g (NDC 58597-0081-4); b) 100g (NDC 58597-0081-6); c) 500g (NDC 58597-0081-7); d) 1000g (NDC 58597-0081-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
86225 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0512-2018

Code Information:
Lot #: a) 012716-1, 012716-2, Exp. 01/12/2019; 110316-3, Exp. 09/21/2021 b) 012716-1, 012716-3, Exp. 01/12/2019; 110316-1, 110316-3, Exp. 09/21/2021; c) 012716-1, 012716-3, Exp. 01/12/2019; 110316-1, 110316-2, Exp. 09/21/2021; exp. 09/21/2021; d) 012716-1, 012716-3, Exp. 01/12/2019; 041717-2, Exp. 04/06/2022; 110316-1, 110316-2, Exp. 09/21/2021.

Product Description:
Nifedipine USP for prescription compounding, packaged in a) 5g (NDC 58597-8025-2); b) 25g (NDC 58597-8025-4); c) 100g (NDC 58597-8025-6); d) 500g (NDC 58597-8025-7), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
44500 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0513-2018

Code Information:
Lot #: a) 020615-2, Exp. 12/04/2018; b) 020615-2, Exp. 12/04/2018; c) 020615-1, Exp. 12/04/2018; d) 020615-1, Exp. 12/04/2018; 020615-2, Exp. 12/04/2018.

Product Description:
Oxandrolone USP for prescription compounding, packaged in a) 25g (NDC 58597-0082-4); b)100g (NDC 58597-0082-6); c) 500g (NDC 58597-0082-7), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
24025 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0514-2018

Code Information:
Lot #: a) 012616-2, Exp. 01/08/2019; b) 012616-1, Exp. 01/08/2019; 012616-2, Exp. 01/08/2019; c) 012616-1, Exp. 01/08/2019; 012616-3, Exp. 01/08/2019.

Product Description:
Pentoxifylline USP for prescription compounding, packaged in a) 25g (NDC 58597-8429-4); b) 100g (NDC 58597-8429-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
29550 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0515-2018

Code Information:
Lot #: a) 092515-1, Exp. 5/31/2020; b) 092515-1, Exp. 5/31/2020.

Product Description:
Phentolamine Mesylate USP for prescription compounding, packaged in a) 1g (NDC 58597-8077-3); b) 5g (NDC 58597-8077-4); c) 500g (NDC 58597-8077-7), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
6000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0516-2018

Code Information:
Lot #: a) 080315-1, Exp. 04/05/2018; b) 080315-1, Exp. 04/05/2018, c) 080315-1, Exp. 04/05/2018.

Product Description:
Prilocaine HCl USP for prescription compounding, packaged in a) 100g (NDC 58597-8028-6); b) 500g (NDC 58597-8028-7); c) 1000g (NDC 58597-8028-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
20700 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0517-2018

Code Information:
Lot #: a) 071117-1, Exp. 06/16/2020; b) 071117-1, Exp. 06/16/2020; c) 071117-1, Exp. 06/16/2020

Product Description:
Progesterone USP (Micronized) (Yam) for prescription compounding, packaged in a) 1g (NDC 58597-8471-1); b) 10g (NDC 58597-8471-3); c) 25g (NDC 58597-8471-4); d) 100g (NDC 58597-8471-6); e) 500g (NDC 58597-8471-7); f) 1000g (NDC 58597-8471-8); g) 5000g (NDC 58597-8471-9), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
1,050,000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0518-2018

Code Information:
Lot #: a) 031115-3, Exp. 12/24/2019; b) 031115-3, Exp. 12/24/2019 c) 031115-3, Exp. 12/24/2019; 050815-3, Exp. 04/14/2020; d) 010716-1, 010716-6, Exp. 11/10/2018; 030116-4, Exp. 12/04/2018; 031115-2, Exp. 12/24/2019; 060116-9, Exp. 4/28/2019; 080416-1, 080416-4, Exp. 06/05/2019; 080615-4, Exp. 07/29/2020; 112015-6, Exp. 10/7/2018; 121916-7, Exp. 11/10/2018; e) 080615-5, Exp. 07/29/2020; 010716-4, 010716-5, Exp. 11/10/2018; 030116-2, Exp. 12/04/2018; 031115-5, Exp. 12/24/2019; 060116-1, 060116-4, 060116-5, Exp. 04/28/2019; 080416-1, 080416-2, exp. 06/05/2019; 112015-1, Exp. 10/07/2018; 121916-2,121916-3, 121916-6, Exp. 11/02/2019; f) 112015-5, Exp. 10/07/2018; 010716-1, Exp. 11/10/2018; 030116-3, Exp. 12/04/2018; 010716-1, 010716-2, 010716-3, 010716-8, Exp. 11/10/2018; 030116-1, 030116-3, 030116-4,030116-5, Exp. 12/4/2018; 031115-5, Exp. 12/24/2019; 060116-4, 060116-6, 060116-8, 060116-9, Exp. 04/28/2019; 080416-3, 080416-4, 080416-5, Exp. 06/05/2019; 112015-2, 112015-3, 112015-4,112015-6, 112015-7, Exp. 10/07/2018; 121916-1, Exp. 11/02/2019; 121916-3, 121916-4, 121916-5, 121916-7 121916-8, Exp.11/02/2019; g) 060116-2, 060116-3 060116-7, Exp. 04/28/2019.

Product Description:
Sildenafil Citrate USP for prescription compounding, packaged in a) 5g (NDC 58597-8088-2);b) 25g (NDC 58597-8088-4); c) 50g (NDC 58597-8088-5); d) 100g (NDC 58597-8088-6); e) 500g (NDC 58597-8088-7); f)1000g (NDC 58597-8088-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
307500 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0519-2018

Code Information:
Lot #: a) 021317-4, Exp. 12/31/2021; b) 021317-2R, 021317-4, Exp. 12/31/2021; 050115-4, Exp. 3/31/2020; 101915-5, Exp. 08/31/2020 c) 050115-3, 050115-4, Exp. 03/31/2020; d) 021317-3R, Exp 12/31/2021; 050115-2, 050115-3, Exp. 03/31/2020; 101915-3, 101915-4,101915-5, Exp. 08/31/2020; e) 021317-2R, Exp. 12/31/2021; 050115-2, exp. 03/31/2020; 101915-1, 101915-2,101915-5, Exp. 08/31/2020; f) 021317-1R, 021317-2R,021317-3R, Exp. 12/31/2021; 050115-1, 050115-2, Exp. 03/31/2020; 101915-1, 101915-2, Exp. 08/31/2020.

Product Description:
Stanozolol USP for prescription compounding, packaged in a) 25g (NDC 58597-8525-3);b)100g (NDC 58597-8525-6); c) 500g (NDC 58597-8525-7); d)1000g (NDC 58597-8525-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
12300 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0520-2018

Code Information:
Lot #: a) 080616-1, 4/26/2019; b) 080616-1, 4/26/2019; c) 080616-1, 4/26/2019; d) 080616-1, 4/26/2019.

Product Description:
Sumatriptan Succinate USP for prescription compounding, 25g, RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327, NDC 58597-8633-4.

Product Quantity:
10000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0521-2018

Code Information:
Lot #: 061615-1, Exp.12/31/2019

Product Description:
Sumatriptan USP for prescription compounding, packaged in 10g (NDC 58597-8089-3); b) 25g (NDC 58597-8089-4); c)100g (NDC 58597-8089-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
10000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0522-2018

Code Information:
Lot #: a) SUT1213030SP-11192014, Exp. 11/30/2018; b) SUT1213030SP-11192014, exp. 11/30/2018; c) SUT1213030SP-7222015, Exp.11/30/2018.

Product Description:
Tacrolimus USP (Monohydrate) for prescription compounding, packaged in a) 1g (NDC 58597-8029-4); b) 5g (NDC 58597-8029-5), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
75 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0523-2018

Code Information:
Lot #: a) 053116-1R, Exp.04/30/2018; b) 053116-1R, Exp.04/30/2018

Product Description:
Tadalafil USP (Monohydrate) for prescription compounding, packaged in a) 5g (NDC 58597-8538-2); b) 25g (NDC 58597-8538-4); c)100g (NDC 58597-8538-6); d) 500g (NDC 58597-8538-7); d) 1000g (NDC 58597-8538-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
90000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0524-2018

Code Information:
Lot #: a) 020717-3, Exp. 12/31/2021; b) 020717-2 020717-4, 020717-5 Exp. 12/31/2021; 092816-2, 092816-3, Exp. 07/31/2021; 121015-4, 121015-5, 121015-6, Exp.10/31/2020; c) 020717-1, 020717-4, 020717-5, Exp. 12/31/2021; 092816-1, Exp. 07/31/2021; 092816-2, Exp. 07/31/2021; 121015-1,121015-3, Exp. 10/31/2020; d) 020717-1, 020717-2, Exp. 12/31/2021; 092816-1, Exp. 07/31/2021; 121015-2, Exp. 10/31/2020; e) 020717-1,020717-2 Exp. 12/31/2021.

Product Description:
Testosterone (Soy) (Micronized) USP for prescription compounding, packaged in a) 25g (NDC 58597-0077-4); b) 100g (NDC 58597-0077-6), c) 500g (NDC 58597-0077-7); d)1000g (NDC 58597-0077-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
33000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0525-2018

Code Information:
Lot #: a) 071516-3, Exp. 04/01/2019; b) 071516-3, Exp. 4/1/2019; c) 071516-1, 071516-2, Exp. 04/01/2019; d) 071516-1, 071516-3, Exp. 04/01/2019, 032117B-1, Exp. 2/9/2020.

Product Description:
Testosterone Cypionate USP (Micronized) for prescription compounding, packaged in a)100g (NDC 58597-0078-6); b) 500g (NDC 58597-0078-7); c) 1000g (NDC 58597-0078-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
611400 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0526-2018

Code Information:
Lot #: a) 032117A-6, Exp. 01/21/2019; 112916-2, 112916-4, Exp. 10/17/2018; b) 032117A-4, 032117A-5, Exp. 01/21/2019; 112916-1, Exp. 10/17/2018; 112916-4, Exp. 10/17/2018; c) 032117A-1, 032117A-2, 032117A-3, 032117A-4, 032117A-5, Exp. 01/21/2019; 112916-1, 112916-2, 112916-3, 112916-4, Exp. 10/17/2018.

Product Description:
Testosterone Enanthate USP for prescription compounding, packaged in a) 25g (NDC 58597-0079-4); b) 100g (NDC 58597-0079-6); c) 500g (NDC 58597-0079-7); d) 1000g (NDC 58597-0079-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
47500 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0527-2018

Code Information:
Lot #: a) 042016-2, Exp. 4/6/2019; b) 041217-1, Exp. 02/09/2019; 042016-2, 042016-3, Exp. 4/6/2019; c) 041217-1, 041217-3, Exp. 02/09/2019; 042016-1, Exp. 04/06/2019; 042016-2, Exp. 4/6/2019; d) 041217-3, Exp. 01/09/2019; 042016-1, Exp. 4/6/2019.

Product Description:
Testosterone USP (Micronized) (Yam) for prescription compounding, packaged in a) 25g (NDC 58597-8546-4); b) 100g (NDC 58597-8546-6); c) 500g (NDC 58597-8546-7); d) 1000g (NDC 58597-8546-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
192000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0528-2018

Code Information:
Lot #: a) b) 032117C-1, Exp. 02/11/2020; 070716-2, Exp. 03/22/2019; 121616-1, Exp. 08/20/2019; 071516-3, Exp. 4/1/2019; c) 032117C-1, Exp. 02/11/2020; 070716-1, Exp. 03/22/2019; 070716-2, Exp. 03/22/2019; 121616-1, Exp. 08/20/2019 d) 032117C-1, Exp. 02/11/2020; 061317-1, Exp. 4/30/2020; 061617-1, Exp. 05/01/2020; 070716-1, 070716-2, Exp. 03/22/2019; 121616-1, Exp. 8/20/2019.

Product Description:
Tramadol HCl USP (CIV) for prescription compounding, packaged in a) 25g (NDC 58597-8032-4); b) 100g (NDC 58597-8032-6); c) 500g (NDC 58597-8032-7); d)1000g (NDC 58597-8032-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
63975 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure

system.

Recall Number:
D-0529-2018

Code Information:
Lot #: a) UT2140602-1132014, Exp. 05/31/2019; b) UT2140602-1142014, UT2140602-4222015, Exp. 05/31/2019; UT2140602-10292014, Exp. 05/31/02019; UT2131205UI-1192015, Exp.11/30/2018; UT2140602-10292014, Exp. 05/31/2019; c) UT2140602-10282014, Exp. 05/31/2019; UT2131205UI, Exp. 11/30/2018; UT2140602-4222015, Exp. 5/31/2019; d) UT2140602-10282014, Exp. 05/31/2019; UT2131205UI, UT2131205UI-1192015, Exp. 11/30/2018.

Product Description:
Tretinoin USP for prescription compounding, packaged in a) 5g (NDC 58597-8033-2); 1b) 10g (NDC 58597-8033-3); c) 25g (NDC 58597-8033-4), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
2100 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0530-2018

Code Information:
Lot #: a) 062615-1, Exp. 06/09/2018; 071816-1, exp. 06/05/2019; b) 043015-1, Exp. 04/01/2018; 062615-1, Exp. 06/09/2018; 071816-1, exp. 06/05/2019; c) 062615-1, Exp. 06/09/2018; 071816-1, Exp. 06/05/2019.

Product Description:
Ursodiol USP for prescription compounding, packaged in a) 100g (NDC 58597-8038-6); b) 500g (NDC 58597-8038-7), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
25000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0531-2018

Code Information:
Lot #: a) 071316-1, Exp. 05/27/2019; b) 071316-1, Exp. 05/27/2019

Product Description:
Vancomycin HCl USP for prescription compounding, packaged in a) 25g (NDC 58597-8091-4); b) 100g (NDC 58597-8091-6); c) 500g (NDC 58597-8091-7), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
12725 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0532-2018

Code Information:
Lot #: a) 013117-1, Exp. 06/30/2019; b) 013117-1, Exp. 06/30/2019; c) 013117-1, Exp. 06/30/2019.

Product Description:
Vardenafil HCl USP (trihydrate) for prescription compounding, packaged in a) 5g (NDC 58597-8575-2); b) 100g (NDC 58597-8575-6);c) 500g (NDC 58597-8575-7); d) 1000g (NDC 58597-8575-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
10000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0533-2018

Code Information:
Lot #: a) 070717-2, Exp. 05/31/2020; b) 070717-1, Exp. 05/31/2020; c) 070717-1, Exp. 05/31/2020; d) 070717-1, Exp. 05/31/2020.

Product Description:
Verapamil HCl USP for prescription compounding, packaged in a) 100g (NDC 58597-8039-6); b) 500g (NDC 58597-8039-7); c) 1000g (NDC 58597-8039-8), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
50000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0534-2018

Code Information:
Lot #: a) 072216-1, Exp. 11/26/2019; b) 072216-1, Exp. 11/26/2019; c)0 72216-1, Exp. 11/26/2019;

Product Description:
Ascorbic Acid USP, for prescription compounding, packaged in a) 100g (NDC 58597-8120-6); b) 500g (NDC 58597-8120-7); c) 1000g (NDC 58597-8120-8); d) 5000g (NDC 58597-8120-9); e) 25000g (NDC 58597-8120-3), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
200000 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0535-2018

Code Information:
Lot #: b) 030816-1, Exp. 05/20/2018; c) 030816-1, Exp. 05/20/2018; d) 030816-3, Exp. 05/20/2018; e) 030816-2, Exp. 05/20/2018;

Product Description:
Biotin USP (Vitamin H) for prescription compounding, packaged in a) 500mg (NDC 58597-8142-1); b) 1g (NDC 58597-8142-2); c) 5g (NDC 58597-8142-3); d) 25g (NDC 58597-8142-4), Rx only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
7255 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0536-2018

Code Information:
Lot #: a) 070815-2, Exp. 04/24/2018; b) 070815-2, Exp. 04/24/2018; c) 070815-2, Exp. 04/24/2018; 110416-2, Exp. 06/30/2019; d) 110416-1, Exp. 06/30/2019; 070815-1, Exp. 04/24/2018.

Product Description:
Methylcobalamin (Vitamin B12) for prescription compounding, packaged in a) 500mg (NDC 58597-8142-1); b) 1g (NDC 58597-8056-2); c) 5g (NDC 58597-8056-3); d) 10g (NDC 58597-8056-4), e) 25 g (NDC 58597-8056-4); f) 100g (NDC 58597-8056-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:
10769 g

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0537-2018

Code Information:
Lot #: a) b) 012216-1, Exp. 12/31/2019; 051515-3, Exp. 02/28/2019; 051515-3, Exp. 02/28/2019; c) 012216-1, Exp. 12/31/2019; 051515-3, Exp. 02/28/2019 d) 012216-1, Exp. 12/31/2019; 051515-2, Exp. 02/28/2019; 061516-1, Exp. 01/31/2020; e) 051515-2, exp. 02/28/2019; 061516-1, Exp. 01/31/2020; ; 082117A-1, Exp. 05/31/2021; f) 012216-1, Exp. 12/31/2019; 051515-1, Exp. 02/28/2019; 061516-1, Exp. 01/31/2020; ; 082117A-1, Exp. 05/31/2021

Product Description:
Cyanocobalamin USP (Vitamin B12) for prescription compounding, packaged in a) 1g (NDC 58597-8044-1), b) 5g (NDC 58597-8044-2), c) 25g (NDC 58597-8044-4), d) 100g (NDC 58597-8044-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0538-2018

Code Information:
Lot #: a) 031815-2, Exp. 1/14/2020; b) 031815-2, Exp. 1/14/2020; c) 031815-2, Exp. 1/14/2020; d) 031815-1, Exp. 1/14/2020

Product Description:
Fluticasone propionate USP (Micronized) for prescription compounding, packaged in a) 1g (NDC (58597-8276-1), b) 10g (NDC 58597-8276-3), c) 25g (NDC 58597-8276-4), d) 100g (NDC 58597-8276-6), RX only, packed by American Pharmaceutical Ingredients, LLC 6650 Highland Road, Waterford, MI 48327

Product Quantity:

Reason for Recall:
CGMP Deviations: Lack of stability data and controls to support the manufacturers assigned retest or expiration date in firm's container/closure system.

Recall Number:
D-0539-2018

Code Information:
Lot #: a) 052615-2, Exp. 4/30/2020; 020916-1, Exp. 12/31/2020; b) 092115-1, Exp. 8/31/2020; 092115-2, Exp. 8/31/2020; 020916-1, Exp. 12/31/202

0; 110315-3, Exp. 9/30/2020; c) 020916-1, Exp. 12/31/2020, 110315-2, Exp. 9/30/2020; d) 020916-1, Exp. 12/31/2020

Class III Drugs Event

Event ID:
79119

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/02/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/16/2018

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide within the US

Associated Products

Product Description:
Metformin Hydrochloride Tablets, USP 1000 mg, 500-count bottles, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc. 2400 Route 130 North Dayton, NJ 08810, Manufactured by: Aurobindo Pharma Limited Unit -VII (SEZ)) Mahabubnagar (Dt)_509302 India, NDC 65862-010-05.

Product Quantity:
7476 bottles

Reason for Recall:
Presence of Foreign Tablet: Metformin BP 1000mg was found in bottle of Metformin HCl 1000mg

Recall Number:
D-0427-2018

Code Information:
Lot#: MTSC17145-A, Exp. July 2021

Class III Drugs Event

Event ID:
79210

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/13/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/20/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Nostrum Laboratories Inc
1800 N Topping Ave
Kansas City MO United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Calcium Acetate Capsules, 667 mg, 200 Capsules per bottle, Rx Only. Manufactured by Nostrum Laboratories, Inc. Kansas City, MO 64120. NDC 29033-026-02

Product Quantity:
1,439,000 oral capsules

Reason for Recall:
Presence of Foreign Tablets/Capsules

Recall Number:
D-0473-2018

Code Information:
Lot: CAL173502; Exp. 09/19