Gateway Health
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2019 Drug Recall List

Drug Name/Manufacturer	Dose/Package size	Press Release Date	Reason	Recall Classification
Mirtazapine (Aurobindo)	7.5mg, 15mg; 500 ct	12/31/19	The product is being recalled due to a label error on declared strength; bottles labeled as Mirtazapine 7.5 mg may contain 15 mg tablets.	consumer-level
Gamunex C (Grifols)	10%	12/31/19	This withdrawal is being conducted due to a higher rate of allergic/hypersensitivity reactions, a smaller number of which were considered medically significant. Hypersensitivity and anaphylactic/anaphylactoid reactions are a known risk with IVIG products.	consumer-level
Ranitidine (Denton /Northwind)	150mg and 300mg	12/26/2019 and 1/8/2020	The recall is in response to the Glenmark Pharmaceuticals, Inc. USA ("Glenmark") recall of all unexpired lots of Ranitidine Tablets, 150 mg and 300 mg which were repackaged by the Northwind affiliate.	consumer-level
Blisovi iron (Lupin)	1.5/30mg iron	12/26/19	This recall is being issued due to complaints related to tablet crumbling when popped out of the blister pack.	retail-level
ketorolac Tromethamine (Hikma)	30mg/ml; 60mg/ml	12/26/2019	This recall is being issued due to small black particles being noted during routine retain visual inspection of Ketorolac lots.	retail-level
Hydrocortisone and Acetic Acid otic solution (Akorn)	10ml	12/24/2019	This recall is being issued due to observed out of specificiation (OOS) results for Hydrocortisone assay during continued testing of retain samples at 18 month controlled room temperature for the upright orientation.	retail-level
LemonPrep®, PediaPrep® and Wave Prep 4-ounce tubes and single use cups, Cardio Prep and Collodions, Collodion removers (Mavidon)	skin prepping lotion for enhancement of electrode site	12/23/2019	This recall is being issued due to contamination with *Burkholderia cepacia* .	consumer-level
amantadine (Jubilant Cadista Pharmaceuticals)	100mg 100 count	12/18/2019	This recall is being issued due to the presence of a foreign substance and the presence of a foreign object in a single tablet.	retail-level
Ranitidine (Allegiant Health)	150mg tablets, 100 count unit dose blisters and individual dose	12/17/2019	This recall is being issued due to the potential for product to contain a nitrosamine impurity called N-nitrosodimethylamine at low levels.	retail-level
Accu-Check Aviva Plus (Roche)	50 count	12/19/2019	The inability of test strips to be dosed as intended.	consumer-level
Levetiracetam (Lannett)	100mg.ml oral solution	12/18/19	Due to contamination with *Bacillus subtilis* . The *Bacillus subtilis* was identified during an evaluation of a raw material used to manufacture the product.	consumer-level
Bull Platinum 30000, Stallion Platinum 30000, Rhino 7 Platinum 30000, Panther Platinum 30000 (Moto International)	2,4 and 10 capsule blister pack	12/17/2019	The supplements are tainted with undeclared tadalafil. Tadalafil is an FDA approved drug indicated for the treatment of male sexual enhancement. The presence of tadalafil in these products renders them unapproved drugs for which safety and efficacy has not been established and, therefore, subject to recall.	consumer-level
ranitidine (Glenmark)	tablets 150mg and 300mg	12/17/2019	The presence or potential presence of N-nitrosodimethylamine (NDMA) levels above the acceptable daily intake levels established by the FDA, based on FDA-validated tests.	consumer-level
Bupivicaine Liposome (Exparel)	Injectable Suspension 1.3% 266 mg/20 mL Sterile 20 mL Vial	12/11/2019	Due to it being a sub-potent drug out of specification.	retail-level
Levetiracetam (Lannett)	100mg/ml	12/11/2019	This recall is being issued due to the presence of elevated levels of Bacillus subtilis found within the product.	retail-level
Mirtazapine (Aurobindo)	7.5mg	12/11/2019	The possibility that the bottle label indicates the incorrect strength of the contents.	retail-level
Energy FX (Basic Reset and Biogenyx)	original Aluminum (100-3A) and sleek (adult and kid & pet) (100-3B)	12/10/2019	Basic Reset and Biogenyx have not received the FDA's approval for the sale of their drugs and one device, despite the companies' claims that these products can be used to diagnose, cure, mitigate, treat or prevent conditions such as inflammation, chronic diarrhea, bacterial infections, head lice, allergies and pain.	consumer-level

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TrimUp (Basic Reset and Biogenyx)	80 capsules per plastic bottle, SKU: 100-5A	12/10/2019	Basic Reset and Biogenyx have not received the FDA's approval for the sale of their drugs and one device, despite the companies' claims that these products can be used to diagnose, cure, mitigate, treat or prevent conditions such as inflammation, chronic diarrhea, bacterial infections, head lice, allergies and pain.	consumer-level
Q-min (Basic reset and Biogenyx)	50 capsules per plastic bottle, SKU: 100-9B	12/10/2019	Basic Reset and Biogenyx have not received the FDA's approval for the sale of their drugs and one device, despite the companies' claims that these products can be used to diagnose, cure, mitigate, treat or prevent conditions such as inflammation, chronic diarrhea, bacterial infections, head lice, allergies and pain.	consumer-level
GH-C (Basic reset and Biogenxyx)	60 capsules per plastic bottle, SKU: 100-4F	12/10/2019	Basic Reset and Biogenyx have not received the FDA's approval for the sale of their drugs and one device, despite the companies' claims that these products can be used to diagnose, cure, mitigate, treat or prevent conditions such as inflammation, chronic diarrhea, bacterial infections, head lice, allergies and pain.	consumer-level
Body Mass Reset(Basic reset and Biogenyx)	4 fl. oz. plastic bottle, SKU: 100-8C	12/10/2019	Basic Reset and Biogenyx have not received the FDA's approval for the sale of their drugs and one device, despite the companies' claims that these products can be used to diagnose, cure, mitigate, treat or prevent conditions such as inflammation, chronic diarrhea, bacterial infections, head lice, allergies and pain.	consumer-level
AquaLyte (Basic reset and biogenyx)	30g pkg./foil pouch, SKU: 1023	12/10/2019	Basic Reset and Biogenyx have not received the FDA's approval for the sale of their drugs and one device, despite the companies' claims that these products can be used to diagnose, cure, mitigate, treat or prevent conditions such as inflammation, chronic diarrhea, bacterial infections, head lice, allergies and pain.	consumer-level
SlimUp (Basic reset and biogenyx)	60 capsules per plastic bottle, SKU: 100-5B	12/10/2019	Basic Reset and Biogenyx have not received the FDA's approval for the sale of their drugs and one device, despite the companies' claims that these products can be used to diagnose, cure, mitigate, treat or prevent conditions such as inflammation, chronic diarrhea, bacterial infections, head lice, allergies and pain.	consumer-level
pH-FX (Basic reset and biogenyx)	4 fl. oz. plastic bottle, SKU: 100-1A	12/10/2019	Basic Reset and Biogenyx have not received the FDA's approval for the sale of their drugs and one device, despite the companies' claims that these products can be used to diagnose, cure, mitigate, treat or prevent conditions such as inflammation, chronic diarrhea, bacterial infections, head lice, allergies and pain.	consumer-level
Ionyte (Basic Reset and Biogenyx)	2 fl. oz. glass bottle, SKU: 100-5C	12/10/2019	Basic Reset and Biogenyx have not received the FDA's approval for the sale of their drugs and one device, despite the companies' claims that these products can be used to diagnose, cure, mitigate, treat or prevent conditions such as inflammation, chronic diarrhea, bacterial infections, head lice, allergies and pain.	consumer-level
Dino-Min (Basic Reset and Biogenyx)	60 capsules per plastic bottle, SKU 100-1C	12/10/2019	Basic Reset and Biogenyx have not received the FDA's approval for the sale of their drugs and one device, despite the companies' claims that these products can be used to diagnose, cure, mitigate, treat or prevent conditions such as inflammation, chronic diarrhea, bacterial infections, head lice, allergies and pain.	consumer-level
Beta Factor, DIETARY SUPPLEMENT (Basic Reset and Biogenyx)	60 capsules per plastic bottle, SKU: 100-4F	12/10/2019	Basic Reset and Biogenyx have not received the FDA's approval for the sale of their drugs and one device, despite the companies' claims that these products can be used to diagnose, cure, mitigate, treat or prevent conditions such as inflammation, chronic diarrhea, bacterial infections, head lice, allergies and pain.	consumer-level
vancymycin HCL (Auromedics)	1 gram injection	12/9/2019	Due to the receipt of several market complaints for discoloration after reconstitution of vials.	retail-level
ranitidine (Gericare)	75mg and 150 mg	12/9/2019	Due to the presence of NDMA levels found within the product in excess of amounts allowed by the FDA.	retail-level

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Raloxifene (American Health)	60mg	12/9/2019	This recall is being issued due to dissolution failure at 12-month timepoint of the repackaged lot.	retail-level
Moxifloxacin Ophthalmic Solution (Aurobindo)	ophthalmic Solution 0.5% w/v	12/6/19	This recall is being issued due to receipt of several market complaints for discoloration of bottle contents.	retail-level
Healon GV® PRO (Johnson and Johnson)	0.85ml	12/5/19	This recall is being issued due to complaints that the device may be difficult to remove from the eye, and potential clogging of phacoemulsification equipment leading to delay in the procedure or possible injury.	retail-level
VCF Contraceptive Foam (Apothecus)		12/4/19	This recall was issued because in some cases, individual VCF canisters did not dispense properly, rendering the product unusable.	retail-level
Timolol Maleate Ophthalmic Solution (Rising Pharmaceuticals	Ophthalmic Solution 0.5% 5 mL	12/3/19	This recall is being issued due to product complaint where the recalled product was found inside a carton pre-printed with the incorrect NDC for a different product.	retail-level
Dextrose injection (Hospira)	25% syringe	12/2/19	This recall is being issued due to confirmed reports that the expiration date printed on the syringe (8/1/2021) is incorrect and does not match the expiration date on the carton (8/1/2019).	retail-level
Ranitidine (Amneal)	ranitidine 150mg, 300mg	11/22/19	This recall was issued because of potential N-nitrosodimethylamine (NDMA) amounts above levels established by the FDA. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.	consumer-level
Ranitidine (Amneal)	Ranitidine 150mg, 300mg, 15mg/ml	11/25/19	This recall was issued because of potential N-nitrosodimethylamine (NDMA) amounts above levels established by the FDA. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.	consumer-level
Ranitidine (Amneal)	150mg (50, 60,100, 180, 500, 1000 ct) and 300mg tabs (30, 100, 250 ct) 15mg/ml syrup 473ml	11/25/2019	Recalled because of potential N-Nitrosodimethylamine (NDMA) amounts above levels established by the FDA.	consumer-level
Ranitidine (Amneal)	150mg (50, 100, 180, 500, 1000 ct) and 300mg tabs (30, 100, 250 ct)	11/22/2019	Recalled because of potential N-Nitrosodimethylamine (NDMA) amounts above levels established by the FDA.	consumer-level
Gabapentin (aurobindo)	100mg capsules	11/22/19	This recall is being issued due to the possibility that a tablet of Losartan/HCTZ may be present mixed with the labeled product.	retail-level
Ranitidine (American Health Packaging)	tablets, 100 count unit dose blisters and individu	11/22/2019	This recall is being issue due to the potential NDMA amounts above levels established by the FDA.	consumer-level
0.9% Sodium Chloride (Baxter)	Irrigation 5000 mL	11/20/19	This recall is being issued due to reported leaks of the solution bag allowing for a delay or interruption of surgical procedure or microbial contamination.	retail-level
Ranitidine Oral Solution (Amneal)	15mg/ml (473mL), 150 mg/10 mL (unit dose cups, 30 pack, 100-pack cartons)	11/14/19	This recall was issued because of potential N-nitrosodimethylamine (NDMA) amounts above levels established by the FDA. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests.	retail-level
Fluphenazine Decanoate (AuroMedics)	125 mg/5 mL Injection	11/20/19	This recall is being issued due to a confirmed customer report of a hazy solution in one vial instead of a clear solution.	retail-level
Timolol Maleate (Rising Pharmaceuticals)	Ophthalmic Solution 0.25% 5 mL	11/18/19	This recall is being issued due to product complaint where the recalled product was found inside a carton pre-printed with the incorrect NDC of 64980051405, which is for a different product.	retail-level

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Myorisan (Akorn)	20 mg Capsules	11/18/19	This recall is being issued due to a market complaint indicated that one 10 count blister card of the 20 mg product contained 40 mg capsules and the other two blister cards of 10 capsules contained the 20 mg product.	retail-level
Amiodarone Hydrochloride (AuroMedics)	900 mg/18 mL, 150 mg/3 mL, 450 mg/9 mL injection	11/15/19	This recall is being issued due to the visible particulate matter within test vials of the product.	retail-level
Lidocaine Hydrochloride (AuroMedics)	2% Injectio, 100 mg/5 mL	11/15/2019	This recall is being issued due to the discovery of foreign material in a test vial of the product.	retail-level
Silver Bullet (Nature's Rx)	10 capsules/boxes	11/14/19	This recall has been initiated after an FDA laboratory analysis found the product to contain undeclared sildenafil, the active ingredient in Viagra, which is a PDE-5 inhibitor.	consumer-level
Ranitidine Syrup (Amneal)	Syrup 15mg/mL 16 fl. Oz.	11/11/19	This recall was issued because of potential N-nitrosodimethylamine (NDMA) amounts above levels established by the FDA. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests.	consumer-level
Ranitidine (Amneal)	300mg (30, 100, 250, 1000cts)	11/11/2019 11/14/19	This recall was issued because of potential N-nitrosodimethylamine (NDMA) amounts above levels established by the FDA.	consumer-level
Ranitidine (Amneal)	150mg (60, 100, 180, 500, 1000cts)	11/11/2019 11/14/19	This recall was issued because of potential N-nitrosodimethylamine (NDMA) amounts above levels established by the FDA. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests.	consumer-level
Up2 Dietary Supplement (Med Man Distribution)	All	11/8/2019	The presence of sildenafil in Up2 products renders them unapproved drugs for which safety and efficacy have not been established, therefore subject to recall.	consumer-level
Ranitidine (McKesson)	150mg caps (500ct), 300mg caps (100ct)	11/7/2019	This recall is being issued due to the potential presence of N-Nitrosodimethylamine (NDMA) in the drug product above levels established by the FDA.	consumer-level
Gamunex-C (Grifols Therapeutics)	10% 200 mL bottle	11/7/2019	This withdrawal issued due to a higher rate of allergic/hypersensitivity type reactions, a small number of which were considered medically significant.	consumer-level
Ranitidine Syrup (Lannett)	150mg/10ml, individual unit dose cups	11/5/2019	This recall is being issued due to the due to the presence of NDMA in the Ranitidine syrup.	consumer-level
Ranitidine Syrup (Lannett)	150mg/10ml, case of 50 unit dose cups	11/5/2019	This recall is being issued due to the due to the presence of NDMA in the Ranitidine syrup.	consumer-level
Ranitidine Syrup (Lannett)	150mg/10ml, case of 40 unit dose cups	11/5/2019	This recall is being issued due to the due to the presence of NDMA in the Ranitidine syrup.	consumer-level
Raniditine (Aurobindo)	150mg tabs/caps, 300 mg caps, 15mg/ml syrup	11/6/19	Due to the detection of NDMA (Nitrosodimethylamine) Impurity in the finished product.	consumer-level
Raniditine (Aurobindo)	150mg tabs	11/6/19	Due to the detection of NDMA (Nitrosodimethylamine) Impurity in the finished product.	retail-level
Ranitidine Syrup (American Health Packaging)	150mg/10mL	11/5/19	This recall is being issued due to the due to the presence of NDMA in the Ranitidine syrup.	consumer-level
Aripiprazole (Alembic)	2mg tablets,	11/4/19	This recall is being issued due to incorrect quantities of product being packaged.	retail-level
Lets Gel Kit convenience packs (Fagron Inc.)	n/a	10/31/2019	FDA analysis identified Bacillus fortis/Geobacillus toebii, Bacillus spp, and Bacillus circulans as contaminants in some samples obtained during an inspection of Fagron Inc.	voluntary
0.9% Sodium Chloride (ICU Medical)	Injection	10/30/19	The products are being recalled to the hospital level due to the presence of particulate matter.	hospital-level
Lactated Ringer's ICU Medical)	Injection	10/30/19	The products are being recalled to the hospital level due to the presence of particulate matter.	hospital-level
Prasugrel (Mylan)	5 mg tablets	10/28/19	This recall is being issued due to dissolution results obtained during routine stability testing that were below specification.	retail-level

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Ranitidine Syrup (Lannett)	15mg/ml	10/25/19	This recall was issued because of potential N-nitrosodimethylamine (NDMA) amounts above levels established by the FDA.	consumer-level
Alprazolam (Mylan)	0.5 mg, 500 ct	10/25/19	Due to the potential presence of foreign substance.	consumer-level
Ranitidine (Novitium)	150mg (60, 500 ct), 300mg (30, 100 ct)	10/25/19	This recall was issued because of potential N-nitrosodimethylamine (NDMA) amounts above levels established by the FDA.	consumer-level
Neomycin and Polymyxin B Sulfates and Dexamethasone (Sandoz)	Eye Drops 5 mL	10/25/19	This recall is being issued, because certain safety label changes were not updated in the patient insert.	retail-level
Gatifloxacin (Sandoz)	Eye Drops 2.5 mL	10/25/19	This recall is being issued, because certain safety label changes were not updated in the patient insert.	retail-level
Ranitidine (Dr. Reddy's Laboratories, Inc.)	75, 150, 300 (all counts, OTC and RX)	10/23/2019	Confirmed contamination with N-Nitrosodimethylamine (NDMA) above levels established by the FDA.	consumer-level
Zantac OTC (Sanofi)	150mg, 150mg Cool Mint, and 75mg (all OTC)	10/25/19	U.S Food and Drug Administration issued a public statement alerting that some ranitidine medicines, including Zantac OTC, could contain NDMA at low levels and asked manufacturers to conduct testing.	voluntary
Green Lumber (GL Holdings)	2,4,10 capsule packages (OTC)	10/22/19	FDA analysis has found one lot of Green Lumber distributed between June and August 2019 to be tainted with tadalafil.	voluntary
Monsel (Gordon Laboratories)	Solution 60 mL	10/18/19	This recall is being issued due to the improper storage condition of the drug.	retail-level
Isotretinoin (Amneal)	10mg capsules	10/18/19	This recall is being initiated due to % Tretinoin levels being slightly above the specification limit.	retail-level
BD Posiflush™	n/a	10/14/19	This recall was issued because syringes labeled "Posiflush Experimental Product" and "Not for Human Use" being mixed with standard BD Posiflush Pre-Filled Normal Saline Syringe.	consumer-level
BD™ Posiflush Pre-Filled Normal Saline Syringes (BD)	n/a	10/16/19	This recall is being issued as BD has become aware that a limited number of syringes labeled "Posiflush Experimental Product" and "Not for Human Use" being mixed with standard BD Posiflush Pre-Filled Normal Saline Syringes.	consumer-level
Ranitidine HCl (Avkare)	150mg (500 ct), 300mg (500 ct) capsules	10/18/2019	This recall is being issued due to the USFDA alert notice regarding low levels of N-nitrosodimethylamine (NDMA) impurity found in some samples of Ranitidine medicines.	retail-level
Viatrex (Viatrexx Bio Inc.)	10 ml sterile injectable vials	10/15/19	The products were manufactured in a manner that cannot guarantee its sterility.	consumer-level
NATPARA® (Takeda)	for Injection	10/2/19	This recall was issued due to a potential issue related to rubber particulates originating from the rubber septum of the NATPARA cartridge.	class I
Ranitidine (Allegiant Health)	150 mg Tablets	10/10/19	This recall is being issued due to the potential for product to contain a nitrosamine impurity called N-nitrosodimethylamine at low levels.	retail-level
Methylphenidate (KVK Tech)	5 mg/5 mL Solution	10/8/19	This recall is being issued due to possible presence of fiber particles which were found in the lot during initial filling operation.	retail-level
Rifampin (Mylan)	Injection 600 mg	10/9/19	This recall is being issued due to unknown impurity results obtained during routine stability testing that were either out of specification or approaching specification.	retail-level
Ranitidine (Dr. Reddy's Laboratories, Inc.)	150mg (60, 500ct), 300mg (30, 100ct) capsules	10/2/2019	This issue is being recalled due to USFDA alert notice regarding low levels of N-nitrosodimethylamine (NDMA) impurity found in some samples of Ranitidine medicine.	retail-level
9% LMD in 5% Dextrose Injection (Hospira, In	n/a	10/7/2019	This recall was issued due to a manufacturing molding process defect resulting in variations on the additive port surface, which may lead to potential product leakage.	hospital-level
Vivitrol (Alkermes)	n/a	9/27/2019	This recall is being issued due to 1 inch needles being placed in the 1 1/2 inch needle cardboard sleeve.	retail-level

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Prednisolone (Wockhardt)	15 mg/5 mL Solution	9/27/2019	This recall is being issued due to Test results for Unknown Degradant/Impurity at Relative Retention Time (RRT) 2.37 not meeting the specification of Not More Than 0.1%.	retail-level
Nucala (Mepolizumab) Injection (GlaxoSmithKline, LLC)	100 mg/mL Prefilled Syringe, Single-Dose	10/2/2019	This recall was issued due to temperature abuse and the product was stored and shipped outside of labeled storage requirements.	class II
LemonPrep	Single Use Cups	9/26/2019	These products have been found to be contaminated with Burkholderia cepacia.	consumer-level
LemonPrep	4 oz Tubes	9/26/2019	These products have been found to be contaminated with Burkholderia cepacia.	consumer-level
Amphetamine Mixed Salts (Aurobindo Pharma USA)	20 mg Tablets	9/27/2019	This recall was issued due to some tablets in the batch being found to be out of specification for weight and thickness.	retail-level
Phenylephrine Hydrochloride (Akorn)	2.5% Ophthalmic Solution 15 mL	9/27/2019	This recall is being issued due to out of specification test results at 12 month LTT stability sample for container closure test.	retail-level
stradiol (Epic Pharma)	0.5 mg Tablets, 100 count	9/27/2019	This recall is being issued due to customer complaints stating a single tablet of Estradiol 1 mg was found in a 100-count bottle of Estradiol Tablets USP, .5 mg, Lot #19094A.	retail-level
Aimovig (Amgen)	70 mg/mL injection	9/26/2019	This recall was issued due a discontinuation of this package sizing.	retail-level
Benazepril HCl (Amneal)	40 mg tablets	9/25/2019	This recall is being issued due to one Promethazine HCL, USP, 25 mg tablet being found in a bottle of Benazepril HCL, USP Tablets 40 mg, Lot BB02619A.	retail-level
Lidocaine HCl (Akorn)	2% Jelly 30 mL	9/25/2019	Observed particulates (shavings) during in-process checks in time of filling operation of the batch.	retail-level
Ranitidine (Apotex)	75mg, 150mg	9/25/2019	This recall is due to the detection of trace ammounts of NMBA .	retail-level
Oxcarbazepine (West-ward)	Oral Susp 300mg/5ml, 250 ml bottle	9/25/19	This recall was issued due to failed impurities/degradation specification.	class II
Ranitidine (Sandoz)	150mg, 300mg Caps	9/23/19	This recall is due to the detection of trace ammounts of NMBA .	consumer-level
losartan/HCTZ/Torrent	50/12.5mg; 100mg/25mg	9/19/19	This recall is due to the detection of trace ammounts of NMBA .	consumer-level
losartan/Torrent	50mg, 100mg	9/19/19	This recall is due to the detection of trace ammounts of NMBA .	consumer-level
Calcilo XD powder (Abbott)	375g 13.2 oz	9/16/19	This recall was due to an inconsistency in aroma and color in a small number of cans from this batch.	consumer-level
fexofenadine; manufacturer: Aurobindo	180 mg tablet	9/23/19	This recall was issued due to a stability failure.	retail-level
Homatropaire; manufactuere: Altaire	ophthalmic solution 5mL	9/17/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Goniotaire; manufacturer: Altaire	ophthalmic solution 15mL	9/17/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Flourescien Sodium and Proparacaine HCl; manufacturer: Altaire	ophthalmic solution 5mL	9/17/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
ActivEyes Altachlore, manufacturer: Altaire	5% solution, 15mL	9/17/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
ActivEyes Altachlore, manufacturer: Altaire	5% oint, 3.5g	9/17/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Sodium chloride; manufacturer: Guerbet	0.9% 125ml injection	9/17/19	This recall was issued due to a recent software update affecting the products ability to be used properly.	retail-level
Optiray; manufacturer: Guerbet	320 injection 100ml	9/17/19	This recall was issued due to a recent software update affecting the products ability to be used properly.	retail-level
Artificial Passion Fruit Flavored Vit C liquid supplement; manufacturer: Fitoterapia		9/17/19	FDA analysis has found the product to be tainted with tadalafil. Tadalafil is an active ingredient in a FDA-approved prescription drug that is used for the treatment of male erectile dysfunction. The presence of tadalafil in Mero Macho renders it an unapproved drug for which safety and efficacy have not been established, and therefefore, subject to recall.	consumer-level

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Quinacrine dihydrochloride; manufacturer: Darmerica	25g, 50g, 500g	9/17/19	This product is being recalled due to a label mix-up. Product intended for further compounding use by pharmacies labeld as quinacrine API was tested and identified as Artemisinin API. Artemisinin and is semisynthetic derivatives are a group of drugs used against malaria. Receiving artemisinin rather than quinacrine could lead to deteoriation of disease that is being treated, serious adverse reactions, due to prolonged exposure to artemisinin, which would need medical or surgical intervention as well as mistaken evalutation and remediation of adverse reactions.	consumer-level
Human Sterile Drug and Animal Drug Products; manufacturer: KBS Global Biotechnology		9/13/19	The products are being recalled voluntarily due to lack of assurance of sterility. The administration of a drug product intended to be sterile that is not sterile could result in serious infections which may be life-threatening. Consumers should ocntact their phsyicians or healthcare provider if they ha ve any of these recalled products and if htey are experiencing any problems that may be related to taking or using these drug products.	consumer-level
Metrix Secure EVA Dual Chamber and Baxter ExactaMix; manufacturer: Metrix Company	n/a	9/10/19	This recall was initiated after receipt of eight complaints of leaking bags, in which the leak occurred near the divider rod and channel, when the rod was being removed. Use of the defective product, with a break of the sterile barrier could result in serious infection to the patient. Subsequent investigation indicates the problem was caused by the assembly machine malfunction, creating additional stress on the rod, channel and bag film resulting in a potential to cause a material anomaly that is concealed until the rod is removed at the point of use. No reports of death, illnesses or injuries haven reported to date from the use of this product. Patients are urged to immediately inform their Health care provider, if they observe a leaking bag. If a patient observes a leak, DO NOT INFUSE THE BAG.	retail-level
Bacteriostatic water for injection; Manufacturer: Hospira, Inc.	30mL,multi-dose vial	9/10/19	This recall was initiated due to lack of confirmation of sterilization for some vials from this lot. In the even that impacted product is administered to a patient, there is an increased risk that severe adverse events such as an invasive bacterial infection, including bacterial meningitis, septicemia, and limited adverse events such as fever, chills, malaise, and cutaneous abscess may occur. To date, Hospira has not received reports of any such adverse events associated with this issue for this lot.	hospital-level

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Milk of Magnesia; manufacturer: Plastikon Healthcare	2400mg/30ml oral suspension	9/10/19	This recall was initiated because these product lots idd not meet Plastikon's in-house microbiological sepcification for Ttoal Aerobic Microbial Count. This product is packaged for institutional use and is sold to clinics and hospitals, the patient population most likely to use the product are likely immunocompromised. Patients with compromised immune systems, such as patients in hospitals and nursing homes, have a higher probability of developing potentially life-threatening infections after taking a contaminated product. To date, Plastikon has not received any customer complaints or reports of adverse events related to this issue. Milk of Magnesia 2400mg/30mL is indicated for the occasional relief of constipation (irregularity) in adults and children 12 years and older or for children under 12 as recommended by a doctor.	consumer-level
Fexofenadine Hydrochlorothiazide; manufacturer: Aurobindo	180mg tablets	9/6/19	This recall was issued due to a stability failure.	retail-level
Natpara (parathyroid hormone) injection; manufacturer: Takeda	25mcg, 50mcg, 75mcg, 100mcg injections	9/6/19	It is recalled due to the possible presence of small ruber particulates in the Natpara cartridge originating from the rubber septum. Healthcare professionals and patients are being advised not to abruptly discontinue Natpara therapy as stated in the product labeling due to the risk of severe hypocalcemia.	consumer-level
Monoject Needles; manufacturer: Cardinal Health		9/5/19	This recall was issued due to a manufacturing defect that was found for the cartridge component, which could compromise the sterility barrier of the product.	class II
Fexofenadine Hydrochlorothiazide; manufacturer: Avkare	180mg tablets	9/5/19	This recall was issued due to a stability failure.	retail-level
Pantoprazole sodium DR ; manufacturuer: Jubilant Generics, Ltd.	40mg tablets; 90-count bottle	9/5/19	This recall was issued due to the presence of dark brown discoloration on tablet edges found during visual inspection of control samples.	retail-level
Bevacizumab; manufacturer: AmExPharmacy	1.25mg/0.05mL 31G Injectable	8/30/19	These lots are being recalled out of an abudnace of caution following an FDA inspection. While all products associated with this voluntary recall passed compendial testing per USP71 and USP85, administration of a non-sterile drug prodcut intended to be sterile may present the risk of infection. The product involved in this recall is used for Wet Age-related macular degeneration and diabetic retinopathy. It is individually wrapped and labeled in a Tyvek puch which is then placed in a labeled maber bag to protect from light.	voluntary
Bexarotene; manufacturer: Upsher-Smith Laboratories, LLC	75mg capsules; 100 capsules per bottle	8/28/19	This recall was issued due to failed dissolution specifications.	class II
Ketamine; Manufacturer: SCA Pharmaceuticals	50mg/5ml in 0.9% Sodium Chloride injection for IV or IM use 6ml syringe	8/28/19	This recall was issued due to the lack of quality assurance of sterility.	class II
Losartan Potassium; manufacturer: Sandoz	50mg	8/28/19	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 is not child-resistant which could pose a risk of harm if the tablets are swallowed by children.	consumer-level
Ezetimibe; manufacturer: Sandoz	10mg	8/28/19	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 is not child-resistant which could pose a risk of harm if the tablets are swallowed by children.	consumer-level
Vetropolycin opthalmic ointment; manufacturer: Altaire Pharmaceuticals, Inc.	3.6gm	8/23/19	This recall was issued due to concerns regarding some QA controls in the manufacturing facility.	retail-level
Vetropolycin HC ophthalmic ointment; manufacturer: Altaire Pharmaceuticals, Inc.	3.5gm	8/23/19	This recall was issued due to concerns regarding some QA controls in the manufacturing facility.	retail-level

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Puralube Vet ophthalmic ointment; manufacturer: Altaire Pharmaceuticals, Inc.	3.5gm	8/23/19	This recall was issued due to concerns regarding some QA controls in the manufacturing facility.	retail-level
Gamunex; manufacturer: Grifols	200mL bottle	8/23/19	This withdrawal was issued due to a higher rate of allergic/hypersensitivity type reactions, a small number of which were considered medically significant. Hypersensity and anaphylactic/anaphylactoid reactions are a known risk with IVIG products.	consumer-level
Gamunex-C; manufacturer: Grifols	10	8/22/19	This withdrawal is being conducted due to a higher rate of allergic/hypersensitivity reactions, a smaller number of which were considered medically significant. Hypersensitivity and anaphylactoid reactions are a known risk with IVIG products	consumer-level
Sooth & Cool Protect Moisture Guard Skin Protectant	3.5 oz tube	8/21/2019	This recall was issued due to CGMP deviations and out of specficiation results for either total microbial count or total organic carbon in the purified water utilized in the manufacturing process.	retail-level
Exactamed Oral Dispenser manufactured by Baxter	5mL	8/19/2019	This safety alert is being issued due to the potential for the 3mL dispenser to be misinterpreted or not recognized based on the package labeling and used as a 5mL dispenser. This could result in medication errors.	retail-level
Relpax (eletriptan hydrobromide); manufacturer: Pfizer	40mg tablets; 6 tablets and 12 tablets pack size	8/15/2019	This recall was issued because the product may not meet Pfizer's in-house micrbiological specification for th epotential presence of Genus Pseudomonas and Burkholderia. This may represent a potential health hazard or safety risk to plan members who may be using product affected by this recall.	retail-level
Eptifibatide SDV 20 mg/100 mL	20 mg/100 mL	8/9/19	This recall is being issued due to out-of-specification impurities. During routine stability resting at 18-month samples resulted in 0.3% for D-aspartic acid.	retail-level
Eptifibatide SDV 20 mg/10 mL	20 mg/10 mL	8/9/19	This recall is being issued due to out-of-specification impurities. During routine stability resting at 18-month samples resulted in 0.3% for D-aspartic acid.	retail-level
Eptifibatide SDV 75 mg/100 mL	75 mg/100 mL	8/9/19	This recall is being issued due to out-of-specification impurities. During routine stability resting at 18-month samples resulted in 0.3% for D-aspartic acid.	retail-level
Vivitrol; manufacturer: Alkemes		8/8/19	This recall is being issued due to 1 inch needles being placed in the 1 1/2 inch needle cardboard sleeve.	retail-level
PreTAT in Cream by TAT BALM 3 in 1 Pre-Tattoo Prep with Lidocaine	1,2, & 4 ounce jars	8/8/19	FDA analysis has found these products to have microbiological contamination and the potency is higher than the labeled amount for lidocaine.	retail-level
PreTAT in Liquid Gel by TAT BALM 3 in 1 Pre Tattoo Prep with Lidocaine	1,2, & 4 ounce jars	8/8/19	FDA analysis has found these products to have microbiological contamination and the potency is higher than the labeled amount for lidocaine.	retail-level
Superior Pain & Itch Releif in Cream	1,2, & 4 ounce jars	8/8/19	FDA analysis has found these products to have microbiological contamination and the potency is higher than the labeled amount for lidocaine.	retail-level
Superior Pain & Itch Releif in Liquid Gel	1,2, & 4 ounce jars	8/8/19	FDA analysis has found these products to have microbiological contamination and the potency is higher than the labeled amount for lidocaine.	retail-level
Soothing Sore Releif in Cream Fast Acting of Pain and Itching Associated with Minor Sores in Cream	1,2, & 4 ounce jars	8/8/19	FDA analysis has found these products to have microbiological contamination and the potency is higher than the labeled amount for lidocaine.	retail-level
Soothing Sore Releif In Liquid Gel Fast Acting Releif of Pain and Itching Associated with Minor Sores in Liquid Gel	1,2, & 4 ounce jars	8/8/19	FDA analysis has found these products to have microbiological contamination and the potency is higher than the labeled amount for lidocaine.	retail-level
Doxycycline Hyclate	100 mg tablets	8/7/19	This recall was issued due to out of specficiation result for the dissolution test.	class II

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Freshkote drops; manufacturer: Focus Laboratories	15mL	8/6/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Mometasone Furoate; manufacturer: Glenmark	0.1% cream	8/2/19	This recall is being issued due to grittiness observed in the product.	retail-level
GRIPPER Needles; manufacturer: Smiths Medical		8/1/19	This recall is being issued due to certain individual GRIPPER needles, which were manufacturered between June 11, 2018, and February 21, 2019, including those that are provided in a certain PORT-A-CATH trays, may contain an occluded or blocked needle.	retail-level
Nitrofurantoin Monohydrate/Macrocrystals capsules/Alvogen	100mg	8/1/19	This recall is being issued due to the lot failing to meet the specification for dissolution at the twelve-month stability test interval.	retail-level
Lisinopril-HCTZ 20-12.5 mg Tab /Lupin	20-12.5 mg	8/1/19	This recall is being issued due to a product complaint where one tablet of Lupin's Fenofibrate 145 mg was observed in the 500's count product bottle.	retail-level
Diphenhydramine Oral Liquid Alcohol Free//geritrex	12.5 mg/5 mL, 4 fl oz.	7/31/19	This recall was issued due to cGMP deviations and the products may have microbial contamination.	retail-level
Ritussin DM Children & Adults /geritrex	4fl oz	7/31/19	This recall was issued due to cGMP deviations and the products may have microbial contamination.	retail-level
Gericare Diocto Liquid Docusate Sodium Stool Softener, /geritrex	50 mg/5mL, 16 fl oz.	7/31/19	This recall was issued due to cGMP deviations and the products may have microbial contamination.	retail-level
Gericare Iron Supplement Elixir Ferrous Sulfate,	220mg, 16 fl.oz	7/31/19	This recall was issued due to cGMP deviations and the products may have microbial contamination.	retail-level
Preferred Plus Pharmacy Iron Elixir Ferrous Sulfate, /geritrex	220mg, 16 fl.oz	7/31/19	This recall was issued due to cGMP deviations and the products may have microbial contamination.	retail-level
Ritussin DM Double strength/Geritrex	4fl.oz	7/31/19	This recall was issued due to cGMP deviations and the products may have microbial contamination.	retail-level
Gericare Geri-Tussin DM/geritrex	16 fl.Oz	7/31/19	This recall was issued due to cGMP deviations and the products may have microbial contamination.	retail-level
Preferred Plus Dioctyl Liquid Stool Softener (Docusate Sodium)/geritrex	50mg/5mL, 16 fl oz.	7/31/19	This recall was issued due to cGMP deviations and the products may have microbial contamination.	retail-level
Neomycin Sulfate 3.5 mg/Polymxin B Sulfate 10,000 units/Dexamethasone 1 mg Ophthalmic Ointment		7/31/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Oliver's Harvest CBD+Capsaicin 0.2% Pain Relief (Capsaicin 0.2%) Topical Analgesic Cream, /pharma-natural	4 oz	7/31/19	The products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing process violations.	retail-level
AbeeMed Cream (Menthol 1.48% and Histamine DHCL 0.05%), 2 oz. /pharma-natural	2 oz	7/31/19	The products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing process violations.	retail-level
Army Health With Curcumin (Menthol 3.00%) Pain Reliever Roll-On, 2.5 fl oz. /pharma-natural	2.5 fl.oz	7/31/19	The products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing process violations.	retail-level
Oliver's Harvest CBD+Lidocaine HCL 4% Pain Relief (Lidocaine HCL 4%) Topical Analgesic Cream, 4 oz. /pharma-natural	4oz	7/31/19	The products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing process violations.	retail-level
Army Health Pain Reliever Gel With Curcumin (Menthol 3.00%), 0.5 oz. /pharma natural	0.5 oz	7/31/19	The products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing process violations.	retail-level
Gencontuss (Chlorpheniramine Maleate, 2mg; Dextromethorphan HBr, 10 mg; Phenylephrine HCl, 5 mg) in each 5 mL tsp, Cherry Flavor, 16 fl oz. /pharma-natural	16 fl.Oz	7/31/19	The products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing process violations.	retail-level

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Double Tussin DM (Dextromethorphan Hbr 20 mg, Guaifenesin 300 mg) in each 5 ml teaspoon, 4 fl oz. /pharma-natural	16 fl.Oz	7/31/19	The products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing process violations.	retail-level
LidoAID (Lidocaine HCL 4%) portable pain relieving Topical Analgesic Gel, 0.17 oz. /pharma-natural	0.17 oz	7/31/19	The products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing process violations.	retail-level
Dermanak Original Crema Blanqueador (Hydroquinone 2%) Skin Fade Cream, 2 oz. /pharma-natural	2 oz	7/31/19	The products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing process violations.	retail-level
Lido E.R. (Lidocaine HCL 4%) Pain Relieving Topical Analgesic Cream, 4 oz. /pharma-natural	4 oz	7/31/19	The products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing process violations.	retail-level
Lid O Creme (Lidocaine HCL 4% and Menthol 1%) Topical Analgesic Cream, 2.5 oz. /pharma-natural	2.5 oz	7/31/19	The products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing process violations.	retail-level
Dayma Super Forte XL10 (Camphor 0.5%, Menthol 2%, Methyl Salicylate 2%) Pain Relieving Topical Analgesic Gel, 4 oz. /pharma-natural	4 oz	7/31/19	The products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing process violations.	retail-level
Tusslin (Dextromethorphan HBr, 28 mg; Guaifenesin, 388 mg; Phenylephrine HCl, 10 mg) in each 5 mL tsp, Grape Flavor, 16 fl oz. /pharma-natural	16 fl.Oz	7/31/19	The products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing process violations.	retail-level
Sorbugen NR (Dextromethorphan HBr, 15 mg; Glyceryl Guaiacolate (Guaifenesin), 150 mg) in each 7.5 mL 1 1/2 tsp), Grape Flavor, 16 fl oz. /pharma-natural	16 fl.Oz	7/31/19	The products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing process violations.	retail-level
Neogen-D (Dextromethorphan HBr, 30 mg; Guaifenesin, 200 mg; Phenylephrine HCl, 7.5 mg) in each 5 mL tsp, Raspberry Flavor, 16 fl oz. /pharma-natural	16 fl.Oz	7/31/19	The products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing process violations.	retail-level
Workvie Instant Pain Relieving Roll On (Lidocaine HCL 4% + Menthol 1% & Arnica), 2.5 oz. /pharma-natural	2.5 oz	7/31/19	The products were manufactured with lack of process validation, cleaning validation, stability studies, and other current good manufacturing process violations.	retail-level
Clear eyes Assorted IRC		7/29/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Clear eyes drop packet 0.2oz CT12	0.2 oz	7/29/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Clear eyes Max Redness relief		7/29/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Clear eyes max redness club pack		7/29/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Clear Eyes Redness Relief 1 oz.		7/29/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Clear Eyes Redness Relief 0.5 oz.	0.5 oz	7/29/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Clear Eyes Redness Relief Club Pack		7/29/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level

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Clear Eyes Redness Relief Club Pack		7/29/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Clear Eyes Redness Relief Pocket Tray		7/29/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Clear Eyes Redness Relief Max 0.5 oz.		7/29/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Clear Eyes Seasonal Relief 0.5 oz.		7/29/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
TS Clear Eyes 0.2 oz. CT12		7/29/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
MPB Temozolom Cap 100 mg 14		7/26/19	This recall was issued due to a potential "beta-lactam cross contamination risk involving Temozolomide Capsules."	retail-level
MPB BDI Temozolom Cap 100 mg 5		7/26/19	This recall was issued due to a potential "beta-lactam cross contamination risk involving Temozolomide Capsules."	retail-level
MPB BDI Temozolom Cap 20 mg 5		7/26/19	This recall was issued due to a potential "beta-lactam cross contamination risk involving Temozolomide Capsules."	retail-level
MPB BDI Temozolom Cap 250 mg 5		7/26/19	This recall was issued due to a potential "beta-lactam cross contamination risk involving Temozolomide Capsules."	retail-level
MPB BDI Temozolom Cap 5 mg 5		7/26/19	This recall was issued due to a potential "beta-lactam cross contamination risk involving Temozolomide Capsules."	retail-level
MPB BDI Temozolom Cap 140 mg 5		7/26/19	This recall was issued due to a potential "beta-lactam cross contamination risk involving Temozolomide Capsules."	retail-level
MPB BDI Temozolom Cap 180 mg 14		7/26/19	This recall was issued due to a potential "beta-lactam cross contamination risk involving Temozolomide Capsules."	retail-level
Temozolomid Cap 100 mg ASC 5		7/26/19	This recall was issued due to a potential "beta-lactam cross contamination risk involving Temozolomide Capsules."	retail-level
Temozolomid Cap 100 mg ASC 14		7/26/19	This recall was issued due to a potential "beta-lactam cross contamination risk involving Temozolomide Capsules."	retail-level
Temozolomid Cap 140 mg ASC 14		7/26/19	This recall was issued due to a potential "beta-lactam cross contamination risk involving Temozolomide Capsules."	retail-level
Temozolomid Cap 140 mg ASC 5		7/26/19	This recall was issued due to a potential "beta-lactam cross contamination risk involving Temozolomide Capsules."	retail-level
Temozolomid Cap 180 mg ASC 5		7/26/19	This recall was issued due to a potential "beta-lactam cross contamination risk involving Temozolomide Capsules."	retail-level
Temozolomid Cap 180 mg ASC 14		7/26/19	This recall was issued due to a potential "beta-lactam cross contamination risk involving Temozolomide Capsules."	retail-level
Temozolomid Cap 20 mg ASC 14		7/26/19	This recall was issued due to a potential "beta-lactam cross contamination risk involving Temozolomide Capsules."	retail-level
Temozolomid Cap 20 mg ASC 5		7/26/19	This recall was issued due to a potential "beta-lactam cross contamination risk involving Temozolomide Capsules."	retail-level
Temozolomid Cap 250 mg ASC 5		7/26/19	This recall was issued due to a potential "beta-lactam cross contamination risk involving Temozolomide Capsules."	retail-level
Temozolomid Cap 5 mg ASC 14		7/26/19	This recall was issued due to a potential "beta-lactam cross contamination risk involving Temozolomide Capsules."	retail-level
Temozolomid Cap 5 mg ASC 5		7/26/19	This recall was issued due to a potential "beta-lactam cross contamination risk involving Temozolomide Capsules."	retail-level
OCuSOFT Tears Again Lubricant Eye Drops/Altaire		7/25/19	. This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level

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OCuSOFT Retaine NaCl Solution		7/25/19	. This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
OCuSOFT Retaine NaCl Solution/Altaire		7/25/19	. This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
OCuSOFT Tears Again Lubricant Eye Drops/Altaire		7/25/19	. This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Anemia Off	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Drospirenone and Ethinyl Estradiol 3 mg/0.02 mg tablets/Jubilant Cadist	Tablets	7/24/19	This recall was issued due to the out-of-specification dissolution results obtained at the 3-month stability time point.	retail-level
Fluorouracil Injection 5g/100 mL/Fresenius Kabi	Injection	7/24/19	. This recall was issued because glass particulates found during an inspection for a quality investigation.	retail-level
Appetrol	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Asma Aid	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level

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"Asma" Stopper	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Asthma Balm	Ointment	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Awake	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Baby Saver	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Bone Fixer	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level

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Cardia Forte	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Deafness Off	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Detensin	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Dragon Pain Balm	Ointment	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Dragon Pain Oil	Massage Oil	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level

Edema Off	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Fungo Balm	Ointment	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Fungo Off	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Glauco-Catar	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Hair Back	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level

Herpes-G	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Herpes-P	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Herpes-S	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Herpes-V Balm	Ointment	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Lipidtrol	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level

Lube Lax	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Lump Off	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Lung Fixer	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Lung Saver	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Lung Tonic EX	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level

Mental Tonic	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Migraine Off	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Pain Away	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Pain Stopper	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Prostatin	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level

Psoriasis Balm	Ointment	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Smoke End	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Sperm Booster	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Stomach Flu	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Stone Purger	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level

Thyro-H	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Thyro-Lo	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Vertigo Off	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Worm Off	Capsules	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level
Yeast Douche Powder	Powder	7/24/19	These products have been marketed without FDA approval and were manufactured outside of the controls required by current Good Manufacturing Practices (cGMP). These products could potentially result in risk to consumers as they are marketed with intended uses not amendable to self-diagnosis. In addition, lack of controls in the manufacture of the products do not provide assurances of finished product quality. These products are intended to be used as Chinese Herbal Medicines marketed for treatment of disease conditions in humans which the FDA has determined may constitute unapproved new drugs.	retail-level

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Homatropine Eye Drops/Altaire	5%, 5mL bottles	7/22/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Flucane Opthalmic solution/Altaire	5mL	7/22/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
OCuSOFT eye wash/Altaire	N/A	7/22/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
OCuSOFT Goniosoft/Altaire	2.5%, 15 mL	7/22/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
OCuSOFT Tetcaine Hydrchloride Ophthalmic Solution/Altaire	0.5%, 15 mL	7/22/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Tetravisc /Altaire	0.5%, 0.6mL	7/22/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Tetravisc Forte/Altaire	0.5%, 0.6mL	7/22/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Tetravisc Forte O/S /Altaire	0.5%, 5mL	7/22/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Tetravisc O/S/Altaire	0.5%, 5mL	7/22/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Altaire Ciprofloxacin HCl Ophthalmic Solution	0.3%, 5 mL	7/22/19	This recall was issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Sodium Chloride injection 0.9%/Baxter	0.9%, 100mL	7/22/19	This recall was issued due to the potential presence of leaks.	retail-level
Monsel S Solution /Gordon labratories	8mL	7/22/19	This recall was issued due to high levels of iron and microbiological contamination.	retail-level
Kogenate® FS vials /bayer	N/A	7/19/19	This recall was issued because vials that were labeled as Kogenate FS actually contained FVIII hemophilia A, Jivi® antihemophilic factor (recombinant) PEGylated-aucl 3000 IU.	retail-level
TRP/Target Up & Up Intensive Relief Lubricating Eye Drop/ TRP	N/A	7/19/2019	This recall was issued due to Altaire management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
TRP Stye Relief/ TRP	4g	7/19/2019	This recall was issued due to Altaire management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
TRP Pink eye relief/TRP	10mL	7/19/2019	This recall was issued due to Altaire management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Blur Relief Homeo Eye Drp/TRP company	N/A	7/19/2019	This recall was issued due to Altaire management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.	retail-level
Methylergonovine Maleate Tablets/Amneal	0.2mg, 12 count and 28 count	7/19/2019	This recall was issued as a conservative measure as the two lots are different packaging configurations of the same common bulk lot.	retail-level
0.9% sodium chloride injection	100mL	7/18/2019	This recall was issued due to potential presence of leaks.	retail-level
Letsgetchecked Home STD TST/Privapath diagnostics	N/A	7/18/2019	This recall was issued due to a potential for blood leakage due to a hole/damage at the base of the tube which could result in leaked samples.	retail-level

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Letsgetchecked HME Perhlth Test/Privapath diagnostics	N/A	7/18/2019	This recall was issued due to a potential for blood leakage due to a hole/damage at the base of the tube which could result in leaked samples.	retail-level
Anastrozole tablets/Cadila healthcare	1mg tabs, 30 count and 1000 count	7/17/2019	This recall was issued due to GMP deviations and potential cross contamination due to cleaning procedure failure.	retail-level
Omega-3 1000/DaVinci Labratories	1000mg capsules	7/11/2019	A small number of bottles may contain undeclared (anchovy and sardine) allergen.	retail-level
Drospirenone and Ethinyl Estradiol 3 mg/0.02 mg tablets/Jubilant Cadista	3 mg/0.02 mg tablets	7/10/2019	This recall was issued due to the out-of-specification dissolution results obtained at the 3-month stability time point.	retail-level
Milrinone lactate injection/Hospira	20mg/100mL, 40mg/200mL	7/10/2019	This recall was issued due to a molding defect in the additive ports in some units, which may lead to potential product leakage.	retail-level
CVS Health Natural Tears Lubricant Eye Drops Preservative Free Item #:538397	0.6 mL x 32 ct	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Lubricant Eye Drops for Mild to Moderate Dry Eye Item#: 317916	15 mL	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Lubricant Eye Drops for Mild to Moderate Dry Eye Item#: 247887	30 mL	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Dry Eye Relief Eye Drops Item#: 317914	15mL	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Dry Eye Relief Eye Drops Item#: 457802	30mL	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Preservative Free Lubricant Eye Drops Sensitive Solution Item#: 495334	Product Size: 0.6 mL x 60 ct	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Preservative Free Lubricant Eye Drops Sensitive Solution Item#: 994883	Product Size: 0. 6 mL x 30 ct	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
Product Description: CVS Health Preservative Free Lubricant Gel Drops Dry Eye Relief Item#: 634634	Product Size: 0.6 mL x 30	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Lubricating Gel Drops for Anytime Use Item#: 563420	Product Size: 10 mL	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Overnight Lubricating Eye Ointment Item#: 881532	Product Size: 3.5 gram	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Lubricant Eye Ointment Item#: 247881	Product Size: 3.5 gram	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Extra Strength Lubricant Gel Drops Item#: 799143	Product Size: 15 mL	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level

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CVS Health Extra Strength Lubricant Gel Drops Twin Pack Item#: 258587	Product Size: 2 x 15 mL	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Fast Acting Lubricant Eye Drops Dry Eye Therapy Item#: 895160	Product Size: 15 mL	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Fast Acting Lubricant Eye Drops Dry Eye Therapy Twin Pack Item#: 994881	Product Size: 2 x 10 mL	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Preservative Free Lubricant Eye Drops Sensitive Solution Item#: 495301	Product Size: 0.6 mL x 30ct	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Preservative Free Lubricant Eye Drops Sensitive Solution Item#: 457791	Product Size: 0.6 mL x 70ct	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Preservative Free Lubricant Eye Drops Advanced Relief Item#: 563442	Product Size: 0.6 mL x 30	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Lubricant Eye Drops Advanced Relief Item#: 563419	Product Size: 10 mL	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Fast Acting Lubricant Eye Drops Preservative Free Item#: 994882	Product Size: 0.6 mL x 24 ct	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Preservative Free Lubricant Eye Drops Fast Acting Item#: 258625	Product Size: 0.6 mL x 60 ct	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Lubricant Gel Drops-Moderate to Severe Dry Eye Relief Item#: 799145	Product Size: 30 mL	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Multi-Action Relief Drops Item#: 694954	Product Size: 15 mL	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Lubricant Eye Drops Lasting Dry Eye Relief Item#:968210	Product Size: 10 mL	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Lubricant Eye Drops Lasting Dry Eye Relief Twin Pack Item#: 495323	Product Size: 2 x 10 mL	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Maximum Redness Relief Eye Drops Item#: 994880	Product Size: 15 mL	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Redness Relief Item#: 317912	Product Size: 15 mL	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level

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CVS Health Redness Relief Item#: 457799	Product Size: 30 mL	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Lubricant Eye Drops Multi-Symptom Eye Relief Item#: 563431	Product Size: 15 mL	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Lubricant Eye Ointment Sensitive Formula Item#: 247885	Product Size: 3.5 gram	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
CVS Health Natural Tears Lubricant Eye Drops Preservative Free	Various sizes	7/10/2019	The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.	retail-level
Neomycin and Polymixin B and Bacitracin Zinc Ophthalmic Ointment/Altaire	3.5 gram ointment	7/3/19	As a precautionary measure, Altaire is initiating the recall due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility. This recall is being carried out to the retail level and is only for the specific lots listed. No other lots are being recalled. Administration of a non-sterile product intended to be sterile may result in serious and potentially life-threatening infections or death. To date, Altaire has received no reports of adverse events, nor has Altaire obtained any out of specifications results including sterility testing, for the products.	retail-level
Neo-Poly Dex (Neomycin and polymixin B and Dexamethasone) Ophthalmic ointment/Altaire	3.5 gram ointment	7/3/19	As a precautionary measure, Altaire is initiating the recall due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility. This recall is being carried out to the retail level and is only for the specific lots listed. No other lots are being recalled. Administration of a non-sterile product intended to be sterile may result in serious and potentially life-threatening infections or death. To date, Altaire has received no reports of adverse events, nor has Altaire obtained any out of specifications results including sterility testing, for the products.	retail-level
Wintergreen essential oil/Nature's truth	15mL	7/9/19	This recall was issued due to failure to comply with a regulation under the Poison Prevention Packaging Act enforced by the Consumer Product Safety Commission.	retail-level
Gablofen PFS/Piramel Critical Care	50 mcg/mL, 1mL	7/9/19	This recall was issued due to the presence of an unknown impurity observed during shelf life of the product.	retail-level
Neo-Polycin HC (Newmycin and Polymixin B and Bacitracin Zinc and Hydrocortisone Acetate) Ophthalmic Ointment/Altaire	3.5 gram ointment	7/3/19	As a precautionary measure, Altaire is initiating the recall due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility. This recall is being carried out to the retail level and is only for the specific lots listed. No other lots are being recalled. Administration of a non-sterile product intended to be sterile may result in serious and potentially life-threatening infections or death. To date, Altaire has received no reports of adverse events, nor has Altaire obtained any out of specifications results including sterility testing, for the products.	retail-level

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Polycin (Polymixin B and Bacitracin Zinc) Ophthalmic ointment/Altaire	3.5 gram ointment	7/3/19	As a precautionary measure, Altaire is initiating the recall due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility. This recall is being carried out to the retail level and is only for the specific lots listed. No other lots are being recalled. Administration of a non-sterile product intended to be sterile may result in serious and potentially life-threatening infections or death. To date, Altaire has received no reports of adverse events, nor has Altaire obtained any out of specifications results including sterility testing, for the products.	retail-level
Bacitracin Ophthalmic Ointment/Altaire	3.5 gram ointment	7/3/19	As a precautionary measure, Altaire is initiating the recall due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility. This recall is being carried out to the retail level and is only for the specific lots listed. No other lots are being recalled. Administration of a non-sterile product intended to be sterile may result in serious and potentially life-threatening infections or death. To date, Altaire has received no reports of adverse events, nor has Altaire obtained any out of specifications results including sterility testing, for the products.	retail-level
Sulfacetamide sodium ophthalmic ointment/Altaire	3.5 gram ointment	7/3/19	As a precautionary measure, Altaire is initiating the recall due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility. This recall is being carried out to the retail level and is only for the specific lots listed. No other lots are being recalled. Administration of a non-sterile product intended to be sterile may result in serious and potentially life-threatening infections or death. To date, Altaire has received no reports of adverse events, nor has Altaire obtained any out of specifications results including sterility testing, for the products.	retail-level
Puralube Ophthalmic Ointment/Altaire	3.5 gram ointment and 1 gram ointment	7/3/19	As a precautionary measure, Altaire is initiating the recall due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility. This recall is being carried out to the retail level and is only for the specific lots listed. No other lots are being recalled. Administration of a non-sterile product intended to be sterile may result in serious and potentially life-threatening infections or death. To date, Altaire has received no reports of adverse events, nor has Altaire obtained any out of specifications results including sterility testing, for the products.	retail-level
Lubricant Eye Drops Moisturizing Walgreens/Altaire	15 mL	7/3/19	Due to Potential for Non-sterility.	retail-level
Lubricant Eye Drops Moisturizing Twin Pack Walgreens/Altaire	2x15 mL	7/3/19	Due to Potential for Non-sterility.	retail-level
Sodium Chloride Ophthalmic Ointment, 5% Hypertonicity Eye Ointment Walgreens /Altaire	3.5 gram	7/3/19	Due to Potential for Non-sterility.	retail-level
Sodium Chloride Ophthalmic Solution, 5% Hypertonicity Eye Drops Walgreens/Altaire	15 mL	7/3/19	Due to Potential for Non-sterility.	retail-level
Lubricant Eye Ointment PF Soothing Walgreens /Altaire	3.5 gram	7/3/19	Due to Potential for Non-sterility.	retail-level

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Kaitlib Fe 0.8 mg/0.025 mg Chewable tablets/Lupin	0.8 mg/0.025 mg	7/3/19	This recall was issued due to an out of specification result observed in Related Substances test for Ethinyl Estradiol Impurity-B at long term stability study.	retail-level
Acetaminophen Children's Liquid/Torrent	160 mg/5mL, 4 ounce bottle	7/3/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B.cepacia) and Ralstonia pickettii (R. pickettii).	class II
Diphenhydramine HCL liquid/Torrent	12.5 mg/5 mL, 4 ounce bottle	7/3/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B.cepacia) and Ralstonia pickettii (R. pickettii).	class II
Fluorouracil injection/Fresenius Kabi USA	5g/100mL, 100 mL vials, FRE and FRE NOV+	7/2/19	The company is issuing this notification after finding glass particulate in five vials in retained sample inventory of lot 6120341 during an inspection for a quality investigation. The second lot 6120420 is included in the recall as a precautionary measure as it was produced in the same filling campaign. The administration of glass particulate, if present in a parenteral drug, poses a moderate safety risk to patients. Reports in the literature suggest that sequelae of thromboembolism, such as pulmonary emboli, phlebitis, granulomas, or fibrosis may occur.	consumer-level
Exactamed oral dispenser/Baxter	5 mL	7/1/19	This recall was issued due to the potential for volume of a 10mL dispenser to be misinterpreted or not recognized based on the package labeling. This could result in medication errors.	retail-level
0.5 mg/mL HYDROmorphone HCl in 0.9% Sodium Chloride 1 mL in 3 mL BD Syringe /PharMEDium services	1mL in 3mL	6/28/19	The electronic customer ordering system stated it is sulfite-free, but the product contains sulfite.	retail-level
Gamunex-C/ Grifols theraputics	10%, 20g vial (NDC 13533-0800-24)	6/28/2019	This withdrawal is being conducted due to a higher rate of allergic/hypersensitivity reactions, a smaller number of which were considered medically significant. Hypersensitivity and anaphylactic/anaphylactoid reactions are a known risk with IVIG products.	retail-level
Losartan Potassium Tablets/MacLeod's Pharmaceuticals	50 mg tablet, 90 count bottle; 50 mg tablet, 100 count bottle	6/20/19	trace amounts of an unexpected impurity found the finished product. The impurity detected is N-Nitroroso-N-Methyl-4-aminobutyric acid (NMBA). The impurity is a known animal and human carcinogen.	consumer-level
Losartan & hydrochlorothiazide tablets/MacLeod's Pharmaceuticals	50 mg/12.5 mg tablet, 90 count bottle; 100 mg/12.5 mg tablet, 90 count bottle; 100 mg/25 mg tablet, 90 count bottle	6/20/19	trace amounts of an unexpected impurity found the finished product. The impurity detected is N-Nitroroso-N-Methyl-4-aminobutyric acid (NMBA). The impurity is a known animal and human carcinogen.	consumer-level
Heparin Sodium in 5% dextrose injection/ Braun	25,000 units, 250 mL bag	6/18/19	This recall was issued due to an out-of-specification result identified at the 104 week stability interval for the drug anti-factor lla potency.	retail-level
Senna Syrup/Geritrex	8.8 mg/5mL, 8 oz	6/18/19	This recall was issued due to complaints received noting an atypical odor and taste associated with the subject lots.	retail-level
Atropine Sulfate syringe/Premier Pharmacy Labs	0.8mg/2 mL PF injection 2 mL syringe	6/18/19	Premier Pharmacy Labs is issuing a voluntary product recall for all sterile products, within expiration date, due to a lack of sterility assurance. Concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination, and lack of product specific process validations.	voluntary
Brilliant Blue Ophthalmic PF injection/Premier Pharmacy Labs	0.5 mg/mL (0.05%), 1 mL vial	6/18/19	Premier Pharmacy Labs is issuing a voluntary product recall for all sterile products, within expiration date, due to a lack of sterility assurance. Concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination, and lack of product specific process validations.	voluntary

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Buprenorphine HCL Preserved injection/Premier Pharmacy Labs	12mg/20 mL injection, 20 mL vial	6/18/19	Premier Pharmacy Labs is issuing a voluntary product recall for all sterile products, within expiration date, due to a lack of sterility assurance. Concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination, and lack of product specific process validations.	voluntary
Chlorpromazine HCL injection/Premier Pharmacy Labs	25mg/mL, 1 mL vial	6/18/19	Premier Pharmacy Labs is issuing a voluntary product recall for all sterile products, within expiration date, due to a lack of sterility assurance. Concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination, and lack of product specific process validations.	voluntary
Dexamethasone Sodium Phosphate injection/Premier Pharmacy Labs	24mg/mL PF injection, 1 mL syringe	6/18/19	Premier Pharmacy Labs is issuing a voluntary product recall for all sterile products, within expiration date, due to a lack of sterility assurance. Concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination, and lack of product specific process validations.	voluntary
Droperidol injection/Premier Pharmacy Labs	0.625mg/mL, 1 mL injection syringe	6/18/19	Premier Pharmacy Labs is issuing a voluntary product recall for all sterile products, within expiration date, due to a lack of sterility assurance. Concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination, and lack of product specific process validations.	voluntary
Isoproterenol Sterile-Sterile/Premier Pharmacy Labs	200mcg/50mL bag	6/18/19	Premier Pharmacy Labs is issuing a voluntary product recall for all sterile products, within expiration date, due to a lack of sterility assurance. Concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination, and lack of product specific process validations.	voluntary
Isoproterenol Non-Sterile to Sterile/Premier Pharmacy Labs	500 mcg/50 mL bag	6/18/19	Premier Pharmacy Labs is issuing a voluntary product recall for all sterile products, within expiration date, due to a lack of sterility assurance. Concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination, and lack of product specific process validations.	voluntary
Isoproterenol Non-Sterile to Sterile/Premier Pharmacy Labs	200 mcg/50mL bag	6/18/19	Premier Pharmacy Labs is issuing a voluntary product recall for all sterile products, within expiration date, due to a lack of sterility assurance. Concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination, and lack of product specific process validations.	voluntary
Lidocaine/Phenylephrine injection/Premier Pharmacy Labs	0.5%/0.75% PF injection, 1mL vial	6/18/19	Premier Pharmacy Labs is issuing a voluntary product recall for all sterile products, within expiration date, due to a lack of sterility assurance. Concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination, and lack of product specific process validations.	voluntary
Mitomycin irrigation/Premier Pharmacy Labs	40mg/10mL, 10 mL PF irrigation	6/18/19	Premier Pharmacy Labs is issuing a voluntary product recall for all sterile products, within expiration date, due to a lack of sterility assurance. Concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination, and lack of product specific process validations.	voluntary

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Naloxone HCL Preserved Injection/Premier Pharmacy Labs	10mg/mL, 50 mL vial	6/18/19	Premier Pharmacy Labs is issuing a voluntary product recall for all sterile products, within expiration date, due to a lack of sterility assurance. Concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination, and lack of product specific process validations.	voluntary
Neostigmine Methylsulfate/Premier Pharmacy Labs	1mg/mL, 5 mL syringe	6/18/19	Premier Pharmacy Labs is issuing a voluntary product recall for all sterile products, within expiration date, due to a lack of sterility assurance. Concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination, and lack of product specific process validations.	voluntary
Orphenadrine Citrate/Premier Pharmacy Labs	30mg/mL, 1 mL syringe	6/18/19	Premier Pharmacy Labs is issuing a voluntary product recall for all sterile products, within expiration date, due to a lack of sterility assurance. Concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination, and lack of product specific process validations.	voluntary
Phenylephrine HCL in Sodium Chloride PF/Premier Pharmacy Labs	1000mcg/10mL, 10 mL syringe	6/18/19	Premier Pharmacy Labs is issuing a voluntary product recall for all sterile products, within expiration date, due to a lack of sterility assurance. Concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination, and lack of product specific process validations.	voluntary
Riboflavin 5 Phosphate Sodium Ophthalmic Solution dropper/Premier Pharmacy Labs	6.35mg/mL, 3 mL dropper	6/18/19	Premier Pharmacy Labs is issuing a voluntary product recall for all sterile products, within expiration date, due to a lack of sterility assurance. Concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination, and lack of product specific process validations.	voluntary
Succinylcholine Chloride Injection/Premier Pharmacy Labs	100mg/5mL, 5 mL syringe	6/18/19	Premier Pharmacy Labs is issuing a voluntary product recall for all sterile products, within expiration date, due to a lack of sterility assurance. Concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination, and lack of product specific process validations.	voluntary
Succinylcholine Chloride Injection/Premier Pharmacy Labs	200mg/10mL, 10 mL syringe	6/18/19	Premier Pharmacy Labs is issuing a voluntary product recall for all sterile products, within expiration date, due to a lack of sterility assurance. Concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination, and lack of product specific process validations.	voluntary
Sodium Bicarbonate injection/Premier Pharmacy Labs	8.4% 50mEq/50mL, 50 mL vial	6/18/19	Premier Pharmacy Labs is issuing a voluntary product recall for all sterile products, within expiration date, due to a lack of sterility assurance. Concerns presented during the latest FDA inspection including insufficient environmental controls, potential cross contamination, and lack of product specific process validations.	voluntary
Estradiol Vaginal Inserts/Glenmark	10 mcg, 8 applicators	6/14/19	This recall was issued due to difficulty in pushing the plunger of the applicator.	retail-level
Zileuton/Prasco	600 mg ER tablet, 120 tablet bottle	6/14/19	This recall was issued due to an out of specification stability result for the dissolution release profile.	retail-level

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Testosterone Pump/Cipla	30 mg/1.5 mL Pump	6/14/19	This recall was issued due to improper functioning of pump actuation and dose deliveries from device notified viz'-a'-viz' a market complaint. Based on health hazard evaluation, the observed minimum delivered dose may impact the required therapeutic effect of the product, however the maximum delivered dose will not have any significant adverse impact on the safety of patients.	retail-level
Losartan Potassium/Teva (repackaged and redistributed by Golden State Medical Supply)	50 mg tablets, 1000 count bottle; 50 mg tablets, 90 count bottle; 50 mg tablets, 30 count bottle; 100 mg tablets, 90 count bottle	04/27/2019, 06/11/2019	This expanded recall includes six (6) lots of bulk losartan potassium USP Tablets (two lots of 50 mg strength and four lots of 100 mg strength) due to the detection of an impurity – N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) – that is above the US Food & Drug Administration's interim acceptable exposure limit of 9.82 ppm. The source of the NMBA impurity was detected in one lot of active pharmaceutical ingredient (API), manufactured by Hetero Labs Limited, which was used in the manufacturing of the six (6) bulk lots of these drug products. Based on the available information, there is a potential risk of developing cancer in a few patients following long-term use of products containing high levels of NMBA.	consumer-level
Child Pain-Fever/Torrent (distributed by Rugby and Major)	160 mg/5 mL	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Extra Action Cough Syrup/Torrent (distributed by Rugby and Major)	10 ml, 473 mL bottle	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Guaifenesin/Torrent (distributed by Rugby and Major)	100 mg/5 mL, 473 mL bottle	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Banophen Allergy/Torrent (distributed by Rugby and Major)	12.5 mg/5mL, 118 mL bottle	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Mapap liquid/Torrent (distributed by Rugby and Major)	160 mg/5 mL, 118 mL bottle	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Biscolax suppository/Torrent (distributed by Rugby and Major)	10 mg	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Nasal Decongestant 0.05% spray/Torrent (distributed by Rugby and Major)	15 mL bottle	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Child Pain-Fever/Torrent (distributed by Rugby and Major)	160 mg/5 mL	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Diphenhist solution/Torrent (distributed by Rugby and Major)	12.5 mg/5 mL	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Cough syrup/Torrent (distributed by Rugby and Major)	10 ml, 473 mL bottle	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Bisacodyl suppository/Torrent (distributed by Rugby and Major)	10 mg	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Hemorrhoidal suppository/Torrent (distributed by Rugby and Major)	12 suppository carton	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Pseudoephed solution/Torrent (distributed by Rugby and Major)	30 mg/5 mL	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Nasal Decon(P-Ephed) solution/Torrent (distributed by Rugby and Major)	30 mg/5 mL, 118 mL bottle	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Kidkare cough and cold liquid/Torrent (distributed by Rugby and Major)	118 mL bottle	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level

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Robafen-DM syrup/Torrent (distributed by Rugby and Major)	118 mL bottle	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Robafen syrup/Torrent (distributed by Rugby and Major)	100 mg/5 mL, 118 mL bottle	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Pedia Relief cough-cold liquid/Torrent (distributed by Major and Rugby)	118 mL bottle	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Child All Day Allergy/Torrent (distributed by Major and Rugby)	1 mg/mL, 118 mL bottle	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Robafen AC oral solution/Torrent (distribued by Major and Rugby)	473 mL bottle	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Anu-med suppository/Torrent (distributed by Major and Rugby)	12 suppository carton	6/7/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Risperidone Oral Solution/Heritage	1 mg/mL, 30 ml	6/5/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. Cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Mononine/CSL Behring	1000 (high) vial	6/4/19	This recall was issued as a precautionary measure due to the potential for inadequate aseptic technique during the filling process.	retail-level
Acetic Acid 2% ear solution/Rising	15 mL	6/3/19	This recall was issued due to potential product contamination with Burkholderia cepacian (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Zyflo CR Tablets/Chiesi	600 mg tablet/120 tablets per bottle	6/3/19	This recall was issued due to an out of specification stability result for the dissolution release profile.	retail-level
Cetirizine Oral Solution/Heritage	1 mg/mL, 120 mL bottle	6/3/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. Cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Zemaira/CSL Behring	1000 mg vial (single-use)	6/3/19	This recall was issued as a precautionary measure due to the potential for inadequte aseptic technique during the filling process.	hospital-level
Guaifenesin AC Cough Syrup/Rising	5 ml, 473 ml bottle	6/3/19	This recall was issued due to potential product contamination with Burkholderia cepacian (B. cepacia) and Ralstonia pickettii (R. pickettii). Pharmaceutical products that are contaminated with B. cepacia and R. pickettii may pose potential risk to vulnerable patients (e.g., immunocompromised patients) and/or patients with cystic fibrosis and persons with decreased immunity such as neonates, infants and the elderly. Some of these infections may be serious or even life threatening in the at-risk patient population.	retail-level
Guaifenesin DAC Oral Solution/Rising	5 ml, 473 ml bottle	6/3/19	This recall was issued due to potential product contamination with Burkholderia cepacian (B. cepacia) and Ralstonia pickettii (R. pickettii). Pharmaceutical products that are contaminated with B. cepacia and R. pickettii may pose potential risk to vulnerable patients (e.g., immunocompromised patients) and/or patients with cystic fibrosis and persons with decreased immunity such as neonates, infants and the elderly. Some of these infections may be serious or even life threatening in the at-risk patient population.	retail-level
Phenobarbital solution/Rising	20 mg/5 mL, 473 mL bottle	6/3/19	This recall was issued due to potential product contamination with Burkholderia cepacian (B. cepacia) and Ralstonia pickettii (R. pickettii). Pharmaceutical products that are contaminated with B. cepacia and R. pickettii may pose potential risk to vulnerable patients (e.g., immunocompromised patients) and/or patients with cystic fibrosis and persons with decreased immunity such as neonates, infants and the elderly. Some of these infections may be serious or even life threatening in the at-risk patient population.	retail-level

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PECGEN DMX liquid cough syrup/NOVIRS PR	16 oz	5/31/19	This recall was issued because product has been found to provide incorrect dosage information on its label due to a typographical error. The drug facts label incorrectly states children 6 to under 2 years of age, 1 teaspoonful every 4 hours, not to exceed 4 teaspoonfuls in 24 hours or directed by physician. The label should state children 6 to under 12, 1 teaspoonful every 4 hours, not to exceed 4 teaspoonfuls in 24 hours or as directed by physician. Additionally, the label does not advise consumers to consult a doctor for children under 2 years of age.	consumer-level
Cyproheptadine HCl syrup/Patrin	2 mg/5mL, 473 mL	5/29/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacian) and Ralstonia pickettii (R. pickettii).	retail-level
Hyoscyamine sulfate elixir/Patrin	0.125 mg/5mL, 473 mL	5/29/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacian) and Ralstonia pickettii (R. pickettii).	retail-level
Hyoscyamine sulfate drops/Patrin	0.125 mg/mL, 15 mL	5/29/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacian) and Ralstonia pickettii (R. pickettii).	retail-level
Memantine solution/Patrin	10 mg/5mL, 360 mL	5/29/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacian) and Ralstonia pickettii (R. pickettii).	retail-level
Cefdinir Oral Suspension/Lupin	250 mg/5mL	5/29/19	This recall was issued due to a product complaint where a small metal piece was identified in the product bottle prior to the reconstitution.	retail-level
Articaine DENTAL, Articaine hydrochloride 4% and epinephrine/Novocol	40 mg/ml, 1:100,000 (0.018 mg/mL), 1.7 mL each cartridge	5/29/19	This recall was issued due to mislabeling. The printed carton used in manufacturing both batches contained text for both 2% Xylocaine DENTAL and Articadent DENTAL. Xylocaine DENTAL is a trade name for Lidocaine HCL 2% and Epinephrine 1: 100,000 formulation, while Articadent DENTAL is a trade name for Articaine HCl 4% and Epinephrine 1 :100,000. The cartridges contained within the printed carton are labeled appropriately as Articadent DENTAL.	class II
Amikacin Sulfate Injection/Emcure Pharmaceuticals Ltd., distributed by Heritage Pharmaceuticals, Inc.	1 gm/mL (250 mg/mL)	5/28/19	The voluntary recall is being initiated due to microbial growth having been detected in one unreleased sublot of Lot VPCA172 and one unreleased sublot Lot VEAC025, which may indicate a lack of sterility in the other sublots.	consumer-level
Prochlorperazine Edisylate Injection/Emcure Pharmaceuticals Ltd., distributed by Heritage Pharmaceuticals, Inc.	10 mg/2mL (5 mg/mL)	5/28/19	The voluntary recall is being initiated due to microbial growth having been detected in one unreleased sublot of Lot VPCA172 and one unreleased sublot Lot VEAC025, which may indicate a lack of sterility in the other sublots.	consumer-level
Ondansetron Injection/Fresenius Kabi	2 mg/mL injection, 20 mL vial	5/28/19	This recall was issued due to out-of-specification (OOS) results for Ondansetron Related Compound D (an impurity) at the 3-month stability test.	retail-level
Hydrocodone-homatropine/Torrent/Bio-Pharm, Inc. Pharma	473 mL	5/23/2019, 05/24/2019	This recall was issued due to potential product contamination with Burkholderia cepacia (B. cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Cetirizine/Torrent/Bio-Pharm, Inc.	1 mg/mL solution, 120 mL	5/22/2019, 05/24/2019	This recall was issued due to potential product contamination with Burkholderia cepacia (B. Cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Hydrocortisone AC/Torrent/Bio-Pharm, Inc.	25 mg suppository, 12 and 24 count	5/22/2019, 05/24/2019	This recall was issued due to potential product contamination with Burkholderia cepacia (B. Cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Mematine/Torrent/Bio-Pharm, Inc.	2 mg/mL solution, 360 mL	5/22/2019, 05/24/2019	This recall was issued due to potential product contamination with Burkholderia cepacia (B. Cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Risperidone/Torrent/Bio-Pharm, Inc.	1 mg/mL solution, 30 mL	5/22/2019, 05/24/2019	This recall was issued due to potential product contamination with Burkholderia cepacia (B. Cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
All Sterile Compounded Drugs/PharmD Solutions, LLC	All Sterile Compounded Drug Products	5/24/19	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.	consumer-level

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Lactulose/Torrent/Bio-Pharm, Inc.	10 gm/15 mL solution, 473 mL, 16 oz, 32 oz	5/22/19	This recall was issued due to potential product contamination with Burkholderia cepacia (B. Cepacia) and Ralstonia pickettii (R. pickettii).	retail-level
Pramipexole/distributed by American Health Packaging	0.25 mg tablet, 0.25 mg tablet (individual dose), 0.125 mg tablet, 0.125 mg tablet (individual dose), 0.5 mg tablet, 0.5 mg (individual dose), 1 mg tablet, 1 mg tablet (individual dose)	5/15/19	This recall was issued as a precautionary measure as though no evidence has been found in any product testing, AHP cannot rule out at this time cross contamination due to a GMP cleaning procedure failure in the Fluid Bed Dryer Processer area.	retail-level
Senna Syrup/Geritrex	8.8 mg/5mL	5/14/19	This recall was issued due to an atypical odor and taste associated with the subject lots.	retail-level
Hydrocortisone and Acetic Acid otic solution/ Akorn	10 mL	3/14/2019, 05/14/2019	This recall was issued due to an OOS result observed for the Hydrocortisone assay during routine stability testing at 12 month controlled room temperature.	class II
Anastrozole/Zydus	1 mg tablets, 30 count-unit dose blisters (individual-dose and carton)	5/13/19	This recall is being initiated in support of the recall by the manufacturer, Zydus, dated May 3, 2019, which included lots that were repackaged by American Health Packaging. This recall was issued due to a GMP cleaning procedure failure in the Fluid Bed Dryer Processor area.	retail-level
Promacta (eltrombopag)/Novartis	12.5 mg for oral suspension, carton and packet	5/12/19	This recall was issued because of a risk of potential peanut flour contamination that occurred at a third-party contract manufacturing site.	consumer-level
Pramipexole/Zydus	0.125 mg 1000 count, 0.125 mg 90 count, 0.25 mg 1000 count, 0.25 mg 90 count, 0.5 mg 90 count, 1 mg 90 count, 1.5 mg 1000 count, 1.5 mg 90 count	5/9/19	This recall was issued due to a GMP cleaning procedure failure in the Fluid Bed Dryer Processor area.	retail-level
Detrol LA/Pfizer	2 mg	5/7/19	This withdrawal was issued due to the potential that product from these lots may not meet the specification for impurities through the shelf life.	retail-level
Methylprednisolone/Zydus	4mg 100 and 21 count, 8 mg 25 count, 16 mg 50 count, 32 mg 25 count	5/7/19	This recall has been initiated due to a GMP cleaning procedure failure in the Fluid Bed Dryer Processor Area.	retail-level
Dermoplast Pain Spray	2.75 oz	5/7/19	This recall was issued to a small quantity of lot # 14049A, intended to contain only the 2.0 oz item, also contained 2.75 oz. canisters which were filled to a 2.0 oz level, i.e. the wrong component was introduced into the lot.	retail-level
Losartan Potassium/ Hetero Labs Limited	25 mg, 50 mg, and 100 mg	5/3/19	due to the detection of an N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) a possible process impurity or contaminant in an active pharmaceutical ingredient	consumer-level
Mycophenolate Mofetil for Injection/ Par	500 mg/vial	5/1/19	following the discovery of a glass fragment within a reconstituted vial.	retail-level
Relpax/Pfizer	40 mg, 12 and 6 count blister pack	5/1/19	This recall was issued due to an artwork error in the secondary packaging. One side of the carton for 5 lots listed indicates that each tablet contains eletriptan hydrobromide equivalent to 20 mg eletriptan; the cartons should instead note eletriptan hydrobromide equivalent to 40 mg eletriptan	retail-level
Ketorolac Tromethamine / Zydus	60mg/2mL (30mg per mL)	4/30/19	due to microbial growth detected during a routine simulation of the manufacturing process, which represents the potential introduction of microorganisms into the products.	voluntary
Losartan Potassium/ Major	25 mg, 50 mg, and 100 mg	4/30/19	This recall was issued due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited. The impurity in the API is N-Methylnitrosobutyric acid (NMBA).	retail-level
Ceftazidime/Braun	2 gm Injection	4/30/19	This recall was issued due to one (1) test result was found to exceed the specification limits for High Molecular Weigh Polymers (HMWP) at the 52-week stability interval.	retail-level

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Divalproex ER/Major Pharmaceuticals	250 mg, unit dose cartons of 100 tablets	4/30/19	This recall was issued due to exposure of the product to above 50% relative humidity levels during packaging operations.	retail-level
Bevacizumab / AmEx Pharmacy	1.25mg/0.05mL 31G Injectable	4/29/19	The additional force needed to express the drug product could potentially result in damage to the eye while the needle is in the eye. To date, AmEx Pharmacy has received three reports associated with the Lot being recalled as either being difficult to express, two of which, resulted in an Adverse Drug Event.	voluntary
ThermaCare Back Pain Therapy Heatwraps/Pfizer	N/A	4/29/19	This recall was issued due to the potential that a HeatWrap could include cells that have a higher cell temperature than specified.	consumer-level
Losartan Potassium / Teva	25 mg Tablets, 30 and 90 and 1000 count-bottle, 100 mg Tablets, 90 and 1000 count-bottle	4/27/19	This recall was issued due to the detection of an impurity – N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) .	consumer-level
Fentanyl Citrate/Akorn	100 mcg injection	4/26/19	This recall was issued due to out of specification result for total impurity at 4% (Limit: NMT 3.0%) during routine stability testing at 12 month time point.	retail-level
Losartan potassium/ Torrent	25 mg Tablets	4/24/19	This recall was issued due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited. The impurity detected in the API is N-Methylnitrosobutyric acid (NMBA).	consumer-level
Fentanyl Transdermal System/ distributed by Alvogen, Inc and manufactured by 3M Drug Delivery Systems	12 mcg/h transdermal patches	4/21/19	This recall was issued due to product mislabeling.	consumer-level
Divalproex ER/ Dr. Reddy's	250 mg Tablets, 100 and 500 count bottle	4/19/19	This recall was issued due to exposure of the product to above 50% relative humidity levels during packaging operation.	retail-level
Losartan potassium	25 mg AND 50 mg and 100 mgTablets; 90 count, Losartan potassium 25 and 50 and 100 mg Tablets; 1000 count,	4/18/19	This recall was issued due to the detection of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited. The impurity detected in the API is N-Methylnitrosobutyric acid (NMBA).	consumer-level
Losartan Potassium/Hydrochlorothiazide	50mg/12.5mg Tablets, 30 count, 50mg/12.5mg Tablets, 90 count, 50mg/12.5mg Tablets, 1000 count, 100mg/12.5mg Tablets, 30 count, 100mg/12.5mg Tablets, 90 count, 100mg/25mg Tablets, 1000 count, 100mg/25mg Tablets, 90 count, 100mg/25mg Tablets, 1000 count	4/18/19	This recall was issued due to the detection of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited. The impurity detected in the API is N-Methylnitrosobutyric acid (NMBA).	consumer-level
Bismuth Subsalicylate Oral Suspension/ Lohxa	262mg/15mL and 20 mg/5mL unit-dose cups	4/17/19	This recall was issued because the label contains an incorrect Exp Date.	class II
Gavilyte-N Oral Solution/ Lupin	N/A	4/17/19	This recall was issued because the orange and cherry flavor packets incorrectly list "natural lemon flavor" as an ingredient.	class II
Testosterone Cypionate / Cipla	100 AND 200 mg/mL injection	4/11/19	This recall was issued due to confirmed presence of particulate matter.	retail-level
8.4% Sodium Bicarbonate Injection/ Hospira	50 mEq single-dose vials	4/10/19	This recall was issued because of the presence of particulate matter, confirmed as glass.	class I
Aphrodisiac Capsules/ SD Import	All lots of Aphrodisiac (Capsules) UPC Code 644118128135	4/9/19	due to presence of undeclared Sildenafil.	voluntary
Pravastin sodium/ Glenmark	20 mg tablets	4/9/19	This recall was issued due to the presence of a foreign tablet.	retail-level
Glipizide ER/ American Health Packaging	2.5 mg Tablets	4/9/19	This recall was issued due to dissolution failure at time zero of the repackaged lot.	retail-level
Nystatin/ Akorn	100,000 unit/ mL oral suspension 473 mL bottle	4/5/19	This recall was issued due to an out of specification result observed for unknown impurity at 4.1% during stability testing at 18 months, controlled room temperature, sideways, storage condition.	retail-level
Combigan/ Allergan, Inc	0.2%/0.5% 5 mL	4/3/19	This recall was issued due to cGMP Deviations.	class II
Kopi Jantan Tradisional Natural Herbs Coffee		4/2/19	FDA analysis has found the product to be tainted with Sildenafil and Tadalafil.	voluntary
Clonidine/ Xgen	1000 mcg/ 10 mL single-dose vial	4/2/19	This recall was issued due to a discrepancy on the carton labeling.	retail-level

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Pantoprazole sodium	40 mg DR tablets	3/29/19	This recall was issued out of an abundance of caution due to the presence of dark brown discoloration on the edges of the tablets within the control sample of lot PA217060A.	retail-level
Valsartan/ Acetris Health	40 mg tablets	3/27/19	This recall was issued due to the detection of a trace amount of unexpected impurity N-nitrosodiethylamine (NDEA) found in finished products.	class II
Valsartan/ Acetris Health	80 mg tablets	3/27/19	This recall was issued due to the detection of a trace amount of unexpected impurity N-nitrosodiethylamine (NDEA) found in finished products.	class II
Valsartan/ Acetris Health	160 mg tablets	3/27/19	This recall was issued due to the detection of a trace amount of unexpected impurity N-nitrosodiethylamine (NDEA) found in finished products.	class II
Valsartan/ Acetris Health	320 mg tablets	3/27/19	This recall was issued due to the detection of a trace amount of unexpected impurity N-nitrosodiethylamine (NDEA) found in finished products.	class II
CHEMO DRUG SPILL KIT CS24/ Cardinal Health	CHEMO KIT	3/27/19	This recall was issued due to kit labels stating, "not made with natural rubber latex", however, Cardinal Health has become aware that the safety goggles within the kits contain natural rubber latex in the goggle strap.	retail-level
CHEMO SPILL KIT CT4004 BIO CS4/ Cardinal Health	CHEMO KIT	3/27/19	This recall was issued due to kit labels stating, "not made with natural rubber latex", however, Cardinal Health has become aware that the safety goggles within the kits contain natural rubber latex in the goggle strap.	retail-level
CHEMOPLUS PROTECTIVE WRAP-AROUND GOGGLES/ Cardinal Health	CHEMO KIT	3/27/19	This recall was issued due to kit labels stating, "not made with natural rubber latex", however, Cardinal Health has become aware that the safety goggles within the kits contain natural rubber latex in the goggle strap.	retail-level
CHEMOTHER SPILL KIT CS6/ Cardinal Health	CHEMO KIT	3/27/19	This recall was issued due to kit labels stating, "not made with natural rubber latex", however, Cardinal Health has become aware that the safety goggles within the kits contain natural rubber latex in the goggle strap.	retail-level
Testosterone Cypionate	100 mg/mL injection, 200 mg/mL injection	3/26/19	This recall was issued due to confirmed presence of particulate matter.	retail-level
CLINDAMYCIN	600 MG/4 ML, 900 MG/6 ML, 300 MG/2 ML ADDVAN	3/26/19	This recall was issued due to product not meeting specification for impurities at expiry.	hospital-level
Cleocin Phos	0.6 gm 4 mL, 0.6 gm 4 mL single vial, 0.9 gm 6 mL, 0.9 gm 6 mL single vial, 300 mg / 2 mL, 300 mg / 2 mL single vial	3/26/19	This recall was issued due to product not meeting specification for several specified impurities.	retail-level
Fayosim™	91 Tablets	3/26/19	This recall was issued due to out of specification results observed in related substance test (Any Other Individual Impurity and Total impurities) in Ethinyl Estradiol Tablets USP 0.01mg at 12 month long term stability study.	retail-level
Losartan Potassium/ Camber Pharmaceuticals, Inc	25mg, 50mg, and 100mg tablets	3/25/19	due to the detection of trace amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA) a possible process impurity or contaminant in an active pharmaceutical ingredient, manufactured by Hetero Labs Limited, (API manufacturer).	voluntary
Alprazolam	0.25 mg, 0.5 mg, 1 mg tablet	3/21/19	This recall was issued due to related compound results obtained during routine stability testing that were elevated above specifications.	retail-level
Diclofenac	1.5% Topical Solution	3/21/19	This recall was issued due to the potential leakage of drug product.	retail-level
BLUEFUSION Capsules/ Ata Int. Inc.		3/21/19	FDA analysis has found the product to be tainted with sildenafil, tadalafil, desmethyl carbodenafil, dithiodesmethyl carbodenafil, scutellarin and daidzein	voluntary
Telmisartan and Hydrochlorothiazide	40mg/12.5 mg tablets	3/20/19	This recall was issued because the product is out of specification for blend uniformity.	class II

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Telmisartan and Hydrochlorothiazide	80mg/12.5 mg tablets	3/20/19	This recall was issued because the product is out of specification for blend uniformity.	class II
Telmisartan and Hydrochlorothiazide	80 mg/25 mg tablets	3/20/19	This recall was issued because the product is out of specification for blend uniformity.	class II
DG™/health NATURALS baby Cough Syrup + Mucus	2-fluid ounce (59 mL) bottles	3/20/19	because it has the potential to be contaminated with Bacillus cereus/ Bacillus circulans. Bacillus cereus in food products has the potential to produce two forms of gastrointestinal illness, one being a syndrome primarily of vomiting, and the other of diarrhea.	voluntary
Levoleucovorin Injection/ Alidac Pharmaceuticals Limited	250 mg/25 mL	3/18/19	The Levoleucovorin Injection is being recalled due to the presence of particulate matter identified as copper salts. The particulate matter was discovered during 12-month stability testing.	voluntary
Sodium Bicarbonate Injection	50 mEq/50 mL, case pack 4 x 25, 50mL	3/18/19	This recall was issued to the presence of particulate matter, confirmed as glass.	hospital-level
Losartan potassium/ Kingston Pharma, LLC of Massena	50 mg tablets	3/15/19	This recall was prompted due to Torrent Pharmaceuticals LTD issuing a voluntary nationwide recall of Losartan tablets, USP, due to the detection of trace amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA) a possible process impurity or contaminant in an active pharmaceutical ingredient, manufactured by Hetero Labs Limited, (API manufacturer).	consumer-level
Losartan potassium/ Legacy Pharmaceutical Packaging	25 mg, 50 mg and 100 mg tablets	3/15/19	This recall was prompted due to Camber Pharmaceuticals, Inc. issuing a voluntary nationwide recall of Losartan tablets, USP, due to the detection of trace amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA) a possible process impurity or contaminant in an active pharmaceutical ingredient, manufactured by Hetero Labs Limited, (API manufacturer).	consumer-level
Sodium Bicarbonate Injection/ Hospira, Inc., a Pfizer company	50 mEq/50 mL (1 mEq/mL)	3/15/19	The recall was initiated due to the presence of particulate matter, confirmed as glass.	hospital-level
Testosterone/ Lupin	30 mg/1.5 mL Pump	3/15/19	This recall was issued due to repetitive product complaints indicating “pump not working”.	retail-level
Pilocarpine/ Stokes Healthcare Inc.	0.1% Ophthalmic Solution	3/13/19	The ophthalmic solution has been found to contain a higher level of the preservative benzalkonium chloride than is typical.	voluntary
Lansoprazole/ Teva	ODT 15 mg Tablet	3/13/19	This recall was issued due to a low, out of specification assay test result reported during routine stability testing activities.	retail-level
losartan potassium tablets/ Torrent Pharmaceuticals	50 mg Tablets	3/12/19	This recall was issued due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited.	consumer-level
losartan potassium /hydrochlorothiazide/ Torrent Pharmaceuticals	50 mg/12.5 mg, 100 mg/12.5 mg Tablets	3/12/19	This recall was issued due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited.	consumer-level
Docetaxel injection/ Dr. Reddy’s	80 mg / 4 mL	3/8/19	This recall was issued due to product complaint received for seal and cap defect observed in the above batch lot.	retail-level
valsartan/ Aurobindo Pharma	160 mg tablets blister pack, 160 mg tablets carton	3/7/19	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).	consumer-level
Valsartan Tablets/ Aurobindo Pharma	160 mg (100 count Unit Dose Blisters)	3/7/19	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).	consumer-level

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Valsartan/ Acetris	40 mg tablets 30 count bottle, 80, 160, 320mg tablets 90 count bottle	3/6/19	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.	consumer-level
Valsartan/ Aurobindo	40 mg tablets 30 count bottle, 80, 160, 320mg tablets 90 count bottle	3/6/19	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.	consumer-level
Amlodipine and Valsartan	10mg/160 mg Tablets 30 count bottle	3/6/19	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.	consumer-level
Aspirin Dipyridam ER/ American Health Packaging	25-200 mg (carton), 25-200 mg (individual unit dose)	3/5/19	This recall was issued due to an out of specification result for an unknown impurity in stability samples.	retail-level
Losartan potassium/ Torrent	50 mg	3/4/19	This recall was issued due to the detection of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited.	consumer-level
losartan potassium and hydrochlorothiazide/ Torrent	50 mg/12.5 mg, 100 mg/12.5 mg tablets	3/4/19	This recall was issued due to the detection of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited.	consumer-level
Losartan potassium/ Torrent	25 mg Tablets, 90 count, 25 mg Tablets, 1000 count, 50 mg Tablets, 30 count, 50 mg Tablets, 90 count, 50 mg Tablets, 1000 count, 100 mg Tablets, 90 count, 100 mg Tablets, 1000 count	2/28/19	This recall was issued due to the detection of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited. The impurity detected in the API is Methylnitrosobutyric acid (NMBA).	consumer-level
Losartan Potassium/Hydrochlorothiazide/ Torrent	50mg/12.5mg Tablets, 30 count, 50mg/12.5mg Tablets, 90 count, 50mg/12.5mg Tablets, 1000 count, 100mg/12.5mg Tablets, 30 count, 100mg/12.5mg Tablets, 90 count, 100mg/25mg Tablets, 30 count, 100mg/25mg Tablets, 90 count, 100mg/25mg Tablets, 1000 count	2/28/19	This recall was issued due to the detection of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited. The impurity detected in the API is Methylnitrosobutyric acid (NMBA).	consumer-level
Gamunex®-C 10%	10%	2/22/19	This withdrawal is being conducted due to a higher rate of allergic/hypersensitivity reactions, a small number of which were considered medically significant.	consumer-level
Levoleucovorin	250mg / 25 mL single-dose vial	2/5/19	This recall was issued due to the presence of sub-visible particulate matter exceeding the specification.	consumer-level
Levetiracetram in 0.54% Sodium Chloride Injection	1,500 mg/100 mL (15 mg/mL) single-dose infusion bags	2/4/19	The recall, which began in October 2018, was originally initiated due to a product complaint received for mislabeling. The pre-printed text content on the infusion bag (primary container) for the lot indicates product information as Levetiracetam in 0.75% Sodium Chloride Injection (1000mg/100ml). The label on the external foil pouch has the product information as Levetiracetam in 0.54% Sodium Chloride Injection (1500mg/100ml). To date, there have been no reports of adverse events related to this recall.	voluntary

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ChemoLock Vial Spike	20mm	1/30/19	This recall was issued due to identified potential for burr particulate in one lot of ChemoLock Vial Spike 20mm, originating from the protective cap used in the assembly of the device.	retail-level
Bimatoprost Ophthalmic Solution	0.03% 5mL and 7.5mL	1/29/19	This recall was issued due to the out of specification results observed in any other individual impurity and total impurities.	retail-level
Clobetasol propionate	0.05% cream 30 grams and 60 grams	1/29/19	This recall was issued due to OOS results observed for a preservative, Imidurea, during routine stability testing at 9 months at room temperature, sideways, storage conditions.	retail-level
Infants' Ibuprofen Concentrated Oral Suspension	(NSAID) 50 mg per 1.25 mL, in 0.5 oz. bottle & 50 mg per 1.25 mL, in 1.0 oz. bottle	1/29/2019 (updated from 12/6/2018)	The recalled lots of the product have been found to potentially have higher concentrations of ibuprofen.	retail-level
Silver Bullet 10x	10 capsule package	1/29/19	This recall has been initiated because the product was found to contain undeclared sildenafil and tadalafil, the active ingredient in Viagra and Cialis respectively, which are PDE-5 inhibitors.	voluntary
Bromsite Ophthalmic Solution	0.075%	1/28/19	This recall was issued due to an unidentified equipment issue that caused leaking/damaged bottles, thus there is a possibility of a lack of sterility assurance.	retail-level
EEMT™	HS 0.625 mg/1.25 mg and 1.25 mg/2.5 mg and tablets	1/23/19	This recall was issued due to sub-potency and cGMP violations.	class II
Olmesartan Medoxomil and Hydrochlorothiazide	40 mg/25 mg Tablets, 90 count & 30 Count bottles	1/23/19	This recall was issued due to failed dissolution specifications.	class II
Cephalexin for Oral Suspension	USP 250mg/5mL, 200 mL	1/23/19	This recall was issued due to CGMP Deviation; manufacturing batch record could not be located.	class II
Sterile Saline and Sterile Water for Inhalation	Device	9/5/2017 **Updated 01/23/2019	Smiths Medical is recalling the sterile saline and sterile water products for inhalation due to the potential exposure to infectious agents (bacillus infantis and staphylococcus epidermidis) because of damage to the containers used to package the finished products. Use of these products in patients could result in infection and may require treatment with antibiotics. Serious or untreated infections could result in patient death. The company initiated a voluntary recall on September 5, 2017. That recall covered several products, including some that are outside the scope of this notice. The FDA is auditing the recall to ensure the company has notified all affected customers and that affected product has been returned.	class I
Curaplex Epi Safe Administration and Training	Vials	1/23/19	This recall was issued due to incorrect or missing Lot and/or exp date: vials of epinephrine within kit 8600-01100 expired on December 2018, but the outer kit label has an expiration date of January 2020. In addition, device component (syringe) may lack 510(k) clearance.	class II
losartan potassium and hydrochlorothiazide	50 mg/ 12.5 mg and 100 mg/ 12.5 mg tablets	1/22/19	The previous Torrent losartan recalls only involved single ingredient losartan potassium. 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 finished drug product is N-nitrosodiethylamine (NDEA).	consumer-level

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losartan potassium and hydrochlorothiazide	LOSARTAN POTASSIUM TAB, USP 100mg,30count bottles; LOSARTAN POTASSIUM TAB, USP 100mg,90count bottles; LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles; LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles; LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles; LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles; LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles; LOSARTAN POTASSIUM TAB, USP 50mg,30count bottles; LOSARTAN POTASSIUM TAB, USP 50mg,90count bottles; LOSARTAN POTASSIUM TAB, USP 50mg,90count bottles; LOSARTAN POTASSIUM TAB, USP 50mg,1000-count bottles; LOSARTAN POTASSIUM TAB, USP 25mg,90count bottles; LOSARTAN POTASSIUM and HYDROCHOLOROTHIAZIDE TABLETS, USP 50mg/12.5 mg, 90 count bottles. LOSARTAN POTASSIUM and HYDROCHOLOROTHIAZIDE TABLETS, USP 50mg/12.5 mg, 1000 count bottles. LOSARTAN POTASSIUM and HYDROCHOLOROTHIAZIDE TABLETS, USP 100 mg/12.5 mg, 90 count bottles. LOSARTAN POTASSIUM and HYDROCHOLOROTHIAZIDE TABLETS, USP 100 mg/12.5 mg, 90 count bottles. LOSARTAN POTASSIUM and HYDROCHOLOROTHIAZIDE TABLETS, USP 100 mg/12.5 mg, 1000 count bottles. LOSARTAN POTASSIUM and HYDROCHOLOROTHIAZIDE TABLETS, USP 100 mg/12.5 mg, 1000 count bottles.	1/22/19	Torrent Pharmaceuticals Limited is expanding its voluntary recall from 10 lots of Losartan potassium tablets USP to include 6 lots of Losartan potassium and hydrochlorothiazide tablets, USP, to the consumer level due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited.	consumer-level
Irbesartan products	Irbesartan 300 mg tablets 90 count; Irbesartan/hydrochlorothiazide 300 mg/12.5 mg tablets 90 count; Irbesartan/hydrochlorothiazide 150 mg/12.5 mg tablets 90 count; Irbesartan/hydrochlorothiazide 300 mg/12.5 mg tablets 30 count; Irbesartan/hydrochlorothiazide 150 mg/12.5 mg tablets 30 count	1/18/19	This recall was issued due to the detection of trace amount on an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceuticals.	consumer-level
Docusate Sodium	100 mg soft gel caps	1/16/19	This recall was issued due to a secondary labeling error.	retail-level
Nevirapine ER	400 mg Tablets	1/16/19	This recall was issued due to failure of dissolution test at the 3-month long-term stability interval.	retail-level
Vecuronium Bromide for Injection	10 mg (carton), 10 mg (vial), 20 mg (carton),20 mg (vial)	1/16/19	This recall was issued because foreign matter identified as glass was detected in one (1) vial.	class I
Ceftriaxone	Ceftriaxone for Injection 250 mg; Ceftriaxone for Injection 500 mg; Ceftriaxone for Injection 1 g; Ceftriaxone for Injection 2 g (Single vials and cartons)	1/16/19	This recall was issued due to repetitive product complaints indicating grey flecks in reconstituted vials.	class I
Ceftriaxone Sodium Injection	Ceftriaxone for Injection 250mg Ceftriaxone for Injection 250mg Ceftriaxone for Injection 500mg Ceftriaxone for Injection 500mg Ceftriaxone for Injection 1g Ceftriaxone for Injection 1g Ceftriaxone for Injection 2g	1/7/2019 **1/16/2019	This recall was issued due to repetitive product complaints indicating grey flecks in constituted vials. Note: This recall was originally received as CVS Retail-Level Recall Notice 18-178 on 12/21/18. FDA classified this as a Class I Recall on 01/16/2019.	class I
Vecuronium Bromide for Injection	Vecuronium Bromide for Injection 20mg Vecuronium Bromide for Injection 10mg Vecuronium Bromide for Injection 10mg Vecuronium Bromide for Injection 10mg	1/9/19	Sun Pharmaceutical Industries announced a voluntary recall of 3 lots of Vecuronium Bromide for Injection 10mg and 1 lot of Vecuronium Bromide for Injection 20mg after the product was found to contain glass.	voluntary
Rhino 5k capsules	5000mg 30 capsules	1/8/19	Happy Together, Inc. Boynton Beach, FL is voluntarily recalling all lots within expiry of the Rhino 5k capsules to the consumer level. FDA analysis founds these products to be tainted with sildenafil and Tadalafil. Sildenafil/Tadalafil is an FDA approved drug for the treatment of erectile dysfunction, the presence of sildenafil in the Rhino 5k products renders them unapproved drugs for which safety and efficacy have not been established, therefor subject to recall.	voluntary
Estradiol Vaginal	Estradiol Vaginal 10 mcg Inserts 8 each Estradiol Vaginal 10 mcg Inserts 18 each	1/4/19	This recall was issued due to difficulty in pushing the plunger of the applicator.	consumer-level

2019 Drug Recall List

Losartan Potassium	Losartan Potassium 25 mg Tablets, 90 count Losartan Potassium 50 mg Tablets, 30 count Losartan Potassium 50 mg Tablets, 90 count Losartan Potassium 50 mg Tablets, 1,000 count Losartan Potassium 100 mg Tablets, 1,000 count losartan potassium 25 mg tablets, 90 count bottle losartan potassium 50 mg tablets, 30 count bottle losartan potassium 50 mg tablets, 90 count bottle losartan potassium 50 mg tablets, 1,000 count bottle losartan potassium 100 mg tablets, 1,000 count bottle	1/3/19	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 finished drug product is N-nitrosodiethylamine (NDEA). Note: This notice contains an expanded number of impacted batches adding Losartan Potassium 25 mg Tablets and Losartan Potassium 50 mg Tablets to the ongoing recall. It also contains additional lot numbers for Losartan Potassium 100 mg Tablets that were not part of the previous Recall notice received on December 20, 2018.	consumer-level
Cefdinir Oral Suspension	125mg/5 mL 60 mL, 125mg/5 mL 100 mL, 250mg/5 mL 60 mL, 250mg/5 mL 100 mL	1/3/19	This recall was issued due to the repetitive product complaints indicating reconstituted suspension as observed to be thick.	retail-level
Ozurdex implants	Implants	1/2/19	This recall was issued due to during routine manufacturing inspection, a silicon particulate, approximately 300 microns in diameter, was observed in dispensed Ozurdex implants.	retail-level
Amlodipine and Valsartan Tablets, USP, Valsartan and HCTZ Tablets, USP and Valsartan Tablets	5mg/160mg, 5mg/160mg, 5mg/160mg, 5mg/160mg, 10mg/160mg, 10mg/160mg , 10mg/160mg, 10mg/160mg, 10mg/160mg, 10mg/160mg, 10mg /320mg, 10mg /320mg, 10mg /320mg, 10mg /320mg, 10mg /320mg, 10mg /320mg, 10mg /320mg, 5mg /320mg, 5mg /320mg, 5mg /320mg, 5mg /320mg 5mg /320mg, 5mg /320mg, 10mg/160mg, 10mg /320mg, 10mg /320mg, 320mg/12.5mg, 320mg/12.5mg, 320mg/12.5mg, 320mg/12.5mg, 320mg/12.5mg, 160mg/12.5mg, 160mg/12.5mg, 160mg/12.5mg, 160mg/12.5mg, 160mg/12.5mg 160mg/12.5mg, 160mg/12.5mg, 160mg/12.5mg 320mg/25mg, 320mg/25mg, 320mg/25mg, 320mg/25mg, 320mg/25mg, 320mg/25mg, 320mg/25mg, 320mg/25mg, 320mg/25mg, 320mg/25mg, 320mg/25mg 320mg/25mg, 320mg/25mg, 320mg/25mg 320mg/25mg, 320mg/25mg, 320mg/25mg 320mg/25mg, 320mg/25mg, 320mg/25mg, 320mg/25mg, 320mg/25mg, 80mg/12.5mg 80mg/12.5mg, 80mg/12.5mg,160mg/25mg 160mg/25mg, 160mg/25mg, 160mg/25mg 160mg/25mg, 160mg/25mg, 160mg/25mg 160mg/25mg, 160mg/25mg, 160mg/25mg, 160mg/12.5mg, 160mg/12.5mg, 320mg/25mg 320mg/25mg, 320mg/25mg, 320/25mg, 320mg 320mg. (30 count and 90 count bottles)	1/1/19	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).	consumer-level