lass I Drugs Event

Event ID:
76858
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
03/28/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/25/2017
Initial Firm Notification of Consignee or Public:
Other
Recalling Firm:
Envy Me
7018 Southhaven Dr
Corp Christi TX United States
Distribution Pattern:
Product sold nationwide through internet sales. No foreign consignees were reported.

Associated Products

Product Description:
LaBri's Body Health Atomic, 60 capsules
Product Quantity:
unknown
Reason for Recall:
Marketed without an approved NDA/ANDA: Product contains undeclared Sibutramine.
Recall Number:
D-0867-2017
Code Information:
All lot codes, manufacturing codes and expiration dates.

Class I Drugs Event

Event ID:
77009
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
04/13/2017
Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/24/2017
Initial Firm Notification of Consignee or Public:
Press Release
Recalling Firm:
Standard Homeopathic Company
154 W 131st St
Los Angeles CA United States
Distribution Pattern:
Nationwide in the USA and Puerto Rico.

Associated Products

Product Description:
Hyland's Baby Teething Tablets [Calcarea Phosporica 6X HPUS, Chamomilla 6X HPUS, Coffea Cruda 6X HPUS, Belladonna 12X HPUS (0.0000000000003% alkaloids, calculated)] Quick-Dissolving Tablets, packaged in a) 40-count bottles (NDC 54973-3127-3) (UPC 3 54973 31273 9); b) 135-count bottles (NDC 54973-3127-1) (UPCs 3 54973 31271 5, 3 54973 31371 2, 3 54973 31481 8); and 250-count bottles (NDC 54973-3127-2) (UPCs 3 54973 31272 2, 3 54973 31521 1), Manufactured for: Hyland's, Inc., Los Angeles, CA 90061.
Product Quantity:
10,263,585 bottles
Reason for Recall:
Superpotent Drug: FDA analysis found inconsistent amounts of belladonna alkaloids that may differ from the calculated amount on the productlabels.
Recall Number:
D-0863-2017
Code Information:
All lots within expiry

Product Description:
Hyland's Baby Nighttime Teething Tablets [Belladonna 12X HPUS (0.0000000000003% alkaloids, calculated), Calcarea Phosphorica 6X HPUS, Chamomilla 6X HPUS, Coffea Cruda 6X HPUS, Magnesia Phosphorica 6X HPUS, Rheum 6X HPUS, Silicea 12X HPUS] Quick-Dissolving Tablets, 135-count bottle, Manufactured for: Hyland's, Inc., Los Angesles, CA 90061, NDC 54973-3197-1, UPC 3 54973 31971 4.
Product Quantity:
692,115 bottles
Reason for Recall:
Superpotent Drug: FDA analysis found inconsistent amounts of belladonna alkaloids that may differ from the calculated amount on the product labels.
Recall Number:
D-0864-2017
Code Information:
All lots within expiry

Class I Drugs Event
Event ID:
77111

Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
04/21/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/24/2017
Initial Firm Notification of Consignee or Public:
Press Release
Recalling Firm:
Hospira Inc.
600 N Field Dr
Lake Forest IL United States
Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Infant 25% DEXTROSE Injection, USP, 2.5 g (250 mg/mL), 10 mL Unit of Use Single-dose Syringe per carton, Rx only, Hospira Inc., Lake Forest, IL 60045, NDC 0409-1775-10
Product Quantity:
71,550 syringes
Reason for Recall:
Presence of Particulate Matter: human hair found within an internal sample syringe.
Recall Number:
D-0862-2017
Code Information:
Lot 58382EV*, Exp 1OCT 2017, *lot may be followed by 01 or 02

Class II Drugs Event

Event ID:
76561
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
02/22/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/23/2017

Initial Firm Notification of Consignee or Public:
E-Mail
Recalling Firm:
Advanced Pharma Inc.
9265 Kirby Dr
Houston TX United States
Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Bupivacaine HCl in 0.9% Sodium Chloride all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0794-2017
Code Information:
all lots

Product Description:
Ropivacaine HCl in 0.9% Sodium Chloride all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0795-2017
Code Information:
all lots

Product Description:
Lidocaine all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0796-2017
Code Information:
all lots

Product Description:
Nalbuphine all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.

Recall Number:
D-0797-2017
Code Information:
all lots

Product Description:
RECK PeriCapsular injection all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0798-2017
Code Information:
all lots

Product Description:
NOVA PeriCapsular injection all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0799-2017
Code Information:
all lots

Product Description:
Ofirmev (Acetaminophen) injection all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0800-2017
Code Information:
all lots

Product Description:
Ropi/ Epi/ Clon PeriCapsular injection all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0801-2017
Code Information:
all lots

Product Description:
NICU STARTER TPN all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0802-2017
Code Information:
all lots

Product Description:
TPN Neonatal all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0803-2017
Code Information:
all lots

Product Description:
Standard Starter TPN all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0804-2017
Code Information:
all lots

Product Description:
Early TPN (Neonatal) all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0805-2017
Code Information:
all lots

Product Description:
Early Baby TPN (Neonatal) all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.

Recall Number:
D-0806-2017
Code Information:
all lots

Product Description:
ADD HEPARIN PF 50 Units ONLY TO TPN all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0807-2017
Code Information:
all lots

Product Description:
Sufentanil Citrate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0808-2017
Code Information:
all lots

Product Description:
Fentanyl Citrate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0809-2017
Code Information:
all lots

Product Description:
Hydromorphone HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0810-2017
Code Information:
all lots

Product Description:
Meperidine HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0811-2017
Code Information:
all lots

Product Description:
Morphine Sulfate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0812-2017
Code Information:
all lots

Product Description:
Ketamine HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0813-2017
Code Information:
all lots

Product Description:
Midazolam HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0814-2017
Code Information:
all lots

Product Description:
Lorazepam HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.

Recall Number:
D-0815-2017
Code Information:
all lots

Product Description:
Methohexital Sodium all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0816-2017
Code Information:
all lots

Product Description:
Cefazolin all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0817-2017
Code Information:
all lots

Product Description:
Vancomycin HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0818-2017
Code Information:
all lots

Product Description:
Penicillin G Potassium all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0819-2017
Code Information:
all lots within expiry

Product Description:
Gentamicin Sulfate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0820-2017
Code Information:
all lots within expiry

Product Description:
Oxytocin all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0821-2017
Code Information:
all lots within expiry

Product Description:
Heparin sodium all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0822-2017
Code Information:
all lots within expiry

Product Description:
0.9% Sodium Chloride Slip Tip all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0823-2017
Code Information:
all lots within expiry

Product Description:
Diltiazem HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.

Recall Number:
D-0824-2017
Code Information:
all lots within expiry

Product Description:
Phenylephrine HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0825-2017
Code Information:
all lots within expiry

Product Description:
Ephedrine Sulfate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0826-2017
Code Information:
all lots within expiry

Product Description:
Norepinephrine Bitartrate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0827-2017
Code Information:
all lots within expiry

Product Description:
Epinephrine HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0828-2017
Code Information:
all lots within expiry

Product Description:
Calcium Gluconate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0829-2017
Code Information:
all lots within expiry

Product Description:
Amiodarone all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0830-2017
Code Information:
all lots within expiry

Product Description:
Succinylcholine Chloride all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0831-2017
Code Information:
all lots within expiry

Product Description:
Adenosine all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0832-2017
Code Information:
all lots within expiry

Product Description:
Nitroglycerin all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.

Recall Number:
D-0833-2017
Code Information:
all lots within expiry

Product Description:
Nicardipine HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0834-2017
Code Information:
all lots within expiry

Product Description:
Rocuronium Bromide all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0835-2017
Code Information:
all lots within expiry

Product Description:
Labetalol HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0836-2017
Code Information:
all lots within expiry

Product Description:
Esmolol HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0837-2017
Code Information:
all lots within expiry

Product Description:
Glycopyrrolate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0838-2017
Code Information:
all lots within expiry

Product Description:
Neostigmine Methylsulfate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0839-2017
Code Information:
all lots within expiry

Product Description:
Atropine Sulfate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0840-2017
Code Information:
all lots within expiry

Product Description:
Betamethasone Sodium Phosphate & Betamethasone Acetate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0841-2017
Code Information:
all lots within expiry

Product Description:
Famotidine HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.

Recall Number:
D-0842-2017
Code Information:
all lots within expiry

Product Description:
Ondansetron HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0843-2017
Code Information:
all lots within expiry

Product Description:
Bumetadine all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0844-2017
Code Information:
all lots within expiry

Product Description:
Dexamethasone Sodium Phosphate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0845-2017
Code Information:
all lots within expiry.

Product Description:
Dexmedetomidine HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0846-2017
Code Information:
all lots within expiry.

Product Description:
Cardioplegic Solution Maintenance all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0847-2017
Code Information:
all lots within expiry.

Product Description:
Magnesium Sulfate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0848-2017
Code Information:
all lots within expiry

Product Description:
Potassium Phosphate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0849-2017
Code Information:
all lots within expiry.

Product Description:
Sodium Phosphate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0850-2017
Code Information:
all lots within expiry

Product Description:
Sodium Citrate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.

Recall Number:
D-0851-2017
Code Information:
all lots within expiry.

Product Description:
Fentanyl Citrate with Ropivacaine HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0852-2017
Code Information:
all lots within expiry.

Product Description:
Fentanyl Citrate and Bupivacaine HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054
Product Quantity:
Reason for Recall:
Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.
Recall Number:
D-0853-2017
Code Information:
all lots within expiry.

Class II Drugs Event
Event ID:
76861
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
04/03/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/24/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Cell Distributors
675 Rahway Ave
Union NJ United States
Distribution Pattern:
Nationwide

Associated Products

Product Description:
Refresh Tears (Carboxymethylcellulose Sodium Solution) 0.5%, Lubricant Eye Drops, Sterile packaged as 1) two 15 mL bottles, USPC Code 784190442214, 2) 4x15 mL and one 5 mL bonus bottles, USPC Code 069886941746, Distributed by Cell Distributors, Union, NJ
Product Quantity:
2,634 bottles (58 bottles/5mL & 2576 bottles/15 mL)
Reason for Recall:
Labeling: Not elsewhere classified; product labeling lacks a NDC number, net weight information and does not contain the Drug Facts Panel.
Recall Number:
D-0865-2017
Code Information:
all lots Expiration date August 2019

Class II Drugs Event
Event ID:
76922
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
06/22/2016
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/24/2017
Initial Firm Notification of Consignee or Public:
E-Mail
Recalling Firm:
Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Rd
Morgantown WV United States
Distribution Pattern:
Nationwide

Associated Products

Product Description:
Alprazolam Extended-release Tablets, USP, 1 mg, 60-count bottle, Rx Only, Manufactured and Distributed by: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 U.S.A., NDC 0378-5022-91
Product Quantity:
24,176 bottles (1,450,560 tablets)
Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0706-2017
Code Information:
Code: 0378-5022-91 Lot: 3065878; Exp. 04/17

Class II Drugs Event

Event ID:
77060
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
04/06/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/19/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Fagron, Inc
2400 Pilot Knob Rd
Saint Paul MN United States
Distribution Pattern:
Nationwide in US and PR and Australia

Associated Products

Product Description:
Estriol, For Prescription Compounding, packaged in a) 1 G bottle (NDC: 51552-1392-1), b) 5 G bottle (NDC: 51552-1392-2), c) 25 G bottle (NDC: 51552-1392-3), d) 100 G bottle (NDC: 51552-1392-5), RX only, Distributed by Fagron, Inc. 2400 Pilot Knob Rd, St. Paul, MN 55120 Tel. 1-(800) 423-6967 Also packaged as: Estriol USP Micronized, For prescription compounding, packaged in a 100 G bottle (NDC 52372-9292-01), Rx only, Distributed by FREEDOM, 801 W. New Orleans St. Broken Arrow, OK 74011
Product Quantity:
15283 grams
Reason for Recall:
cGMP Deviations: lack of quality assurance at the API manufacturer.
Recall Number:
D-0791-2017
Code Information:
Lot #, Expiration Date: a) 1 G bottle: 16D08-U02-030005, Exp. 3/6/2018; 16F23-U05-033657, Exp. 5/26/2018; 17C02-U02-035889, Exp. 1/19/2019. b) 5 G bottle: 16D08-U02-030004, 16D08-U02-032486, Exp. 3/6/2018; 16F23-U05-033656, 16F23-U05-035093, Exp. 5/26/2018; 17C02-U02-035890, Exp. 1/19/2019. c) 25 G bottle: 16D08-U02-030003, 16D08-U02-032475, Exp. 3/6/2018; 16F23-U05-033655, 16F23-U05-035092, Exp. 5/26/2018; 17C02-U02-035887, Exp. 1/19/2

019. d) 100 G bottle: 16D08-U02-030002, 16D08-U02-032474, Exp. 3/6/2018; 16F23-U05-031158,16F23-U05-033654, 16F23-U05-035091,16G18-F002, Exp. 5/26/2018; 17C02-U02-035888, Exp. 1/19/2019.

Product Description:
Estrone, For Prescription Compounding, packaged in a) 1 G bottle (NDC: 51552-0445-1), b) 5 G bottle (NDC 51552-0445-2), c) 25 G bottle (NDC: 51552-0445-4), d) 100 G bottle (NDC: 51552-0445-5), RX only, Distributed by Fagron, Inc. 2400 Pilot Knob Rd, St. Paul, MN 55120 Tel. 1-(800) 423-6967 Also packaged as: Estrone USP, For Prescription Compounding, packaged in a) 1 G bottle (NDC 52372-9494-01), b) 5 G bottle (NDC 52372-9494-05), c) 25 G bottle (NDC 52372-9494-03), d) 100 G bottle (NDC 52372-9494-02), Rx only, Distributed by FREEDOM 801 W. New Orleans St. Broken Arrow, OK 74011 Tel. (877) 839-8547
Product Quantity:
1313 grams
Reason for Recall:
cGMP Deviations: lack of quality assurance at the API manufacturer.
Recall Number:
D-0792-2017
Code Information:
Lot #, Expiration Date: a) 16J05-U01-032346, 16G18-F003A, Exp. 5/17/2018; 16J25-U05-033898, Exp. 5/18/2018. b) 16F23-U04-031011, 16J05-U02-032345, 16G18-F003A, Exp. 5/17/2018; 16J25-U05-033897, 16J25-U05-034708, 16J25-U05-035527, Exp. 5/18/2018; c) 16F23-U04-031024, 16K16-U337-033665, 16G18-F003; 16G18-F003A, Exp. 5/17/2018. d) 16K16-U337-033664, 16G18-F003, Exp. 5/17/2018; 16J25-U05-034707, Exp. 5/18/2018.

Class II Drugs Event
Event ID:
77161
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
02/16/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/23/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Sato Pharmaceutical Co., Ltd.
1468 Hazama-Machi
Hachioji Japan
Distribution Pattern:
US: Hawaii, Guam, Saipan, SPI

Associated Products

Product Description:
Optic Splash (naphazoline hydrochloride) Eye Drops, packaged in 0.5 FL OZ (15mL) bottles, Manufactured by SATO Pharmaceuticals CO., LTD. 1-5-27 Motoakasaka Minato-Ku Tokyo, Japan, NDC 49873-501-01.
Product Quantity:
10,130 units
Reason for Recall:
Lack of Assurance of Sterility: Firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas.
Recall Number:
D-0854-2017
Code Information:
Lot #: XXWC, Exp. August 2018

Product Description:
SATO CLEAR (naphazoline hydrochloride) Redness Reliever Eye Drops, packaged in 0.5 FL OZ (15mL) bottles, Manufactured by SATO Pharmaceuticals CO., LTD. 1-5-27 Motoakasaka Minato-Ku Tokyo, Japan, NDC 49873-044-01
Product Quantity:
4,790 units
Reason for Recall:
Lack of Assurance of Sterility: Firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas.
Recall Number:
D-0855-2017
Code Information:
Lot #: WXWZ, Exp. March 2019; WXTS, Exp. October 2019

Product Description:
DORAMA-NEO (naphazoline hydrochloride) Eye wash, packaged in 0.5 FL OZ (15mL) bottles, Manufactured by SATO Pharmaceuticals CO., LTD. 1-5-27 Motoakasaka Minato-Ku Tokyo, Japan, NDC 49873-020-01
Product Quantity:
14,325 units
Reason for Recall:
Lack of Assurance of Sterility: Firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas.
Recall Number:
D-0856-2017
Code Information:
Lot #: WXTZ, Exp. Sep 2019

Class II Drugs Event
Event ID:
77196
Product Type:
Drugs
Status:
Ongoing

Date Terminated:
Recall Initiation Date:
04/19/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/24/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Gentell, Inc
2701 Bartram Rd
Bristol PA United States
Distribution Pattern:
Nationwide and Puerto Rico

Associated Products

Product Description:
Shield and Protect Moisture Barrier Cream, 1.1% Clotrimazole, Net Weight 4 oz - 115 g Anti-Fungal, Gentell, Inc., Bristol, PA NDC 61554-232-40
Product Quantity:
65 gallons
Reason for Recall:
GMP Deviations; product may not meet cGMP requirements
Recall Number:
D-0866-2017
Code Information:
Product Code GEN-23240

Class II Drugs Event

Event ID:
77329
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
05/16/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/22/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
GlaxoSmithKline, LLC

1011 N Arendell Ave
Zebulon NC United States
Distribution Pattern:
Nationwide in the US and Puerto Rico

Associated Products

Product Description:
Ventolin HFA (albuterol sulfate) Inhalation, 90 mcg per actuation, 200 Metered Inhalations, Net Wt. 18 g inhalers, Rx only, GlaxoSmithKline, Research Triangle Park, NC 27709, NDC 0173-0682-20.
Product Quantity:
562,883
Reason for Recall:
Defective Delivery System: Elevated number of units with out of specification results for leak rate
Recall Number:
D-0793-2017
Code Information:
Lot#: 7ZP0634, 7ZP0810, 7ZP0990, Exp. 5/18

Class III Drugs Event
Event ID:
77065
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
01/30/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/23/2017
Initial Firm Notification of Consignee or Public:
E-Mail
Recalling Firm:
Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Rd
Morgantown WV United States
Distribution Pattern:
Nationwide in USA

Associated Products

Product Description:
Tarina Fe 1/20 (Norethindrone Acetate and Ethinyl Estradiol Tablets, USP and Ferrous Fumarate Tablets), 1 blister pack containing 28 tablets (NDC 50102-128-01), packaged in 3

pouches, each pouch contains one blister pack of 28 tablets (NDC 50102-128-03), Rx only, Manufactured for: Afaxys, Inc., Charleston, SC 29403, USA, Product of India.
Product Quantity:
43,848 cartons
Reason for Recall:
Chemical Contamination: out of specification results for impurities were found to be the result of contamination of product from vapors associated with paint thinner used in repair of the manufacturing room.
Recall Number:
D-0860-2017
Code Information:
Lot #: 6843F002D, Exp 02/18

Product Description:
Norethindrone Acetate and Ethinyl Estradiol Tablets, USP, 1 mg/0.02 mg, 1 blister pack containing 21 tablets (NDC 0378-7280-85), packaged in 3 pouches, each contains one blister pack of 21 tablets (NDC 0378-7280-53), Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 U.S.A., Made in India.
Product Quantity:
8,605 cartons
Reason for Recall:
Chemical Contamination: out of specification results for impurities were found to be the result of contamination of product from vapors associated with paint thinner used in repair of the manufacturing room.
Recall Number:
D-0861-2017
Code Information:
Lot #: 6327A006, Exp 02/18

Class III Drugs Event
Event ID:
77103
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
04/18/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/23/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Sun Pharmaceutical Industries, Inc.
270 Prospect Plains Rd
Cranbury NJ United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Children's Cetirizine Hydrochloride Chewable Tablets, 5 mg, 30-count bottle, Manufactured by: Sun Pharmaceutical Ind. Ltd., Halol-Baroda Highway, Halol - 389 350, Gujarat, India; Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, NDC 47335-343-83.
Product Quantity:
13,200 bottles
Reason for Recall:
Failed Tablet/Capsule Specifications: out of specification results for increased tablet hardness.
Recall Number:
D-0857-2017
Code Information:
Lot #: JKR5135A, Exp 11/17

Class III Drugs Event

Event ID:
77210
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
05/08/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/23/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Vintage Pharmaceuticals LLC, DBA Qualitest Pharmaceuticals
150 Vintage Dr NE
Huntsville AL United States
Distribution Pattern:
Nationwide in the USA and Puerto Rico.

Associated Products

Product Description:
HYDROCORTISONE LOTION, USP, 2.5%, 2 FL OZ (59 mL) bottle, Rx only, Manufactured for: QUALITEST PHARMACEUTICALS, HUNTSVILLE, AL 35811, NDC 0603-7785-52.
Product Quantity:
109,620 bottles
Reason for Recall:
Superpotent Drug: above specification for the assay.

Recall Number:
D-0859-2017
Code Information:
Lot #: 0000004961, Exp. 05/17; 0000005197, 0000005198, 0000005199, Exp. 07/17; 00000052 01, 0000005202, 0000005203, 0000005204, Exp. 09/17; 0000005200, 0000007998, 00000079 99, 0000007022, Exp. 12/17; 0000009176, Exp. 04/18; 0000012281, 0000012282, Exp. 12/18

Class III Drugs Event

Event ID:
77311
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
05/09/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/23/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Strides Pharma INC
2 Tower Center Blvd Ste 1102
East Brunswick NJ United States
Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Benzonatate capsules, 200 mg, 100-count bottle, Rx only, Manufactured by: Strides Shasun Limited Bangaluru -560076 India, Distributed by Strides Pharma Inc East Brunswick, NJ 08816, NDC 64380-713-06
Product Quantity:
127,517 bottles
Reason for Recall:
Failed Stability Specifications: Out of Specification results obtained for preservative Methylparaben content.
Recall Number:
D-0858-2017
Code Information:
Lot #: 7225075, 7225076, 7225077, 7225078, 7225079, 7225080 Exp 7/2017; 7225180, 72251 81, 7225322, 7225323, Exp 8/2017; 7225649A, 7225650A , 7225651A , 7225652A, 7225653A, 7225654A, Exp 9/2017