

Drug Information Update

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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Clonidine 0.17 mg ER oral tablet	Nexiclon XR	Vertical	Treatment of hypertension
Orlistat 120 mg oral capsule	Xenical	Novartis	 Reversible inhibitor of gastrointestinal lipases indicated: For obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet To reduce the risk for weight regain after prior weight loss
Estradiol 0.25, 0.5, 0.75, 1, 1.25 mg gel packets	Divigel	EMD Serono	Treatment of moderate to severe vasomotor symptoms due to menopause
Fingolimod 0.5 mg oral capsule	Gilenya	AstraZeneca	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older
Cetrorelix acetate 0.25 mg SQ kit	Cetrotide	Vertical	For the inhibition of premature LH surges in women undergoing controlled ovarian stimulation
Roflumilast 500 mcg oral tablet	Daliresp	Novartis	Indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations



NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description	Comments
Tadliq 20 mg/5 mL (4 mg/mL) oral suspension	tadalafil	New oral suspension formulation of tadalafil indicated for the treatment of pulmonary arterial hypertension (WHO Group 1) to improve exercise ability. This is the same indication as Adcirca, which is the oral tablet dosage form of tadalafil.	New Dosage Form
Skysona 4x to 30x10 ⁶ cell/mL intravenous suspension	elivaldogene autotemcel	Novel gene therapy indicated to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy (CALD). This indication is approved under accelerated approval based on 24-month Major Functional Disability (MFD)-free survival; continued approval is contingent on a clinical benefit observed in confirmatory trials. The product consists of the patient's own CD34+ hematopoietic stem cells transduced with the lentiviral vector encoding for ABCD1 cDNA. Price will be \$3.6 million.	New Entity
Cimerli 0.3 mg/0.05 ml, 0.5 mg/0.05 mL intravitreal solution	ranibizumab-eqrn	Interchangeable biosimilar to Lucentis having all 5 indications: neovascular (wet) AMD, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, and myopic choroidal neovascularization.	Interchangeable biosimilar to Lucentis
Fylnetra 6 mg/0.6 mL subcutaneous syringe	pegfilgrastim-pbbk	Biosimilar referencing Neulasta indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.	Biosimilar to Neulasta



Drug Name	Generic Name	Description	Comments
Auvelity 45 mg-105 mg ER tablet	Dextromethorphan/ bupropion	New combination of dextromethorphan (DXM) and bupropion extended release indicated for major depressive disorder in adults.	New Combination
Pedmark 12.5 gram/100 mL (125 mg/mL) intravenous solution	sodium thiosulfate	New dosage form and indication of sodium thiosulfate that underwent the 505(b)(2) pathway and now indicated to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors.	New Strength
methocarbamol 1,000 mg tablet	methocarbamol	New 1,000 mg tablet. Was previously only available as 500 and 750 mg tablets.	New Strength
Relyvrio 3 gram-1 gram oral powder packet	sodium phenylbutyrat/taururso diol	New entity for the treatment of amyotrophic lateral sclerosis (ALS) in adults. FDA advisory committee initially voted against this in March but due to new data suggesting increased life-expectancy, another FDA advisory meeting was convened which voted in favor of approval. Data analysis was questionable and may have been performed to find a greater clinical benefit than was actually there.	New Entity
Rolvedon 13.2 mg/0.6 mL subcutaneous syringe	eflapegrastim-xnst	New leukocyte growth factor similar to Neupogen but only indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia. This is one of Neupogen's indications, however, this product lacks the remaining indications for Neupogen.	New Entity
Kyzatrex 100, 150, 200 mg capsule	testosterone undecanoate	New strength of oral testosterone that underwent 505(b)(2) pathway.	New Entity



Drug Name	Generic Name	Description	Comments
Terlivaz 0.85 mg intravenous solution	terlipressin acetate	Vasopressin receptor agonist indicated to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function.	New Entity
Furoscix 80 mg/10 mL subcutaneous wearable injector kit	furosemide	New subcutaneous formulation of furosemide indicated for the treatment of congestion due to fluid overload in adults with New York Heart Association Class II/III chronic heart failure. It is delivered by a wearable micropump placed under the skin. Bioavailablilty was 99.6% with similar efficacy to intravenous furosemide. Furoscix enables subcutaneous administration at home by the patient or a caregiver with the use of the Furoscix On-Body Infusor.	New Dosage Form
allopurinol 200 mg tablet	allopurinol	Newly available authorized generic strength of allopurinol. Was previously only available as 100 mg and 300 mg oral tablets and 500 mg vials.	NDA Authorized Generic
Fragmin 2,500 anti-Xa unit/mL subcutaneous solution	dalteparin sodium, porcine	New strength of Fragmin. Was previously only available as 2500 units/0.2 mL syringe, 5000 units/0.2 mL syringe, 7500 units/0.3 mL syringe, 10000 units/mL syringe, 12500 units/0.5 mL syringe, 15000 units/0.6 mL syringe, 18000 units/0.72 mL syringe, and 95000 units/3.8 mL vial. This version is 10000 units/4 mL vial (2500 units/mL).	New Strength



NEW INDICATIONS (EXISTING DRUGS)

†Bolded items reflect newly approved indication; strikethrough of removed indication/age limit/etc.

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication ⁺
Orkambi	lumacaftor/ivacaftor 75 mg/94 mg, 100 mg/125 mg, 150 mg/188 mg oral granule packet	Vertex	For the treatment of cystic fibrosis (CF) in patients age d 1 2 -year s and older who are homozygous for the F508del mutation in the CFTR gene
Pedmark	sodium thiosulfate injection 12.5 g/100 mL for intravenous infusion	Fennec	To reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors. (Previously used for acute cyanide poisoning but this is a unique dosage form and indication)
Dupixent	dupilumab 100 mg/0.67 mL, 200 mg/1.14 mL, and 300 mg/2 mL syringes; 200 mg/1.14 mL and 300 mg/2 mL pens	Regeneron	 For the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable Add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma Add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP) For the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE) For the treatment of adult patients with prurigo nodularis (PN)
Retevmo	selpercatinib 40, 80 mg oral capsules	Loxo Oncology	 Adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a rearranged during transfection (RET) gene fusion, as detected by an FDA-approved test



Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication ⁺
			 Adult and pediatric patients 12 years of age and older with advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation, as detected by an FDA-approved test, who require systemic therapy¹ Adult and pediatric patients 12 years of age and older with advanced or metastatic thyroid cancer with a RET gene fusion, as detected by an FDA-approved test, who require systemic therapy and who are radioactive iodine- refractory (if radioactive iodine is appropriate)¹ Adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options¹ ¹This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
Firdapse	amifampridine 10 mg oral tablet	Catalyst	For the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults and pediatric patients 6 years of age and older
Boostrix TDAP	diphth, Pertuss(Acell), T Et Vaccine	GlaxoSmithKline	 Vaccine indicated for: Active booster immunization against tetanus, diphtheria, and pertussis in individuals aged 10 years and older Immunization during the third trimester of pregnancy to prevent pertussis in infants younger than 2 months of age
Moderna COVID Bivalent (6 years and up) EUA	COVID-19 vaccine, bivalent (Moderna)/PF	Moderna	 Authorized for use in individuals 12 6 years of age and older as a single booster dose administered at least 2 months after either: Completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine, or Receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine



Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication ⁺
Rinvoq	upadacitinib 15, 30, 45 mg ER tablet		 Adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers Adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable Adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers Adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers
Vemlidy	tenofovir alafenamide 25 mg oral tablet	Gilead	For the treatment of chronic hepatitis B virus infection in adults and pediatric patients 12 years of age and older with compensated liver disease



RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Antica Farmacista Hand Sanitizer Ocean Citron (ethyl alcohol, denatured 65%) packaged in 473 mL/16 fl. oz. bottles, Dist. By Antica Farmacista Seattle, WA 98122 UPC 8 47005 00450 9	Class I	Drugs	Lot #: 1166A Exp. 6/18/2023	Chemical Contamination: product found to contain benzene	Salon Technologies International Inc
Neoral soft gelatin capsules (cyclosporine capsules, USP) Modified, 25 mg, Rx Only, 30 Soft Gelatin Capsules per carton, Mfg by: Novartis Pharmaceuticals Corporation, East Hanover, NJ 07936, NDC # 0078-0246-15.	Class II	Drugs	Lot # APCD162, Exp. 01/2023	CGMP deviations: Out of specification results obtained during routine stability testing for ethanol content.	Novartis Pharmaceutic als Corporation
Budesonide Inhalation Suspension 0.25mg/2mL, For Inhalation Only, Rx Only, 1 envelope x five 2 mL Single Dose Ampules per pouch, Sterile Suspension, Manufactured by: Cipla Ltd., India, Manufactured for Cipla USA Inc., Warren NJ, NDC# 69097-318-86.	Class II	Drugs	Lot #s: GA20080, GA20081, GA20094, Exp. 01/2024	Lack of Assurance of Sterility	CIPLA
Rifampin Capsules, USP, 150 mg, 30-count bottle, Rx only, Distributed by: Akorn Operating Company, LLC, Gurnee, IL 60031, NDC 61748-015-30	Class II	Drugs	Lot#: 3192818, Exp 10/31/2022; 3199700, Exp 03/31/2023; 3203853, Exp 02/29/2024	Failed impurities/degradation specifications: Finished product exceeds the 5 ppm interim limit for 1-Methyl-4-Nitrosopoperazine (MNP).	Akorn, Inc.
Rifampin Capsules, USP, 300 mg, a) 30-count bottle (NDC 61748-018-30), b) 60-count bottle (NDC 61748-018-60), c) 100-count bottle (NDC 61748-018-01), Rx only, Distributed by: Akorn Operating Company, LLC, Gurnee, IL 60031.	Class II	Drugs	Lot#: a) 3192827, Exp 10/31/2022; 3196136, Exp 12/31/2022; 3202198, Exp 07/31/2023; 3203658, Exp 07/31/2023; 3209114, Exp 11/30/2023; 3203851, Exp	Failed impurities/degradation specifications: Finished product exceeds the 5 ppm interim limit for 1-Methyl-4-Nitrosopoperazine (MNP).	Akorn, Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			02/29/2024; b) 3191254, Exp 09/30/2022; 3192820, Exp 09/30/2022; 3192822, Exp 10/31/2022; 3192824, Exp 10/31/2022; 3192825, Exp 10/31/2022; 3196141, Exp 01/31/2023; 3196143, Exp 02/28/2023; 3203870, Exp 11/30/2023; 3203871, Exp 02/29/2024; c) 3190636, Exp 09/30/2022; 3192813, Exp 09/30/2022; 3196132, Exp 12/31/2022; 3196133, Exp 12/31/2022; 3196138, Exp 01/31/2023; 3199702, Exp 03/31/2023; 3199703, Exp 03/31/2023		
Ampicillin for Injection, USP, 2 grams/vial NDC 67457-352-02, packaged in 10 x 2 g vials per carton NDC 67457-352-10, Rx only, Mylan Manufactured in India for: Mylan Institutional LLC Rockford, IL 61103 U.S.A	Class II	Drugs	Lot 7105130, exp 9/2023	Presence of Particulate Matter: A complaint was received for the presence of a single strand of hair in one vial.	Viatris Inc
Sanitizing Hand Spray 80% (alcohol 80% v/v) Packaged in 2 FL OZ (60 mL) bottles, Salon Technologies International 8810 Commodity Circle STE 22-23, Orlando, FL 32819, UPC 6 96952 12904 5	Class II	Drugs	Lot #: 20-018 Exp. 4/3/2023	GMP Deviations: FDA analysis found product to contain acetaldehyde and acetal above specification limits.	Salon Technologies International Inc



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Aminophylline Injection, USP 250 mg/10 mL (25 mg/mL) 25x10 mL Single-dose vial, Rx only, Distributed by Hospira, Inc. Lake Forest, IL 60045 USA. NDC 0409-5921-16 (vial) 0409-5921-01 (carton)	Class II	Drugs	Lot: 30-137-DK Exp. 1 DEC. 2022	Presence of Particulate Matter: A complaint was received for the presence of a hair in one vial.	Pfizer Inc.
Arformoterol Tartrate Inhalation Solution, 15 mcg/2mL, 2 mL Sterile Unit-Dose Vial packaged in 5 x 2 mL Sterile Unit-Dose Vials per pouch, NDC 69097-168-48; 60 (12 x 5) x 2 mL Sterile Unit-Dose Vials per carton, NDC 69097-168-64, Rx Only, Manufactured by: Cipla Ltd., Indore SEZ, Pithampur, India; Manufactured for: Cipla USA, Inc., 10 Independence Boulevard, Suite 300, Warren, NJ 07059.	Class II	Drugs	Batch No: IA10082, IA10083, IA10084, IA10085, IA10086, exp. date 01/2023; IA10122, IA10123, IA10124, IA10125, IA10126, IA10127, IA10128, IA10129, IA10130, exp. date 02/2023	Lack of Assurance of Sterility: environmental monitoring failure.	CIPLA
Skincell Mole & Skin Corrector Serum, 1 fl. oz./30 mL jars, Distributed By: Justified Laboratoires, Arlington, TX 76011 USA UPC 8 10077 53220 1	Class II	Drugs	All lots remaining within expiry.	Marketed Without An Approved NDA/ANDA; Unapproved new drug	Justified Laboratories
Skincell Mole & Skin Corrector Serum, 1 fl. oz./30 mL jars, Distributed By: Justified Laboratoires, Arlington, TX 76011 USA UPC 8 10077 53221 8	Class II	Drugs	All lots remaining within expiry.	Marketed Without An Approved NDA/ANDA; Unapproved new drug	Justified Laboratories
Acyclovir Sodium Injection, 500mg/10mL (50mg/mL), 10 mL Single Dose Vial, Rx only, Distributed by: AuroMedics Pharma LLC, 279 Princeton-Hightstown Rd., E. Windsor, NJ 08520; Made in India, NDC 55150-154-10.	Class II	Drugs	Lot: AC22006, Exp 08/2023	Presence of Particulate Matter: Customer complaint for a dark red, brown and black particulate floating inside vial.	AuroMedics Pharma LLC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Flunisolide Nasal Solution, USP 0.025%, 25 mL bottles, Rx only, Manufactured for: Ingenus Pharmaceuticals, LLC Orlando, FL 32839-6408; NDC 50742-317-25 UPC 3 50742 31725 7	Class II	Drugs	Lot #: 22E040 Exp. 07/2023; 22F038 Exp. 08/2023	Out of specification for related substances (impurities).	Ingenus Pharmaceutic als Llc
Rifampin Capsules, USP, 300 mg, packaged in a) 30-count bottle (NDC 51407-323-30), b) 60-count bottle (NDC 51407-323-60), c) 100- count bottle (NDC 51407-323-01), Rx only, Manufactured by Patheon Pharmaceuticals Inc., OH, Packaged by GSMS, Incorporated, CA.	Class II	Drugs	Lot#: a) GS041430, GS041941, Exp 1/31/2023; GS041315, GS042991, GS043027, GS043367, GS043501, GS044421, Exp 3/31/2023; b) GS041431, GS041799, GS042287, GS042414, GS042879, Exp: 1/31/2023; GS041316, GS042992, GS043368, GS043579, Exp 3/31/2023; c) GS041429, GS041877, Exp 1/31/2023; GS041317, GS043028, GS043366, GS044422, Exp 3/31/2023	Failed impurities/degradation specifications: Finished product exceeds the 5 ppm interim limit for 1-Methyl-4-Nitrosopoperazine (MNP).	Golden State Medical Supply Inc.
Rifampin Capsules, USP, 150 mg, 30-count bottle, Rx only, Manufactured by Patheon Pharmaceuticals Inc., OH, Packaged by GSMS, Incorporated, CA, NDC 51407-322-30	Class II	Drugs	Lot #: GS036715, GS037569, GS038132, GS038665, GS038750, GS039565, GS039997, GS040673, Exp 10/31/2022; GS040674, GS041237, GS041652, GS042152, GS043365, Exp 3/31/2023; GS045441,	Failed impurities/degradation specifications: Finished product exceeds the 5 ppm interim limit for 1-Methyl-4-Nitrosopoperazine (MNP).	Golden State Medical Supply Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
0.9% Sodium Chloride Injection, USP, Each 100 mL contains: SODIUM CHLORIDE, USP - 900 mg, WATER FOR INJECTION, USP - qs, 1000mL Bag, 12 PK, Rx Only, Fresenius Medical Care North America, Waltham, MA 02451, NDC 49230-300-10	Class II	Drugs	GS045677, GS046111, Exp 2/29/2024. Lot # 22EU05043, EXP 5/21/2023; 22HU05018, EXP 6/9/2023; 22HU05019, EXP 6/10/2023; 22HU05025, 22HU05026, EXP 6/12/2023; 22HU05049, EXP 6/22/2023; 22HU05053, EXP 6/24/2023; 22HU05054, 22HU05055, EXP 6/25/2023; 22HU06027, EXP 6/11/2023; 22HU06049, EXP 6/23/2023; 22HU06055, EXP 6/24/2023; 22HU06056, EXP 6/25/2023; 22JU05008, EXP 7/4/2023; 22KU06036, EXP 8/19/2023; 22JU06023, EXP 7/8/2023	Lack of Assurance of Sterility: Leakage of 0.9% Sodium Chloride for Injection, 1L, 12pk Saline Solution.	Fresenius Medical Care Holdings, Inc.
Clonidine Hydrochloride Tablets, USP, 0.3 mg, 100-count bottle, Rx Only, Manufactured by: UNICHEM LABORATORIES LTD. Pilerne Ind. Estate, Pilerne, Bardez, Goa 403 511, India Manufactured for: UNICHEM	Class III	Drugs	Lot # GCLH22005, exp. date 02/29/2024	Product mix-up:0.2 mg strength Clonidine Hydrochloride Tablets, USP in a 100-count bottle of 0.3 mg strength Clonidine Hydrochloride Tablets,	UNICHEM PHARMACEUT ICALS USA INC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
PHARMACEUTICALS (USA), INC. East Brunswick, NJ 08816. NDC# 29300-137-01					
ClomiPRAMINE Hydrochloride Capsules, USP 25mg, 100-count bottles, Rx only, LEADING PHARMA, Manufactured by: Leading Pharma, LLC, Fairfield, NJ 07004, NDC 69315-167-01	Class III	Drugs	Lot#: B14221, Exp. Date 02/2023	Superpotent Drug: Assay value found to be 110.6% in Chlomipramine Hydrocholoride capsules	Leading Pharma, LLC
Xolegel (ketoconazole) gel 2%, 45 gram tubes, Rx only, Manufactured by: DPT Laboratories, San Antonio, TX 78215, NDC 16110-080-45	Class III	Drugs	Lot #: RGAF, Exp. Date 12/2022	Failed Viscosity specification: Slightly higher OOS results obtained for viscosity	ALMIRALL, LLC
Esomeprazole Magnesium Delayed-Release Capsules, USP 20mg, Rx Only, 90 Capsules per bottle, Manufactured by: Ohm Laboratories Inc. New Brunswick, NJ 08901, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, NDC 63304-734-90.	Class III	Drugs	Lot AC14299, Exp 12/2022	Superpotent Drug: Out of specification for assay at the 12-month timepoint.	SUN PHARMACEUT ICAL INDUSTRIES INC
Esomeprazole Magnesium Delayed-Release Capsules, USP, 40mg, Rx Only, 90 Capsules per bottle, Manufactured by: Ohm Laboratories Inc. New Brunswick, NJ 08901, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, NDC 63304-735-90.	Class III	Drugs	Lot AC14304, Exp 12/2022.	Superpotent Drug: Out of specification for assay at the 12-month timepoint.	SUN PHARMACEUT ICAL INDUSTRIES INC
oxyTOCIN 30 Units/500 mL (0.06 Units/mL) added to 0.9% Sodium Chloride, Injection for IV Use, High Alert, This is a Compounded Product for Institutional or Office Use Only, Not for Resale, QuVa PHARMA 519 Route	Class III	Drugs	Lot 30027403, BUD 11/14/2022	Incorrect Product Formulation: Oxytocin 30 units was added to an IV bag of 0.45% Sodium Chloride (500mL) instead of 0.9% Sodium Chloride (500mL).	QuVa Pharma, Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
173, Bloomsbury, NJ 08804, Total volume: 500 mL bag, NDC: 70092-1068-07.					
Antibacterial Foaming Wash with Hydria Moisturizing Formula, Cucumber-Melon Scent, 1250 mL (42 fl oz.), Manufactured for: Triple S, 800-323-2251, Made in USA, NDC 11429-1010-8	Class III	Drugs	Lot #: VDAF017, Exp 4/24; VDAF018, Exp 5/24	Labeling: Not Elsewhere Classified - Incorrect label-incorrect scent listed on label.	Woodbine Products Co Inc
Phytonadione Injectable Emulsion USP, 10 mg/mL, 25x 1 mL single dose ampules per carton, Rx only, Distributed by: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540, NDC 43598-405-16	Class III	Drugs	Lot # ACB101, Exp 03/2023	Failed Stability Specifications: Out of specification results reported at 12-month stability testing for aluminum content.	Dr. Reddy's Laboratories, Inc.
Tranexamic Acid Injection, USP, 1000mg per 10 mL (100mg / 10mL), 10mL single-dose vial, Rx Only, Distributed by: AuroMedics Pharma LLC E. Windsor, NJ 08520, Made in India, NDC 55150-188-10	Class III	Drugs	Lot: CTA210006, Exp. 02/2024	Presence of Particulate Matter: Piece of metal found in a vial	AuroMedics Pharma LLC
Walgreens Sinus Pressure, Pain & Cough ACETAMINOPHEN/ PAIN RELIEVER DEXTROMETHORPHAN HBr/ COUGH SUPPRESSANT GUAIFENESIN/ EXPECTORANT PHENYLEPHRINE HCI/ NASAL DECONGESTANT Maximum Strength Decongestant Free DISTRIBUTED BY: WALGREENS CO. 200 WILMOT RD., DEERFIELD, IL 60015 walgreens.com	Class III	Drugs	P129910 P129911 P130240	Boxes mislabeled to read "Decongestant Free", but the product contains Phenylephrine HCI 5mg	LNK International, Inc.

*Please refer to FDA website for further information at: <u>http://www.fda.gov/Safety/Recalls</u>



CURRENT DRUG SHORTAGES

Below is the list of drugs listed by the FDA as currently in shortage . Please refer to the FDA website for more information at: <u>https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm</u>

Generic Name or Active Ingredient

Albuterol Sulfate Inhalational Solution Alprostadil (Muse) Suppository **Amifostine Injection** Amino Acids **Amoxapine Tablets** Amphetamine; Dextroamphetamine Tablets **Atropine Sulfate Injection** Azacitidine for Injection Azithromycin (Azasite) Ophthalmic Solution 1% Bacteriostatic 0.9% Sodium Chloride Injection **Bacteriostatic Water for Injection** Belatacept (Nulojix) Lyophilized Powder for Injection **Belladonna and Opium Suppositories Bumetanide Injection** Bupivacaine Hydrochloride and Epinephrine Injection **Bupivacaine Hydrochloride Injection** Calcium Disodium Versenate Injection Calcium Gluconate Injection **Cefazolin Injection Cefixime Oral Capsules Cefotaxime Sodium Injection** Cefotetan Disodium Injection Chloroprocaine Hydrochloride Injection Conivaptan Hydrochloride (Vaprisol) in 5% Dextrose Plastic Container Conjugated Estrogens/Bazedoxifene (DUAVEE) Tablet, Film Coated Cyclopentolate Ophthalmic Solution Cytarabine Injection **Dacarbazine Injection** Desmopressin Acetate Nasal Spray **Dexamethasone Sodium Phosphate Injection Dexmedetomidine Injection Dextrose 10% Injection Dextrose 25% Injection** Dextrose 5% Injection **Dextrose 50% Injection Diazepam Rectal Gel Diflunisal Tablets Digoxin Injection**



Diltiazem Hydrochloride Injection Disopyramide Phosphate (Norpace) Capsules Dobutamine Hydrochloride Injection Dopamine Hydrochloride Injection Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution **Enalaprilat Injection** Epinephrine Injection, 0.1 mg/mL Epinephrine Injection, Auto-Injector Erythromycin Ophthalmic Ointment **Etomidate Injection** Fentanyl Citrate (Sublimaze) Injection Floxuridine for Injection Fludarabine Phosphate Injection **Fluorescein Injection** Flurazepam Hydrochloride Capsules **Fluvoxamine ER Capsules Furosemide Injection Gentamicin Sulfate Injection Guanfacine Hydrochloride Tablets** Heparin Sodium and Sodium Chloride 0.9% Injection Hydromorphone Hydrochloride Injection Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert **Ibutilide Fumarate Injection** Indigotindisulfonate Sodium Injection **Iodixanol Injection Iohexol Injection Iomeprol** injection Iopromide (Ultravist) Injection Isoniazid Injection **IV Fat Emulsion Ketamine Injection Ketoprofen Capsules Ketorolac Tromethamine Injection** Leucovorin Calcium Lyophilized Powder for Injection Leuprolide Acetate Injection Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags Lidocaine Hydrochloride (Xylocaine) Injection Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine Lithium Oral Solution Lorazepam Injection Mannitol Injection Mepivacaine Hydrochloride Injection Methyldopa Tablets Methylprednisolone Acetate Injection Metronidazole Injection Midazolam Injection



Morphine Sulfate Injection Multi-Vitamin Infusion (Adult and Pediatric) **Nizatidine Capsules Oxytocin Injection** Paclitaxel Injection (protein-bound particles) Pantoprazole Sodium for Injection Parathyroid Hormone (Natpara) Injection Pentostatin Injection **Physostigmine Salicylate Injection Potassium Acetate Injection** Potassium Chloride Concentrate Injection Promethazine (Phenergan) Injection **Propofol Injectable Emulsion Remifentanil Injection Rifampin Capsules Rifampin Injection Rifapentine Tablets Ropivacaine Hydrochloride Injection** Semaglutide (Ozempic) Injection Semaglutide (WEGOVY®) Injection Sincalide (Kinevac) Lyophilized Powder for Injection Sodium Acetate Injection Sodium Bicarbonate Injection Sodium Chloride 0.9% Injection Bags Sodium Chloride 14.6% Injection Sodium Chloride 23.4% Injection Sodium Chloride Injection USP, 0.9% Vials and Syringes Sodium Phosphates Injection Sterile Water for Injection Streptozocin (Zanosar) Sterile Powder Sufentanil Citrate Injection Sulfasalazine Tablets Technetium TC-99M Mebrofenin Injection Technetium Tc99m Succimer Injection (DMSA) Teprotumumab-trbw Triamcinolone Acetonide Injectable Suspension Triamcinolone Hexacetonide Injectable suspension Trimethobenzamide Hydrochloride Capsules Valproate Sodium Injection Vandetanib Tablets Vecuronium Bromide for Injection Verteporfin (Visudyne) Injection