

2018 Drug Recall

Drug Name/Manufacturer	Dose/Package size	Press Release Date	Reason	Recall Classification
January				
Fosphenytoin PE	500 mg/10 mL Single-Dose Vials	1/2/2018	This recall was issued due to the potential presence of particulate matter (sub-visible) associated with the active ingredient.	Retail Level Recall
Alcohol Prep Pads	70%	1/3/2018	This recall was issued due to a lack of assurance of sterility and cGMP deviations.	Class 2 Recall
Ampicillin and Sulbactam for Injection	USP 1.5 g/ Vial	1/3/2018	AuroMedics Pharma LLC is voluntarily recalling lot AFO I 17001-A, Expiry date Dec 2018, of Ampicillin and Sulbactam for Injection USP, 1.5 g (equivalent to 1 g ampicillin as the sodium salt plus 0.5 g Sulbactam as the sodium salt) in a Single-Dose vial, to the hospital level. The product has been found to contain glass particles	Voluntary Recall - Nationwide
Midazolam	1 mg/mL 2 mL prefilled syringes	1/10/2018	This recall was issued due to a report of two blister packages (secondary) labeled as Midazolam Injection containing syringes of Ondansetron Injection.	Class I Recall
Clopidogrel Tablets	USP 75 mg, packaged in bottles of 30 tablets	1/10/2018	International Laboratories, LLC is voluntarily recalling Lot# 117099A of Clopidogrel Tablets, USP 75 mg, packaged in bottles of 30 tablets, to the consumer level due to mislabeling. The product is labeled as Clopidogrel tablets USP 75 mg but may contain Clopidogrel 75mg or Simvastatin Tablets USP 10 mg.	Voluntary Recall
Docetaxel injection USP	20mg/mL	1/10/2018	This recall was issued due to defect observed in the seal of some Docetaxel injection vials in the lot mentioned above.	Retail Level Recall
Lovastatin	40 mg tablets	1/10/2018	This recall was issued due to an "Out of Spec" for dissolution during annual stability testing.	Retail Level Recall
PharMEDium Services, LLC - Various Drug Products to the Hospital/User Level	2 mg/mL Fentanyl Citrate and 0.2% Ropivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 2 mg/mL Fentanyl Citrate and 0.2% Ropivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 2 mg/mL Fentanyl Citrate and 0.15% Ropivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 1 mg/mL Morphine Sulfate in 0.9% Sodium Chloride, 1 mg/mL Morphine Sulfate (Preservative Free) in 0.9% Sodium Chloride, 1 mg/mL HYDROMORPHONE HCl in 0.9% Sodium Chloride, 2 mg/mL Fentanyl Citrate and 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 20 mg/mL Succinylcholine Chloride Injection (Preserve) Kit Check Tagged, 2 mg/mL Fentanyl Citrate and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 0.2 mg/mL Glycopyrrolate 3 mL in 3 mL BD Syringe Kit Check Tagged, 50 mg/mL Fentanyl Citrate (Preservative Free) Injection, 3 mg/mL Fentanyl Citrate and 0.2% Ropivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 1 mg/mL HYDROMORPHONE HCl in 0.9% Sodium Chloride, 4 mg/mL Fentanyl Citrate (Preservative Free) Injection Kit Check Tagged, 10 mg/mL Fentanyl Citrate (Preservative Free) Injection Kit Check Tagged, 50 mg/mL Fentanyl Citrate (Preservative Free) Injection, 1 mg/mL Midazolam HCl (Preservative Free) in 0.9% Sodium Chloride Injection USP, 1 mg/mL Morphine Sulfate (Preservative Free) in 0.9% Sodium Chloride, 0.5 mg/mL Midazolam HCl in 0.9% Sodium Chloride, 3 mg/mL Adenosine Injection 30 mL in 30 mL BD Syringe, 4 mg/mL Fentanyl Citrate and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 3 mg/mL Fentanyl Citrate and 0.2% Ropivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 50 mcg/mL Fentanyl Citrate (Preservative Free) Injection Kit Check Tagged, 50 mg/mL Ephedrine Sulfate Injection (Preservative Free), 2 mg/mL Morphine Sulfate in 0.9% Sodium Chloride, 1 mg/mL Morphine Sulfate in 0.9% Sodium Chloride, 50 mcg/mL Fentanyl Citrate (Preservative Free) Injection, 2 mg/mL Fentanyl Citrate and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 1 mg/mL Fentanyl Citrate and 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 1 mg/mL HYDROMORPHONE HCl in 0.9% Sodium Chloride, 1 mg/mL Morphine Sulfate (Preservative Free) (Contains Sulfites) in 5% Dextrose, 1 mg/mL HYDROMORPHONE HCl in 0.9% Sodium Chloride, 1 mg/mL HYDROMORPHONE HCl in 0.9% Sodium Chloride, 1 mg/mL Midazolam HCl in 0.9% Sodium Chloride, 1 mg/mL Midazolam HCl in 0.9% Sodium Chloride, 1 mg/mL HYDROMORPHONE HCl in 0.9% Sodium Chloride, 0.25% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 5 mg/mL Morphine Sulfate (Preservative Free) in 0.9% Sodium Chloride, 1 mg/mL HYDROMORPHONE HCl in 0.9% Sodium Chloride, 2 mg/mL Fentanyl Citrate and 0.2% Ropivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 20 mg/mL Fentanyl Citrate (Preservative Free) in 0.9% Sodium Chloride, 1 mg/mL Morphine Sulfate (Preservative Free) (Contains Sulfites) in 0.9% Sodium Chloride, 10 mEq Potassium Chloride in 0.9% Sodium Chloride 100 mL in 150 mL Intrava Bag, 50 mg/mL Fentanyl Citrate (Preservative Free) Injection, 5 mg/mL Labetalol HCl, 3 mg/mL Morphine Sulfate (Preservative Free) (Contains Sulfites) in 0.9% Sodium Chloride, 1 mg/mL Morphine Sulfate (Preservative Free) (Contains Sulfites) in	1/11/2018	PharMEDium Services, LLC (PharMEDium) is voluntarily recalling the below lots of drug products to the hospital/user level due to a lack of assurance of sterility.	Voluntary Recall - Nationwide
Blephamide ophthalmic ointment	10% 3.5 GM	1/12/2018	This recall was issued due to Phenylmercuric Acetate (PMA) preservative concentration not measured during stability testing.	Retail Level Recall
NEXTERONE (amiodarone HCl)	150 mg/100 mL Premixed Injection	1/16/2018	Following the issuance of a voluntary recall dated November 10, 2017 of one lot of NEXTERONE (amiodarone HCl) 150 mg/100 mL Premixed Injection, Baxter International Inc. announced today it is expanding the recall to include a second lot (NC109123) of NEXTERONE due to the potential presence of particulate matter. The affected lots were distributed between 7/21/2017 and 10/2/2017 in the United States to wholesalers/distributors and healthcare facilities. The particulate matter may have entered the solution during the manufacturing process.	Voluntary Recall
Levofloxacin	5% Dextrose Injection 250mg/50mL in a Single-Use flexible container	1/17/2018	The product has been found to contain visible particulate matter tentatively identified as mold. This problem was discovered as a result of a product complaint in which the contents of one flexible bag was found to contain white particulate matter.	Voluntary Recall
Gabapentin	800 mg tablets	1/17/2018	Some bottles labeled as Gabapentin 800 mg contain Gabapentin 600 mg.	Class II Recall
Levofloxacin in 5% Dextrose Injection	250mg/50mL	1/17/2018	This recall was issued due to a confirmed customer report for the presence of visible particulate matter, tentatively identified as mold, within one flexible container.	Retail Level Recall
Vecuronium Bromide	10 mg Vial	1/17/2018	This recall was issued due to a recall notification from Fresenius Kab's third party manufacturer for an out-of-specification (OOS) result for USP related compound F at the 12-month stability test station for batch ZG603.	Retail Level Recall
Ibuprofen	800 mg tablets	1/18/2018	This recall was issued due to odor related issues observed in the specified lots for these products.	Retail Level Recall
INFeD®	50 mg/mL 2 mL vials	1/19/2018	This recall was issued due to product stability testing results not meeting specifications for iron content. Recall extended as of 1/25/2018 - CVS Notificaiton & FDA Website Notification	Retail Level Recall

Mycamine	100 mg 10 mL vials	1/23/2018	This recall was issued due to reports of mislabeled 100 mg Mycamine vials.	Retail Level Recall
Ultane	250 mL P.E.N	1/23/2018	This recall was issued due to a quality defect of the cap liners found during packaging.	Retail Level Recall
Alprazolam	0.25 mg tablets	1/23/2018	This recall was issued due to an out-of-specification result for an unknown impurity during a recent investigation. The impurity had an LC-Value of 0.3%, the stability protocol specification is NMT 0.2%.	Retail Level Recall
Alprazolam	0.25 mg tablets	1/23/2018	This withdrawal was issued due to a recent investigation where test results on 3 other lots resulted in an out-of-specification result for an unknown impurity.	Retail Level Withdrawal
Senna Laxative	8.6mg tablets	1/22/2018	One lot of Basic Drugs brand of Senna Laxative 8.6mg tablets (Magno-Humphries) is being recalled due to a customer complaint of a 'Senna Laxative' labeled bottle containing Naproxen Sodium 220mg tablets.	Retail Level Recall
Diecto Liquid	50 mg/ 5 mL	1/25/2018	This recall was issued due to microbial contamination of Non Sterile Product. Presence of yeast and potential B. cepacia contamination. This recall affects all lots remaining within expiry.	Class II Recall
Ibuprofen	Tablets	1/26/2018	This recall was issued due to odor related issues observed in the specific lots for these products.	Retail Level Recall
Ibuprofen	800 mg tablets	1/18/2018	This recall was issued due to odor related issues observed in the specific lots for these products.	Retail Level Recall
Divalproex Sodium	500 mg Delayed Release Tablets	1/24/2018	This recall was issued due to cross contamination with other products. Metronidazole powder was found in one bottle of Divalproex Sodium.	Class II Recall
Aller-chlor	2 mg 4 fl oz	1/24/2018	This recall was issued due to microbial contamination of Non Sterile Product. Presence of yeast and potential B. cepacia contamination.	Class II Recall
Liquid Natural Vegetable Products	Senexon Liquid Natural Vegetable Stimulant 8.8 mg 8 fl oz (Rugby Label) & Senna Syrup Natural Vegetable Laxative Sennoside 8.8 mg 8 fl oz (Major Label)	1/24/2018	This recall was issued due to microbial contamination of Non Sterile Product. Presence of yeast and potential B. cepacia contamination.	Class II Recall
Diecto Syrup	60 mg/15 mL	1/24/2018	This recall was issued due to microbial contamination of Non Sterile Product. Presence of yeast and potential B. cepacia contamination.	Class II Recall
Megestrol Acetate	40mg / mL Oral Suspension	1/30/2018	This recall was issued due to the discovery of out-of-specification results for Assay results.	Retail Level Recall
Limbrel® products manufactured by Primus Pharmaceuticals, Inc.	Limbrel® (flavocoxid) 250 mg capsules, Limbrel® 250 (250 mg flavocoxid with 50 mg citrated zinc bisglycinate) capsules, Limbrel® (flavocoxid) 500 mg capsules, Limbrel® 500 (500 mg flavocoxid with 50 mg citrated zinc bisglycinate) capsules	1/30/2018	This recall was issued due to rare but serious and reversible side effects associated with Limbrel®.	Patient Level Recall
Doxorubicin Hydrochloride Liposome Injection	2 mg/mL	1/30/2018	This recall was issued after it was determined that a portion of the subject batch was inadvertently distributed despite the occurrence of an environmental monitoring excursion being recorded during the filling processes.	Retail Level Recall
Pravastatin Sodium	10 mg & 20 mg Tablets	1/31/2018	This recall was issued due to the presence of foreign tablets/capsules. Bottles could contain both pravastatin sodium 10 mg and 20 mg tablets in the same bottle.	Class II Recall
February				
Fentanyl patches	Fentanyl 100 mcg/hour patches, Fentanyl 100 mcg/hour individual patch, Fentanyl 25 mcg/hour patches, Fentanyl 25 mcg/hour individual patch, Fentanyl 50 mcg/hour patches, Fentanyl 50 mcg/hour individual patch, Fentanyl 75 mcg/hour patches, Fentanyl 75 mcg/hour individual patches	2/1/2018	This recall was issued because the Fentanyl-n-Oxide (FNO) degradant exceeded the specification limits for some of the lots within the scope of this recall.	Retail Level Recall
Metformin Tablets	Metformin 1000 mg Tablets	2/5/2018	This recall was issued due to confirmed customer reports of mixed tablets of metformin 1000 mg with a different imprint in a bottle. In the event that the tablet with a different imprint is administered to a patient, it may not result in any harm since it is the exact same formulation and strength.	Retail Level Recall
Divalproex DR Tablets	Divalproex DR 500 mg tablets	2/6/2018	This recall was issued due to a remote possibility for the product to be contaminated with traces of metronidazole.	Retail Level Recall
SPIRIVA HandiHaler	SPIRIVA HandiHaler 18 mcg/capsules	2/7/2018	This recall was issued due to failed stability specifications.	Class II Recall
Famciclovir Tablets	Famciclovir 500 mg	2/8/2018	This recall was issued due to similar nature of pharmacy complaints from different pharmacies, where the disintegrated coating layer of the tablets has peeled off	Retail Level Recall
Ace Ankle Brace	Ace Ankle Brace manufactured by 3M	2/8/2018	. This recall was issued due to inaccurate labeling. The product contains natural rubber latex, however the package does not include the appropriate caution statement.	Retail Level Recall
Hydromorphone	Hydromorphone Hydrochloride 10mg/mL Single-dose	2/12/2018	This recall was issued due to confirmed customer reports for the presence of empty or cracked vials.	Retail Level Recall
Hydromorphone	Hydromorphone Hydrochloride 10 mg/mL 1 mL injection	2/12/2018	This recall was issued due to confirmed customer reports for the presence of empty or cracked vials.	Retail Level Recall
Acyclovir Tablets	Acyclovir Tablet, USP, 400mg, 50ct Unit Dose	2/13/2018	A small number of blister cards containing Acyclovir Tablets, 400mg, UD Blister Cards may potentially also include Torsemide, 20mg, Tablets.	Retail Level Recall
Linezolid IV Solution	Linezolid Injection 600 mg/300 mL (2 mg/mL) IV Solution	2/14/2018	This recall was issued due to presence of particulate matter; white particulate matter identified as mold was found in one bag. Note: This recall was originally issued on December 22, 2017 to the retail-level. The FDA classified this as a Class I Recall on February 14, 2018.	Class I Recall
Ampicillin and Sulbactam for Injection	Ampicillin and Sulbactam for Injection 1.5 g vial	2/14/2018	This recall was issued due to presence of particulate matter: a confirmed customer report was received for the presence of visible particulate matter, confirmed as glass, within a single vial.	Class I Recall
Pantoprazole Sodium for Injection	Pantoprazole Sodium for Injection 40 mg per Vial	2/14/2018	This recall was issued due to presence of particulate matter: one vial from a lot of Pantoprazole Sodium for Injection (40 mg) contained a piece of glass.	Class I Recall
Calcium Acetate Capsules	Calcium Acetate 667 mg capsules	2/14/2018	This recall was issued due to a tablet from another product being found inside a bottle of Calcium Acetate capsules.	Retail Level Recall

Valacyclovir Tablets	Valacyclovir 1 gm tablets	2/15/2018	This recall was issued due to extended exposure of the product at a higher temperature at airport/cargo transporter.	Retail Level Recall
Acyclovir Tablets	Acyclovir 400 mg	2/15/2018	This recall was issued due to a product mix-up. A small number of blister cards containing Acyclovir 400mg tablets, UD Blister Cards may potentially also include Torsemide 20mg tablets.	Retail Level Recall
Valganciclovir Tablets	Valganciclovir 450 mg tablets	2/16/2018	This recall was issued due to extended exposure of the product at a higher temperature at airport/cargo transporter	Retail Level Recall
INFeD® Vials	INFeD® 50 mg/mL 2 mL vials	2/16/2018	This recall was issued due to product stability testing results not meeting specifications for iron content.	Retail Level Recall
Sodium Chloride for Irrigation	0.9 % Sodium Chloride USP, 1000 mL Plastic Irrigation Container	2/20/2018	This recall was issued due to a customer complaint reporting particulate matter in batch J7N912. This particulate matter has been identified as polyethylene, which is consistent with the material used to manufacture the container cap.	Retail Level Recall
Klonopin Tablets	Klonopin 0.5 mg tablets	2/20/2018	This recall was issued due to the schedule IV controlled substance indicator of CIV being omitted from the product carton.	Retail Level Recall
Ibuprofen Capsules	Ibuprofen 600 mg tablets, Ibuprofen 800 mg tablets, Ibuprofen 400 mg tablets	2/21/2018	This recall was issued due to odor related issues observed in the specified lots for these products. This notice had additional products at lot numbers that were not part of the previous recall on this product.	Retail Level Recall
Labetalol HCl Injection	Labetalol HCl 5 mg/mL	2/21/2018	This recall was issued due to the potential of cracked glass at the sealing surface of the vials for these lots.	Retail Level Recall
Evamist Transdermal Spray	Evamist (estradiol transdermal spray) 8.1 mL	2/27/2018	This recall was issued due to a manufacturing defect, cracks in some vials may result in product leaking or the inability to properly dispense the product.	Retail Level Recall
Ranitidine Tablets	Ranitidine 150 mg UD tablets	2/27/2018	This recall was issued due to the discovery of OOS (out-of-specification for related compounds)	Retail Level Recall
March				
Atropine Sulfate Ophthalmic Solution	Atropine sulfate ophthalmic solution 1 % 5 mL	3/2/2018	This recall was issued due to low viscosity in the product. This recall affects lot number 011037A exp. 07/31/18.	Retail Level Recall
Hydromorphone HCl Injection	Hydromorphone HCl Injection, USP CII 10 mg/mL, 1 mL in 2 mL Single Dose Vials	3/5/2018	Hospira, Inc. initiated this recall on February 07, 2018 due to the potential that units from these lots may be empty or cracked at the bottom of the glass vial.	Voluntary Recall
Labetalol Hydrochloride Injection	Labetalol Hydrochloride Injection, USP, 100 mg/20 mL; Labetalol Hydrochloride Injection, USP, Novaplus®	3/5/2018	Hospira, Inc. initiated this recall due to the discovery of cracks on the rim surface of vials for these lots, which is covered by the stopper and crimp seal.	Voluntary Recall
Estradiol Transdermal Spray	Evamist (estradiol transdermal spray)	3/5/2018	A voluntary recall of 1 batch of Evamist (estradiol transdermal spray) has been initiated by Perrigo due to potential product damage. The recall is being issued at the pharmacy level. The Company states that cracks in the vial neck near the crimp may result in product evaporation or leaking which would make it difficult for patients to properly dispense the dose.	Voluntary Recall
Methylprednisolone Sodium Succinate for Injection	Methylprednisolone Sodium Succinate for Injection in 40mg, 125mg, and 1g strengths	3/6/2018	The recall was initiated due to the discovery of high out of specification impurity results during routine quality testing of stability samples for 2 lots. While the impurity has not yet been identified, an elevated presence can potentially decrease the efficacy of the product in patients. No adverse events have been reported from using the affected product lots.	Voluntary Recall
PVP Scrub Solution Povidone Iodine	PVP Scrub Solution Povidone Iodine 4 FL ounces	3/7/2018	This recall was issued because of product not meeting the iodine assay level requirements through the labeled expiry.	Class II Recall
SyrSpend SF Suspending Base	SyrSpend SF Suspending Base 500 mL, SyrSpend SF Suspending Base 4 L	3/7/2018	This recall was issued due to microbial contamination of Non-Sterile Product. Product contamination with yeast and mold (Paecilomyces saturatus and Aspergillus fumigatus).	Class II Recall
INFeD	INFeD 50 mg/mL 2 mL vials	3/7/2018	This recall was issued due to product stability testing results not meeting specifications for iron content. Please note: This NDC was not part of the previous recalls issued on this product.	Class II Recall
Velcade	Velcade 3.5 mg 10 mL	3/7/2018	This recall was issued was issued due to loose vial crimps.	Retail Level Recall
Triamcinolone Acetonide lotion	0.1 % 60 mL	3/12/2018	This recall was issued due to out of specification results due to impurities.	Retail Level Recall
Psoriasis Cream	All manufactured by Alva-Amco - Psoriasis Advanced Treatment Cream 2 oz & Psoriasis Daytime Relief Cream 2 oz	3/14/2018	This recall was issued due to a stability testing failure in which product has failed to maintain its label claim of 1.25% coal tar throughout its labeled 24-month expiry period.	Retail Level Recall
Ibuprofen	200 mg tablets	3/14/2018	This recall was issued due to CGMP deviations.	Class II Recall
Vardenafil HCl	500 GM	3/14/2018	This recall was issued due to cGMP Deviations, There is a lack of stability data and controls to support the manufacturer's assigned retest or expiration date in firm's container/closure system.	Class II Recall
Bayer's Alka-Seltzer Plus products	Bayer is voluntarily recalling Alka-Seltzer Plus® packages that: • Were sold only in the U.S. at Walmart, CVS, Walgreens and Kroger (including Dillons Food Stores, Fred Meyer, Fry's Food Stores, Ralphs, King Soopers and Smith's Food and Drug) after February 9, 2018. • Can be identified by checking the Bayer logo located on the lower left corner of the front of the carton. If the logo has an orange or green background, the product is included in the recall.	3/16/2018	The affected packages are being recalled because the ingredients listed on the front sticker of the carton may be different from the ingredients listed on the back of the carton as well as the product in the carton.	Voluntary Recall
E-Z Paste Barium Sulfate Cream	All manufactured by Bracco.	3/16/2018	This recall was issued due to an out of specification (OOS) result for preservative assay, methylparaben, during stability testing.	Retail Level Recall
Indomethacin	50 mg capsules	3/20/2018	This recall was issued due to findings of an incorrect usual adult dosage on the bottle label of the 50 mg, 100 count bottles	Retail Level Recall

Estradiol	Vaginal Inserts manufactured by Teva - Estradiol Vaginal Insert 10 mcg 2x4 & Estradiol Vaginal Insert 10 mcg 3x6	3/20/2018	This recall was issued due to product complaints regarding difficulty in dispensing the tablet from the applicator.	Retail Level Recall
BD Vacutainer® Push Button and BD Vacutainer® Ultra Touch™ Blood Collection set manufactured by Becton Dickinson	BD Vacutainer® Push Button Blood Collection Set 0.6 x 19 mm x 305 mm 23G x 3/4" x 12" & BD Vacutainer® Push Button Blood Collection Set 0.8 x 19 mm x 305 mm 21G x 3/4" x 12" & BD Vacutainer® Ultra Touch™ Push Button Blood Collection Set 0.6 x 19 mm x 305 mm 23G x 3/4" x 12"	3/22/2018	This recall was issued because they do not meet the labelled sterility claim of a Sterility Assurance Level (SAL) 10-6.	Professional Level Recall
Hydromorphone hydrochloride injection C-II 10 mg/mL	Teva hydromorphone hydrochloride injection C-II 10 mg/mL 1 mL single-dose vials & Teva hydromorphone hydrochloride injection C-II 10 mg/mL 1 mL single-dose vials Carton of 10 vials & Hospira hydromorphone hydrochloride injection C-II 10 mg/mL 1 mL single-dose vials.	3/21/2018	This recall was issued due to the potential that units from the affected lots may be empty or cracked at the bottom of the glass vial.	Class I Recall
Oxytocin USP powder and Sermorelin Acetate powder	Oxytocin USP powder 1gm bottle, & Sermorelin Acetate powder 1 gm bottle, & Sermorelin Acetate powder 5 gm bottle, & Sermorelin Acetate powder 10 gm bottle.	3/21/2018	This recall was issued due to stability data from manufacturer does not support expiration dates listed.	Class II Recall
Fabior 0.1 %	Foam	3/26/2018	This recall was issued due to an out of specification result that occurred during stability testing.	Retail Level Recall
Kcentra	1000 IU single use vials	3/29/2018	This recall was issued due to an increased risk of breakage during transport and handling of the product due to a change in the secondary packaging configuration in January 2018.	Retail Level Recall
Pasta De Lassar Andromaco Skin Protectant	25% zinc oxide	3/29/2018	FDA analysis of this product confirmed that Pasta De Lassar Andromaco is contaminated with high levels of yeast, mold, and bacteria. The specific lot associated to the positive findings was never sold in the US. However, due to the amount and type of contamination the remaining four lots in the US market are being recalled out of an abundance of caution.	Voluntary Recall
April				
Kcentra	1000 Units	4/6/2018	CSL Behring is recalling certain lots of Kcentra 1000 Units due to a potential risk of breakage of the glass vials during transport because of a change in the secondary packaging configuration.	Voluntary Recall
Chlorhexidine Gluconate	15 mL	4/5/2018	This recall was issued due to product crystallization with accompanying out of specification assay results for chlorhexidine.	Retail Level Recall
Ferrous Sulfate	Tablets	4/6/2018	This recall was issued due to complaints that one Beano tablet was found co-mingled with FeroSul tablets.	Retail Level Recall
Triamterene/Hydrochlorothiazide	75-50 mg tablets	4/10/2018	This recall was issued to the presence of unrelated ingredients (i.e. traces of Lisinopril, Mannitol, Iron, Calcium and Phosphorous), which were identified through a complaint investigation.	Retail Level Recall
Amantadine	100 mg capsules	4/10/2018	This recall was issued due to an "out of spec" for dissolution during annual stability testing.	Retail Level Recall
Levofloxacin	5% Dextrose Injection	4/11/2018	This recall was issued due to a confirmed customer report of a leaking bag.	Retail Level Recall
Linezolid Injection	600mg/300mL bags	4/11/2018	This recall was issued due to leaking bags. This recall affects all unexpired lot numbers.	Retail Level Recall
Levetiracetam Injection	1000mg*100mL, 1500mg/100mL, 500mg/100mL	4/11/2018	This recall was issued due to leaking bags. This recall affects the affected products and lot numbers.	Retail Level Recall
Morphine Sulfate	(Single Dose Syringe) 2mg/mL Preservative Free Injection & (Single Dose Syringe) 4mg/mL Preservative Free Injection	4/11/2018	Premier Pharmacy Labs is voluntarily recalling the following products due to a potential lack of sterility assurance.	Voluntary Recall
Hydromorphone HCL	(Single Dose Syringe) 1mg/mL Preservative Free Injection	4/11/2018	Premier Pharmacy Labs is voluntarily recalling the following products due to a potential lack of sterility assurance.	Voluntary Recall
Neostigmine Methylsulfate	(Single Dose Syringe) 1mg/mL Injection	4/11/2018	Premier Pharmacy Labs is voluntarily recalling the following products due to a potential lack of sterility assurance.	Voluntary Recall
Daytrana	10 mg/9 HR Patch	4/13/2018	This recall was issued to this lot no longer meeting the adhesive transfer specification.	Retail Level Recall
All non-expired products marketed as sterile made by Coastal Meds LLC, of Biloxi, Mississippi	All Non-Expired	4/13/2018	Visible particles in some of the drug vials for injection.	Voluntary Recall
Rhino 69 Extreme 50000	Capsules	4/16/2018	FDA analysis found the product to be tainted with undeclared tadalafil. Tadalafil is an active ingredient in a FDA-approved prescription drug that is used for erectile dysfunction.	Voluntary Recall
Easy Touch Insulin Syringe	29 gauge 1 mL ½"	4/16/2018	This recall was issued because the device and its packaging are mislabeled. - While the case carton and the poly bag are labeled correctly, some retail shelf cartons are incorrectly labeled as lot number 45016 which is associated with Easy Touch insulin 29 gauge 0.5 mL ½" insulin syringes (Item 829555). This incorrect labeling could result in abnormal product use and could delay patient treatment.	Consumer Level Recall
Olysio	150 mg Capsules	4/19/2018	This recall was issued due to Janssen discontinuing commercial availability of Olysio.	Retail Level Withdrawal
Sulfamethoxazole/Trimethoprim	800 mg/160 mg tablets	4/23/2018	This recall was issued in response to foreign matter identified as polyethylene detected in two (2) tablets to date.	Retail Level Recall
Bupropion HCl	150 mg SR Tablets	4/23/2018	This recall was issued due to a failure of dissolution testing observed during long term stability testing of first three validation batches of 150 mg at 18 months interval for 60's and 100's count.	Retail Level Recall

Metoprolol Succinate ER	100 mg tablets	4/24/2018	This recall was issued due to a product complaint received for comingling. One foreign tablet was found in a 100 count bottle of Metoprolol Succinate Extended-Release Tablets.	Retail Level Recall
Diltiazem HCl capsules	120 mg, 240 mg & 180 mg ER Capsules	4/24/2018	This recall was issued due to the discovery of OOS (out-of-specification for Dissolution results).	Retail Level Recall
Amantadine HCl Capsules, USP	100 mg, 50 Capsules (5x10) Unit Dose	4/25/2018	This recall was issued due to failed dissolution specifications.	Class II Recall
Lupin Cefdinir powder for Oral Suspension USP	250 mg/5 mL in 60 mL & 100 mL	4/25/2018	This recall was issued due to superpotent drug.	Class II Recall
Fluconazole Injection, USP	Iso-Osmotic Sodium Chloride Diluent, 200 mg in 100 mL (2 mg/mL), package in 100 mL bags	4/25/2018	This recall was issued due to labeling mix-up. A complaint was received of one bag of Fluconazole Injection, Iso-Osmotic Sodium Chloride Diluent, USP, 2mg/mL, 50 mL found within the package of 100 mL bags.	Class II Recall
BD Syringes	Prefilled Syringes	4/25/2018	This recall was issued due to a potential for contamination with <i>Serratia marcescens</i> bacterium.	Retail Level Recall
Easy Touch insulin syringes manufactured by MHC Medical Products.	Easy Touch 29 gauge, 1 mL / . ½" insulin syringes & Easy Touch 29 gauge, 0.5 mL / ½" insulin syringes	4/27/2018	This recall was issued because the device and its packaging are mislabeled.	Consumer Level Recall
Medical supplies manufactured by Baxter	Exacta-Mix Non-Vented Inlet, Exacta-Mix Syringe Inlet, Micro Volume Inlet Exacta-Mix Vented Inlet.	4/30/2018	This recall was issued due to incorrectly performed over-labeling.	Retail Level Recall
May				
Ibuprofen distributed by Time-Cap Laboratories, Inc	600 mg and 800 mg tablets	5/2/2018	This recall was issued due to CGMP deviations. Various strengths of ibuprofen tablets/caplets are being recalled due to complaints of odor related to CGMP deficiencies.	Class II Recall
Docetaxel	20mg /mL 1 mL vial	5/2/2018	This recall was issued due to the possibility of a low number of potentially over-concentrated vials in the above noted lots.	Retail Level Recall
Diclofenac sodium and Misoprostol DR	50/0.2 mg tablets, & DR 75/0.2 mg tablets	5/2/2018	This recall was issued due to out of trend stability results specific to these two lots.	Retail Level Recall
Ampicillin-Sulbactam	3 gm vial	5/2/2018	This recall was issued due to a confirmed customer report of a presence of visible particulate matter.	Retail Level Recall
Piperacillin and Tazobactam for injection	3.375g single dose vial	5/2/2018	This recall was issued as the products have been found to contain particulate matter, visible only after reconstitution	Hospital Level Recall
Calendula Cream	Manufactured by	5/2/2018	This recall was issued due to mislabeling stating the active ingredient of Calendula as being 7% on the outer packing instead of the correct listing of 10%.	Retail Level Recall
Lidocaine 5% Patch	Patch	5/4/2018	This recall was issued because of an out of specification (OOS) test result for water content obtained during routing stability testing activities.	Retail Level Recall
BD PosiFlush and BD Pre-Filled Normal Saline Syringes	Flush syringe, 30, 50, 60, 200, 300, 500 units/ 3, 5mL	5/4/2018	This recall was issued due to potential for contamination with <i>Serratia marcescens</i> bacterium	Patient Level Recall
Accu-Chek Aviva Plus	50, 100 count Test Strips	5/7/2018	This recall was issued four test strip lots were identified as being out of specification during ongoing quality monitoring and marketing surveillance processes	Consumer Level Recall
Piperacillin and Tazobactam for injection	3.375, 4.5g vials, cartons	5/9/2018	This recall was issued due to retaining samples containing vials with changes in product appearance resulting in melt back and partially collapsed lyophilized powder cakes due to incomplete removal of water during the lyophilization process	Retail Level Recall
Fluocinolone Oils	Otic Oil 0.01% 20 mL, Body Oil 0.01% 4 oz., Scalp Oil 0.01% 4 oz.	5/9/2018	This recall was issued due to the products not meeting a potency for specification at stability	Retail Level Recall
Minivelle	0.0375mg, 0.1mg Transdermal Patch	5/9/2018	This recall was issued due to these lots no longer meeting the specification for shear	Retail Level Recall
Medline Remedy Essentials No-Rinse Cleansing Foam	4oz, 8oz bottles	5/9/2018	This recall was issued as the products had been identified as positive for <i>B. cepacia</i>	Voluntary Recall
Scopolamine Transdermal Patch	1mg/3day 4, 10, 24 count patches	5/14/2018	This recall was issued due to out of specification drug release results which occurred during stability testing	Retail Level Recall
Piperacillin and Tazobactam for injection	3.375 g Carton, 3.375g vial, 4.5 g carton, 4.5 g vial	5/14/2018	This recall was issued due to product containing elevated levels of impurities that may result in decreased potency. The decreased potency of piperacillin and tazobactam could result in worsening of the infection under treatment and under extreme circumstances lead to serious morbidities depending upon the severity of the illness. Elevated levels of impurities may result in various toxicities, such as liver, renal, and hematological toxicities. There have not been any reports of adverse events related to this recall to date.	Retail Level Recall
Accu-Chek Aviva Plus	50, 100 count Test Strips	5/15/2018	This recall was issued due to identifying four test strip lots that are out of specification during ongoing quality monitoring and marketing surveillance processes	Consumer Level Recall
7K and Poseidon 4500	1000mg tablets	5/17/2018	This recall was issued as FDA analysis found samples of these products to contain undeclared Sildenafil and/or Tadalafil which renders them unapproved drugs for which safety and efficacy have not been established	Consumer Level Recall
Accu-Chek Inform II / Performa	Test Strips	5/18/2018	This recall was issued due to two test strip lots that are out of specification	Retail Level Recall
My Way	1.5mg tablets	5/22/2018	This recall was issued due to lack of appropriate regulatory approval of additional packaging configuration	Retail Level Recall
Amlodipine and Benazapril HCl capsules	5mg/40mg, 100 count bottles	5/23/2018	This recall was issued due to cGMP deviations; cleaning process for equipment used to manufacture the specified batches was not followed according to procedure	Class II Recall
2.5% Hydrocortisone Ointment	20g ointment	5/23/2018	This recall was issued due to failed stability specifications	Class II Recall
Amlodipine and Benazapril HCl capsules	5mg/10mg, 100 count bottles	5/23/2018	This recall was issued due to cGMP deviations	Class II Recall

Hydrocodone and Acetaminophen	5/325mg tablets	5/25/2018	This recall was issued due to a wholesale customer's email notification to a Lupin customer service representative indicating they received two unlabeled bottles	Retail Level Recall
Taytulla (norethindrone acetate and ethinyl estradiol capsules and ferrous fumarate capsules)	1mg/20mcg, 6x28 physicians sample pack	5/29/2018	This recall was issued due to identification of out of order placebo capsules in a sample pack of Taytulla. Specifically, the first four days of therapy had 4 non-hormonal placebocapsules instead of active capsules	Retail Level Recall
PrednisolONE Sodium Phosphate Orally Disintegrating Tablets	10mg tablets/48 count bottle, 15mg tablets/48 count bottle, 30mg tablets/48 count bottle	5/30/2018	This recall was issued due to a GMP deviation(s)	Class II Recall
Loxapine	25mg, 50mg capsules	5/30/2018	This recall was issued due to a GMP deviation(s)	Class II Recall
0.9% Sodium Chloride Injection	1000mL	5/30/2018	This recall was issued due to a lack of assurance of sterility	Class II Recall
Orajel Teething Products	Gel Cherry Flavored 0.36 OZ, Gel Cherry Flavored 0.18 oz, Gel 0.33 oz, Swabs Berry Flavor 12 each, Gel 0.18 oz	5/30/2018	This recall was issued due to a request from the FDA to stop selling oral health products containing benzocaine for the temporary relief of sore gums due to teething in infants or children	Retail Level Recall
Fluticasone Propionate Nasal Spray	50mcg Nasal Spray	5/31/2018	This recall was issued because the product was found to contain small glass particles which could block the actuator and impact the functionality of the pump. Potential for exposed glass particles and mechanical irritation, local trauma to nasal mucosa may occur	Retail Level Recall
Fluticasone Propionate Nasal Spray	50mcg Nasal Spray	5/31/2018	This recall was issued because the product was found to contain small glass particles which could block the actuator and impact the functionality of the pump.	Retail Level Recall
Fluticasone Propionate Nasal Spray	50mcg, 120 metered sprays Nasal Spray	5/31/2018	This recall was issued because the product was found to contain small glass particles which could block the actuator and impact the functionality of the pump. Discovered through customer complaint. No adverse events related to recall reported	Retail Level Recall
June				
Atorvastatin	80mg tablet	6/1/2018	This recall was issued due to a product complaint received for a defective tablet, with an embedded foreign object observed in a bottle of the mentioned lot.	Retail Level Recall
Naloxone Hydrochloride Injection	0.4 mg/mL, 1mL in 2.5mL Carpuject single-use cartridge syringe system	6/4/2018	This recall was issued due to the potential presence of embedded and loose particulate matter on the syringe plunger, this recall was also classified at the retail level	Hospital Level Recall
Naloxone Hydrochloride Injection	0.4mg/mL, 1 mL in 2.5 mL, Carpuject Single-use cartridge syringe system	6/4/2018	This recall was issued due to potential presence of embedded and loose particulate matter on the syringe plunger.	Hospital Level Recall
Apex 26 - Lead Transfer Set	Set	6/5/2018	This recall was issued due to the potential for valves to be incorrectly orientated	Retail Level Recall
Daytrana	20mg/9hr patch 30 count	6/5/2018	This recall was issued as it no longer met adhesive transfer specification and this lot was found to be out of specification for mechanical peel	Retail Level Recall
Acetaminophen Elixir	160 mg/5 mL	6/8/2018	This recall was issued due to a Total Aerobic Microbial count in a water sample by the preceding entity.	Retail Level Recall
Senna Syrup	8 Ounces	6/11/2018	This recall was issued due to an out of specification in water sample.	Retail Level Recall
Varied injections manufactured by ICU Medical	Dextrose Solution 5% 250 mL, Sodium Chloride Injection 0.9% 100 mL, Sodium Chloride Solution 0.9% 250 mL, Sodium Chloride Solution 0.45% 100 mL, Sodium Chloride Solution 0.9% 100 mL	6/12/2018	This recall was issued due to identified container leaks, potentially related to a manufacturing issue, in returned complaint samples and in ICU Medical reserve samples.	Retail Level Recall
Atorvastatin	Tablets manufactured by Dr. Reddy: 10 mg tablets 90 count, 20 mg tablets 90 count, 40 mg tablets 500 count, 40 mg tablets 90 count.	06/13/2018	This recall was issued because an out-of-specification result or atypical trend in related substances have been observed.	Retail Level Recall
Maxzide	37.5/25 mg tablets	06/12/2018	This recall was issued due to composite assay results obtained during routine stability testing that were slightly above the specification.	Retail Level Recall
Senna Syrup	40 UD	06/14/2018	This recall was issued due to an OUT OF SPECIFICATION total aerobic microbial count in a water sample.	Retail Level Recall
Profilnine, Factor IX Complex	1000 Units	06/15/2018	On June 15, 2018 Grifols announced a patient-level recall of one lot of Profilnine, Factor IX Complex because the incorrect volume of sterile water for injection was packaged with Profilnine.	Patient Level Recall
Gericare Diocto Liquid	50 mg/5 mL 473 mL	06/20/2018	These recalls were issued due to an out of specification total aerobic microbial count in a water sample.	Class II Recall
Preferred Plus Pharmacy Antacid Extra Strength	355 mL	06/20/2018	These recalls were issued due to an out of specification total aerobic microbial count in a water sample.	Class II Recall
Preferred Plus Pharmacy	Antacid 355 mL	06/20/2018	These recalls were issued due to an out of specification total aerobic microbial count in a water sample.	Class II Recall
RPC Senna Syrup	237 mL	06/20/2018	These recalls were issued due to an out of specification total aerobic microbial count in a water sample.	Class II Recall
RPC Children's Non-Aspirin Elixir	118 mL	06/20/2018	These recalls were issued due to an out of specification total aerobic microbial count in a water sample.	Class II Recall
Gericare Liquid Pain Relief Acetaminophen	Cherry Flavor 160mg/5mL/47mL	06/20/2018	These recalls were issued due to an out of specification total aerobic microbial count in a water sample.	Class II Recall
GeriCare Senna Syrup	237 mL	06/20/2018	These recalls were issued due to an out of specification total aerobic microbial count in a water sample.	Class II Recall
Ritussin DM Hextromethorphan Hydrobormide	118mL	06/20/2018	These recalls were issued due to an out of specification total aerobic microbial count in a water sample.	Class II Recall
SDA Senna Syrup	236 mL	06/20/2018	These recalls were issued due to an out of specification total aerobic microbial count in a water sample.	Class II Recall
Gericare Iron Supplement Elixir Ferrous Sulfate	473 mL	06/20/2018	These recalls were issued due to an out of specification total aerobic microbial count in a water sample.	Class II Recall
Enalapril Maleate	2.5 mg tablets, 5 mg tablets	06/21/2018	This recall was issued due to out-of-specification results for the Enalapril Diketopiperazine degradation product during commercial stability.	Retail Level Recall
Acetylcysteine	6 gram/30 mL vial	06/27/2018	This recall was issued due to L-Cystine and L-Cysteine stability testing is not able to be performed due to chromatography issues.	Retail Level Recall

Profilinine	1000 IU for solution	06/28/2018	This recall was issued because an incorrect volume of sterile water for injection was packaged with Profilinine.	Retail Level Recall
Enalapril Maleate	5mg UD Tablets	06/28/2018	This recall was issued due to out-of-specification results for the Enalapril Diketopiperazine degradation product during commercial stability.	Retail Level Recall
Gericare Diocto Liquid	50 mg/5 mL 473 mL	06/28/2018	This recall was issued due to an out of specification total aerobic microbial count in a water sample.	Retail Level Recall
Enalapril Maleate	2.5 mg and 5 mg tablets	06/29/2018	This recall was issued due to "out-of-specification results for the Enalapril Diketopiperazine degradation product during commercial stability.	Retail Level Recall
Neostigmine Methylsulfate	5mL syringes	06/29/2018	The specified product lots are being recalled because of a confirmed customer complaint that some syringe units containing Neostigmine Methylsulfate 1mg/mL, 5mg per 5mL are incorrectly labelled as Neostigmine Methylsulfate 1mg/mL, 3mg per 3mL. Secondary packages are properly labelled as Neostigmine Methylsulfate 1mg/mL, 5mg per 5mL.	Voluntary Recall - Nationwide
July				
Acetylcysteine	200 mg/mL single-dose vials	07/02/2018	This recall was issued due to L-Cysteine and L-Cysteine stability testing not being able to be performed due to chromatography issues.	Retail Level Recall
kratom (mitragyn a speciosa) powder products	All products with this lot	07/03/2018	https://www.fda.gov/Safety/Recalls/ucm612376.htm?utm_campaign=Blissful%20Remedies%20Issues%20Voluntary%20Nationwide%20Recall%20of%20Certain%20Kratom%20Powder%20Capsule&utm_medium=email&utm_source=Eloqua	Voluntary Recall - Nationwide
Enalapril Maleate	2.5 mg tablets	07/02/2018	This recall was issued due to out-of-specification results for the Enalapril Diketopiperazine degradation product during commercial stability. This recall had an additional affected lot that was not on the original recall notice received for these products.	Retail Level Recall
Entresto	24/16 mg unit dose tablets carton and blister card, 49/51 mg unit dose tablets carton and blister card, 97/103 mg unit dose tablets carton and blister card	07/06/2018	This recall was issued due to the products not being packaged in child-resistant packaging posing a risk of harm if the tablets are swallowed by children.	Consumer Level Recall
Zofran	4 mg ODT carton & blister card, 8 mg ODT carton & blister card	07/06/2018	This recall was issued due to the products not being packaged in child-resistant packaging posing a risk of harm if the tablets are swallowed by children.	Consumer Level Recall
Sandoz Hospital Unit Dose Products - Donepezil ODT	5 mg, 10 mg 30 count blister pack	07/05/2018	This recall was issued because the packaging for these products are not child-resistant which could pose a risk of harm if the tablets are swallowed by children.	Patient Level Recall
Sandoz Hospital Unit Dose Products - Haloperidol	0.5 mg, 1mg, 2mg, 5mg, 10mg tablets 100 count blister pack	07/05/2018	This recall was issued because the packaging for these products are not child-resistant which could pose a risk of harm if the tablets are swallowed by children.	Patient Level Recall
Sandoz Hospital Unit Dose Products - Imipramine	25 mg and 50 mg tablets 100 count blister pack	07/05/2018	This recall was issued because the packaging for these products are not child-resistant which could pose a risk of harm if the tablets are swallowed by children.	Patient Level Recall
Sandoz Hospital Unit Dose Products - Isosorbide dinitrate	10 mg and 20 mg tablets 100 count blister pack	07/05/2018	This recall was issued because the packaging for these products are not child-resistant which could pose a risk of harm if the tablets are swallowed by children.	Patient Level Recall
Sandoz Hospital Unit Dose Products - Naratriptan	2.5 mg tablets 9 count blister packs	07/05/2018	This recall was issued because the packaging for these products are not child-resistant which could pose a risk of harm if the tablets are swallowed by children.	Patient Level Recall
Sandoz Hospital Unit Dose Products - Ondansetron	8 mg tablets 3 count blister packs	07/05/2018	This recall was issued because the packaging for these products are not child-resistant which could pose a risk of harm if the tablets are swallowed by children.	Patient Level Recall
Sandoz Hospital Unit Dose Products - Perphenazine	2 mg tablets 100 count blister packs, 4 mg tablets 100 count blister packs, 8 mg tablets 100 count blister packs	07/05/2018	This recall was issued because the packaging for these products are not child-resistant which could pose a risk of harm if the tablets are swallowed by children.	Patient Level Recall
Sandoz Hospital Unit Dose Products - Azithromycin	250 mg tablets 50 count blister pack	07/05/2018	This recall was issued because the packaging for these products are not child-resistant which could pose a risk of harm if the tablets are swallowed by children.	Patient Level Recall
Ondansetron	4 mg ODT 30 count, 8 mg ODT 10 count , 8 mg ODT 30 count - Cartons and blister packs	07/05/2018	This action is not a result of any quality or safety concerns with these products. This recall was issued because the packaging for these products are not child-resistant which could pose a risk of harm if the tablets are swallowed by children. As a result, Sandoz is implementing a corrective action plan to the patient level. To avoid potential interruption of patients' current supply of medication and dosing regimen, Sandoz is offering patients child-resistant pouches in which to store the affected drugs already in patients' possession. This is an interim measure until child resistant packaging is available for household use.	Patient Level Recall
Risperidone	0.5 mg ODT 28 count, 1mg ODT 28 count, 2 mg ODT 28 count, 3 mg ODT 28 count, 4 mg ODT 28 count - Cartons and blister packs	07/05/2018	This action is not a result of any quality or safety concerns with these products. This recall was issued because the packaging for these products are not child-resistant which could pose a risk of harm if the tablets are swallowed by children. As a result, Sandoz is implementing a corrective action plan to the patient level. To avoid potential interruption of patients' current supply of medication and dosing regimen, Sandoz is offering patients child-resistant pouches in which to store the affected drugs already in patients' possession. This is an interim measure until child resistant packaging is available for household use.	Patient Level Recall
Daptomycin	500 mg for injection	07/03/2018	This withdrawal was issued based on a review of safety information regarding reported infusion reactions associated with the above product.	Retail Level Recall
Fluocinolone Acetonide	.01 % Solution, 60mL	07/09/2018	This recall was issued because out of specification (OOS) test results were obtained for assay and degradants.	Retail Level Recall
Enalapril Maleate	5mg UD tablets, 2.5 mg tablets	07/06/2018	This recall was issued due to out-of-specification results for the Enalapril Diketopiperazine degradation product during commercial stability. This notice contained additional affected lot numbers that were not on the previous recall notice received for these products.	Retail Level Recall

Gardasil® 9 Syringe	(Single-Syringe) 0.5 mL and (Carton of 10) 0.5 mL	07/10/2018	This recall was issued because a limited number of pre-filled syringes in Lot N029069 may be labeled with an incorrect lot number and expiration date. The correct lot number and expiry date are N029069, 17May2020, and the incorrect lot number and expiry are M743R56, 01/02/03. The incorrect lot number and expiry is a default setting of the label printer.	Retail Level Recall
Irinotecan HCl Injection	100 mg/5 mL 1 x 5 mL Single Dose Vial, 40 mg/2 mL 1 x 5 mL Single Dose Vial	07/11/2018	This recall was issued due to high out of specification assay value results for potency.	Class II Recall
Valsartan tablets	Valsartan 40 mg tablets, Valsartan 80 mg tablets, Valsartan 160 mg tablets, Valsartan 320 mg tablets, Valsartan 80/12.5 mg tablets, Valsartan 160/12.5 mg tablets, Valsartan 160/25 mg tablets, Valsartan 320/12.5 mg tablets, Valsartan 320/25 mg tablets	07/13/2018	This recall was issued due to the detection of a trace amount of an unexpected impurity, N-nitrosodimethylamine (NDMA), made by the manufacturer – Zhejiang Huahai Pharmaceutical Co. Ltd. -- that is used in the manufacture of the subject product lots.	Retail Level Recall
Testosterone Cypionate Injection	USP, 200 mg/mL 10 mL vial	07/16/2018	This recall was issued due to foreign matter (black particle) identified as a mixture of organic and inorganic compounds detected in one vial to date.	Retail Level Recall
Entresto® Hospital Unit Dose (HUD) tablets	Entresto 24/16 mg unit dose tablets carton, Entresto 24/16 mg unit dose tablets blister card, Entresto 49/51 mg unit dose tablets carton, Entresto 49/51 mg unit dose tablets blister card, Entresto 97/103 mg unit dose tablets carton, Entresto 97/103 mg unit dose tablets blister card.	07/06/2018	The blister cards in which the affected products are packaged are not child-resistant, posing a risk of harm if the tablets are swallowed by children. As a result, Novartis is voluntarily recalling the products in the United States. Novartis is asking wholesalers and pharmacies to return any affected product in stock. To avoid potential interruption of patients' current supply of medication and dosing regimen, Novartis is offering patient child-resistant pouches in which to store the affected drugs as an interim measure to address this issue. Patients may continue to use the products as directed.	Patient Level Recall
Zofran® Orally Disintegrating Tablets (ODT)	*Zofran 4 mg ODT carton *Zofran 8 mg ODT carton Zofran 4 mg ODT blister card Zofran 8 mg ODT blister card	07/06/2018	This action is not a result of any quality or safety concerns with the medications for their intended use. The blister cards in which the affected products are packaged are not child resistant, posing a risk of harm if the tablets are swallowed by children. As a result, Novartis is voluntarily recalling the products in the United States. Novartis is asking wholesalers and pharmacies to return any affected product in stock. To avoid potential interruption of patients' current supply of medication and dosing regimen, Novartis is offering patient child-resistant pouches in which to store the affected drugs as an interim measure to address this issue. Patients may continue to use the products as directed.	Patient Level Recall
Donepezil ODT	Donepezil ODT 5 mg 30 count blister pack, Donepezil ODT 10 mg 30 count blister pack	07/05/2018	This recall was issued because the packaging for these products are not child-resistant which could pose a risk of harm if the tablets are swallowed by children. As a result, Sandoz is implementing a corrective action plan to the patient level. To avoid potential interruption of patients' current supply of medication and dosing regimen, Sandoz is offering patients child-resistant pouches in which to store the affected drugs already in patients' possession. This is an interim measure until child resistant packaging is available for household use.	Patient Level Recall
Haloperidol	Haloperidol 0.5 mg tablets 100 count blister pack, Haloperidol 1 mg tablets 100 count blister pack, Haloperidol 2 mg tablets 100 count blister pack, Haloperidol 5 mg tablets 100 count blister pack, Haloperidol 10 mg tablets 100 count blister pack	07/05/2018	This recall was issued because the packaging for these products are not child-resistant which could pose a risk of harm if the tablets are swallowed by children. As a result, Sandoz is implementing a corrective action plan to the patient level. To avoid potential interruption of patients' current supply of medication and dosing regimen, Sandoz is offering patients child-resistant pouches in which to store the affected drugs already in patients' possession. This is an interim measure until child resistant packaging is available for household use.	Patient Level Recall
Imipramine	Imipramine 25 mg tablets 100 count blister pack, Imipramine 50 mg tablets 100 count blister pack	07/05/2018	This recall was issued because the packaging for these products are not child-resistant which could pose a risk of harm if the tablets are swallowed by children. As a result, Sandoz is implementing a corrective action plan to the patient level. To avoid potential interruption of patients' current supply of medication and dosing regimen, Sandoz is offering patients child-resistant pouches in which to store the affected drugs already in patients' possession. This is an interim measure until child resistant packaging is available for household use.	Patient Level Recall
Isosorbide dinitrate	Isosorbide dinitrate 10 mg tablets 100 count blister pack, Isosorbide dinitrate 20 mg tablets 100 count blister pack	07/05/2018	This recall was issued because the packaging for these products are not child-resistant which could pose a risk of harm if the tablets are swallowed by children. As a result, Sandoz is implementing a corrective action plan to the patient level. To avoid potential interruption of patients' current supply of medication and dosing regimen, Sandoz is offering patients child-resistant pouches in which to store the affected drugs already in patients' possession. This is an interim measure until child resistant packaging is available for household use.	Patient Level Recall
Nitrofurantion	25 mg/5 mL suspension	07/02/2018	This recall was issued due to Out of Specification Results for Lot # S700065 and Lot # S700619	Retail Level Recall
Valsartan - Teva Pharmaceuticals	Valsartan 40mg tablets 90 count, Valsartan 40mg tablets 30 count, Valsartan 80mg 1000 count, Valsartan 80mg 90 count, Valsartan 160mg 1000 count, Valsartan 160mg 90 count, Valsartan 320mg 500 count, Valsartan 320mg 90 count	07/17/2018	This recall was issued due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceutical. The impurity detected in the API is N- nitrosodimethylamine (NDMA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.	Retail Level Recall

Valsartan/Hydrochlorothiazide - TEVA Pharmaceuticals	Valsartan/Hydrochlorothiazide 80/12.5mg 90 count, Valsartan/Hydrochlorothiazide 160/12.5mg 90 count, Valsartan/Hydrochlorothiazide 160/25mg 90 count, Valsartan/Hydrochlorothiazide 320/12.5mg 90 count, Valsartan/Hydrochlorothiazide 320/25mg 90 count	07/17/2018	This recall was issued due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceutical. The impurity detected in the API is N-nitrosodimethylamine (NDMA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.	Consumer Level Recall
Valsartan - Major Pharmaceuticals	Valsartan 80mg tablets 100 count blister packs, Valsartan 160mg tablets 100 count blister packs	07/13/2018	This recall was issued after Major Pharmaceuticals learned of a potential issue with the active pharmaceutical ingredient in Valsartan supplied by Teva Pharmaceuticals which may contain the probable carcinogen N-nitrosodimethylamine (NDMA).	Consumer Level Recall
Valsartan HCTZ- Actavis Pharma	Valsartan HCTZ 160/12.5 mg, Valsartan HCTZ 160/25 mg, Valsartan HCTZ 320/12.5 mg, Valsartan HCTZ 320/25 mg, Valsartan HCTZ 80/12.5 mg	07/19/2019	This recall was issued due to an impurity, N-nitrosodimethylamine (NDMA) that was reported in the Valsartan USP active drug substance manufactured by Zhejiang Huahai Pharmaceutical Co., Ltd.	Consumer Level Recall
Indomethacin- Camber	Indomethacin 50 mg capsules	07/23/2018	This recall was issued due to some of the capsules looking misshaped, melted and stuck together.	Retail Level Recall
Omega-3-Acid Ethyl Esters - TEVA Pharmaceuticals	Omega-3-Acid Ethyl Esters 1 gm capsules	07/23/2018	This recall was issued due to the use of an API material awaiting regulatory approval for use.	Retail Level Recall
Valsartan- Zhejiang Huahai Pharmaceuticals	Valsartan 40 mg tablets, Valsartan 80 mg tablets, Valsartan 160 mg tablets, Valsartan 320 mg tablets	07/16/2018	This recall was issued due to the detection of a trace amount of an unexpected impurity, N-nitrosodimethylamine (NDMA), made by the manufacturer – Zhejiang Huahai Pharmaceutical Co. Ltd. -- that is used in the manufacture of the subject product lots. This impurity has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.	Patient Level Recall
Valsartan HCTZ- Zhejiang Huahai Pharmaceuticals	Valsartan HCTZ 80/12.5mg tablets, Valsartan HCTZ 160/12.5mg tablets, Valsartan HCTZ 160/25mg tablets, Valsartan HCTZ 320/12.5mg tablets, Valsartan HCTZ 320/25mg tablets	07/16/2018	This recall was issued due to the detection of a trace amount of an unexpected impurity, N-nitrosodimethylamine (NDMA), made by the manufacturer – Zhejiang Huahai Pharmaceutical Co. Ltd. -- that is used in the manufacture of the subject product lots. This impurity has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.	Patient Level Recall
Moxifloxacin HCL Ophthalmic Solution- Lupin	Moxifloxacin HCL Ophthalmic Solution 0.5% - 3mL	07/27/2018	This recall was issued due to an out of specification result that was observed in the related substance test (any other individual impurity) at the three-month long-term stability study	Retail Level Recall
Doxycycline Hyclate- West Ward	Doxycycline Hyclate 100 mg tablets 50 count bottle, Doxycycline Hyclate 100 mg tablets 500 count bottle	07/26/2018	This recall was issued due to an out of specification result for the dissolution test.	Retail Level Recall
Metformin Hydrochloride - Sun Pharmaceutical	Metformin HCl ER 500 mg tablet	07/30/2019	This recall was issued due to presence of foreign substance identified as a piece of rubber glove detected in one tablet.	Class II Recall
Potassium Citrate- Vensum Pharmaceuticals	Potassium Citrate ER 10 MEQ tablets , Potassium Citrate 15 MEQ tablets	07/26/2018	This recall was issued due to tablet breakage	Retail Level Recall
Prednisolone Solution	15 mg/5 mL 237 mL	07/27/2018	This recall was issued because on June 19, 2018, a "Tamper Evident" bottle seal integrity issue was noted for the 12 month 25°C/60%RH stability sample of batch US1259 which prompted an investigation. The "Foil Seal/Heat Seal" present in MGP's Prednisolone Sodium Phosphate Oral Solution Batch US1259 is included as a "TAMPER EVIDENT" feature. There is no risk to patient safety or product quality as a result of the foil seal/heat seal not being completely intact or pulling away from the lip of the bottle; however, patients or pharmacists may have concerns that the material has had tampering.	Retail Level Recall
All Sterile Compounded Products Within Expiry	The recall encompasses compounded sterile drug products, within expiry, that were dispensed between January 17, 2018, and July 10, 2018. The sterile drug products subject to this recall were distributed only within the State of Pennsylvania and directly to customers and/or medical facilities. The recall does not affect the pharmacy's non-sterile compounded products or retail pharmacy operations.	07/28/2018	These drug products are being voluntarily recalled due to concerns that practices at the pharmacy have the potential to pose a risk of contamination to products that are intended to be sterile. These concerns arose following a routine inspection of the pharmacy by FDA.	Voluntary Recall
Ranier's Rx Laboratory	All sterile compounded drug products within expiry to the hospital or consumer level.	07/30/2018	These drug products are being voluntarily recalled due to concerns that practices at the pharmacy have the potential to pose a risk of contamination to products that are intended to be sterile. These concerns arose following a routine inspection of the pharmacy by FDA.	Voluntary Recall
Piperacillin and Tazobactam for injection	USP 3.375 g (Piperacillin Sodium equivalent to 3 g of Piperacillin USP and Tazobactam Sodium equivalent to 0.375 g of Tazobactam USP. Each vial contains 7.05 mEq (162 mg) of Sodium) in a Single-Dose vial, to the hospital level.	07/31/2018	One vial from lot# PP0317012-A was found to contain particulate matter, identified as glass within the vial and another vial from lot# PP0317059-A was found to contain silicone material. This problem was discovered as a result of two product complaints in which the contents of one vial from batch PP0317012-A was found to contain a glass particle and the contents of one vial from batch PP0317059A was found to contain a silicone particle.	Hospital Level Recall
August				
Lidocaine & Prilocaine	2.5% cream	08/01/2018	This recall was issued due to observed out of specification results for unknown impurity at the 12 month stability testing.	Retail Level Recall
Doxycycline Hyclate	Doxycycline Hyclate 100 mg tablets	08/03/2018	This recall was issued due to an out of specification result for the dissolution test.	Retail Level Recall
Atorvastatin	Atorvastatin 40 mg tablets	08/06/2018	This recall was issued due to out-of-specification result observed for ATV Cyclo FP impurity and Total Degradation Impurities when tested at 18th month stability time point.	Retail Level Recall
Levofloxacin Bag 9/4/18 / Baxter	Levofloxacin Bag 250 mg/ 50 mL; Levofloxacin Bag 500 mg/ 100 mL; Levofloxacin Bag 750 mg/ 150 mL	08/03/2018	This recall was issued due to out-of-specification test results.	Retail Level Recall

CVS Health 12 Hour Sinus Relief Nasal Mist/ Product Quest Manufacturing	CVS Health 12 Hour Sinus Relief Nasal Mist	08/08/2018	The product was found to have had microbiological contamination identified as <i>Pseudomonas aeruginosa</i> .	Retail Level Recall
Metformin Hydrochloride / Teva	Metformin Hydrochloride ER 500 mg and 1000 mg	08/09/2018	This recall was issued due to the potential for some tablets to be missing the laser drilling which might affect drug release	Retail Level Recall
Valsartan / Camber Pharmaceuticals	Valsartan Tablets, USP, 40mg, 80mg, 160mg and 320mg	08/09/2018	This recall was issued due to the detection of trace amounts of nitrosodimethylamine (NDMA), a possible process impurity or contaminant in an active pharmaceutical ingredient, (API manufacturer).	Consumer Level Recall
Blissful Remedies Red Maeng Da 100% Mitragyna Speciosa capsules, Blissful Remedies Red Maeng Da Liquid Kratom Mitragyna Speciosa, Blissful Remedies 4 Hour Chill Slow Motion Blend / Worls Organix	Blissful Remedies Red Maeng Da 100% Mitragyna Speciosa capsules, Blissful Remedies Red Maeng Da Liquid Kratom Mitragyna Speciosa, Blissful Remedies 4 Hour Chill Slow Motion Blend	08/14/2018	These products have been tested by the U.S. Food and Drug Administration ("FDA") and found to be contaminated with High Microbial Loads	Voluntary Recall - Nationwide
Paliperidone ER tablets/ Teva	Paliperidone ER 3 mg tablets 90 count bottle Paliperidone ER 3 mg tablets 30 count bottle Paliperidone ER 9 mg tablets 90 count bottle Paliperidone ER 9 mg tablets 30 count bottle	08/09/2018	This recall was issued because there is a potential for some tablets to be missing the laser drilling which might affect drug release.	Retail Level Recall
Fortamet ER / Teva	Fortamet ER 1,000 mg tablets 60 count bottle	08/09/2018	This recall was issued because there is a potential for some tablets to be missing the laser drilling which might affect drug release.	Retail Level Recall
Levothyroxine and Liothyronine (Thyroid Tablets, USP) Westminister Pharmaceuticals	Levothyroxine and Liothyronine (Thyroid Tablets, USP)	08/10/2018	This recall was issued as a precaution because they were manufactured using active pharmaceutical ingredients that were sourced prior to the FDA's Import Alert of Sichuan Friendly Pharmaceutical Co., Ltd., which as a result of a 2017 inspection were found to have deficiencies with Current Good Manufacturing Practices (cGMP).	Retail Level Recall
(Super Green Maeng Da Premium Kratom powder, Powerful Red Vein Bali Premium Kratom powder, Super Green Maeng Da Premium Kratom capsules, and Powerful Red Vein Bali Premium Kratom capsules / Zakah Life	Super Green Maeng Da Premium Kratom powder, Powerful Red Vein Bali Premium Kratom powder, Super Green Maeng Da Premium Kratom capsules, and Powerful Red Vein Bali Premium Kratom capsules	08/16/2018	They have the potential of being contaminated with <i>Salmonella</i> , an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems	Retail Level Recall
Lisinopril / Lupin	Lisinopril 10 mg	08/13/2018	This recall was issued due to a product complaint related to metal contamination observed in one tablet.	Retail Level Recall
Kit for the Preparation of Technetium Tc99m Medronate / Pharmalucence	Kit for the Preparation of Technetium Tc99m Medronate, 20mg in 10 mL vial, 5-count box Kit for the Preparation of Technetium Tc99m Medronate, 20mg in 10 mL vial, 30-count box	08/15/2018	This recall was issued due to lack of assurance of sterility: Technetium TC-99M Medronate Kit has a reported breach of sterility	Class II Recall
Doxycycline Hyclate / American Health Packaging	Doxycycline 100 mg	08/07/2018	This recall was issued due to an out of specification result for the dissolution test.	Retail Level Recall
Dymista® Nasal Spray	Dymista® Nasal Spray 137 mcg/50 mcg per spray	08/10/2018	This recall was issued due to a potential of broken glass in the neck area of the glass bottles.	Retail Level Recall
Azelastine Hydrochloride	Azelastine Hydrochloride 0.05% Ophthalmic Solution 6 mL	08/13/2018	This recall was issued due to observed out of specification results for Azelastine N-oxide impurity at the 6 month stability testing.	Retail Level Recall
Contrave	Contrave® 8mg/90 mg tablets	08/14/2018	This recall was issued due to rare occurrences of punctures in the bottle.	Retail Level Recall
Valsartan	Valsartan 160 mg tablets, 160 mg tablets inner pack, 320 tablets, 320 tablets inner pack, 40 mg, 40 mg Inner Pack, 80 mg, 80 mg tablets inner pack	08/15/2018	This recall was issued due to the detection of trace amounts of nitrosodimethylamine (NDMA), a possible process impurity or contaminant in an active pharmaceutical ingredient, (API manufacturer).	Retail Level Recall
Kit for the Preparation of Technetium Tc99m Medronate / Pharmalucence	Kit for the Preparation of Technetium Tc99m Medronate, 20mg in 10 mL vial	08/15/2018	This recall was issued due to lack of assurance of sterility: Technetium TC-99M Medronate Kit has a reported breach of sterility	Retail Level Recall
Megestrol Acetate / Mckesson	Megestrol Acetate 40 mg / mL Oral Solution	08/15/2018	This recall was issued due to the discovery of OOS (Out-Of-Specification for Assay results).	Retail Level Recall
Valsartan / Jubilant	Valsartan 40 mg 30 count, Valsartan 80 mg 90 count, Valsartan 160 mg 90 count, Valsartan 320 mg 90 count	08/17/2018	This voluntary recall has been initiated out of an abundance of caution due to the inability to rule out the potential utilization of an incorrect grade of excipient during manufacturing.	Retail Level Recall
Valsartan/Amlodipine/HCTZ / Torrent	Amplodipine,Valsartan, HCTZ 10mg/320mg/25mg, 10mg/160mg/25mg, 5mg/160mg/12.5mg, 10mg/160mg/12.5mg, 5mg/160mg/25mg	08/20/2018	Torrent Pharmaceuticals Limited is voluntarily recalling 14 lots of Valsartan/Amlodipine/HCTZ tablets to the consumer level due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceuticals. The impurity detected in the API is N nitrosodimethylamine (NDMA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.	Retail Level Recall
Amlodipine/Valsartan and Hydrochlorothiazide	10mg/320mg/25mg tablets 10mg/160mg/12.5mg tablets 10mg/160mg/25mg tablets 5mg/160mg/12.5mg tablets 5mg/160mg/25mg tablets	08/20/2018	This recall was issued due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceuticals.	Retail Level Recall
Levothyroxine and Liothyronine / Westminster	Levothyroxine and Liothyronine 15mg X 100ct Levothyroxine and Liothyronine 60mg X 100ct Levothyroxine and Liothyronine 90mg X 100ct Levothyroxine and Liothyronine 30mg X 100ct Levothyroxine and Liothyronine 120mg X 100ct	08/17/2018	FDA issued a new alert to active pharmaceutical ingredient (API) repackagers and distributors, finished drug manufacturers, and compounders that Sichuan Friendly Pharmaceutical Co. Limited, China, is recalling certain lots of porcine thyroid API due to inconsistent quality of the API.	Patient Level Recall

Gamunex®-C 10% / Grifols	Gamunex®-C 10%	08/21/2018	This recall was issued due to a higher rate of allergic/hypersensitivity type reactions, a small number of which were considered serious and involved the possible risk of a life threatening situation.	Consumer Level Recall
EpiPenâ 0.3 mg Auto-Injectors / Pfizer and Mylan	Epinephrine Injection, USP 0.3 mg Auto-Injectors	08/21/2018	Pfizer and Mylan's recommendation to extend the expiration dates of specific lots, and the FDA's decision were based on a careful review of data provided by Pfizer. We believe the extension of the expiration date will temporarily address patients' access to and use of EpiPen 0.3 mg Auto-Injectors, and its authorized generic, particularly during back-to-school season as demand increases.	
Valsartan/Amlodipine/HCTZ / Torrent	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/160mg/25mg, 30 Tablets Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 5mg/160mg/12.5mg, 30 Tablets Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 5mg/160mg/25mg, 30 Tablets	08/24/2018	The impurity detected in the API is N-nitrosodimethylamine (NDMA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.	Consumer Level Recall
Hydrochlorothiazide 12.5 mg Tablets / Accord	Hydrochlorothiazide 12.5 mg Tablets 100 count	08/23/2018	This recall was issued due to a product quality complaint where a single 100 count bottle of Hydrochlorothiazide Tablets USP 12.5 mg contained 100 Spironolactone Tablets 25 mg, which represents a potential health hazard.	Retail Level Recall
Morphine Carpuject Luer Lock Glass Syringe / Hospira	Morphine Carpuject Luer Lock Glass Syringe 4mg/mL 1 mL	07/30/2018	This safety alert was issued due to the potential of cracked needle hubs and particulate in multiple products manufactured in the Carpuject Luer Lock Glass Syringe products.	Retail Level Recall
Children's Advil® Suspension Bubble Gum / Pfizer	Children's Advil® Suspension Bubble Gum Flavored 4 FL OZ Bottle	08/27/2018	Voluntarily recalling one lot of Children's Advil® Suspension Bubble Gum Flavored 4 FL OZ Bottle because of customer complaints that the dosage cup provided is marked in teaspoons and the instructions on the label are described in milliliters (mL).	Voluntary Recall
Hydrochlorothiazide Tablets / Accord	Hydrochlorothiazide Tablets USP, 12.5 mg	08/28/2018	A 100 count bottle of Hydrochlorothiazide Tablets USP 12.5 mg has been found to contain 100 Spironolactone Tablets USP 25 mg. Since the individual lot, PW05264, of the product is involved in a potential mix-up of labeling, Accord is recalling this individual lot from the market.	Voluntary Recall
Weight Away Remedy/ Living Well Remedies	Weight Away Remedy	08/28/2018	The independent manufacturing facility that produced this lot reported it to be out of specification for microbial testing.	Voluntary Recall
Hydrochlorothiazide Tablets / Accord	Hydrochlorothiazide 12.5 mg Tablets 100 count	08/28/2018	This recall was issued due to a product quality complaint where a single 100 count bottle of Hydrochlorothiazide Tablets USP 12.5 mg contained 100 Spironolactone 25 mg Tablets, which represents a potential health hazard.	Consumer Level Recall
Piperacillin and Tazobactam Injection /AuroMedics	Piperacillin and Tazobactam Injection 3.375 GM	07/05/2018	This recall was issued due to a confirmed customer report of a presence of visible particulate matter.	Retail Level Recall
Children's Advil® Suspension Bubble Gum Flavored/ Pfizer	Children's Advil® Suspension Bubble Gum Flavored 4 fl oz. bottle	08/28/2018	This recall was issued because of customer complaints that the dosage cup provided is marked in teaspoons and the instructions on the label are described in milliliters (mL).	Retail Level Recall
Ethosuximide/ Akorn	Ethosuximide 250 mg capsules	08/30/2018	This recall was issued due to observed apparent out of specification (OOS) results for unspecified impurity	Retail Level Recall
Montelukast Sodium / Camber Pharmaceuticals	Montelukast Sodium 10 mg Tablets	08/31/2018	This recall was issued due to incorrect drug in bottles	Consumer Level Recall
Neuroveen/ HelloLife	Neuroveen	08/29/2018	Neuroveen has been tested and found to be contaminated with Staphylococcus saprophyticus and Burkholderia cepacia.	Voluntary Recall
Respitrol/ HelloLife	Respitrol	08/29/2018	Respitrol and Thyroveev are still pending bacterial identification.	Voluntary Recall
Thyroveev/ HelloLife	Thyroveev	08/29/2018	Respitrol and Thyroveev are still pending bacterial identification.	Voluntary Recall
Compulsin/ HelloLife	Compulsin	08/29/2018	Compulsin has been identified as containing Burkholderia cepacia.	Voluntary Recall
CVS Health 12 Hour Sinus Relief Nasal Mist/ Product Quest Manufacturing	CVS Health 12 Hour Sinus Relief Nasal Mist	08/28/2018	its voluntary recall of Lot# 173089J of CVS Health 12 Hour Sinus Relief Nasal Mist due to a finding of microbial contamination identified as Pseudomonas aeruginosa	Voluntary Recall
Gamunex-C (immune globulin [human]) 10% injection/ Grifols	Gamunex-C (immune globulin [human]) 10% injection	08/16/2018	due to a higher rate of allergic/hypersensitivity type reactions, a small number of which were considered serious and involved the possible risk of a life-threatening situation.	Consumer Level Recall
DK Attention & Learning Enh.	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Level Recall
Chicken Pox Symptom Relief	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Level Recall
Children's Appetite & Weight	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Level Recall
Children's Appetite Enhance	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Level Recall

Children's Cough Relief	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Lever Recall
Children's Fever Reliever	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Lever Recall
Children's Growth & Development	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Lever Recall
DK Newborn Tonic	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Lever Recall
DK Nosebleed Relief	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Lever Recall
TonsilPlex	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Lever Recall
Children's Ear Relief Formula	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Lever Recall
DK Teething	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Lever Recall
DK Colic Relief	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Lever Recall
Tummy Aches	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Lever Recall
Kids Multi- Strain Flu Relief	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Lever Recall
Kids Stress & Anxiety	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Lever Recall
Kids Sleep Aid	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Lever Recall
Kids Bed Wetting (NP)	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Lever Recall
Kids Candida 4 oz	4 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Lever Recall
Kids Attention & Learning (SCRX)	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Lever Recall

Bed Wetting Prevention (SCRX)	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Level Recall
Chicken Pox Symptom Relief (SCRX)	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Level Recall
Childrens Cough (SCRX)	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Level Recall
Children's Ear Formula (SCRX)	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Level Recall
Children's Fever Reliever (SCRX)	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Level Recall
Children's Growth & Development (SCRX)	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Level Recall
Colic Relief (SCRX)	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Level Recall
Newborn Tonic (SCRX)	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Level Recall
Teething (SCRX)	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Level Recall
Tummy Aches (SCRX)	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Level Recall
Children's Appetite & Weight (SCRX)	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Level Recall
Children's Appetite Enhancer (SCRX)	2 oz. bottle	8/22/2018	A small percentage of our products produced between 08/01/2015 and 08/01/2018 have tested positive for microbial contamination. Out of an abundance of caution, we are recalling the products and lot numbers below.	Consumer Level Recall
Montelukast sodium	10 mg tablets	08/31/2018	This recall was issued because sealed bottles labeled as montelukast sodium 10 mg tablets 30-count bottle from Camber were found to instead contain 90 tablets of losartan potassium 50 mg tablets	Consumer Level Recall
September				
Accu-Chek Performa / McKesson	Accu-Chek Performa Test Strips Accu-Chek Informa II Test Strips	09/04/2018	This notice was issued because two test strip lots that are out of specification due to cracked reagent	Retail Level Recall
0.9% Sodium Chloride Injection USP 100 mL bags/ Baxter	0.9% Sodium Chloride Injection USP 100 mL bags	09/05/2018	This recall was issued due to CGMP deviations.	Class II Recall
Alprostadil	500 mcg/mL Injection 5 vials carton	09/28/2018	This recall was issued due to out-of-specification test results for impurities obtained during routine stability testing activities.	Retail Level Recall
Levonorgestrel & Ethinyl Estradiol	0.15-0.03 mg tablets	09/05/2018	This recall was issued due to incorrect NDC and product name appearing on some blister packs	Retail Level Recall
Tizanidine	2mg tablets 150 count bottle	09/06/2018	This recall was issued due to a product complaint received on comingling	Retail Level Recall
Entire aqueous/alcohol-based p	Entire product line	09/05/2018	The administration or use of drug products with microbial contamination could potentially result in increased infections that may require medical intervention, and could result in infections that could be life threatening to certain individuals	Consumer Level Recall
0.9% Sodium Chloride Injection	USP 50 mL bags	09/11/2018	This recall was issued due to the product being shipped by Baxter's third party logistics provider without Baxter's approval	Retail Level Recall

Minivelle Transdermal Patches	0.0375 mg / 24 hr Transdermal Patch 8 units Each, 0.075 mg / 24 hr Transdermal Patch 8 units Each, 0.1 mg / 24 hr Transdermal Patch 8 units Each, 0.025 mg / 24 hr Transdermal Patch 8 units Each, 0.05 mg / 24 hr Transdermal Patch 8 units Each	09/10/2018	This recall was issued due to these lots no longer meeting the specification for shear, an attribute related to the adhesive properties of the Minivelle transdermal patche	Retail Level Recall
Lamotrigine ER	200 mg Tablets	09/13/2018	This recall is based upon high out of specification dissolution results detected during routine quality testing of stability samples for this batch	Retail Level Recall
Actoplus/MET® XR	15-1,000 mg Tablets 30 count bottle	09/13/2018	This recall has been initiated due to a potential defect of tablets missing, in whole or in part, the laser drilled holes on the metformin core of the Actoplus met XR tablets	Retail Level Recall
TRUEplus® and Store Brand 0.3cc	0.3cc Insulin Syringes	09/13/2018	This recall was issued due to a defect in which a small crack in the top end of the barrel near the needle creates the inability to aspirate insulin into the syringe barrel from the insulin vial. Inability to draw insulin into the syringe deems the syringe unusable	Retail Level Recall
Zoledronic Acid Injection	5mg/100 mL, 5mg/100 mL (Novaplus)	09/14/2018	This recall was issued due to out-of-specification result observed for related substances: unknown impurity	Retail Level Recall
Calcitriol	1 mcg/mL	09/14/2018	This recall was issued due to a laboratory result that indicates a lower than expected potency	Retail Level Recall
Cortaid Anti-Itch Cream and Spr	1 oz., 12 hour anti-itch 1.5 oz., 2 oz.	09/17/2018	This recall was issued due to possible microbial contamination identified as Pseudomonas Aeruginosa	Retail Level Recall
TRUEplus 0.3cc insulin syringes	TRUEplus 0.3cc insulin syringes	09/19/2018	This recall was issued because certain lots of TRUEplus and Store Brand 0.3cc Insulin Syringes manufactured during a specific timeframe contain a defect in which a small crack in the top end of the barrel near the needle creates the inability to aspirate insulin into the syringe barrel from the insulin vial	Consumer Level Recall
Glipizide XL	5 mg Tablets	09/21/2018	This recall was issued due to the potential presence of particulate matter	Retail Level Recall
Robaxin	750 mg tablets, 100 count bottle	09/21/2018	This recall was issued due to Robaxin 750 mg, 100 count bottle label (revision 2) artwork included incorrect daily dosing information	Retail Level Recall
Meropenam	1 gram Injection	09/24/2018	This recall was issued due to a customer report for yellow discoloration of vial contents after reconstitution	Retail Level Recall
Clozapine ODT	12.5 mg Tablets 100 count bottle	09/25/2018	This recall was issued due to an out of specification disintegration test result obtained during routine stability testing activities	Retail Level Recall
Nystatin & Triamcinolone Cream	Cream manufactured by Dr. Reddy's	09/25/2018	This recall was issued due to an out-of-specification result observed for the test parameter: Composition of Nystatin during stability testing	Retail Level Recall
Ocean Saline Nasal Spray	Nasal Spray 1.5 oz	09/26/2018	This recall was issued due to possible out-of-specification results related to microbial contamination	Retail Level Recall
Levofloxacin Bag	250 mg/ 50 mL 500 mg/100 mL 750 mg/150 mL	09/27/2018	This recall was issued due to out-of-specification test results	Retail Level Recall
Synjardy	5 mg / 1000 mg Tablets	09/27/2018	This recall was issued due to an out of expectation (OOE) result (peak) that was observed for the degradants determination, during routine stability testing	Retail Level Recall
Prevacid® OTC 24 Hour	Prevacid OTC 24 Hour 15mg capsules 14 count, Prevacid OTC 24 hour 15mg capsules 28 count, Prevacid OTC 24 Hour 15mg capsules 42 count	09/28/2018	This recall was issued due to the microbiological out of specification results obtained for one lot of Prevacid 24HR capsules that remains within GSK control and has not been distributed	Retail Level Recall
October				
Azelastine Hydrochloride Nasal Solution 0.1 %	0.1 % (137 mcg/spray); 1 BOTTLE, SPRAY IN 1 BOX (47335-779-91) > 200 SPRAY, METERED IN 1 BOTTLE, SPRAY	10/03/2018	laboratory results that indicate a high variability of droplet size	Retail Level Recall
Native Remedies VertiFree oral spray	2 oz. bottle	10/04/2018	microbial contamination could potentially result in increased infections that may require medical intervention and could result in infections that could be life threatening to certain individuals	Consumer Level Recall
Native Remedies VaricoGo oral spray	2 oz. bottle	10/04/2018	microbial contamination could potentially result in increased infections that may require medical intervention and could result in infections that could be life threatening to certain individuals	Consumer Level Recall
Native Remedies HypoSlim oral spray	2 oz. bottle	10/04/2018	microbial contamination could potentially result in increased infections that may require medical intervention and could result in infections that could be life threatening to certain individuals	Consumer Level Recall
Native Remedies EyeClear Pro oral spray	2 oz. bottle	10/04/2018	microbial contamination could potentially result in increased infections that may require medical intervention and could result in infections that could be life threatening to certain individuals	Consumer Level Recall
Healthful Naturals DizziFree oral spray	2 oz. bottle	10/04/2018	microbial contamination could potentially result in increased infections that may require medical intervention and could result in infections that could be life threatening to certain individuals	Consumer Level Recall
Healthful Naturals Leg Cramp Support	2 oz. bottle	10/04/2018	microbial contamination could potentially result in increased infections that may require medical intervention and could result in infections that could be life threatening to certain individuals	Consumer Level Recall
ThermaCare Menstrual 8 Hour Heat Wraps	3 Ct. box	10/05/2018	potential for leakage of the ingredients contained in the heat wrap	Retail Level Recall
Magnesium Sulfate in Water for Injection	40 mg/500 mL	10/08/2018	This recall was issued because a single unit of Heparin in 0.45% Sodium Chloride for Injection was found inside a case of Magnesium Sulfate in Water for Injection.	Retail Level Recall
Exactamix	Various Exactamix products manufactured by Baxter: Exactamix Total Parental Nutrition 1000 mL bag; Exactamix Total Parental Nutrition 1000 mL bag; Exactamix Total Parental Nutrition 500 mL bag; Exactamix 250 mL bag; Exactamix 3 liter bag.	10/08/2018	This recall was issued due to potential ability of the bags to leak once used for compounding.	Retail Level Recall

Elelyso	200 Units/ Vial	10/05/2018	This recall was issued because the metal crimp on the vial may be lifted or dislodged while attempting to flip off the orange colored plastic button.	Retail Level Recall
Aqueous-based homeopathic product line for human use	All lots within expiry from 10/18-7/22.	10/09/2018	All products manufactured by the contract manufacturer, King Bio, have been recalled due to possible microbial contamination.	Voluntary Recall
Thyroid Powder	25kg/drum	10/10/2018	This recall was issued due to CGMP Deviations. The thyroid Powder has inconsistent levels of the active ingredients levothyroxine and liothyronine.	Class II Recall
Pantoprazole Sodium DR	40 mg tablets	10/10/2018	This recall was issued due to the presence of dark brown discoloration on the edges of the tablets within control samples.	Retail Level Recall
Contrave ER	8-90 mg tablets	10/10/2018	This recall was issued due to rare occurrences of punctures in the bottle.	Retail Level Recall
Gentamicin	0.3 % eye drops	10/10/2018	This recall was issued due to out of specification results for Gentamicin Sulfate Ophthalmic Solution, 0.3%. Crystalline particles were noticed at the 24 month clarity testing.	Retail Level Recall
Testosterone	T/S 30 mg/1.5 mL 80 mL	10/12/2018	This recall was issued due to repetitive product complaints indicating pump not working.	Retail Level Recall
Zero Xtreme	Capsules	10/15/2018	FDA analysis has found Zero Xtreme to be tainted with sibutramine. Sibutramine is an appetite suppressant that was withdrawn from the U.S. market due to safety concerns. The presence of Sibutramine in Zero Xtreme renders it an unapproved drug for which safety and efficacy has not been established and, therefore, subject to recall.	Consumer Level Recall
Sodium chloride and dextrose intravenous solutions	5% dextrose injection, 250 mL flexible container; 5% dextrose injection, 25 mL flexible container; 0.9% sodium chloride injection, 250 mL flexible container; 0.9% sodium chloride injection, 150 mL flexible container; 0.9% sodium chloride injection, 50 mL flexible container; 0.9% sodium chloride injection, 100 mL flexible container	10/12/2018	On October 12, 2018, ICU Medical announced a user-level recall of some lots of sodium chloride and dextrose intravenous solutions due to the potential for flexible container leaks.	User Level Recall
Metoprolol Tartrate Injection USP	1 mg/mL	10/16/2018	This recall was issued due to out-of-specification stability test results.	Retail Level Recall
Multi IV Solutions manufactured by ICU Medical	0.45% Sodium Chloride injection, 100 mL Flexible Container; 5% Dextrose Water IV Solution 250 mL Flexible Container; 5% Dextrose Water IV Solution 25 mL Flexible Container; 0.9% Sodium Chloride Solution 250 mL Flexible Container; 0.9% Sodium Chloride Solution 150 mL Flexible Container; 0.9% Sodium Chloride Solution 100 mL Flexible Container; 0.9% Sodium Chloride Solution 50 mL Flexible Container; 0.9% Sodium Chloride Solution 100 mL Flexible Container	10/17/2018	This recall was issued due to the potential for flexible container leaks. Note: The lot number on the shipping carton label may be followed by additional digits (Ex. 85-023-JT-XX).	Retail Level Recall
Cidofovir	375mg/5mL vial	10/19/2018	This recall was issued due to the discovery of a potential lack of container integrity for the product.	Retail Level Recall
Prednisolone and Gatifloxacin Ophthalmic Solution	1%/0.5% sterile, 3ml vials	10/22/2018	Promise Pharmacy is voluntarily recalling one lot of Prednisolone and Gatifloxacin Ophthalmic Solution 1%/0.5% sterile, 3ml vials, to the patient consumer level. The product has been found to have unidentified small particulate floating in the solution.	Consumer Level Recall
Clonazepam	2 mg ODT 60 count bottle	10/19/2018	This recall was issued due to an out-of-specification test result for water content obtained during routine stability testing activities.	Retail Level Recall
Rocaltrol	1 mcg oral solution 15 mL	10/22/2018	This recall was issued due to a laboratory result that indicate a lower than expected potency.	Retail Level Recall
Hydroxyzine hydrochloride	Oral Solution	10/22/2018	This recall was issued due to the presence of unknown impurities found during the stability testing near the expiration date of Hydroxyzine Hydrochloride Oral Solution.	Retail Level Recall
Metoprolol	50 mg ER tablets	10/22/2018	This recall was issued due to an out of specification dissolution test result obtained during routine stability testing activities.	Retail Level Recall
Catapres	0.2 mg tablets	10/23/2018	This recall was issued due to out of specification (OOS) results that were obtained during routine stability testing for the dissolution test.	Retail Level Recall
Ciprofloxacin ophthalmic solution	0.30%	10/24/2018	This recall was issued due to out of specification impurity results at the 17 months' time point.	Retail Level Recall
Ortho-Novum tablets	1-35 28 tablets & 7-7-7 28 tablets	10/25/2018	This recall was issued because the Brief Summary included in the Veridate dispenser does not include instructions to use the Veridate dispenser.	Retail Level Recall
Irbesartan tablets	150 mg tablets 30 count, 150 mg tablets 90 count, 300 mg tablets 30 count, 300 mg tablets 90 count, 75 mg tablets 30 count, 75 mg tablets 90 count	10/29/2018	This recall was issued due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Aurobindo Pharmaceuticals Limited. Secondary notification: Note: This notice contains additional products distributed by Golden State Medical Supply, Inc that were not on the Westminster notice.	Retail Level Recall
Levetiracetam	1500 mg/100 mL Injection	10/30/2018	This recall was issued due to product complaint received for mislabeling. (Manufactured by Dr. Reddy's)	Retail Level Recall
Fortamet	1000 mg Tablets	10/31/2018	This recall was issued due to a potential for some tablets to be missing the laser drilling which might affect drug release.	Retail Level Recall
Meropenem for Injection	1 gram/vial 25 vials per carton	10/31/2018	This recall was issued due to a lack of assurance of sterility: loss of container integrity.	Retail Level Recall
Fluocinolone Acetonide Topical Solution	USP 0.01%	10/31/2018	This recall was issued due to failed impurities/degradation specifications: out of specification result noticed for total impurities observed during stability.	Retail Level Recall
November				

CoaguChek XS PT Test Strips	2x24 Strips	11/01/2018	This recall was issued due to inaccurate INR test results, when compared to laboratory results. Roche re-calibrated the CoaguChek XS PT Test Strips in January 2018 to correspond to a newly released INR International Standard. Since this re-calibration, Roche Diagnostics has received reports of patients experiencing abnormally high or inaccurate INR test results when testing with the affected CoaguChek XS PT Test Strips.	Class I Recall
Clindamycin Topical Solution	1% (Pledgets) 60 each	11/02/2018	This recall was issued due to an out-of-specification result obtained in one lot for an unknown impurity at 14 months stability testing.	Retail Level Recall
Nitrofurantoin capsules	100 mg capsules 100 count (Sandoz Label), 1,000 mg capsules 100 count (Sandoz Label), 100 mg capsules 100 count (North Star Label)	11/06/2018	This recall was issued due to the potential presence of unrelated ingredients (i.e., traces of active ingredients of Benazepril, Haloperidol and Perphenazine), which were identified through a manufacturing investigation.	Retail Level Recall
Isosorbide	20 mg tablets	11/07/2018	This recall was issued due to the potential of unrelated ingredients (i.e. traces of active ingredients of Nitrofurantoin, Benazepril, Haloperidol and Perphenazine), which were identified through a manufacturing investigation.	Retail Level Recall
Calcium Antacid	PA17-077 exp. 11/30/18	11/07/2018	This recall was issued due to a potential for the finished packaged product to contain metal particles.	Retail Level Recall
Losartan Potassium Hydrochlorothiazide Tablets	USP 100mg/25mg, 1000 count plastic bottles	11/08/2018	This product is being recalled due to the trace amount of an impurity, N-nitrosodiethylamine (NDEA) contained in the API Losartan, USP manufactured by Zhejiang Huahai Pharmaceutical Co. Ltd. Sandoz Inc. Losartan Potassium Hydrochlorothiazide product is manufactured by Lek Pharmaceuticals dd, Ljubljana, Slovenia. This impurity, which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC).	Consumer Level Recall
Testosterone	30 mg/1.5 mL Pump	11/09/2018	This recall was issued due to repetitive product complaints indicating pump not working.	Retail Level Recall
Amitiza*	8 mcg gel Capsules 60 count bottle	11/12/2018	This recall was issued to the elevated level of a known impurity in the 20-month stability sample testing.	Retail Level Recall
Nitrofurantoin	100 mg capsules	11/12/2018	This recall was issued due to the potential presence of unrelated ingredients (i.e. traces of active ingredients of Benazepril, Haloperidol and Perphenazine), which were identified through a manufacturing investigation.	Retail Level Recall
Clopidogrel	300 mg Tablets	11/12/2018	This recall was issued due to out-of-specification results observed for dissolution at the 18th month stability testing.	Retail Level Recall
INFeD	50 mg/mL 2 mL vial	11/15/2018	This recall was issued due to product stability testing not meeting specification for iron content.	Retail Level Recall
Valsartan Tablets	80 mg Tablets, 90 count bottle, 160 mg Tablets, 90 count bottle, 40 mg Tablets, 30 count bottle, 320 mg Tablets, 90 count bottle	11/21/2018	This recall was issued due to detected trace amounts of an impurity, N-nitrosodiethylamine (NDEA) contained in the API Valsartan, USP, manufactured by Mylan Laboratories Limited. NDEA is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen according to the International Agency for Research on Cancer (IARC).	Consumer Level Recall
Amlodipine and Valsartan Tablets	5mg/160mg Tablets, 30 count bottle, 10mg/160mg Tablets, 30 count bottle, 10mg/320mg Tablets, 30 count bottle, 5 mg/160 mg Tablets 90 Count Bottle, 10 mg/160 mg Tablets 90 Count Bottle, 5 mg/320 mg Tablets 30 Count Bottle, 10 mg/320 mg Tablets 30 Count Bottle, 10 mg/320 mg Tablets 90 Count Bottle, 10 mg/160 mg Tablets 30 Count Bottle, 5 mg/320 mg Tablets 90 Count Bottle	11/21/2018	This recall was issued due to detected trace amounts of an impurity, N-nitrosodiethylamine (NDEA) contained in the API Valsartan, USP, manufactured by Mylan Laboratories Limited. NDEA is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen according to the International Agency for Research on Cancer (IARC).	Consumer Level Recall
Valsartan and Hydrochlorothiazide Tablets	320mg/25mg Tablets, 500 count bottle, 5 mg/160 mg/12.5 mg tablets 30 count, 5 mg/160 mg/12.5 mg tablets 90 count, 10 mg/160 mg/12.5 mg tablets 30 count, 10 mg/160 mg/12.5 mg tablets 90 count, 10 mg/160 mg/25 mg tablets 30 count, 10 mg/160 mg/25 mg tablets 90 count, 10 mg/320 mg/25 mg tablets 30 count, 10 mg/320 mg/25 mg tablets 90 count.	11/21/2018	This recall was issued due to detected trace amounts of an impurity, N-nitrosodiethylamine (NDEA) contained in the API Valsartan, USP, manufactured by Mylan Laboratories Limited. NDEA is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen according to the International Agency for Research on Cancer (IARC). Addition from FDA on 11/28/2018 - Updated Information: The United States Food and Drug Administration (FDA) incorrectly listed lot number 3093804 exp. 12/19 as belonging to NDC # 00378-6325-05 in error. Lot number 3093804 exp. 12/19 belongs to NDC # 00378-6325-77 which the FDA did not include on their notice. (Information added to GHP Sheet)	Consumer Level Recall
Sodium Chloride	0.9 % Injection 10mL vial, 20mL vial	11/21/2018	This recall was issued due to an incorrect statement on the product insert for product codes 918610 and 918620 indicating that the stoppers do not contain natural rubber latex. The tray label for these two product codes and the vial label for product code 918620 also incorrectly state that the stoppers do not contain latex. The listed product codes and batches being recalled have stoppers containing natural rubber latex. The investigation reveals this issue is limited to the batches indicated.	Retail Level Recall
Quetiapine	400 mg tablets	11/30/2018	This recall was issued due to a market complaint received from a customer stating that she found a metal shard in one of her tablets.	Retail Level Recall

Clopidogrel	300 mg tablets 30 count blister pack	11/28/2018	This recall was issued due to Out-of-Specification results were observed for dissolution at 18th month stability testing. **This recall was issued as an extension to the Clopidogrel Tablets recall for batch lot T600530 initiated on November 7, 2018 for an out-of-specification results observed for Dissolution during stability testing. Although the batch lots listed in this recall are within specification limits until date, the batch lots have been identified to be impacted by the root cause for the observed out-of-specification results.	Retail Level Recall
December				
Infants' Ibuprofen Concentrated Oral Suspension, USP (NSAID)	50 mg per 1.25 ML bottle	12/05/2018	The recalled lots of the product have been found to potentially have higher concentrations of ibuprofen.	Retail Level Recall
Aprepitant	40 mg capsules	12/04/2018	This recall was issued due to the findings of missing capsule in the blister pack.	Retail Level Recall
Vancomycin	1 GM vials, HCL 750 mg vials	12/05/2018	This recall was issued due to the potential for these lots to contain vials with high or low fill weights for the lyophilized product.	Retail Level Recall
INFed	100 mg elemental iron/2 mL 50 mg/mL	12/05/2018	This recall was issued due to out of specification for iron content.	Class II recall
Sodium Chloride 0.9 % Injection	10 mL vial carton 25 vials, 10 mL vial single vial	12/10/2018	This recall was issued due to an incorrect statement on the product insert for product codes 918610 and 918620 indicating that the stoppers do not contain natural rubber latex. Please note: This recall contained additional products and lot numbers that were not on the previous recall issued on these products.	Retail Level Recall
Levoxyl	112 mcg Tablets	12/12/2018	This recall was issued as the assay result at the six-month stability time point was out of specification.	Retail Level Recall
Oxybutynin Chloride	USP 5 mg Tablets	12/12/2018	This recall was issued because of a customer report that barcode on the drug product label when scanned reads Hydroxyzine Hydrochloride Tablets, USP 10 mg 500's count instead of Oxybutynin Chloride Tablets, USP 5 mg, 500's count.	Retail Level Recall
ciprofloxacin 0.3% ophthalmic solution	2.5 mL, 5 mL, 5 mL	12/14/2018	This recall was issued due to out of specification results at the 18 months (expiry) time point.	Retail Level Recall
Kerlix and Dermacea	KERLIX BANDAGE 4.5X147, DERMACEA 4.5"x4.1 YD 441103, DERMACEA 4.5"x4.1 YD 441103, KERLIX AMD 4.5"x4.1YDS, KERLIX BAND ROLL 4.5X3.1, KERLIX BANDAGE ROLL 4.5"x4YD	12/17/2018	This recall was issued due to a small percentage of product that has the potential to have an open seal or a pinched seal defect in the primary flexible sealed pouches which would result in a sterility breach of the product.	Retail Level Recall
Dyural Kits	Dyural-40, Dyural-80	12/18/2018	This recall was issued because the products include recalled Sodium Chloride, USP, 0.9% manufactured by Fresenius Kabi, which has been recalled due to product labeling incorrectly stating stoppers do not contain latex. For the population most at risk, those with a severe allergic reaction to latex, there is probability of an anaphylactic reaction, and this could result in hospitalization or death.	Retail Level Recall
Monsef's Solution	8 mL	12/18/2018	This recall was issued due to high level of iron.	Retail Level Recall
Lorsartan Potassium	100 mg 90 count bottle, 100 mg 30 count bottle, 100 mg 1,000 count bottle	12/20/2018	This recall was issued due to the detection an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited. The impurity detected in the API is N-nitrosodiethylamine (NDEA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.	Consumer Level Recall
Ceftriaxone Sodium Injection	1 GM, 250 mg, 2 GM, 500 mg	12/21/2018	This recall was issued due to repetitive product complaints indicating grey flecks in constituted vials.	Retail Level Recall
Olmesartan HCTZ	40-25 mg tablets	12/24/2018	This recall was issued due to an out of specification dissolution test result reported during routine stability testing activities.	Retail Level Recall
Cosopt Eye Drops	Cosopt Ophthalmic Solution, 10mL	12/24/2018	This recall was issued due to out of specification results for Cosopt Ophthalmic Solution, 10mL. Out of Specification for opalescence has been registered at 7 month stability study. **CVS Caremark Mail Service received an updated notice on 01/03/2019 from McKesson with correct lot expiration date. Previously, the expiration date was listed as 04/30/2020, the correct expiration date is 03/31/2020. Updated notice: On December 24, 2018, CVS Caremark Mail Service received a retail-level recall notice from CVS Retail regarding Cosopt Eye Drops NDC # 17478-0605-10 manufactured by Akorn. This recall was issued due to out of specification results for Cosopt Ophthalmic Solution, 10mL. Out of Specification for opalescence has been registered at 7 month stability study.	Retail Level Recall
Estradiol	2 mg tablets	12/26/2018	This recall was issued because a single foreign tablet was found in pharmacy dispensed bottle of 30 Estradiol 2 mg tablets	Consumer Level Recall
Nitrofurantoin	25 mg/5 mL oral suspension	12/26/2018	This recall was issued due to Out of Specification Results for Lot # S700065 and Lot # S700619. The root cause was determined to be insufficient headspace to allow for adequate shaking during sample preparation to allow for a representative sample during analysis.	Retail Level Recall

<p>Amlodipine and Valsartan tablets, Valsartan and Hydrochlorothiazide tablets and Valsartan tablets</p>	<p>Valsartan and Hydrochlorothiazide 320mg/25mg tablets 90 counts Valsartan and Hydrochlorothiazide 80mg/12.5mg tablets 90 count Valsartan and Hydrochlorothiazide 160mg/25mg tablets 90 count Valsartan Tablets 320mg tablets 90 count</p>	<p>12/31/2018</p>	<p>This recall was issued due to detected trace amounts of an impurity, N-nitrosodiethylamine (NDEA) contained in the API Valsartan, USP, manufactured by Mylan Laboratories Limited. NDEA is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen according to the International Agency for Research on Cancer (IARC). Additional NDC's added 12/5/2018 - This recall was issued due to detected trace amounts of an impurity, N-nitrosodiethylamine (NDEA) contained in the API Valsartan, USP, manufactured by Mylan Laboratories Limited. NDEA is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen according to the International Agency for Research on Cancer (IARC). The finished products are manufactured by Mylan Pharmaceuticals Inc. and Mylan Laboratories Limited. This notice contained additional affected NDC's that were not part of the previous recall of these products. ** As of 12/31/2018 This recall was issued due to the detection of trace amounts of an unexpected impurity found in the finished drug product. The impurity detected in the finished drug product is N-nitrosodiethylamine (NDEA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification. To date, Aurobindo Pharma USA, Inc. has not received any reports of adverse events related to this recall.</p>	<p>Consumer Level Recall</p>
<p>Lubrisine Eye Drops</p>	<p>Bottles</p>	<p>12/31/2018</p>	<p>This product, in a recent FDA inspection, was found to be manufactured using practices that do not support its sterility and contained undeclared colloidal silver.</p>	<p>Voluntary Recall</p>