Enforcement Report - Week of September 27, 2017

Class II Drugs Event

Event ID:
77856

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/06/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/15/2017

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
PharMedium Services, Llc
12620 W Airport Blvd Ste 130
Sugar Land TX United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Fentanyl Citrate (Preservative Free) 10 mcg per mL (1,000 mcg per 100 mL) 100 mL total volume in a 100 mL LifeCare Bag in Sodium Chloride 0.9% Rx Only, Compounded by PharMEDium Services, LLC, Cleveland, MS 38732, NDC 61553-112-52.

Product Quantity:
590 bags

Reason for Recall:
Labeling: Not Elsewhere Classified- Diluent used to compound product expired prior to the expiration date assigned to the compounded product.

Recall Number:
D-1165-2017

Code Information:
Lots: 170850012C and 170850020C Exp. 06/25/17

Product Description:
Fentanyl Citrate (Preservative Free) 20 mcg per mL (2,000 mcg per 100 mL) 100 mL total volume in a 100 mL LifeCare Bag in Sodium Chloride 0.9% Rx Only, Compounded by PharMEDium Services, LLC, Cleveland, MS 38732, NDC 61553-605-52

Product Quantity:
295 bags

Reason for Recall:
Labeling: Not Elsewhere Classified- Diluent used to compound product expired prior to the expiration date assigned to the compounded product.

Recall Number:
D-1166-2017

Code Information:
Lot: 170850021C Exp. 06/25/17

Class II Drugs Event

Event ID:
77956

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/22/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/15/2017

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
United States Nationwide (including Puerto Rico) and Singapore

Associated Products

Product Description:
HYDROmorphone HCl Injection, USP, 2 mg/mL, 1mL Single-use vial, packaged in cartons of 25 vials, Rx only, Hospira, Inc., Lake Forest, IL 60045 USA, NDC 0409-3365-11 (carton) and 0409-3365-01(vial)

Product Quantity:
115,370 vials

Reason for Recall:
Lack of sterility assurance: resulting from use of a damaged sterilizing filter for nitrogen used in the manufacturing process.

Recall Number:
D-1167-2017

Code Information:
Lot: 760853A

Product Description:
Levophed (norepinephrine bitartrate) injection, USP, 4 mg/4 mL (1mg/mL), 4mL Fill in 5 mL Single dose Fliptop Vial, Rx only, Hospira, Inc., Lake Forest, IL 60045 USA, NDC 0409-3375-04

Product Quantity:
98,050 vials

Reason for Recall:
Lack of sterility assurance: resulting from use of a damaged sterilizing filter for nitrogen used in the manufacturing process.

Recall Number:
D-1168-2017

Code Information:
Lot #: 753003A, Exp 9/18; 762153A, 760803A, 761053A , Exp 10/18

Class II Drugs Event

Event ID:
78021

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/30/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/18/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Noven Pharmaceuticals, Inc.
11960 SW 144th St
Miami FL United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Daytrana (methylphenidate transdermal system) Delivers 10 mg over 9 hours (1.1 mg/hr) Rx Only Contains: 30 Patches Manufactured for: Noven Therapeutics, LLC. Miami, FL 33186 By Noven Pharmaceuticals, Inc., Miami, FL 33186, NDC# 68968-5552-3

Product Quantity:
321,900 patches

Reason for Recall:
Defective Delivery System: Products no longer meet the release liner removal specification and/or z-statistic.

Recall Number:
D-1169-2017

Code Information:
Lot: 80433 Exp. 08/17

Product Description:
Daytrana (methylphenidate transdermal system) Delivers 20 mg over 9 hours (2.2 mg/hr) Rx Only Contains: 30 Patches Manufactured for: Noven Therapeutics, LLC. Miami, FL 33186 By Noven Pharmaceuticals, Inc., Miami, FL 33186, NDC# 68968-5554-3

Product Quantity:
182,850 patches

Reason for Recall:
Defective Delivery System: Products no longer meet the release liner removal specification and/or z-statistic.

Recall Number:
D-1170-2017

Code Information:
Lot: 80431 Exp. 08/17

Product Description:
Daytrana (methylphenidate transdermal system) Delivers 30 mg over 9 hours (3.3 mg/hr) Rx Only Contains: 30 Patches Manufactured for: Noven Therapeutics, LLC. Miami, FL 33186 By Noven Pharmaceuticals, Inc., Miami, FL 33186, NDC# 68968-5555-3

Product Quantity:
331,950 patches

Reason for Recall:
Defective Delivery System: Products no longer meet the release liner removal specification and/or z-statistic.

Recall Number:
D-1171-2017

Code Information:
Lot: 80442 Exp. 10/17 Lot: 80439 Exp. 08/17 Lot: 80438 Exp. 08/17

Product Description:
Daytrana (methylphenidate transdermal system) Delivers 15 mg over 9 hours (1.6 mg/hr) Rx Only Contains: 30 Patches Manufactured for: Noven Therapeutics, LLC. Miami, FL 33186 By Noven Pharmaceuticals, Inc., Miami, FL 33186, NDC# 68968-5553-3

Product Quantity:
234,960 patches

Reason for Recall:
Defective Delivery System: Products no longer meet the release liner removal specification and/or z-statistic.

Recall Number:
D-1172-2017

Code Information:
Lot: 80426 Exp. 10/17

Class II Drugs Event

Event ID:
78110

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/13/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/19/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amgen, Inc.
1 Amgen Center Dr
Thousand Oaks CA United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Procrit (epoetin alfa), 10,000 units/mL, packaged in a) box of 6 single use 1 mL vials (NDC 59676-310-01), b) box of 25 single use 1 mL vials (NDC 59676-310-02), Rx Only, Manufactured by: Amgen, Inc. Thousand Oaks, CA 91320, Manufactured for: Janssen Products, LP Horsham, PA 19044

Product Quantity:
275,380 vials

Reason for Recall:
Presence of particulate matter: glass flakes identified as lamellae observed during a routine quality inspection.

Recall Number:
D-1173-2017

Code Information:
Lot #: a) G290530A, Exp 07/18; b) G290531A, Exp 07/18

Class II Drugs Event

Event ID:
78123

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/14/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/20/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Medisca, Inc.
661 State Route 3 Unit C
Plattsburgh NY United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Aminocaproic Acid, USP (6-Aminohexanoic Acid) active pharmaceutical ingredient, packaged in a) 100 g jar (NDC 38779-0989-05, b) 1 kg jar (NDC 38779-0989-09), and 25 kg drum (NDC 38779-0989-07), Rx only, Packed by Medisca Inc., Plattsburgh, NY 12901, CAS: 60-32-1. 38779-0989-05; jar, 300 ml, white HDPE 38779-0989-07; drum, 15 gallon, Fiber 38779-0989-09; 2.8L, white, HDPE

Product Quantity:
34,600 g

Reason for Recall:
CGMP Deviations: Product manufactured for └Industrial Use but was labeled and distributed for Pharmacy Compounding Use.

Recall Number:
D-1174-2017

Code Information:
Lots# 143595/A,143595/B,143595/D, Exp 02/28/20

Class III Drugs Event

Event ID:
77862

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/04/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/15/2017

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Quillivant XR methylphenidate HCl, for extended-release oral suspension, 600 mg/120 mL total volume (When constituted with 105 mL of water, 25 mg/5 mL (5 mg/mL) when reconstituted, Rx Only, Distributed by Nextwave Pharmaceuticals, Inc. A subsidiary of Pfizer Inc., New York, NY 10017, Manufactured by Tris Pharma, Inc., Monmouth Junction, NJ 08852, NDC 24478-200-20.

Product Quantity:
14,712 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-1163-2017

Code Information:
Lot # 03216048A, Exp. 05/18

Product Description:
Quillivant XR methylphenidate HCl, for extended-release oral suspension, 750mg/150 mL total volume (When constituted with 131 mL of water, 25 mg/5 mL (5 mg/mL) when reconstituted, Rx Only, Distributed by Nextwave Pharmaceuticals, Inc. A subsidiary of Pfizer Inc., New York, NY 10017, Manufactured by Tris Pharma, Inc., Monmouth Junction, NJ 08852, NDC 24478-200-25.

Product Quantity:
11,790 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-1164-2017

Code Information:
Lot # 03216047A Exp. 02/18