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Drug Information

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The Drug Information Center has a wealth of information to help you understand how drugs impact your health as well as their place in today's healthcare environment.

The information you'll find in the center covers a number of important topics ranging from drug safety and side effects to medication costs and errors. You'll also notice from time to time we will display drug alerts. These alerts will let you know when a New Drug is put on the market, if a drug has been recalled, and if a drug has a new indication or use.

Drug Name	Drug Reason	Date
Livmarli The Food and Drug Administration (FDA) expanded approval of Livmarli® (maralixibat oral solution) to include the treatment of cholestatic pruritus in individuals as young as 3 months old with Alagille syndrome. Source: FDA website	Expanded Indication	3/13/2023
Evkeeza The Food and Drug Administration (FDA) expanded approval of Evkeeza® (evinacumab-dgnb injection) to include children ages 5 to 11 years for the treatment of homozygous familial hypercholesterolemia. Source: FDA website	Expanded Indication	3/21/2023
Mekinist with Tafinlar The Food and Drug Administration (FDA) approved Mekinist® (trametinib tablets and oral solution) with Tafinlar® (dabrafenib capsules and oral solution) for pediatric individuals 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy. Source: FDA website	New Indication	3/16/2023
Daybue The Food and Drug Administration (FDA) approved Daybue™ (trofinetide oral solution) for the treatment of Rett syndrome in adults and children 2 years of age and older. Source: FDA website	New Drug	3/10/2023
Zynyz The Food and Drug Administration (FDA) approved Zynyz™ (retifanlimab-dlwr injection) for the treatment of adults with metastatic or recurrent locally advanced Merkel cell carcinoma. Source: FDA website	New Drug	3/22/2023
Rezzayo The Food and Drug Administration (FDA) approved Rezzayo™ (rezafungin injection) for individuals 18 years or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. Source: FDA website	New Drug	3/22/2023
Dabigatran etexilate Ascend Laboratories announced a voluntary recall of dabigatran etexilate 75 mg and 150 mg capsules due to the presence of N-nitrosodimethylamine (NDMA) impurity. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/ascend-laboratories-llc-issues-voluntary-nationwide-recall-dabigatran-etexilate-capsules-usp-75-mg Source: FDA website	Drug Recall	3/23/2023
Trikafta The Food and Drug Administration (FDA) approved Trikafta® (elexacaftor/tezacaftor/ivacaftor tablets and oral granules) to include children with cystic fibrosis (CF) ages 2 through 5 years who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive to Trikafta based on in vitro data. Source: FDA website	Expanded Indication	4/26/2023
Prevnar 20 The Food and Drug Administration (FDA) approved Prevnar 20TM (20-valent pneumococcal conjugate vaccine injection) for the prevention of invasive pneumococcal disease (IPD)	Expanded Indication	4/27/2023

Drug Name	Drug Reason	Date
caused by the 20 Streptococcus pneumoniae (pneumococcal) serotypes contained in the vaccine in infants and children six weeks through 17 years of age, and for the prevention of otitis media in infants six weeks through five years of age caused by the original seven serotypes contained in Prevnar. Source: FDA website		
Sogroya The Food and Drug Administration (FDA) approved Sogroya® (somapacitan-beco subcutaneous injection) for the treatment of pediatric individuals who have growth failure due to inadequate secretion of endogenous growth hormone (GH). Source: FDA website	Expanded Indication	4/28/2023
Liqrev The Food and Drug Administration (FDA) approved Liqrev® (sildenafil oral suspension) for the treatment of pulmonary arterial hypertension (WHO Group 1) in adults to improve exercise ability and delay clinical worsening. Source: FDA website	New Formulation	4/28/2023
Lumryz The Food and Drug Administration (FDA) approved Lumryz™ (sodium oxybate extended-release oral suspension) for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy. Source: FDA website	New Formulation	5/1/2023
Uzedy The Food and Drug Administration (FDA) approved Uzedy™ (risperidone extended-release injectable suspension for subcutaneous use) for the treatment of schizophrenia in adults. Source: FDA website	New Formulation	4/28/2023
Abilify Asimtufii The Food and Drug Administration (FDA) approved Abilify Asimtufii® (aripiprazole extended-release injectable suspension)for the treatment of schizophrenia in adults and as maintenance monotherapy treatment of bipolar I disorder in adults. Source: FDA website	New Formulation	4/28/2023
Zejula The Food and Drug Administration (FDA) approved Zejula™ (niraparib tablets) maintenance treatment of adults with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy and for maintenance treatment of adults with deleterious or suspected deleterious germline BRCA-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Source: FDA website	New Formulation	4/26/2023
Qalsody The Food and Drug Administration (FDA) approved Qalsody™ (tofersen injection for intrathecal use) for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene. Source: FDA website	New Drug	4/25/2023
Vowst The Food and Drug Administration (FDA) approved Vowst™ (fecal microbiota spores, live-brpk capsules) to prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI. Source: FDA website	New Drug	4/26/2023
Arexvy The Food and Drug Administration (FDA) approved Arexvy (respiratory syncytial virus vaccine, adjuvanted injection) for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older. Source: FDA website	New Drug	5/3/2023
Arexvy The Food and Drug Administration (FDA) approved Arexvy (adjuvanted respiratory syncytial virus vaccine injection) for the prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) to include those aged 50-59 years who are considered to be at high risk of RSV infection. Source: FDA website	Expanded Indication	6/7/2024
Augtyro The Food and Drug Administration (FDA) approved AugtyroTM (repotrectinib capsules) for adult and pediatric individuals 12 years and older with solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity, and that have progressed following treatment or have no satisfactory alternative therapy. Source: FDA website	New Indication	6/13/2024
Akorn Operating Company Akorn Operating Company announced a voluntary recall of various within-expiry human and animal products due to company closure. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/akorn-issues-voluntary-nationwide-recall-various-human-and-animal-drug-products-within-expiry-due Source: FDA website	Drug Recall	4/26/2023
Fentanyl Buccal Tablets	Drug Recall	4/27/2023

Drug Name	Drug Reason	Date
Teva Pharmaceuticals announced a voluntary recall of specific lots of various strengths of fentanyl buccal tablets due to a labeling error. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/teva-initiates-voluntary-nationwide-recall-specific-lots-fentanyl-buccal-tablets-cii-due-labeling Source: FDA website		
Kalydeco The Food and Drug Administration (FDA) approved Kalydeco® (ivacaftor tablets and oral granules) for use in children with cystic fibrosis (CF) ages 1 month to less than four months old who have at least one mutation in their cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to Kalydeco based on clinical and/or in vitro assay data. Source: FDA website	Expanded Indication	5/3/2023
Farxiga The Food and Drug Administration (FDA) approved Farxiga® (dapagliflozin tablets) to reduce the risk of cardiovascular death, hospitalization for heart failure and urgent heart failure visit in adults with heart failure (previously for adults with heart failure and reduced ejection fraction). Source: FDA website	Expanded Indication	5/8/2023
Farxiga The Food and Drug Administration (FDA) approved Farxiga® (dapagliflozin tablets) for the treatment of pediatric individuals aged 10 years and above with type-2 diabetes (T2D). Source: FDA website	Expanded Indication	6/12/2024
Rexulti The Food and Drug Administration (FDA) approved Rexulti® (brexpiprazole tablets) for use in the treatment of agitation associated with dementia due to Alzheimer’s disease. Source: FDA website	New Indication	5/10/2023
Zolpidem The Food and Drug Administration (FDA) approved Zolpidem tartrate capsules for the short-term treatment of transient insomnia characterized by difficulties with sleep initiation in adults younger than age 65 years of age. Source: FDA website	New Formulation	5/9/2023
Motpoly XR The Food and Drug Administration (FDA) approved Motpoly XR (lacosamide extended-release capsules) for the treatment of partial-onset seizures in adults and in pediatric individuals weighing at least 50 kg. Source: FDA website	New Formulation	5/4/2023
Motpoly XR The Food and Drug Administration (FDA) approved Motpoly XRTM (lacosamide extended-release capsules) for the treatment of primary generalized tonic-clonic seizures in adults and in pediatric individuals weighing at least 50 kg. Source: FDA website	New Indication	6/7/2024
Elfabrio The Food and Drug Administration (FDA) approved Elfabrio® (pegunigalsidase alfa-iwxj injection) for the treatment of adults with confirmed Fabry disease. Source: FDA website	New Drug	5/9/2023
Mirena The Food and Drug Administration (FDA) approved Mirena® (levonorgestrel intrauterine device) for duration of use up to 8 years for the prevention of pregnancy. Source: FDA website	Expanded Indication	08-12-22
Injectafer The Food and Drug Administration (FDA) approved Injectafer® (ferric carboxymaltose injection) for the treatment of iron deficiency in adults with heart failure and New York Heart Association Class II/III to improve exercise capacity. Source: FDA website	New Indication	5/31/2023
Lynparza The Food and Drug Administration (FDA) approved Lynparza® (olaparib tablets) in combination with abiraterone and prednisone (or prednisolone) for adults with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC), as determined by a Food and Drug Administration (FDA)-approved companion diagnostic test. Source: FDA website	New Indication	5/31/2023
Prevymis The Food and Drug Administration (FDA) approved Prevymis™ (letermovir tablets and injection for intravenous use) for prophylaxis of cytomegalovirus (CMV) disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV-seronegative [D+/R-]). Source: FDA website	New Indication	6/5/2023
Vevye The Food and Drug Administration (FDA) approved Vevye (cyclosporine ophthalmic solution) for the treatment of the signs and symptoms of dry eye disease. Source: FDA website	New Formulation	5/30/2023
Inpefa	New Drug	5/26/2023

Drug Name	Drug Reason	Date
The Food and Drug Administration (FDA) approved Inpefa™ (sotagliflozin tablets) to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure or type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors. Source: FDA website		
Abrysvo The Food and Drug Administration (FDA) approved Abrysvo™ (respiratory syncytial virus vaccine injection) for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years and older. Source: FDA website	New Drug	5/31/2023
Compounded Semaglutide The Food and Drug Administration (FDA) communicated about medications containing semaglutide marketed for type 2 diabetes or weight loss. There are currently three FDA-approved semaglutide products which are only available with a prescription. Due to two of the drugs being in shortage, these are able to be compounded if they meet certain requirements. The FDA has received adverse event reports after people used compounded semaglutide. The FDA has also received reports that in some cases, compounders may be using salt forms of semaglutide, including semaglutide sodium and semaglutide acetate, which have not been shown to be safe or effective. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/medications-containing-semaglutide-marketed-type-2-diabetes-or-weight-loss Source: FDA website	Drug Warning	5/31/2023
Qulipta The Food and Drug Administration (FDA) approved Qulipta™ (atogepant tablet) for the preventative treatment of chronic migraines in adults. Source: FDA website	Expanded Indication	4/17/2023
Coagadex The Food and Drug Administration (FDA) approved Coagadex® (human coagulation factor X injection) to include perioperative management of bleeding in individuals with severe hereditary Factor X deficiency. Source: FDA website	Expanded Indication	4/14/2023
Polivy The Food and Drug Administration (FDA) approved Polivy® (polatuzumab vedotin-piiq injection) in combination with rituximab, cyclophosphamide, doxorubicin and prednisone (R-CHP) for the treatment of adults who have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index (IPI) score of two or greater. Source: FDA website	Expanded Indication	4/19/2023
Lupron Depot-Ped The Food and Drug Administration (FDA) approved Lupron Depot-Ped® (leuprolide acetate injection) 45 mg single-dose, prefilled syringe for 6-month dosing regimen for the treatment of central precocious puberty in pediatrics. Source: FDA website	New Formulation	4/14/2023
RizaFilm The Food and Drug Administration (FDA) approved RizaFilm® (rizatriptan oral film) for the treatment of acute migraine with or without aura in adults and pediatric individuals 12 to 17 years of age weighing 40 kg or more. Source: FDA website	New Formulation	4/14/2023
Opioid Pain Medicines The Food and Drug Administration (FDA) is requiring several updates to the prescribing information for immediate-release (IR) and extended-release/long-acting (ER/LA) opioid pain medicines. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/medical-product-safety-information/all-opioid-pain-medicines-drug-safety-communication-fda-updates-prescribing-information-provide Source: FDA website	Drug Warning	4/13/2023
Kevzara The Food and Drug Administration (FDA) approved Kevzara® (sarilumab injection) for the treatment of polymyalgia rheumatica (PMR), an inflammatory rheumatic disease, in adults who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper. Source: FDA website	New Indication	2/28/2023
Kevzara The Food and Drug Administration (FDA) approved Kevzara® (sarilumab injection) for the treatment of individuals weighing 63 kg or more with active polyarticular juvenile idiopathic arthritis (pJIA). Source: FDA website	New Indication	6/10/2024
Verzenio The Food and Drug Administration (FDA) expanded approval of Verzenio® (abemaciclib tablets) for the adjuvant treatment of adults with hormone receptor-positive, human epidermal growth factor receptor 2-negative, node-positive, early breast cancer at high risk for recurrence. This approval also expands the indication by removing the Ki-67 testing requirement to identify high-risk patients. Source: FDA website	Expanded Indication	3/3/2023

Drug Name	Drug Reason	Date
Naloxone hydrochloride The Food and Drug Administration (FDA) approved Naloxone hydrochloride 4 mg nasal spray for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression for adult and pediatric individuals. Source: FDA website	New Formulation	3/7/2023
Combogesic The Food and Drug Administration (FDA) approved Combogesic® (acetaminophen/ibuprofen tablets) for the short-term management of mild to moderate acute pain. Source: FDA website	New Formulation	3/1/2023
Skyclarys The Food and Drug Administration (FDA) approved Skyclarys™ (omaveloxolone capsules) for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older. Source: FDA website	New Drug	2/28/2023
Zavzpret The Food and Drug Administration (FDA) approved Zavzpret™ (zavegepant nasal spray) for the acute treatment of migraine with or without aura in adults. Source: FDA website	New Drug	3/9/2023
Brimonidine tartrate Apotex announced a voluntary recall for six lots of brimonidine tartrate ophthalmic solution due to cracks that have developed in some caps of solution bottles. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/apotex-corp-issues-voluntary-nationwide-recall-brimonidine-tartrate-ophthalmic-solution-015-due Source: FDA website	Drug Recall	3/3/2023
Opdivo The Food and Drug Administration (FDA) approved Opdivo® (nivolumab injection) to include the pediatric population for the adjuvant treatment of adult and pediatric individuals 12 years and older with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection. Source: FDA website	Expanded Indication	2/15/2023
Yervoy The Food and Drug Administration (FDA) approved Yervoy® (ipilimumab injection) to include the pediatric population for the treatment of unresectable or metastatic melanoma in adult and pediatric individuals 12 years and older. Source: FDA website	Expanded Indication	2/15/2023
Austedo XR The Food and Drug Administration (FDA) approved Austedo® XR (deutetrabenazine extended-release tablets) in adults for tardive dyskinesia (TD) and chorea associated with Huntington's disease (HD). Source: FDA website	New Formulation	2/17/2023
Lamzede The Food and Drug Administration (FDA) approved Lamzede® (velmanase alfa-tycv) for the treatment of non-central nervous system manifestations of alpha-mannosidosis (AM) in adult and pediatric individuals. Source: FDA website	New Drug	2/16/2023
Filspari The Food and Drug Administration (FDA) approved Filspari™ (sparsentan tablets) to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g. Source: FDA website	New Drug	2/17/2023
Syfovre The Food and Drug Administration (FDA) approved Syfovre™ (pegcetacoplan intravitreal injection) for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration. Source: FDA website	New Drug	2/17/2023
Altuviiio The Food and Drug Administration (FDA) approved Altuviiio™ (antihemophilic factor [recombinant], Fc-VWF-XTEN fusion protein-ehtl], lyophilized powder for solution, for intravenous use) for use in adults and children with hemophilia A (congenital factor VIII deficiency) for routine prophylaxis to reduce the frequency of bleeding episodes, on-demand treatment and control of bleeding episodes, and perioperative management of bleeding. Source: FDA website	New Drug	2/22/2023
Descovy The Food and Drug Administration (FDA) approved Descovy® (emtricitabine/tenofovir alafenamide fumarate tablets) to include treatment of human immunodeficiency virus (HIV)-1 infection in pediatric individuals at least 2 years of age and weighing at least 14 kg.Source: FDA website	Expanded Indication	01-07-22
Quviviq The Food and Drug Administration (FDA) approved Quviviq (daridorexant tablets) for the treatment of adults with insomnia characterized by difficulties with sleep onset and/or sleep maintenance.Source: FDA website	New Drug	01-07-22

Drug Name	Drug Reason	Date
Senna Lohxa announced a voluntary recall of one lot of Senna Syrup 8.8 mg/5 mL unit-dose cups due to microbial contamination. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lohxa-llc-issues-voluntary-nationwide-recall-senna-syrup-88mg5ml-due-microbial-contamination Source: FDA website	Drug Recall	01-13-22
Metformin Viona Pharmaceuticals announced a voluntary recall of twenty-three lots of metformin hydrochloride extended-release tablets 750 mg due to detection of N-nitrosamine (NDMA) impurity. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/viona-pharmaceuticals-inc-issues-voluntary-nationwide-recall-metformin-hcl-extended-release-tablets-0 Source: FDA website	Drug Recall	01-12-22
Buprenorphine The Food and Drug Administration (FDA) is warning that dental problems (tooth decay, cavities, oral infection, and loss of teeth) have been reported with medicines containing buprenorphine that are dissolved in the mouth for opioid use disorder and pain. The FDA is requiring a new warning be added to the prescribing information. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/medical-product-safety-information/buprenorphine-drug-safety-communication-fda-warns-about-dental-problems-buprenorphine-medicines Source: FDA website	Drug Warning	01-12-22
Rinvoq The Food and Drug Administration (FDA) approved Rinvoq® (upadacitinib tablets) for the treatment of adults and children 12 years of age and older with refractory, moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable. Source: FDA website	New Indication	01-14-22
Skyrizi The Food and Drug Administration (FDA) approved SkyriziTM (risankizumab-rzaa injection) for the treatment of adults with active psoriatic arthritis (PsA). Source: FDA website	New Indication	01-24-22
Veklury The Food and Drug Administration (FDA) approved Veklury® (remdesivir injection) for the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older and weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, who are not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death. Source: FDA website	Expanded Indication	01-21-22
Ryaltris The Food and Drug Administration (FDA) approved RyaltrisTM (olopatadine hydrochloride/mometasone furoate nasal spray) for the treatment of symptoms of seasonal allergic rhinitis in adults and pediatric individuals 12 years of age and older. Source: FDA website	New Formulation	01-13-22
Cibinqo The Food and Drug Administration (FDA) approved CibinqoTM (abrocitinib tablets) for the treatment of adults with refractory, moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable. Source: FDA website	New Drug	01-14-22
Semglee Mylan Pharmaceuticals announced a voluntary recall of one batch of its non-interchangeable Semglee injection due to the potential for a missing label. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/mylan-pharmaceuticals-inc-viatris-company-conducting-voluntary-recall-one-batch-semgleer-insulin Source: FDA website	Drug Recall	01-19-22
Solosec The Food and Drug Administration (FDA) approved Solosec® (secnidazole oral granules) for the treatment of bacterial vaginosis and trichomoniasis caused by Trichomonas vaginalis in individuals 12 years of age and older. Source: FDA website	Expanded Indication	01-26-22
Pifeltro The Food and Drug Administration (FDA) approved Pifeltro® (doravirine tablets) for the treatment of human immunodeficiency virus (HIV)-1 in pediatric individuals weighing at least 35 kg. Source: FDA website	Expanded Indication	01-27-22
Delstrigo	Expanded Indication	01-27-22

Drug Name	Drug Reason	Date
The Food and Drug Administration (FDA) approved DelstrigoTM (doravirine/lamivudine/tenofovir disoproxil fumarate tablets) for the treatment of human immunodeficiency virus (HIV)-1 in pediatric individuals weighing at least 35 kg. Source: FDA website		
Vonvendi		
The Food and Drug Administration (FDA) approved Vonvendi® (recombinant von Willebrand factor injection) for routine prophylaxis to reduce the frequency of bleeding episodes in individuals with severe Type 3 von Willebrand disease (VWD) receiving on-demand therapy. Source: FDA website	Expanded Indication	01-31-22
Nucala		
The Food and Drug Administration (FDA) approved Nucala (mepolizumab 40 mg prefilled syringe injection) as add-on maintenance treatment for children 6 to 11 years of age with severe asthma and with an eosinophilic phenotype. Source: FDA website	New Formulation	01-22-22
Kimmtrak		
The Food and Drug Administration (FDA) approved Kimmtrak® (tebentafusp-tebn injection) for the treatment of human leukocyte antigen (HLA)-A*02:01-positive adults with unresectable or metastatic uveal melanoma (mUM). Source: FDA website	New Drug	01-26-22
Vabysmo		
The Food and Drug Administration (FDA) approved VabysmoTM (faricimab-svoa injection for intravitreal use) for the treatment of adults with neovascular age-related macular degeneration (nAMD) or diabetic macular edema (DME). Source: FDA website	New Drug	01-28-22
Polymyxin B		
AuroMedics Pharma announced a voluntary recall of one lot of polymyxin B for injection due to a product complaint for the presence of particulate matter. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/auromedics-pharma-llc-issues-voluntary-nationwide-recall-polymyxin-b-injection-usp-500000-unit-vial Source: FDA website	Drug Recall	01-28-22
Xigduo XR		
The Food and Drug Administration (FDA) approved Xigduo® XR (dapagliflozin/metformin hydrochloride extended-release tablets) to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction. Source: FDA website	New Indication	02-03-22
Fleqsuvy		
The Food and Drug Administration (FDA) approved FleqsuvyTM (baclofen oral suspension) for the treatment of spasticity resulting from multiple sclerosis (MS), particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Source: FDA website	New Formulation	02-04-22
Enjaymo		
The Food and Drug Administration (FDA) approved EnjaymoTM (sutimlimab-jome injection) to decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin disease (CAD). Source: FDA website	New Drug	02-04-22
Ukoniq		
The Food and Drug Administration (FDA) is investigating a possible increased risk of death due to the cancer drug Ukoniq® (umbralisib tablets). The FDA is re-evaluating the risk versus benefit of Ukoniq and is continuing to look at results from the UNITY clinical trial. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/medical-product-safety-information/ukoniq-umbralisib-drug-safety-communication-fda-investigating-possible-increased-risk-death-lymphoma Source: FDA website	Drug Warning	02-03-22
Jardiance		
The Food and Drug Administration (FDA) approved Jardiance® (empagliflozin tablets) to treat adults with heart failure regardless of left ventricular ejection fraction. Source: FDA website	Expanded Indication	02-24-22
Norliqva		
The Food and Drug Administration (FDA) approved Norliqva® (amlodipine oral solution) for the treatment of hypertension in adults and children 6 years and older and for the treatment of coronary artery disease and angiographically documented coronary artery disease in individuals without heart failure or an ejection fraction <40%. Source: FDA website	New Formulation	02-24-22
Aspruzyo Sprinkle		
The Food and Drug Administration (FDA) approved Aspruzyo SprinkleTM (ranolazine extended-release oral granules) for the treatment of chronic angina. Source: FDA website	New Formulation	02-28-22
Pyrukynd		
The Food and Drug Administration (FDA) approved Pyrukynd® (mitapivat tablets) for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency. Source: FDA website	New Drug	02-17-22

Drug Name	Drug Reason	Date
Carvykti The Food and Drug Administration (FDA) approved CarvyktiTM (ciltacabtagene autoleucel suspension for intravenous infusion) for the treatment of adults with relapsed or refractory multiple myeloma, after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. Source: FDA website	New Drug	02-28-22
Vonjo The Food and Drug Administration (FDA) approved VonjoTM (pacritinib capsules) for the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 × 109/L. Source: FDA website	New Drug	02-28-22
Opdivo The Food and Drug Administration (FDA) approved Opdivo® (nivolumab injection) in combination with platinum-doublet chemotherapy for adults with resectable non-small cell lung cancer (NSCLC) in the neoadjuvant setting. Source: FDA website	Expanded Indication	03-04-22
Lynparza The Food and Drug Administration (FDA) approved Lynparza® (olaparib tablets) for the adjuvant treatment of adults with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) human epidermal growth factor receptor 2 (HER2)-negative high-risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Source: FDA website	Expanded Indication	03-11-22
Keytruda The Food and Drug Administration (FDA) approved Keytruda® (pembrolizumab injection) as a single agent for individuals with advanced endometrial carcinoma that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), as determined by a Food and Drug Administration (FDA)-approved test, who have disease progression following prior systemic therapy in any setting and who are not candidates for curative surgery or radiation. Source: FDA website	Expanded Indication	03-21-22
Smoflipid The Food and Drug Administration (FDA) approved Smoflipid® (lipid injectable emulsion) as a source of calories and essential fatty acids for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated expanded to include pediatric individuals. Source: FDA website	Expanded Indication	03-22-22
Rinvoq The Food and Drug Administration (FDA) approved Rinvoq® (upadacitinib extended-release tablets) for the treatment of adults with moderately to severely active ulcerative colitis (UC) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers. Source: FDA website	New Indication	03-16-22
Adlarity The Food and Drug Administration (FDA) approved Adlarity® (donepezil transdermal system) for the treatment of adults with mild, moderate, and severe dementia of the Alzheimer type. Source: FDA website	New Formulation	03-11-22
Xelstrym The Food and Drug Administration (FDA) approved XelstrymTM (dextroamphetamine transdermal system) for the treatment of attention-deficit/hyperactivity disorder (ADHD) for adults and pediatric individuals 6 years and older. Source: FDA website	New Formulation	03-23-22
Hyftor The Food and Drug Administration (FDA) approved HyftorTM (sirolimus topical gel) for the treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric individuals 6 years of age and older. Source: FDA website	New Formulation	03-22-22
Ztalmy The Food and Drug Administration (FDA) approved Ztalmy® (ganaxolone oral suspension) for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in individuals 2 years of age or older. Source: FDA website	New Drug	03-18-22
Opdualag The Food and Drug Administration (FDA) approved OpdualagTM (nivolumab/relatlimab-rmbw injection) for the treatment of adult and pediatric individuals 12 years of age or older with unresectable or metastatic melanoma. Source: FDA website	New Drug	03-18-22
Pluvicto The Food and Drug Administration (FDA) approved PluvictoTM (lutetium Lu 177 vipivotide tetraxetan injection) for the treatment of adults with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy. Source: FDA website	New Drug	03-23-22
Sodium acetate	Drug Recall	03-08-22

Drug Name	Drug Reason	Date
Fresenius Kabi announced a voluntary recall of seven lots of sodium acetate injection due to the presence of particulate matter.Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/fresenius-kabi-issues-voluntary-recall-sodium-acetate-injection-usp-due-presence-particulate-matter Source: FDA website		
Quinapril/hydrochlorothiazide Pfizer announced a voluntary recall of six lots of AccureticTM (quinapril HCL/hydrochlorothiazide) tablets distributed by Pfizer as well as five lots of two authorized generics distributed by Greenstone due to the presence of an impurity. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-voluntary-nationwide-recall-lots-accuretictm-quinapril-hclhydrochlorothiazide-quinapril-and Source: FDA website	Drug Recall	03-22-22
Orphenadrine citrate Sandoz announced a voluntary recall of 13 lots of oral orphenadrine citrate 100 mg extended-release tablets due to the presence of an impurity. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sandoz-inc-issues-nationwide-recall-13-lots-orphenadrine-citrate-100-mg-extended-release-tablets-due Source: FDA website	Drug Recall	03-23-22
Symjepi Adamis Pharmaceuticals announced a voluntary recall of certain lots of SymjepiTM (epinephrine injection) due to the potential clogging of the needle preventing the dispensing of epinephrine. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/adamis-pharmaceuticals-corporation-issues-nationwide-voluntary-recall-symjepir-epinephrine-injection Source: FDA website	Drug Recall	03-22-22
Fintepla The Food and Drug Administration (FDA) approved Fintepla® (fenfluramine oral solution) for the treatment of seizures associated with Lennox-Gastaut syndrome in individuals two years of age and older. Source: FDA website	New Indication	03-25-22
Cabenuva The Food and Drug Administration (FDA) approved Cabenuva (cabotegravir extended-release injectable suspension and rilpivirine extended-release injectable suspension) for expanded use of every 2-month dosing regimen to include the treatment of human immunodeficiency virus (HIV)-1 infection in adolescents 12 years of age and older and weighing at least 35 kg. Source: FDA website	Expanded Indication	03-29-22
Vocabria and Edurant The Food and Drug Administration (FDA) approved Vocabria (cabotegravir tablets) for expanded use in combination with Edurant® (rilpivirine tablets) as an oral, short-term treatment regimen followed by Cabenuva injection dosing regimen for the treatment of human immunodeficiency virus (HIV)-1 virus infection in adolescents 12 years of age and older and weighing at least 35 kg. Source: FDA website	Expanded Indication	03-29-22
Tlando The Food and Drug Administration (FDA) approved TlandoTM (testosterone undecanoate oral capsule) for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Source: FDA website	New Formulation	03-28-22
Triumeq PD The Food and Drug Administration (FDA) approved Triumeq PD (abacavir/dolutegravir/lamivudine dispersible tablets for oral suspension) for the treatment of pediatric individuals weighing 10 kg to < 25 kg with human immunodeficiency virus type 1 (HIV-1). The original tablet formulation of Triumeq was also expanded to individuals weighing at least 10 kg. Source: FDA website	New Formulation	03-30-22
Idarubicin Teva Pharmaceuticals announced a voluntary recall of one lot of idarubicin hydrochloride injection due to the presence of particulate matter. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/teva-issues-voluntary-nationwide-recall-one-lot-idarubicin-hydrochloride-injection-usp-5-mg5-ml-due Source: FDA website	Drug Recall	03-30-22
North American Custom Laboratories The Food and Drug Administration (FDA) issued a warning not to use products intended to be sterile produced by North American Custom Laboratories due to a lack of sterility assurance. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-patients-and-health-care-	Drug Warning	03-31-22

Drug Name	Drug Reason	Date
professionals-not-use-sterile-products-north-american-custom?utm_medium=email&utm_source=govdelivery Source: FDA website		
Iodine-containing contrast media The Food and Drug Administration (FDA) approved a new warning to the prescribing label for the entire class of iodinated contrast media injections and monitoring recommendations for children 3 years or younger. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/medical-product-safety-information/iodine-containing-contrast-media-drug-safety-communication-fda-recommends-thyroid-monitoring-babies Source: FDA website	Drug Warning	03-31-22
Yescarta The Food and Drug Administration (FDA) approved Yescarta® (axicabtagene ciloleucel for intravenous infusion) for adults with large B-cell lymphoma (LBCL) that is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy. Source: FDA website	Expanded Indication	04-01-22
Igalmi The Food and Drug Administration (FDA) approved IgalmiTM (dexmedetomidine sublingual film) for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults. Source: FDA website	New Formulation	04-05-22
Vijoice The Food and Drug Administration (FDA) approved Vijoice® (alpelisib tablets) for the treatment of adult and pediatric individuals 2 years of age and older with severe manifestations of PIK3CA-related overgrowth spectrum (PROS) who require systemic therapy. Source: FDA website	New Formulation	04-05-22
Xigduo XR The Food and Drug Administration (FDA) approved Xigduo® XR (dapagliflozin/metformin extended-release tablet) to reduce the risk of sustained estimated glomerular filtration rate decline, end stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression. Source: FDA website	Expanded Indication	04-11-22
Xigduo XR The Food and Drug Administration (FDA) approved Xigduo® XR (dapagliflozin/metformin hydrochloride extended-release tablets) for the treatment of pediatric individuals aged 10 years and above with type-2 diabetes (T2D). Source: FDA website	Expanded Indication	6/12/2024
Insulin glargine Mylan Pharmaceuticals announced a voluntary recall of one batch of insulin glargine injection due to the potential for a missing label. Contact your healthcare provider for questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/mylan-pharmaceuticals-inc-viatris-company-conducting-voluntary-nationwide-recall-one-batch-insulin Source: FDA website	Drug Recall	04-13-22
Zerbaxa The Food and Drug Administration (FDA) approved Zerbaxa® (ceftolozane sulfate/tazobactam sodium injection) in pediatric individuals from birth to less than 18 years of age for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, and complicated intra-abdominal infections (cIAI). Source: FDA website	Expanded Indication	04-21-22
Ultomiris The Food and Drug Administration (FDA) approved Ultomiris® (ravulizumab-cwvz injection) for the treatment of adults with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive. Source: FDA website	New Indication	04-27-22
Epsolay The Food and Drug Administration (FDA) approved Epsolay® (benzoyl peroxide cream) for the treatment of inflammatory lesions of rosacea in adults. Source: FDA website	New Formulation	04-22-22
Cuvrior The Food and Drug Administration (FDA) approved CuvriorTM (trientine tetrahydrochloride tablets) for the treatment of adult patients with stable Wilson's disease who are de-coppered and tolerant to penicillamine. Source: FDA website	New Formulation	04-28-22
Vivjoa The Food and Drug Administration (FDA) approved VivjoaTM (oteseconazole capsules) to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are not of reproductive potential. Source: FDA website	New Drug	04-27-22
Camzyos The Food and Drug Administration (FDA) approved CamzyosTM (mavacamten capsules) for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms. Source: FDA website	New Drug	04-28-22
Accupril	Drug Recall	04-23-22

Drug Name	Drug Reason	Date
Pfizer announced a voluntary recall of five lots of Accupril due to the presence of a nitrosamine above the acceptable level. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-voluntary-nationwide-recall-lots-accuprilr-quinapril-hcl-due-n-nitroso-quinapril-content Source: FDA website		
Rinvoq The Food and Drug Administration (FDA) approved Rinvoq® (upadacitinib extended-release tablets) for the treatment of adults with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers. Source: FDA website	New Indication	04-29-22
Olumiant The Food and Drug Administration (FDA) approved Olumiant® (baricitinib tablets) for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Source: FDA approval	New Indication	05-10-22
Qelbree The Food and Drug Administration (FDA) approved Qelbree® (viloxazine extended-release capsules) for the treatment of attention deficit hyperactivity disorder (ADHD) in adults aged 18 and older. Source: FDA website	Expanded Indication	05-02-22
Enhertu The Food and Drug Administration (FDA) approved Enhertu® (fam-trastuzumab deruxtecan-nxki injection) for the treatment of adults with unresectable or metastatic human epidermal growth factor receptor 2 (HER2) positive breast cancer who have received a prior anti-HER2-based regimen either in the metastatic setting, or in the neoadjuvant or adjuvant setting and have developed disease recurrence during or within six months of completing therapy. Source: FDA website	Expanded Indication	05-04-22
Ermeza The Food and Drug Administration (FDA) approved ErmezaTM (levothyroxine sodium oral solution) in adult and pediatric individuals, including neonates, as replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. Also approved as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer. Source: FDA website	New Formulation	04-29-22
Radicava ORS The Food and Drug Administration (FDA) approved Radicava ORS® (edaravone oral suspension) for the treatment of adults with amyotrophic lateral sclerosis (ALS). Source: FDA website	New Formulation	05-12-22
Mounjaro The Food and Drug Administration (FDA) approved MounjaroTM (tirzepatide subcutaneous injection) to improve blood sugar control in adults with type 2 diabetes as an addition to diet and exercise. Source: FDA website	New Drug	05-12-22
Voquezna Triple Pak and Voquezna Dual Pak The Food and Drug Administration (FDA) approved VoqueznaTM Triple PakTM (vonoprazan tablets/amoxicillin capsules/ clarithromycin tablets co-packaged for oral use) and VoqueznaTM Dual PakTM (vonoprazan tablets/amoxicillin capsules/co-packaged for oral use) for the treatment of Helicobacter pylori (H. pylori) infection in adults. Source: FDA website	New Drug	05-03-22
Dupixent The Food and Drug Administration (FDA) approved Dupixent® (dupilumab injection) to treat eosinophilic esophagitis (EoE) in adults and pediatric individuals 12 years and older weighing at least 40 kg. Source: FDA website	New Indication	05-20-22
Vidaza The Food and Drug Administration (FDA) approved Vidaza® (azacitidine injection) for pediatric individuals with newly diagnosed juvenile myelomonocytic leukemia. Source: FDA website	New Indication	05-20-22
Tibsovo The Food and Drug Administration (FDA) approved Tibsovo® (ivosidenib tablet) in combination with azacitidine for newly diagnosed acute myeloid leukemia (AML) with a susceptible IDH1 mutation, as detected by an FDA-approved test in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy. Source: FDA website	Expanded Indication	05-25-22
TPOXX The Food and Drug Administration (FDA) approved TPOXX® (tecovirimat intravenous) for the treatment of human smallpox disease in adults and pediatric individuals weighing at	New Formulation	05-18-22

Drug Name	Drug Reason	Date
least 3 kg. Source: FDA website		
Tyvaso DPI The Food and Drug Administration (FDA) approved Tyvaso DPI™ (treprostinil oral inhalation) for the treatment of individuals with pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). Source: FDA website	New Formulation	05-23-22
Vtama The Food and Drug Administration (FDA) approved Vtama® (tapinarof topical cream) for the treatment of plaque psoriasis in adults. Source: FDA website	New Drug	05-24-22
Anagrelide Teva Pharmaceuticals announced a voluntary recall of a single lot of anagrelide capsules due to dissolution test failure. Contact your healthcare provider with details. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/teva-issues-voluntary-nationwide-recall-one-lot-anagrelide-capsules-usp-05-mg-due-dissolution-test Source: FDA website	Drug Recall	05-23-22
Evrysdi The Food and Drug Administration (FDA) approved Evrysdi® (risdiplam oral solution) to include treatment of infants under 2 months old with spinal muscular atrophy (SMA). Source: FDA website	Expanded Indication	05-27-22
Opdivo The Food and Drug Administration (FDA) approved Opdivo® (nivolumab injection) in combination with fluoropyrimidine- and platinum-containing chemotherapy and Opdivo plus Yervoy (ipilimumab injection) as a first-line treatment for adults with unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) regardless of programmed death-ligand 1 (PD-L1) status. Source: FDA website	Expanded Inciation	05-27-22
Kymriah The Food and Drug Administration (FDA) approved Kymriah® (tisagenlecleucel injection) for the treatment of adults with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. Source: FDA website	Expanded Inciation	05-28-22
Beovu The Food and Drug Administration (FDA) approved Beovu® (brolucizumab-dbll) for the treatment of diabetic macular edema (DME). Source: FDA website	New Indication	05-27-22
Ukoniq The Food and Drug Administration (FDA) has withdrawn approval for the cancer medication UkoniqTM (umbralisib tablet) due to safety concerns. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/medical-product-safety-information/ukoniq-umbralisib-drug-safety-communication-fda-approval-lymphoma-medicine-withdrawn-due-safety Source: FDA website	Drug Warning	06-01-22
CellCept The Food and Drug Administration (FDA) approved CellCept® (mycophenolate mofetil capsule, tablet, oral suspension, and injection) for the prophylaxis of organ rejection in pediatric recipients of allogenic heart and allogenic liver transplants aged 3 months and older in combination with other immunosuppressants. Source: FDA website	Expanded Indication	06-06-22
Dupixent The Food and Drug Administration (FDA) approved Dupixent® (dupilumab injection) for the treatment of children aged 6 months to 5 years with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or for when those therapies are not advisable. Source: FDA website	Expanded Indication	06-07-22
Priorix The Food and Drug Administration (FDA) approved Priorix (measles, mumps, and rubella vaccine, live suspension for subcutaneous injection) for active immunization for the prevention of measles, mumps, and rubella in individuals 12 months of age and older. Source: FDA website	New Formulation	06-03-22
Olumiant The Food and Drug Administration (FDA) approved Olumiant® (baricitinib tablets) for the treatment of adults with severe alopecia areata. Source: FDA website	New Indication	06-13-22
Imcivree The Food and Drug Administration (FDA) approved ImcivreeTM (setmelanotide subcutaneous injection) for chronic weight management in adult and pediatric individuals 6 years of age and older with obesity due to Bardet-Biedl Syndrome (BBS). Source: FDA website	New Indication	06-16-22
Skyrizi The Food and Drug Administration (FDA) approved Skyrizi® (risankizumab-rzaa injection) for the treatment of adults with moderately to severely active Crohn's disease. Source: FDA	New Indication	06-17-22

Drug Name	Drug Reason	Date
website Skyrizi The Food and Drug Administration (FDA) approved Skyrizi® (risankizumab-rzaa injection) for the treatment of moderately-to-severely active ulcerative colitis in adults. Source: FDA website	New Indication	6/17/2024
Amvuttra The Food and Drug Administration (FDA) approved AmvuttraTM (vutrisiran subcutaneous injection) for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults. Source: FDA website	New Drug	06-13-22
Zulresso The Food and Drug Administration (FDA) approved ZulressoTM (brexanolone injection for intravenous use) for expansion to include individuals 15 years and older diagnosed with postpartum depression. Source: FDA website	Expanded Indication	06-16-22
Vaxneuvance The Food and Drug Administration (FDA) approved VaxneuvanceTM (pneumococcal 15-valent conjugate vaccine intramuscular injection) expanded for active immunization for the prevention of invasive disease caused by certain Streptococcus pneumoniae serotypes in individuals 6 weeks of age and older. Source: FDA website	Expanded Indication	06-22-22
Mekinist plus Tafinlar The Food and Drug Administration (FDA) approved Mekinist® (trametinib tablets) plus Tafinlar® (dabrafenib capsules) for the treatment of adult and pediatric individuals 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. Source: FDA website	Expanded Indication	06-22-22
Breyanzi The Food and Drug Administration (FDA) approved Breyanzi® (lisocabtagene maraleucel suspension for intravenous infusion) for the treatment of adults with large B-cell lymphoma (LBCL) after one prior therapy. Source: FDA website	Expanded Indication	06-24-22
Qsymia The Food and Drug Administration (FDA) approved Qsymia® (phentermine/topiramate extended-release capsules) for chronic weight management in pediatric individuals aged 12 years and older who are obese, defined as a body mass index (BMI) of 95th percentile or greater when standardized for age and sex. Source: FDA website	Expanded Indication	06-24-22
Morphine sulfate Bryant Ranch Prepack announced a voluntary recall of one lot of morphine sulfate 30 mg extended-release tablets and one lot of morphine sulfate 60 mg extended-release tablets due to incorrect labeling. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bryant-ranch-prepack-inc-issues-voluntary-nationwide-recall-morphine-sulfate-30-mg-extended-release Source: FDA website	Drug Recall	06-29-22
Kyprolis The Food and Drug Administration (FDA) approved Kyprolis® (carfilzomib injection) in combination with Sarclisa® (isatuximab-irfc injection) and dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma (RRMM) who have received one to three lines of therapy. Source: FDA website	Expanded Indication	06-30-22
Krystexxa The Food and Drug Administration (FDA) approved Krystexxa® (pegloticase injection) for concomitant use with methotrexate for the treatment of individuals with uncontrolled gout to achieve a complete response to therapy. Source: FDA website	Expanded Indication	07-07-22
Drospirenone The Food and Drug Administration (FDA) approved Drospirenone chewable tablets for use by females of reproductive potential to prevent pregnancy. Source: FDA website	New Formulation	09-29-22
Venbysi XR The Food and Drug Administration (FDA) approved Venbysi XR (venlafaxine besylate extended-release oral tablets) for the treatment of major depressive disorder and generalized anxiety disorder in adults. Source: FDA website	New Formulation	09-29-22
Insulin glargine Mylan Pharmaceuticals announced a voluntary recall of one batch of insulin glargine injection due to the potential of missing labels on some pens. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/mylan-pharmaceuticals-inc-viatris-company-issues-voluntary-nationwide-recall-one-batch-insulin Source: FDA website	Drug Recall	07-06-22
Copiktra	Drug Warning	06-30-22

Drug Name	Drug Reason	Date
The Food and Drug Administration (FDA) is warning that results from a clinical trial show a possible increased risk of death and serious adverse events with the oncology medicine Copiktra® (duvelisib capsules). The FDA will continue to evaluate the safety of this agent. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/medical-product-safety-information/copiktra-duvelisib-drug-safety-communication-fda-warns-about-possible-increased-risk-death-and Source: FDA website		
Xalkori		
The Food and Drug Administration (FDA) approved Xalkori® (crizotinib oral pellets) 20 mg, 50 mg, and 150 mg oral pellets to for all previously approved indications. Source: FDA website	New Formulation	9/7/2023
Temodar		
The Food and Drug Administration (FDA) approved Temodar® (temozolomide injection) for the adjuvant treatment of adults with newly diagnosed anaplastic astrocytoma and the treatment of adults with refractory anaplastic astrocytoma. Source: FDA website	Expanded Indication	9/14/2023
Aphexda		
The Food and Drug Administration (FDA) approved AphexdaTM (motixafortide subcutaneous injection) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in people with multiple myeloma, in combination with filgrastim (granulocyte-colony stimulating factor [G-CSF]). Source: FDA website	New Drug	9/8/2023
Ojjaara		
The Food and Drug Administration (FDA) approved Ojjaara (momelotinib tablets) for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia. Source: FDA website	New Drug	9/15/2023
Sandimmune		
Novartis announced a voluntary recall of one lot of Sandimmune® (cyclosporine oral solution) 100 mg/mL due to crystal formation observed in some bottles. Contact your health care provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/novartis-issues-voluntary-nationwide-recall-one-lot-sandimmuner-oral-solution-cyclosporine-oral Source: FDA website	Drug Recall	9/11/2023
Opzelura		
The Food and Drug Administration (FDA) approved Opzelura™ (ruxolitinib cream) for the topical treatment of nonsegmental vitiligo in adult and pediatric individuals 12 years of age and older. Source: FDA website	New Indication	07-18-22
Diacomit		
The Food and Drug Administration (FDA) approved Diacomit® (stiripentol capsules) for the treatment of seizures associated with Dravet syndrome (DS) in individuals taking clobazam who are 6 months of age and older and weighing 7 kg or more. Source: FDA website	Expanded Indication	07-14-22
Zonisade		
The Food and Drug Administration (FDA) approved Zonisade™ (zonisamide oral suspension) as adjunctive therapy for the treatment of partial onset seizures in adults and pediatric individuals 16 years of age and older. Source: FDA website	New Formulation	07-15-22
Benlysta		
The Food and Drug Administration (FDA) approved Benlysta® (belimumab injection) to include pediatric individuals 5 to 17 years of age with active lupus nephritis who are receiving standard therapy. Source: FDA website	Expanded Indication	07-26-22
Stelara		
The Food and Drug Administration (FDA) approved Stelara® (ustekinumab injection) to include the treatment of pediatric individuals 6 years and older with active psoriatic arthritis. Source: FDA website	Expanded Indication	07-29-22
Rebinyn		
The Food and Drug Administration (FDA) approved Rebinyn® (coagulation factor IX, recombinant injection) to include use in adults and children with hemophilia B for routine prophylaxis to reduce the frequency of bleeding episodes. Source: FDA website	Expanded Indication	08-1-22
Tadliq		
The Food and Drug Administration (FDA) approved Tadliq® (tadalafil oral suspension) for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability. Source: FDA website	New Formulation	06-17-22
Ultomiris	New Formulation	07-22-22
The Food and Drug Administration (FDA) approved Ultomiris® (ravulizumab-cwvz subcutaneous on-body injection) for the treatment of adults with paroxysmal nocturnal		

Drug Name	Drug Reason	Date
hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS). Source: FDA website		
Kyzatrex The Food and Drug Administration (FDA) approved Kyzatrex® (testosterone undecanoate oral capsules) for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Source: FDA website	New Formulation	07-27-22
Zoryve The Food and Drug Administration (FDA) approved ZoryveTM (roflumilast topical) for topical treatment of plaque psoriasis, including intertriginous areas, in individuals 12 years of age and older. Source: FDA website	New Formulation	07-29-22
Magnesium citrate Vi-Jon announced a voluntary recall for all lots of all flavors of Magnesium citrate saline laxative oral solution due to microbial contamination. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/vi-jon-llc-expands-voluntary-nationwide-recall-all-flavors-and-lots-within-expiry-magnesium-citrate Source: FDA website	Drug Recall	07-28-22
Enhertu The Food and Drug Administration (FDA) approved Enhertu® (fam-trastuzumab deruxtecan-nxki injection) for adults with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH) breast cancer who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within six months of completing adjuvant chemotherapy. Source: FDA website	Expanded Indication	08-05-22
Nubeqa The Food and Drug Administration (FDA) approved Nubeqa® (darolutamide tablets) in combination with docetaxel for adults with metastatic hormone-sensitive prostate cancer (mHSPC). Source: FDA website	Expanded Indication	08-05-22
Xofluza The Food and Drug Administration (FDA) approved Xofluza® (baloxavir marboxil tablets and oral suspension) for the treatment of acute uncomplicated influenza in otherwise healthy children aged five to less than 12 years of age who have been symptomatic for no more than 48 hours. Additionally, the FDA approved Xofluza for the prevention (post-exposure prophylaxis) of influenza in children aged five to less than 12 years of age following contact with someone with influenza. Source: FDA website	Expanded Indication	08-11-22
Enhertu The Food and Drug Administration (FDA) approved Enhertu® (fam-trastuzumab deruxtecan-nxki injection) for adults with unresectable or metastatic non-small cell lung cancer (NSCLC) whose tumors have activating human epidermal growth factor receptor 2 HER2 (ERBB2) mutations, as detected by a Food and Drug Administration (FDA)-approved test, and who have received a prior systemic therapy. Source: FDA website	New Indication	08-11-22
Myfembree The Food and Drug Administration (FDA) approved Myfembree® (relugolix, estradiol, and norethindrone acetate tablets) for the treatment of endometriosis-associated pain. Source: FDA website	New Indication	08-05-22
Calquence The Food and Drug Administration (FDA) approved Calquence® (acalabrutinib tablets) for adults with chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL) and for individuals with relapsed or refractory mantle cell lymphoma (MCL). Source: FDA website	New Formulation	08-03-22
Magnesium citrate Vi-Jon expanded a voluntary recall of all flavors and lots within expiry of magnesium citrate saline laxative oral solution due to microbial contamination. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/vi-jon-llc-expands-voluntary-worldwide-recall-all-flavors-and-lots-within-expiry-magnesium-citrate Source: FDA website	Drug Recall	08-04-22
Milk of Magnesia and Magnesium hydroxide/aluminum hydroxide/simethicone Plastikon Healthcare expanded a voluntary recall of Milk of Magnesia oral suspension and Magnesium hydroxide/aluminum hydroxide/simethicone oral suspension due to microbial contamination. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/plastikon-healthcare-expands-voluntary-nationwide-recall-milk-magnesia-oral-suspension-and-magnesium Source: FDA website	Drug Recall	08-03-22
Auvelity The Food and Drug Administration (FDA) approved Auvelity (dextromethorphan hydrobromide and bupropion hydrochloride extended-release tablets) for the treatment of major depressive disorder (MDD) in adults. Source: FDA website	New Formulation	08-18-22

Drug Name	Drug Reason	Date
Zynteglo The Food and Drug Administration (FDA) approved Zynteglo® (betibeglogene autotemcel injection) for the treatment of adult and pediatric individuals with beta-thalassemia who require regular red blood cell (RBC) transfusions. Source: FDA website	New Drug	08-17-22
Takhzyro The Food and Drug Administration (FDA) approved Takhzyro® (lanadelumab-flyo injection) in pediatric individuals 2 to < 12 years of age for prophylaxis to prevent attacks of hereditary angioedema (HAE). Source: FDA website	Expanded Indication	2/3/2023
Synjardy and Synjardy XR The Food and Drug Administration (FDA) approved Synjardy® (empagliflozin/metformin tablets) and Synjardy® XR (empagliflozin/metformin controlled-release tablets) to include the reduction of risk for cardiovascular death and hospitalization for heart failure in adults with heart failure. Source: FDA website	Expanded Indication	2/6/2023
Cibinqo The Food and Drug Administration (FDA) approved Cibinqo™ (abrocitinib tablets) for pediatric individuals 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 is inadvisable. Source: FDA website	Expanded Indication	2/9/2023
Eylea The Food and Drug Administration (FDA) approved Eylea® (aflibercept intravitreal injection) for the treatment of preterm infants with retinopathy of prematurity (ROP). Source: FDA website	New Indication	2/8/2023
Glatiramer acetate autoinjector devices The Food and Drug Administration (FDA) is alerting consumers and healthcare providers that autoinjector devices that are optional for use with glatiramer acetate injection may not be compatible for use across FDA-approved glatiramer acetate injection drug products. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-patients-caregivers-and-health-care-providers-cross-compatibility-issues-autoinjector Source: FDA website	Drug Warning	08-18-22
Imbruvica The Food and Drug Administration (FDA) approved Imbruvica® (ibrutinib tablets, capsules, and oral suspension) for pediatric individuals ≥ 1 year of age with chronic graft versus host disease (cGVHD) after failure of 1 or more lines of systemic therapy. Source: FDA website	New Indication	08-24-22
Pemazyre The Food and Drug Administration (FDA) approved PemazyreTM (pemigatinib tablets) for the treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms or MLNs with fibroblast growth factor receptor 1 (FGFR1) rearrangement. Source: FDA website	New Indication	08-26-22
Imfinzi The Food and Drug Administration (FDA) approved Imfinzi® (durvalumab injection) in combination with gemcitabine and cisplatin for adults with locally advanced or metastatic biliary tract cancer (BTC). Source: FDA website	New Indication	09-02-22
Imfinzi The Food and Drug Administration (FDA) approved Imfinzi® (durvalumab injection) with carboplatin plus paclitaxel followed by single-agent durvalumab for adults with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR). Source: FDA website	New Indication	6/14/2024
Orkambi The Food and Drug Administration (FDA) approved Orkambi® (ivacaftor/lumacaftor tablets and oral granules) to include the treatment of cystic fibrosis (CF) in individuals 1 to less than 2 years of age who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Source: FDA website	Expanded Indication	09-02-22
Konvomep The Food and Drug Administration (FDA) approved KonvomepTM (omeprazole/sodium bicarbonate oral suspension) for short-term treatment (4 to 8 weeks) of active benign gastric ulcer and reduction of risk of upper gastrointestinal bleeding in critically ill adults. Source: FDA website	New Formulation	08-30-22
Xenpozyme The Food and Drug Administration (FDA) approved XenpozymeTM (olipudase alfa-rpcp injection) for the treatment of non–central nervous system (CNS) manifestations of acid sphingomyelinase deficiency (ASMD) in adults and pediatrics. Source: FDA website	New Drug	08-31-22
Spevigo The Food and Drug Administration (FDA) approved Spevigo® (spesolimab-sbzo injection) for the treatment of generalized pustular psoriasis flares in adults. Source: FDA website	New Drug	09-01-22
Daxxify	New Indication	8-10-2023

Drug Name	Drug Reason	Date
The Food and Drug Administration (FDA) approved Daxxify® (daxibotulinumtoxinA-lanm) for the treatment of cervical dystonia in adults. Source: FDA website		
Akeega The Food and Drug Administration (FDA) approved AkeegaTM (niraparib/abiraterone acetate tablets) for use with prednisone in adults with deleterious or suspected deleterious BRCA-mutated castration-resistant prostate cancer (mCRPC), as determined by an FDA-approved test. Source: FDA website	New Formulation	8-11-2023
Hepzato Kit The Food and Drug Administration (FDA) approved Hepzato Kit (melphalan for injection/hepatic delivery system) as a liver-directed treatment for adults with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation. Source: FDA website	New Formulation	8-14-2023
Zurzuvae The Food and Drug Administration (FDA) approved ZurzuvaeTM (zuranolone capsules) for the treatment of postpartum depression (PPD) in adults. Source: FDA website	New Drug	8-4-2023
Izervay The Food and Drug Administration (FDA) approved IzervayTM (avacincaptad pegol intravitreal injection) for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). Source: FDA website	New Drug	8-4-2023
Talvey The Food and Drug Administration (FDA) approved TalveyTM (talquetamab-tgvs injection) for the treatment of adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. Source: FDA website	New Drug	8-9-2023
Elrexfio The Food and Drug Administration (FDA) approved ElrexfioTM (elranatamab-bcmm injection) for adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. Source: FDA website	New Drug	8-14-2023
Sohonos The Food and Drug Administration (FDA) approved SohonosTM (palovarotene capsules) for the reduction in volume of new heterotopic ossification in adults and pediatric individuals aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP). Source: FDA website	New Drug	8-16-2023
Terlivaz The Food and Drug Administration (FDA) approved Terlivaz® (terlipressin injection) to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function. Source: FDA website	New Drug	09-14-22
Rolvedon The Food and Drug Administration (FDA) approved RolvedonTM (eflapegrastim-xnst injection) to decrease the incidence of infection, as manifested by febrile neutropenia, in adults with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia. Source: FDA website	New Drug	09-09-22
Sotyktu The Food and Drug Administration (FDA) approved SotyktuTM (deucravacitinib oral tablets) for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Source: FDA website	New Drug	09-09-22
Retevmo The Food and Drug Administration (FDA) approved Retevmo® (selpercatinib capsules) for adults with locally advanced or metastatic solid tumors with a rearranged during transfection (RET) gene fusion. Source: FDA website	New Indication	09-21-22
Aponvie The Food and Drug Administration (FDA) approved Aponvie™ (aprepitant injection) for the prevention of postoperative nausea and vomiting in adults. Source: FDA website	New Formulation	09-16-22
Pedmark The Food and Drug Administration (FDA) approved Pedmark™ (sodium thiosulfate injection) for the reduction of ototoxicity risk associated with cisplatin in individuals 1 month of age and older with localized, non-metastatic solid tumors. Source: FDA website	New Drug	09-20-22
Skysona The Food and Drug Administration (FDA) approved Skysona® (elivaldogene autotemcel injection) to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy (CALD). Early, active CALD refers to	New Drug	09-16-22

Drug Name	Drug Reason	Date
asymptomatic or mildly symptomatic (neurologic function score, NFS ≤ 1) boys who have gadolinium enhancement on brain magnetic resonance imaging (MRI) and Loess scores of 0.5-9. Source: FDA website		
Dupixent The Food and Drug Administration (FDA) approved Dupixent® (dupilumab injection) for the treatment of adults with prurigo nodularis. Source: FDA website	New Indication	09-28-22
Firdapse The Food and Drug Administration (FDA) approved Firdapse® (amifampridine tablets) to expand the indicated age range to include pediatric individuals six years of age and older for the treatment of Lambert-Eaton myasthenic syndrome (LEMS).Source: FDA website	Expanded Indication	09-29-22
Relyvrio The Food and Drug Administration (FDA) approved Relyvrio (sodium phenylbutyrate and taurursodiol for oral suspension) for the treatment of amyotrophic lateral sclerosis (ALS) in adults. Source: FDA website	New Drug	09-29-22
Omlonti The Food and Drug Administration (FDA) approved Omlonti® (omidenepag isopropyl ophthalmic solution) for the reduction of elevated intraocular pressure in individuals with primary open-angle glaucoma or ocular hypertension. Source: FDA website	New Drug	09-22-22
Golden State Medical Supply Golden State Medical Supply announced a voluntary recall of one lot of clopidogrel 75 mg tablets due to being mislabeled as atenolol 25 mg tablets. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/golden-state-medical-supply-inc-issues-voluntary-nationwide-recall-atenolol-25-mg-tablets-and Source: FDA website	Drug Recall	09-30-22
Acyclovir sodium Eugia US LLC announced a voluntary recall of one lot of AuroMedics acyclovir sodium injection 500 mg per 10 mL due to the presence of particulate matter. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/eugia-us-llc-issues-voluntary-nationwide-recall-acyclovir-sodium-injection-500-mg-10-ml-50-mgml-due Source: FDA website	Drug Recall	09-27-22
Oxlumo The Food and Drug Administration (FDA) approved Oxlumo® (lumasiran injection) to include treatment of individuals with advanced primary hyperoxaluria type 1 (PH1). Source: FDA website	Expanded Indication	06-10-22
Boostrix The Food and Drug Administration (FDA) approved Boostrix® (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed injection) for immunization expansion during the third trimester of pregnancy to prevent pertussis in infants younger than two months of age. Source: FDA website	Expanded Indication	07-10-22
Lyumjev The Food and Drug Administration (FDA) approved Lyumjev® (insulin lispro-aabc injection) to improve glycemic control in pediatric individuals with diabetes mellitus. Source: FDA website	Expanded Indication	14-10-22
Furoscix The Food and Drug Administration (FDA) approved Furoscix® (furosemide injection for subcutaneous use) delivered by an on-body infusor approved for the treatment of congestion due to fluid overload in adults with NYHA Class II/III chronic heart failure. Source: FDA website	New Formulation	07-10-22
Lytgobi The Food and Drug Administration (FDA) approved Lytgobi® (futibatinib tablets) for the treatment of adults with previously treated unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring FGFR2 gene fusions or other rearrangements. Source: FDA website	New Drug	30-09-22
Sodium bicarbonate Exela Pharma Sciences announced a voluntary recall of 49 lots of sodium bicarbonate 8.4% injection due to potential safety concerns with vial breakage and flying glass when pressurized while preparing product for administration. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/exela-pharma-sciences-llc-issues-voluntary-nationwide-recall-sodium-bicarbonate-injection-usp-84-50 Source: FDA website	Drug Recall	10-14-22
Vemlidy The Food and Drug Administration (FDA) approved Vemlidy® (tenofovir alafenamide fumarate tablets) expanded label to include treatment of chronic hepatitis B virus infection in	Expanded Indication	10-17-22

Drug Name	Drug Reason	Date
pediatric individuals 12 years of age and older. Source: FDA website		
Rinvoq The Food and Drug Administration (FDA) approved Rinvoq® (upadacitinib extended-release tablets) for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation who have had an inadequate response or intolerance to tumor necrosis factor (TNF) blocker therapy. Source: FDA website	New Indication	10-21-22
Tecvayli The Food and Drug Administration (FDA) approved TecvayliTM (teclistamab-cqyv injection for subcutaneous use) for the treatment of adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. Source: FDA website	New Drug	10-25-22
Imjudo The Food and Drug Administration (FDA) approved Imjudo® (tremelimumab-actl injection for intravenous use) for treatment of adults with unresectable hepatocellular carcinoma (uHCC) in combination with Imfinzi® (durvalumab injection for intravenous use). Source: FDA website	New Drug	10-21-22
Octreotide acetate Mylan Institutional announced a voluntary recall of one lot of octreotide acetate 500 mcg/mL injection due to glass particulates in a syringe. Contact your health care provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/mylan-institutional-llc-viatris-company-issues-voluntary-recall-one-lot-octreotide-acetate-injection Source: FDA website	Drug Recall	10-26-22
Quinapril and hydrochlorothiazide Aurobindo Pharma announced a voluntary recall of two lots of quinapril and hydrochlorothiazide 20 mg/12.5 mg tablets due to the detection of N-nitroso-quinapril impurity. Contact your health care provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/aurobindo-pharma-usa-inc-initiates-voluntary-nationwide-recall-two-2-lots-quinapril-and Source: FDA website	Drug Recall	10-25-22
Cotellic The Food and Drug Administration (FDA) approved Cotellic® (cobimetinib tablets) for the treatment of adults with histiocytic neoplasms. Source: FDA website	New Indication	10-28-2022
Dupixent The Food and Drug Administration (FDA) expanded approval of Dupixent® (dupilumab single-use prefilled pen injection) to include use in pediatric individuals 2 years of age and older for approved indications. Source: FDA website	Expanded Indication	10-17-2022
Wakix The Food and Drug Administration (FDA) approved Wakix® (pitolisant tablets) for the treatment of excessive daytime sleepiness (EDS) in pediatric individuals 6 years of age and older with narcolepsy. Source: FDA website	Expanded Indication	6/21/2024
Libtayo The Food and Drug Administration (FDA) approved Libtayo® (cemiplimab-rwlc injection) in combination with platinum-based chemotherapy for adults with advanced non-small cell lung cancer (NSCLC) with no epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or ROS1 aberrations. Source: FDA website	Expanded Indication	11-08-2022
Adcetris The Food and Drug Administration (FDA) approved Adcetris® (brentuximab vedotin injection) in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide for pediatric individuals 2 years of age and older with previously untreated high risk classical Hodgkin lymphoma (cHL). Source: FDA website	Expanded Indication	11-10-2022
Liletta The Food and Drug Administration (FDA) approved Liletta® (levonorgestrel intrauterine system) for the prevention of pregnancy for up to 8 years. Source: FDA website	Expanded Indication	11-10-2022
Rotarix The Food and Drug Administration (FDA) approved Rotarix® (rotavirus vaccine oral) as a liquid formulation that does not require reconstitution for the prevention of gastroenteritis caused by G1 and non-G1 types (G3, G4, and G9) in infants. Source: FDA website	New Formulation	11-09-2022
Imjudo The Food and Drug Administration (FDA) approved Imjudo® (tremelimumab-actl injection) for the treatment of adults with unresectable hepatocellular carcinoma (uHCC) in combination with Imfinzi® (durvalumab injection). Source: FDA website	New Drug	11-10-2022
Elahere	New Drug	11-14-2022

Drug Name	Drug Reason	Date
The Food and Drug Administration (FDA) approved ElahereTM (mirvetuximab soravtansine-gynx injection) for the treatment of adults with folate receptor alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Source: FDA website		
Tzield The Food and Drug Administration (FDA) approved TzieldTM (teplizumab-mzwv injection) for the treatment of adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, immunomodulatory agent and an anti-CD38 monoclonal antibody. Source: FDA website	New Drug	11-17-2022
Trulicity The Food and Drug Administration (FDA) approved Trulicity® (dulaglutide injection) as an adjunct to diet and exercise to improve glycemic control in pediatric individuals 10 years of age and older with type 2 diabetes mellitus.Source: FDA website	Expanded Indication	11-17-2022
Blincyto The Food and Drug Administration (FDA) approved Blincyto® (blinatumomab injection) for adult and pediatric individuals one month and older with CD19-positive Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia (Ph-negative BCP ALL) in the consolidation phase of multiphase chemotherapy. Source: FDA website	Expanded Indication	6/14/2024
Brexafemme The Food and Drug Administration (FDA) approved Brexafemme® (ibrexafungerp tablets) for the reduction in incidence of recurrent vulvovaginal candidiasis. Source: FDA website	New Indication	11-30-2022
Tecentriq The Food and Drug Administration (FDA) approved Tecentriq® (atezolizumab injection) for the treatment of adult and pediatric individuals two years of age and older with unresectable or metastatic alveolar soft part sarcoma (ASPS). Source: FDA website	New Indication	12-09-2022
Sezaby The Food and Drug Administration (FDA) approved SezabyTM (phenobarbital injection) for the treatment of neonatal seizures. Source: FDA website	New Formulation	11-17-2022
Jylamvo The Food and Drug Administration (FDA) approved Jylamvo® (methotrexate oral solution) for the treatment of adults with acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen, treatment of adults with mycosis fungoides, treatment of adults with relapsed or refractory non-Hodgkin lymphoma as part of a metronomic combination regimen, treatment of adults with rheumatoid arthritis, and treatment of adults with severe psoriasis. Source: FDA website	New Formulation	11-29-2022
Iyuzeh The Food and Drug Administration (FDA) approved IyuzehTM (latanoprost ophthalmic solution) for the reduction of elevated intraocular pressure (IOP) in individuals with open-angle glaucoma or ocular hypertension. Source: FDA website	New Formulation	12-13-2022
Rezlidhia The Food and Drug Administration (FDA) approved Rezlidhia® (olutasidenib capsules) for adults with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test. Source: FDA website	New Drug	12-01-2022
Krazati The Food and Drug Administration (FDA) approved KrazatiTM (adagrasib tablets) for adults with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy. Source: FDA website	New Drug	12-12-2022
Krazati The Food and Drug Administration (FDA) approved Krazati® (adagrasib tablets) plus cetuximab for adults with KRAS G12C-mutated locally advanced or metastatic colorectal cancer (CRC), as determined by an FDA-approved test, who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy. Source: FDA website	New Indication	6/21/2024
Hemgenix The Food and Drug Administration (FDA) approved Hemgenix® (etranacogene dezaparvovec-drlb injection) for the treatment of adults with hemophilia B (congenital Factor IX deficiency) who currently use Factor IX prophylaxis therapy, or who have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes. Source:	New Drug	11-22-2022
Sodium bicarbonate Exela Pharma Sciences announced an expanded recall, adding 14 lots to the ongoing voluntary recall of sodium bicarbonate injection. Contact your health care provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-	Drug Recall	11-29-2022

Drug Name	Drug Reason	Date
withdrawals-safety-alerts/exela-pharma-sciences-llc-expands-voluntary-nationwide-recall-sodium-bicarbonate-injection-usp-84-50 Source: FDA website		
Prolia The Food and Drug Administration (FDA) is investigating the risk of severe hypocalcemia in individuals with advanced kidney disease on dialysis treated with Prolia® (denosumab injection) for osteoporosis. Contact your health care provider with questions. More details may be viewed at: https://www.fda.gov/safety/medical-product-safety-information/prolia-denosumab-amgen-drug-safety-communication-fda-investigating-risk-severe-hypocalcemia-patients Source: FDA website	Drug Warning	11-22-2022
Avycaz The Food and Drug Administration (FDA) approved Avycaz® (avibactam/ceftazidime injection) for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) to include pediatric individuals aged 3 months to less than 18 years. Source: FDA website	Expanded Indication	12-20-22
Wegovy The Food and Drug Administration (FDA) approved Wegovy® (semaglutide injection) as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in pediatric individuals aged 12 years and older with an initial body mass index (BMI) at the 95th percentile or greater standardized for age and sex (obesity). Source: FDA website	Expanded Indication	12-23-22
Pemfexy The Food and Drug Administration (FDA) approved PemfexyTM (pemetrexed injection) in combination with pembrolizumab and platinum chemotherapy, for the initial treatment of individuals with metastatic non-squamous non-small cell lung cancer, with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations. Source: FDA website	Expanded Indication	12-14-22
Tymlos The Food and Drug Administration (FDA) approved Tymlos® (abaloparatide injection) as a treatment to increase bone density in men with osteoporosis at high risk of fracture (defined as a history of osteoporotic fracture or multiple risk factors for fracture), or individuals who have failed or are intolerant to other available osteoporosis therapy. Source: FDA website	Expanded Indication	12-20-22
Vraylar The Food and Drug Administration (FDA) approved Vraylar® (cariprazine capsules) as adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults. Source: FDA website	New Indication	12-16-22
Actemra The Food and Drug Administration (FDA) approved Actemra® (tocilizumab injection) for the treatment of hospitalized adults with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Source: FDA website	New Indication	12-21-22
Olpruva The Food and Drug Administration (FDA) approved OlpruvaTM (sodium phenylbutyrate for oral suspension) for the chronic management of adult and pediatric individuals weighing 20 kg or greater and with a body surface area (BSA) of 1.2 m2 or greater, with urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS). Source: FDA website	New Formulation	12-22-22
Sunlenca The Food and Drug Administration (FDA) approved Sunlenca® (lenacapavir injection and tablets) for treatment of human immunodeficiency virus type 1 (HIV-1) infection, in combination with other antiretroviral(s), in heavily treatment-experienced adults with multidrug resistant (MDR) HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations. Source: FDA website	New Drug	12-22-22
Briumvi The Food and Drug Administration (FDA) approved BriumviTM (ublituximab-xiiy injection) for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Source: FDA website	New Drug	12-28-22
Nexobrid The Food and Drug Administration (FDA) approved Nexobrid® (anacaulase-bcdb topical gel) for eschar removal in adults with deep partial thickness and/or full thickness thermal burns. Source: FDA website	New Drug	12-28-22
Adstiladrin The Food and Drug Administration (FDA) approved Adstiladrin® (nadofaragene firadenovec-vncg for intravesical use) for the treatment of adults with high-risk Bacillus	New Drug	12-16-22

Drug Name	Drug Reason	Date
Calmette□Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors. Source: FDA website		
Lunsumio The Food and Drug Administration (FDA) approved LunsumioTM (mosunetuzumab-axgb) for the treatment of adults with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy. Source: FDA website	New Drug	12-22-22
Vancomycin hydrochloride Hospira announced a voluntary recall of one lot of vancomycin hydrochloride injection. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/hospira-inc-issues-voluntary-nationwide-recall-one-lot-vancomycin-hydrochloride-injection-usp Source: FDA website	Drug Recall	12-27-22
Daptomycin Accord Healthcare announced a recall of one lot of daptomycin injection. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/accord-healthcare-inc-issues-nationwide-voluntary-recall-daptomycin-injection-500-mgvial-and Source: FDA website	Drug Recall	12-27-22
Quinapril Lupin Pharmaceuticals announced a voluntary recall of four lots of quinapril tablets due to potential presence of an impurity. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lupin-pharmaceuticals-inc-issues-voluntary-nationwide-recall-four-lots-quinapril-tablets-due Source: FDA website	Drug Recall	12-21-22
Rybelsus The Food and Drug Administration (FDA) approved Rybelsus® (semaglutide tablets) as a first-line treatment option for adults with type 2 diabetes. Source: FDA website	Expanded Indication	01-12-2023
Adacel The Food and Drug Administration (FDA) approved Adacel® (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed [Tdap] injection) for immunization during the third trimester of pregnancy to prevent pertussis in infants younger than 2 months of age. Source: FDA website	Expanded Indication	01-11-2023
Airsupra The Food and Drug Administration (FDA) approved AirsupraTM (albuterol/budesonide oral inhalation) for the as-needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations in people with asthma 18 years of age and older. Source: FDA website	New Formulation	01-10-2023
Leqembi The Food and Drug Administration (FDA) approved LeqembiTM (lecanemab injection) for the treatment of Alzheimer’s disease in people with mild cognitive impairment or mild dementia, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. Source: FDA website	New Drug	01-06-2023
Brukinsa The Food and Drug Administration (FDA) approved Brukinsa® (zanubrutinib capsules) for chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). Source: FDA website	New Indication	1/19/2023
Tukysa The Food and Drug Administration (FDA) approved Tukysa® (tucatinib tablets) in combination with trastuzumab for RAS wild-type human epidermal growth factor receptor 2 (HER2)-positive unresectable or metastatic colorectal cancer that has progressed following fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy. Source: FDA website	New Indication	1/19/2023
Keytruda The Food and Drug Administration (FDA) approved Keytruda® (pembrolizumab injection) for adjuvant treatment following resection and platinum-based chemotherapy for stage IB (T2a ≥4 cm), II, or IIIA non-small cell lung cancer (NSCLC). Source: FDA website	Expanded Indication	1/26/2023
Keytruda The Food and Drug Administration (FDA) approved Keytruda® (pembrolizumab injection) with carboplatin and paclitaxel, followed by single-agent pembrolizumab, for adults with primary advanced or recurrent endometrial carcinoma. Source: FDA website	Expanded Indication	6/17/2024
Odactra The Food and Drug Administration (FDA) approved OdactraTM (house dust mite allergen extract tablets for sublingual use) to include treatment of house dust mite (HDM)-induced allergic rhinitis in individuals 12 to 17 years of age. Source: FDA website	Expanded Indication	1/20/2023

Drug Name	Drug Reason	Date
Enjaymo The Food and Drug Administration (FDA) approved Enjaymo® (sutimlimab-jome injection) for the treatment of hemolysis in adults with cold agglutinin disease (CAD) to include individuals with or without a history of transfusions. Source: FDA website	Expanded Indication	1/25/2023
Rykindo The Food and Drug Administration (FDA) approved Rykindo® (risperidone extended-release injectable suspension, for intramuscular use) for the treatment of schizophrenia in adults and as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder in adults. Source: FDA website	New Formulation	1/13/2023
Orserdu The Food and Drug Administration (FDA) approved OrserduTM (elacestrant tablets) for postmenopausal women or adult men with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy. Source: FDA website	New Drug	1/27/2023
Jaypirca The Food and Drug Administration (FDA) approved JaypircaTM (pirtobrutinib tablets) for relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a bruton tyrosine kinase (BTK) inhibitor. Source: FDA website	New Drug	1/27/2023
Brenzavvy The Food and Drug Administration (FDA) approved Brenzavvy® (bexagliflozin tablets) as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM). Source: FDA website	New Drug	1/20/2023
Revatio The Food and Drug Administration (FDA) approved RevatioTM (sildenafil citrate tablets) for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) in pediatric individuals (1 to 17 years old) to improve exercise ability and, in pediatric individuals too young to perform standard exercise testing, pulmonary hemodynamics thought to underly improvements in exercise. Source: FDA website	Expanded Indication	1/31/2023
Trodelvy The Food and Drug Administration (FDA) approved Trodelvy® (sacituzumab govitecan-hziy) for unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer in individuals who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting. Source: FDA website	Expanded Indication	2/3/2023
Tezspire The Food and Drug Administration (FDA) approved TezspireTM (tezepelumab-ekko prefilled single-use pen, self-administration) for the add-on maintenance treatment of individuals 12 years of age and older with severe asthma. Source: FDA website	New Formulation	2/1/2023
Atorvaliq The Food and Drug Administration (FDA) approved Atorvaliq® (atorvastatin calcium oral suspension): --To reduce the risk of myocardial infarction (MI), stroke, revascularization procedures, and angina in adults with multiple risk factors for coronary heart disease (CHD) but without clinically evident CHD, MI and stroke in adults with type 2 diabetes mellitus with multiple risk factors for CHD but without clinically evident CHD, non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure, and angina in adults with clinically evident CHD -- As an adjunct to diet to reduce low-density lipoprotein cholesterol (LDL-C) in adults with primary hyperlipidemia, adults and pediatric individuals aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH) -- As an adjunct to other LDL-C lowering therapies, or alone if such treatments are unavailable, to reduce LDL-C in adults and pediatric individuals aged 10 years and older with homozygous familial hypercholesterolemia (HoFH) --As an adjunct to diet for the treatment of adults with primary dysbetalipoproteinemia and hypertriglyceridemia. Source: FDA website	New Formulation	2/1/2023
Jesduvroq The Food and Drug Administration (FDA) approved Jesduvroq (daprodustat tablets) to treat anemia caused by chronic kidney disease (CKD) in adults who have been on dialysis for at least four months. Source: FDA website	New Drug	2/1/2023
Tirosint IBSA Pharma announced a voluntary recall of 27 lots of Tirosint®-Sol (levothyroxine sodium oral solution) due to subpotency. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/ibsa-pharma-inc-issues-voluntary-nationwide-recall-select-lots-tirosintr-sol-levothyroxine-sodium Source: FDA website	Drug Recall	2/1/2023

Drug Name	Drug Reason	Date
Keytruda The Food and Drug Administration (FDA) approved Keytruda® (pembrolizumab injection) in combination with Padcev® (enfortumab vedotin-ejfv) for individuals with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy. Source: FDA website	New Indication	04-03-23
HyQvia The Food and Drug Administration (FDA) expanded the approval for HyQvia (immune globulin 10% [human] with recombinant human hyaluronidase injection) to include children 2 to 16 years of age with primary immunodeficiency (PI). Source: FDA website	Expanded Indication	04-11-23
Joenja The Food and Drug Administration (FDA) approved Joenja® (leniolisib tablets) for the treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in adult and pediatric individuals 12 years of age and older. Source: FDA website	New Drug	03-24-23
Atovaquone Camber Pharmaceuticals announced a voluntary recall of one lot of atovaquone oral suspension 750 mg/5 mL due to potential Bacillus cereus contamination. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/camber-pharmaceuticals-inc-issues-voluntary-nationwide-recall-atovaquone-oral-suspension-usp Source: FDA website	Drug Recall	04-03-23
Caldolor The Food and Drug Administration (FDA) approved Caldolor® (ibuprofen injection for intravenous use) expansion to include pediatric individuals aged 3 months and older for the management of mild to moderate pain, the management of moderate to severe pain as an adjunct to opioid analgesics, and for the reduction of fever. Source: FDA website	Expanded Indication	5/11/2023
Breo Ellipta The Food and Drug Administration (FDA) approved Breo Ellipta (fluticasone furoate/vilanterol for oral inhalation) expansion to include maintenance treatment of asthma for individuals aged 12 to 17 years and new dosage strength of 50/25 mcg approved for maintenance treatment of asthma in individuals 5 to 11 years. Source: FDA website	Expanded Indication	5/12/2023
Lexapro The Food and Drug Administration (FDA) approved Lexapro® (escitalopram oxalate tablets and oral solution) expansion to include individuals 7 to 17 years of age for the treatment of generalized anxiety disorder (GAD). Source: FDA website	Expanded Indication	5/12/2023
Ayvakit The Food and Drug Administration (FDA) approved Ayvakit® (avapritinib tablets) for the treatment of adults with indolent systemic mastocytosis (ISM). Source: FDA website	Expanded Indication	5/22/2023
Rinvoq The Food and Drug Administration (FDA) approved Rinvoq® (upadacitinib extended-release tablets) for adults with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers. Source: FDA website	New Indication	5/18/2023
Brixadi The Food and Drug Administration (FDA) approved BrixadiTM (buprenorphine extended-release injection for subcutaneous use) to treat moderate to severe opioid use disorder (OUD). Source: FDA website	New Formulation	5/23/2023
Opvee The Food and Drug Administration (FDA) approved Opvee® (nalmefene nasal spray) for the emergency treatment of known or suspected opioid overdose in adults and pediatric individuals 12 years of age and older. Source: FDA website	New Formulation	5/23/2023
Xacduro The Food and Drug Administration (FDA) approved Xacduro® (sulbactam injection; durlobactam injection, co-packaged for intravenous use) for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible strains of Acinetobacter. Source: FDA website	New Drug	5/23/2023
Veozah The Food and Drug Administration (FDA) approved VeozahTM (fezolinetant tablets) for the treatment of moderate to severe vasomotor symptoms due to menopause. Source: FDA website	New Drug	5/12/2023
Miebo The Food and Drug Administration (FDA) approved MieboTM (perfluorohexyloctane ophthalmic solution) for the treatment of the signs and symptoms of dry eye disease. Source: FDA website	New Drug	5/18/2023
Epkinly	New Drug	5/19/2023

Drug Name	Drug Reason	Date
The Food and Drug Administration (FDA) approved EpkinlyTM (epcoritamab-bysp subcutaneous injection) for relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy. Source: FDA website		
Vyjuvek		
The Food and Drug Administration (FDA) approved VyjuvekTM (beremagene geperpavec-svdt biological suspension mixed with excipient gel for topical application) for the treatment of wounds in individuals 6 months of age and older with dystrophic epidermolysis bullosa with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene. Source: FDA website	New Drug	5/19/2023
Stimulants		
The Food and Drug Administration (FDA) is requiring updates to the Boxed Warning and other information in the prescribing information for prescription stimulants to ensure the labels are consistent across the class. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-updating-warnings-improve-safe-use-prescription-stimulants-used-treat-adhd-and-other-conditions Source: FDA website	Drug Warning	5/11/2023
Linzess		
The Food and Drug Administration (FDA) approved Linzess® (linaclotide capsules) to treat functional constipation in pediatric individuals 6 to 17 years of age. Source: FDA website	New Indication	6-12-2023
Liletta		
The Food and Drug Administration (FDA) approved Liletta® (levonorgestrel intrauterine device) for the treatment of heavy menstrual bleeding for up to 5 years in individuals who choose intrauterine contraception as their method of contraception. Source: FDA website	New Indication	6-29-2023
Bylvay		
The Food and Drug Administration (FDA) approved BylvayTM (odevixibat capsules) for the treatment of cholestatic pruritus in individuals 12 months of age and older with Alagille syndrome (ALGS). Source: FDA website	New Indication	6-13-2023
Triumeq; Triumeq PD		
The Food and Drug Administration (FDA) approved Triumeq; Triumeq PD (abacavir/dolutegravir/lamivudine tablets and tablets for oral suspension) for the treatment of human immunodeficiency virus (HIV)-infection in pediatric people aged at least 3 months and weighing at least 6 kg. Source: FDA website	Expanded Indication	6-15-2023
Talzenna		
The Food and Drug Administration (FDA) approved Talzenna® (talazoparib capsules) in combination with enzalutamide for homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC). Source: FDA website	Expanded Indication	6-20-2023
Jardiance		
The Food and Drug Administration (FDA) approved Jardiance® (empagliflozin tablets) as addition to diet and exercise to improve blood sugar control in children 10 years and older with type 2 diabetes. Source: FDA website	Expanded Indication	6-20-2023
Synjardy		
The Food and Drug Administration (FDA) approved Synjardy® (empagliflozin/metformin hydrochloride tablets) as addition to diet and exercise to improve blood sugar control in children 10 years and older with type 2 diabetes. Source: FDA website	Expanded Indication	6-20-2023
Suflave		
The Food and Drug Administration (FDA) approved Suflave® (polyethylene glycol 3350/sodium sulfate/potassium chloride/ magnesium sulfate/sodium chloride for oral solution) for cleansing of the colon in preparation for colonoscopy in adults. Source: FDA website	New Formulation	6-15-2023
Capvaxive		
The Food and Drug Administration (FDA) approved CapvaxiveTM (pneumococcal 21-valent conjugate vaccine injection) for active immunization for the prevention of invasive disease caused by certain Streptococcus pneumoniae and S. pneumoniae serotypes in individuals 18 years of age and older. Source: FDA website	New Formulation	6/17/2024
Yimmugo		
The Food and Drug Administration (FDA) approved Yimmugo (immune globulin intravenous, human - dira, 10% liquid) for the treatment of individuals 2 years of age and older with primary humoral immunodeficiency (PI). Source: FDA website	New Formulation	6/17/2024
Vigafyde		
The Food and Drug Administration (FDA) approved VigafydeTM (vigabatrin oral solution) as monotherapy for the treatment of pediatric individuals 1 month to 2 years of age with infantile spasms for whom the potential benefits outweigh the potential risk of vision loss. Source: FDA website	New Formulation	6/17/2024

Drug Name	Drug Reason	Date
Adbry The Food and Drug Administration (FDA) approved Adbry® (tralokinumab-ldrm, single-dose autoinjector) for self-administration for the treatment of adults with moderate-to-severe atopic dermatitis. Source: FDA website	New Formulation	6/12/2024
Sofdra The Food and Drug Administration (FDA) approved SofdraTM (sofpironium topical gel) for the treatment of primary axillary hyperhidrosis in adults and pediatric individuals 9 years of age and older. Source: FDA website	New Drug	6/20/2024
PiaSky The Food and Drug Administration (FDA) approved PiaSky (crovalimab-akkz injection) for the treatment of adults and pediatrics 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH) and body weight of at least 40 kg. Source: FDA website	New Drug	6/20/2024
Rytelo The Food and Drug Administration (FDA) approved Rytelo (imetelstat injection) for the treatment of adults with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring 4 or more red blood cell (RBC) units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA). Source: FDA website	New Drug	6/17/2024
Iqirvo The Food and Drug Administration (FDA) approved Iqirvo® (elafibranor tablets) for the treatment of adults with primary biliary cholangitis (PBC) either in combination with ursodeoxycholic acid (UDCA; ursodiol oral) with an inadequate response to ursodiol, or as monotherapy in those unable to tolerate ursodiol. Source: FDA website	New Drug	6/10/2024
Lodoco The Food and Drug Administration (FDA) approved Lodoco® (colchicine 0.5 mg tablet) to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death in adults with established atherosclerotic disease or with multiple risk factors for cardiovascular disease. Source: FDA website	New Formulation	6-16-2023
Ngenla The Food and Drug Administration (FDA) approved NgenlaTM (somatrogon-ghla subcutaneous injection) for treatment of pediatric individuals aged three years and older who have growth failure due to inadequate secretion of endogenous growth hormone. Source: FDA website	New Formulation	6-27-2023
Vyvgart Hytrulo The Food and Drug Administration (FDA) approved Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc subcutaneous injection) for use in adults with generalized myasthenia gravis who also have an antibody known as acetylcholine receptor (AchR). It must still be administered by a healthcare provider. Source: FDA website	New Formulation	6-20-2023
Vyvgart Hytrulo The Food and Drug Administration (FDA) approved Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc injection) for the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP). Source: FDA website	New Indication	6/21/2024
Elevidys The Food and Drug Administration (FDA) approved Elevidys (delandistrogene moxeparvovec-rokl intravenous infusion) for the treatment of ambulatory pediatric individuals aged 4 through 5 years with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene. Source: FDA website	New Drug	6-22-2023
Elevidys The Food and Drug Administration (FDA) approved Elevidys® (delandistrogene moxeparvovec-rokl injection) for expanded use in ambulatory and non-ambulatory individuals 4 years of age and older with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene. Source: FDA website	Expanded Indication	6/20/2024
Columvi The Food and Drug Administration (FDA) approved Columvi® (glofitamab-gxbm injection) for the treatment of adults with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) not otherwise specified or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy. Source: FDA website	New Drug	6-16-2023
Rystiggo The Food and Drug Administration (FDA) approved Rystiggo® (rozanolixizumab-noli injection for subcutaneous use) for the treatment of generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive. Source: FDA website	New Drug	6-26-2023
Litfulo	New Drug	6-23-2023

Drug Name	Drug Reason	Date
The Food and Drug Administration (FDA) approved LitfuloTM (ritlecitinib capsules) for the treatment of severe alopecia areata (AA) in adults and adolescents 12 years and older. Source: FDA website		
Roctavian		
The Food and Drug Administration (FDA) approved Roctavian® (valoctocogene roxaparvovec-rvox intraveous infusion) for the treatment of adult males with severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) without pre-existing antibodies to adeno-associated virus serotype 5 (AAV5) detected by a Food and Drug Administration (FDA)-approved test. Source: FDA website	New Drug	6-29-2023
Dronabinol; ziprasidone		
The Harvard Drug Group announced a voluntary recall of a single lot of dronabinol capsules 2.5 mg and ziprasidone hydrochloride capsules, 20 mg due to a label mix-up. Contact your healthcare provider with questions. More details may be available at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/harvard-drug-group-llc-issues-voluntary-nationwide-recall-dronabinol-capsules-usp-25-mg-and Source: FDA website	Drug Recall	6-13-2023
Nucynta		
The Food and Drug Administration (FDA) approved Nucynta® (tapentadol hydrochloride tablets) for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults and pediatric people aged 6 years and older with a body weight of at least 40 kg. Source: FDA website	Expanded Indication	07-03-2023
Leqvio		
The Food and Drug Administration (FDA) approved Leqvio® (inclisiran subcutaneous injection) for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C), as an adjunct to diet and statin therapy. Source: FDA website	Expanded Indication	07-07-2023
Veklury		
The Food and Drug Administration (FDA) approved Veklury® (remdesivir injection for intravenous use) to include treatment of COVID-19 in individuals with severe renal impairment, including those on dialysis. Source: FDA website	Expanded Indication	07-13-2023
Ervebo		
The Food and Drug Administration (FDA) approved Erbevo® (Ebola Zaire vaccine injection, live) to include people 12 months of age and older for the prevention of disease caused by Zaire Ebola virus. Source: FDA website	Expanded Indication	07-27-2023
Lonsurf		
The Food and Drug Administration (FDA) approved Lonsurf® (trifluridine and tipiracil tablets) in combination with bevacizumab for metastatic colorectal cancer (mCRC) previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-vascular endothelial growth factor (VEGF) biological therapy, and if RAS wild-type, an anti-epidermal growth factor receptor (EGFR) therapy. Source: FDA website	Expanded Indiation	08-02-2023
Jemperli		
The Food and Drug Administration (FDA) approved Jemperli (dostarlimab-gxly injection) in combination with carboplatin and paclitaxel, followed by monotherapy, for primary advanced or recurrent endometrial cancer (EC) that is mismatch repair deficient (dMMR), as determined by an FDA-approved test, or microsatellite instability-high (MSI-H). Source: FDA website	New Indication	07-31-2023
ReVive		
The Food and Drug Administration (FDA) approved ReViveTM (naloxone nasal spray) for opioid overdose reversal for over-the-counter (OTC) nonprescription use. Source: FDA website	New Formulation	07-28-2023
Balfaxar		
The Food and Drug Administration (FDA) approved Balfaxar (prothrombin complex concentrate, human-lans solution for intravenous use) for the urgent reversal of acquired coagulation factor deficiency induced by vitamin K antagonist (VKA, eg, warfarin) therapy in adults with need for an urgent surgery or invasive procedures. Source: FDA website	New Formulation	07-24-2023
Beyfortus		
The Food and Drug Administration (FDA) approved BeyfortusTM (nirsevimab-alip injection) for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease (LRTD) in neonates and infants born during or entering their first RSV season and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. Source: FDA website	New Drug	07-01-2023
Vanflyta	New Drug	07-20-2023
The Food and Drug Administration (FDA) approved Vanflyta® (quizartinib tablets) for the treatment of adults with newly diagnosed acute myeloid leukemia (AML) that is FLT3		

Drug Name	Drug Reason	Date
internal tandem duplication (ITD)-positive as detected by a Food and Drug Administration (FDA)-approved test. Source: FDA website		
Ycanth The Food and Drug Administration (FDA) approved YcanthTM (cantharidin topical solution) for the treatment of molluscum contagiosum (MC) in adult and pediatric people 2 years of age and older. Source: FDA website	New Drug	07-21-2023
Xdemvy The Food and Drug Administration (FDA) approved XdemvyTM (lotilaner ophthalmic solution) for the treatment of Demodex blepharitis. Source: FDA website	New Drug	07-24-2023
Tydemy Lupin Pharmaceuticals announced a voluntary recall of two lots of Tydemy (drospirenone/ethinyl estradiol and levomefolate calcium tablets) oral contraceptive due to out of specification test results. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lupin-pharmaceuticals-inc-issues-voluntary-nationwide-recall-2-lots-tydemytm-drospirenone-ethinyl Source: FDA website	Drug Recall	07-28-2023
Albuterol sulfate Cipla Limited announced a voluntary recall of six batches of albuterol sulfate inhalation aerosol 90 mcg due to observed leakage through valve in a single inhaler. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/cipla-issues-voluntary-nationwide-recall-six-batches-albuterol-sulfate-inhalation-aerosol-90-mcg-200 Source: FDA website	Drug Recall	07-10-2023
Ingrezza The Food and Drug Administration (FDA) approved Ingrezza® (valbenazine capsules) for the treatment of chorea associated with Huntington's disease (HD). Source: FDA website	New Indication	08-18-23
Ilaris The Food and Drug Administration (FDA) approved Ilaris® (canakinumab injection) for gout flares in adults in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate. Source: FDA website	New Indication	08-25-23
Abrysvo The Food and Drug Administration (FDA) approved AbrysvoTM (respiratory syncytial virus vaccine injection) for active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age. Source: FDA website	Expanded Indication	08-21-23
Veklury The Food and Drug Administration (FDA) approved Veklury® (remdesivir injection) to include COVID-19 treatment in people with mild to severe hepatic impairment with no dose adjustments. Source: FDA website	Expanded Indication	08-23-23
Reblozyl The Food and Drug Administration (FDA) approved Reblozyl® (luspatercept-aamt injection) for the treatment of anemia without previous erythropoiesis stimulating agent use (ESA-naïve) in adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular red blood cell (RBC) transfusions. Source: FDA website	Expanded Indication	08-28-23
Mekinist The Food and Drug Administration (FDA) approved Mekinist® (trametinib dimethyl sulfoxide tablets) for extended age range of the tumor agnostic indication from people aged 6 years of age and older to people aged 1 year of age and older. Source: FDA website	Expanded Indication	08-31-23
Tafinlar The Food and Drug Administration (FDA) approved Tafinlar® (dabrafenib mesylate capsules) for extended age range of the tumor agnostic indication from people aged 6 years of age and older to people aged 1 year of age and older. Source: FDA website	Expanded Indication	08-31-23
Focinvez The Food and Drug Administration (FDA) approved Focinvez (fosaprepitant injection) in adults and pediatric people 6 months of age and older, in combination with other antiemetic agents, for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC). Source: FDA website	New Formulation	08-22-23
Eylea HD The Food and Drug Administration (FDA) approved Eylea® HD (aflibercept 8 mg higher dose for intravitreal injection) for the treatment of wet age-related macular degeneration	New Formulation	08-18-23

Drug Name	Drug Reason	Date
(wAMD), diabetic macular edema (DME), and diabetic retinopathy. Source: FDA website		
Veopoz The Food and Drug Administration (FDA) approved VeopozTM (pozelimab-bbfg injection) for the treatment of CD55-deficient protein-losing enteropathy (PLE), also known as complement hyperactivation, angiopathic thrombosis, and protein-losing enteropathy (CHAPLE) disease in adult and pediatric people 1 year of age and older. Source: FDA website	New Drug	08-18-23
Inmar Supply Chain Solutions Inmar Supply Chain Solutions announced a voluntary recall of Food and Drug Administration (FDA) regulated products contained in pallets stored in their Arlington, Texas facility between May 1, 2022, and June 30, 2023. The recalled products were stored in this facility during a time when there may have been a pest control problem. In addition, because of recent unusually hot weather, the products may have been subjected to temperatures in excess of the storage condition instructions on the product labeling. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/inmar-supply-chain-solutions-llc-issues-voluntary-recall-product-stored-its-arlington-texas-facility Source: FDA website	Drug Recall	08-25-23
Digoxin Marlex Pharmaceuticals announced a voluntary recall of one lot of digoxin tablets 0.125 mg and one lot of digoxin tablets 0.25 mg due to label mix-up. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/marlex-pharmaceuticals-inc-issues-voluntary-nationwide-recall-digoxin-tablets-usp-0125mg-and-digoxin Source: FDA website	Drug Recall	08-30-23
Bosulif The Food and Drug Administration (FDA) approved Bosulif® (bosutinib tablets and capsules) for pediatric people 1 year of age and older with chronic phase (CP) Ph+ chronic myelogenous leukemia (CML) that is newly diagnosed (ND) or resistant or intolerant (R/I) to prior therapy. Source: FDA website	Expanded Indication	09-26-23
Zoryve The Food and Drug Administration (FDA) approved Zoryve® (roflumilast topical cream) for the topical treatment of plaque psoriasis, including intertriginous areas, to children ages 6 to 11 years. Source: FDA website	Expanded Indication	10-05-23
Jardiance The Food and Drug Administration (FDA) approved Jardiance® (empagliflozin tablets) to reduce the risk of sustained decline in estimated glomerular filtration rate (eGFR), end-stage kidney disease, cardiovascular death and hospitalization in adults with chronic kidney disease (CKD) at risk of progression. Source: FDA website	New Indication	09-21-23
Likmez The Food and Drug Administration (FDA) approved LikmezTM (metronidazole oral suspension) for trichomoniasis in adults, amebiasis in adults and pediatric people, and anaerobic bacterial infections in adults. Source: FDA website	New Formulation	09-22-23
Entyvio Pen The Food and Drug Administration (FDA) approved Entyvio® Pen (vedolizumab subcutaneous injection) to treat moderately to severely active ulcerative colitis (UC) in adults. Source: FDA website	New Dosage Form	09-28-23
Empaveli The Food and Drug Administration (FDA) approved Empaveli® (pegcetacoplan on-body injector for subcutaneous administration) for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH). Source: FDA website	New Dosage Form	09-28-23
Exxua The Food and Drug Administration (FDA) approved Exxua (gepirone extended-release tablets) for treatment of major depressive disorder (MDD) in adults. Source: FDA website	New Drug	09-22-23
Rivfloza The Food and Drug Administration (FDA) approved RivflozaTM (nedosiran subcutaneous injection) to lower urinary oxalate levels in children 9 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function, e.g., estimated glomerular filtration rate (eGFR) ≥30 mL/min/1.73 m2. Source: FDA website	New Drug	09-29-23
Pombiliti The Food and Drug Administration (FDA) approved PombilitiTM (cipaglucosidase alfa-atga injection for intravenous use) in combination with OpfoldaTM (migalastat capsules) for the treatment of adults with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT). Source: FDA website	New Drug	09-28-23

Drug Name	Drug Reason	Date
Opfolda The Food and Drug Administration (FDA) approved OpfoldaTM (migalastat capsules) in combination with PombilitiTM (cipaglucosidase alfa-atga injection for intravenous use) for the treatment of adults with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT). Source: FDA website	New Drug	09-28-23
Brexfemme Scynexis announced a voluntary recall of two lots of Brexafemme® (ibrexafungerp tablets) due to potential cross contamination with a non-antibacterial beta-lactam drug substance. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/scynexis-issues-voluntary-nationwide-recall-brexafemmer-ibrexafungerp-tablets-due-potential-cross Source: FDA website	Drug Recall	09-27-23
Sodium bicarbonate and lidocaine hydrochloride Hospira announced a voluntary recall of 4.2% sodium bicarbonate injection and 1% and 2% lidocaine hydrochloride injection due to the potential for presence of glass particulate matter. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/hospira-inc-issues-voluntary-nationwide-recall-42-sodium-bicarbonate-injection-usp-and-1-and-2 Source: FDA website	Drug Recall	10-03-23
Sucralfate VistaPharm announced a voluntary recall of one lot of sucralfate oral suspension 1 g/10 mL due to Bacillus cereus contamination. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/vistapharm-llc-issues-voluntary-nationwide-recall-sucralfate-oral-suspension-1g10ml-due-microbial Source: FDA website	Drug Recall	09-22-23
Betaxolol KVK-Tech announced a voluntary recall of one lot of betaxolol tablets 10 mg due to a single oxycodone tablet 5 mg found on the packaging line during the line clearance after the subject batch was packaged. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/kvk-tech-inc-issues-voluntary-nationwide-recall-one-lot-betaxolol-tablets-usp-10-mg-batch-number Source: FDA website	Drug Recall	10-03-23
Veltassa The Food and Drug Administration (FDA) approved Veltassa® (patiromer oral suspension) to include treatment of hyperkalemia in pediatric people 12 years of age and older. Source: FDA website	Expanded Indication	10-2-2023
Braftovi and Mektovi The Food and Drug Administration (FDA) approved Braftovi® (encorafenib capsules) in combination with Mektovi® (binimetinib tablets) for adults with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation, as detected by an FDA-approved test. Source: FDA website	Expanded Indication	10-13-2023
Opdivo The Food and Drug Administration (FDA) approved Opdivo® (nivolumab intravenous injection) for the adjuvant treatment of adult and pediatric people 12 years and older with completely resected stage IIB or IIC melanoma. Source: FDA website	Expanded Indication	10-13-2023
Keytruda The Food and Drug Administration (FDA) approved Keytruda® (pembrolizumab intravenous injection) with platinum-containing chemotherapy as neoadjuvant treatment, and with continuation of single-agent Keytruda as post-surgical adjuvant treatment for resectable (tumors ≥4 cm or node positive) non-small cell lung cancer (NSCLC). Source: FDA website	Expanded Indication	10-16-2023
Enbrel The Food and Drug Administration (FDA) approved Enbrel® (etanercep subcutaneous injection) for the treatment of active juvenile psoriatic arthritis (JPsA) in people 2 years of age and older. Source: FDA website	Expanded Indication	10-18-2023
Rozlytrek The Food and Drug Administration (FDA) approved Rozlytrek® (entrectinib capsules and oral pellets) to include pediatric people older than 1 month with solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory standard therapy. Source: FDA website	Expanded Indication	10-20-2023
Voxzogo	Expanded Indication	10-20-2023

Drug Name	Drug Reason	Date
The Food and Drug Administration (FDA) approved Voxzogo® (vosoritide subcutaneous injection) to increase linear growth in pediatric people of all ages with achondroplasia with open epiphyses (growth plates). Source: FDA website		
Orencia The Food and Drug Administration (FDA) approved Orencia® (abatacept injection) for the treatment of people 2 to 17 years of age with active psoriatic arthritis (PsA). Source: FDA website	Expanded Indication	10-30-2023
Tibsovo The Food and Drug Administration (FDA) approved Tibsovo® (ivosidenib tablets) for adults with relapsed or refractory myelodysplastic syndromes (MDS) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation, as detected by an FDA-approved test. Source: FDA website	New Indication	10-24-2023
Vabysmo The Food and Drug Administration (FDA) approved VabysmoTM (faricimab-svoa intravitreal injection) for the treatment of macular edema following retinal vein occlusion (RVO). Source: FDA website	New Indication	10-26-2023
Cosentyx The Food and Drug Administration (FDA) approved Cosentyx® (secukinumab injection) for the treatment of moderate to severe hidradenitis suppurativa (HS) in adults. Source: FDA website	New Indication	10-31-2023
Keytruda The Food and Drug Administration (FDA) approved Keytruda® (pembrolizumab intravenous injection) in combination with gemcitabine and cisplatin for the treatment of locally advanced unresectable or metastatic biliary tract cancer (BTC). Source: FDA website	New Indication	10-31-2023
Cosentyx The Food and Drug Administration (FDA) approved Cosentyx® (secukinumab) intravenous infusion formulation for the treatment of adults with psoriatic arthritis (PsA), ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA). Source: FDA website	New Formulation	10-6-2023
Xphozah The Food and Drug Administration (FDA) approved Xphozah® (tenapanor tablets) to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in people who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. Source: FDA website	New Formulation	10-17-2023
Qlosi The Food and Drug Administration (FDA) approved QlosiTM (pilocarpine 0.4% ophthalmic solution) for the treatment of presbyopia in adults. Source: FDA website	New Formulation	10-17-2023
Combogesic IV The Food and Drug Administration (FDA) approved Combogesic® IV (acetaminophen/ibuprofen intravenous injection) for the relief of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics. Source: FDA website	New Formulation	10-17-2023
Penbraya The Food and Drug Administration (FDA) approved PenbrayaTM (meningococcal groups A, B, C, W, and Y intramuscular injection) for active immunization to prevent invasive disease caused by Neisseria meningitidis serogroups A, B, C, W, and Y for people 10 through 25 years of age. Source: FDA website	New Formulation	10-20-2023
Cabtreo The Food and Drug Administration (FDA) approved CabtreoTM (clindamycin phosphate/adapalene/benzoyl peroxide topical gel) for the treatment of acne vulgaris in people 12 years of age and older. Source: FDA website	New Formulation	10-20-2023
Zymfentra The Food and Drug Administration (FDA) approved Zymfentra (infliximab-dyyb subcutaneous injection) in adults for maintenance treatment of moderately to severely active ulcerative colitis following treatment with an infliximab product administered intravenously and moderately to severely active Crohn’s disease following treatment with an infliximab product administered intravenously. Source: FDA website	New Formulation	10-20-2023
Velsipity The Food and Drug Administration (FDA) approved VelsipityTM (etrasimod tablets) for the treatment of moderately to severely active ulcerative colitis in adults. Source: FDA website	New Drug	10-12-2023
Zilbrysq The Food and Drug Administration (FDA) approved Zilbrysq® (zilucoplan subutaneous injection) for the treatment of generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AChR) antibody positive. Source: FDA website	New Drug	10-17-2023

Drug Name	Drug Reason	Date
Bimzelx The Food and Drug Administration (FDA) approved Bimzelx® (bimekizumab-bkzx subcutaneous injection) for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. Source: FDA website	New Drug	10-17-2023
Agamree The Food and Drug Administration (FDA) approved Agamree® (vamorolone oral suspension) for the treatment of Duchenne muscular dystrophy (DMD) in people 2 years of age and older. Source: FDA website	New Drug	10-26-2023
Omvoh The Food and Drug Administration (FDA) approved OmvohTM (mirikizumab-mrkz injection) for the treatment of moderately to severely active ulcerative colitis in adults. Source: FDA website	New Drug	10-26-2023
Loqtorzi The Food and Drug Administration (FDA) approved LoqtorziTM (toripalimab-tpzi intravenous injection) for use in combination with cisplatin and gemcitabine for first-line treatment of adults with metastatic or with recurrent locally advanced nasopharyngeal carcinoma (NPC) and as a single agent for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy. Source: FDA website	New Drug	10-27-2023
Exela Pharma Sciences Exela Pharma Sciences announced a voluntary recall of sodium bicarbonate, midazolam, and Elcys (cysteine hydrochloride) injections due to the presence of particulate matter. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/exela-pharma-sciences-llc-issues-voluntary-nationwide-recall-84-sodium-bicarbonate-injection-usp-50 Source: FDA website	Drug Recall	10-26-2023
Epkinly The Food and Drug Administration (FDA) approved EpkinlyTM (epcoritamab-bysp injection) for adults with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. Source: FDA website	New Indication	06-26-2024
Zoryve The Food and Drug Administration (FDA) approved ZoryveTM (roflumilast topical cream) for the treatment of mild to moderate atopic dermatitis in adult and pediatric individuals 6 years of age and older. Source: FDA website	New Indication	07-09-2024
Voquezna The Food and Drug Administration (FDA) approved Voquezna® (vonoprazan tablets) for the relief of heartburn associated with nonerosive gastroesophageal reflux disease (GERD) in adults. Source: FDA website	New Indication	07-17-2024
Velphoro The Food and Drug Administration (FDA) approved Velphoro® (ferric oxyhydroxide chewable tables) for the control of serum phosphorus levels in adult and pediatric individuals 9 years of age and older with chronic kidney disease on dialysis. Source: FDA website	Expanded Indication	07-01-2024
Xeomin The Food and Drug Administration (FDA) approved Xeomin® (incobotulinumtoxinA intramuscular or intraglandular injection) for the temporary improvement of the appearance of upper facial lines in adults. Source: FDA website	Expanded Indication	07-05-2024
Tepylute The Food and Drug Administration (FDA) approved Tepylute (thiotepa injection) for the treatment of adenocarcinoma of the breast or ovary. Source: FDA website	New Formulation	06-25-2024
Chewtadzy The Food and Drug Administration (FDA) approved Chewtadzy (tadalafil chewable tablet) for the treatment of erectile dysfunction (ED), benign prostatic hyperplasia (BPH), and ED plus BPH. Source: FDA website	New Formulation	06-28-2024
Vabysmo The Food and Drug Administration (FDA) approved VabysmoTM (faricimab-svoa 6.0 mg single-dose prefilled syringe for intravitreal injection) for use in the treatment of neovascular or wet age-related macular degeneration (nAMD), diabetic macular edema (DME) and macular edema following retinal vein occlusion (RVO). Source: FDA website	New Formulation	07-05-2024
Ohtuvayre The Food and Drug Administration (FDA) approved OhtuvayreTM (ensifentrine oral inhalation using a standard jet nebulizer) for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adults. Source: FDA website	New Drug	06-26-2024
Kisunla	New Drug	07-02-2024

Drug Name	Drug Reason	Date
The Food and Drug Administration (FDA) approved KisunlaTM (donanemab-azbt injection) for the treatment of Alzheimer's disease. Treatment should be initiated in individuals with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials. Source: FDA website		
Clonazepam Endo announced a voluntary recall of one lot of clonazepam orally disintegrating tablets due to mislabeling. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/endo-usa-inc-issues-voluntary-nationwide-recall-one-lot-clonazepam-orally-disintegrating-tablets-usp. Source: FDA website	Drug Recall	07-18-2024
Potassium chloride American Health Packaging on behalf of BluePoint Laboratories announced a voluntary recall of 21 batches of potassium chloride extended-release capsules 750 mg due to failed dissolution. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/american-health-packaging-behalf-bluepoint-laboratories-issues-voluntary-nationwide-recall-potassium Source: FDA website	Drug Recall	06-25-2024
Potassium chloride Glenmark Pharmaceuticals announced a voluntary recall of 114 batches of potassium chloride extended-release capsules 750 mg due to failed dissolution. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/glenmark-pharmaceuticals-inc-usa-issues-voluntary-nationwide-recall-potassium-chloride-extended Source: FDA website	Drug Recall	06-25-2024
Acetaminophen Hikma Pharmaceuticals is extending its recall of one lot of acetaminophen injection 1000 mg/100 mL due to the potential presence of a bag labeled dexmedetomidine HCl injection 400 mcg/100 mL inside the overwrap. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/hikma-pharmaceuticals-usa-inc-extends-voluntary-nationwide-recall-one-lot-acetaminophen-injection Source: FDA website	Drug Recall	07-23-2024
Brineura The Food and Drug Administration (FDA) approved Brineura® (cerliponase alfa injection) expanson to slow the loss of ambulation in children of all ages with neuronal ceroid lipofuscinosis type 2 (CLN2 disease), also known as tripeptidyl peptidase 1 (TPP1) deficiency. Source: FDA website	Expanded Indication	07-24-2024
Livmarli The Food and Drug Administration (FDA) approved Livmarli® (maralixibat oral solution) to include treatment of cholestatic pruritus in individuals 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC). A high concentration formulation was also approved. Source: FDA website	Expanded Indication	07-24-2024
Xembify The Food and Drug Administration (FDA) approved Xembify® (immune globulin subcutaneous human-klhw injection) to include biweekly dosing and use in treatment-naive individuals for primary immunodeficiency. Source: FDA website	Expanded Indication	07-29-2024
Palforzia The Food and Drug Administration (FDA) approved Palforzia® (peanut allergen powder-dnfp) to include initiation of treatment, up-dosing and maintenance in individuals ages 1 through 3 years with a confirmed diagnosis of peanut allergy to mitigate allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanuts. Source: FDA website	Expanded Indication	07-26-2024
Darzalex Faspro The Food and Drug Administration (FDA) approved Darzalex Faspro® (daratumumab and hyaluronidase-fihj injection) in combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in individuals with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant (ASCT). Source: FDA website	Expanded Indication	07-30-2024
Jemperli The Food and Drug Administration (FDA) approved Jemperli (dostarlimab-gxly injection) with carboplatin and paclitaxel, followed by single-agent dostarlimab-gxly, for adults with primary advanced or recurrent endometrial cancer (EC). Source: FDA website	Expanded Indication	08-01-2024
Tofidence	New Indication	07-22-2024
The Food and Drug Administration (FDA) approved TofidenceTM (tocilizumab-bavi injection) for adults with giant cell arteritis (GCA) and hospitalized adults with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental		

Drug Name	Drug Reason	Date
oxygen, non invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Source: FDA website		
Femlyv The Food and Drug Administration (FDA) approved Femlyv (norethindrone acetate and ethinyl estradiol orally disintegrating tablets) for the prevention of pregnancy. Source: FDA website	New Formulation	07-22-2024
Zituvimet XR The Food and Drug Administration (FDA) approved Zituvimet XR (sitagliptin/metformin hydrochloride extended-release tablets) as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Source: FDA website	New Formulation	07-18-2024
Erzofri The Food and Drug Administration (FDA) approved Erzofri® (paliperidone palmitate extended-release injectable suspension for intramuscular injection) for the treatment of schizophrenia in adults. Source: FDA website	New Formulation	07-26-2024
Tezruly The Food and Drug Administration (FDA) approved Tezruly (terazosin oral solution) for the treatment of signs and symptoms of benign prostatic hyperplasia (BPH) and the treatment of hypertension alone or with other antihypertensive agents. Source: FDA website	New Formulation	07-29-2024
Zunveyl The Food and Drug Administration (FDA) approved Zunveyl® (benzgalantamine delayed release tablets) for the treatment of mild-to-moderate dementia in adults. Source: FDA website	New Drug	07-26-2024
Leqselvi The Food and Drug Administration (FDA) approved LeqselviTM (deuruxolitinib tablets) for the treatment of adults with severe alopecia areata. Source: FDA website	New Drug	07-25-2024
Fabhalta The Food and Drug Administration (FDA) approved Fabhalta® (iptacopan capsules) for the reduction of proteinuria in primary IgA nephropathy (IgAN). Source: FDA website	New Indication	08-07-2024
Furoscix The Food and Drug Administration (FDA) approved expanded use of Furoscix® (furosemide injection for subcutaneous use) to include treatment of congestion due to fluid overload in adults with chronic heart failure (CHF), regardless of New York Heart Association (NYHA) functional class. Source: FDA website	NExpanded Indication	08-29-2024
Protonix I.V. The Food and Drug Administration (FDA) approved Protonix® I.V. (pantoprazole sodium injection for intravenous use) for the treatment of gastroesophageal reflux disease (GERD) and a history of erosive esophagitis (EE) for up to 7 days in pediatric individuals 3 months and older.	Expanded Indication	08-12-2024
NexoBrid The Food and Drug Administration (FDA) approved NexoBrid® (anacaulase-bcdb topical gel) for eschar removal in pediatric individuals with deep partial-thickness and/or full-thickness thermal burns. Source: FDA website	Expanded Indication	08-15-2024
Imfinzi The Food and Drug Administration (FDA) approved Imfinzi® (durvalumab injection for intravenous use) with platinum-containing chemotherapy as neoadjuvant treatment, followed by single-agent durvalumab as adjuvant treatment after surgery for adults with resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements. Source: FDA website	Expanded Indication	08-15-2024
Crexont The Food and Drug Administration (FDA) approved CrexontTM (carbidopa/levodapa extended-release capsules) for the treatment of Parkinson’s disease (PD). Source: FDA website	New Formulation	08-07-2024
Zurnai The Food and Drug Administration (FDA) approved Zurnai® (nalmefene hydrochloride auto-injector for intramuscular or subcutaneous use) for the emergency treatment of known or suspected opioid overdose in adults and pediatric individuals 12 years of age and older. Source: FDA website	New Formulation	08-07-2024
Lymphir The Food and Drug Administration (FDA) approved LymphirTM (denileukin diftitox-cxd injection for intravenous use) for the treatment of relapsed or refractory cutaneous T-cell lymphoma (CTCL) after at least 1 prior systemic therapy. Source: FDA website	New Formulation	08-07-2024
Neffy	New Formulation	08-09-2024

Drug Name	Drug Reason	Date
The Food and Drug Administration (FDA) approved Neffy® (epinephrine nasal spray) for the emergency treatment of allergic reactions (Type I), including those that are life-threatening (anaphylaxis), in adult and pediatric individuals who weigh at least 30 kilograms (about 66 pounds). Source: FDA website		
Tecelra The Food and Drug Administration (FDA) approved Tecelra® (afamitresgene autoleucel suspension for intravenous infusion) for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are Human Leukocyte Antigen (HLA)-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the melanoma-associated antigen A4 (MAGE-A4) as determined by FDA-approved or cleared companion diagnostic devices. Source: FDA website	New Drug	08-01-2024
Yorvipath The Food and Drug Administration (FDA) approved Yorvipath® (palopegteriparatide injection for subcutaneous use) for the treatment of hypoparathyroidism in adults. Source: FDA website	New Drug	08-29-2024
Nemluvio The Food and Drug Administration (FDA) approved Nemluvio® (nemolizumab-ilto for injection for subcutaneous use) for the treatment of adults with prurigo nodularis (PN). Source: FDA website	New Drug	08-12-2024
Livdelzi The Food and Drug Administration (FDA) approved Livdelzi® (seladelpar capsules) for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA; ursodiol) in adults who have an inadequate response to UDCA, or as monotherapy in individuals unable to tolerate UDCA. Source: FDA website	New Drug	08-14-2024
Niktimvo The Food and Drug Administration (FDA) approved LymphirTM (axatilimab-csfr injection for intravenous use) for the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric individuals weighing at least 40 kg. Source: FDA website	New Drug	08-14-2024
Voranigo The Food and Drug Administration (FDA) approved Voranigo® (vorasidenib tablets) for the treatment of adults and pediatrics 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation following surgery including biopsy, sub-total resection, or gross total resection. Source: FDA website	New Drug	08-06-2024
Heparin Baxter announced a voluntary recall of one lot of heparin sodium in 0.9% sodium chloride injection due to potential for elevated endotoxin levels. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/baxter-issues-voluntary-nationwide-recall-one-lot-heparin-sodium-09-sodium-chloride-injection-due Source: FDA website	Drug Recall	08-06-2024
Sodium chloride B. Braun Medical announced a voluntary recall of two lots of 0.9% sodium chloride for injection 1000 mL in E3 containers due to the potential for particulate matter and leakage. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/b-braun-issues-voluntary-nationwide-recall-09-sodium-chloride-injection-usp-1000-ml-e3-containers Source: FDA website	Drug Recall	08-08-2024
ACAM2000 The Food and Drug Administration (FDA) approved ACAM2000® (smallpox and mpox vaccine, live suspension, for percutaneous use) to include prevention of mpox disease in individuals determined to be at high risk for mpox infection. Source: FDA website	New Indication	08-30-2024
Tremfya The Food and Drug Administration (FDA) approved Tremfya® (guselkumab injection) to treat moderate-to-severe active ulcerative colitis (UC) in adults. Source: FDA website	New Indication	09-11-2024
Prevymis The Food and Drug Administration (FDA) approved Prevymis® (letermovir tablets, injection, and oral pellets) to expand use to include pediatric hematopoietic stem cell transplant recipients 6 months of age and older and weighing at least 6 kg and pediatric kidney transplant recipients 12 years of age and older and weighing at least 40 kg. An oral pellet formulation was also approved. Source: FDA website	Expanded Indication	08-30-2024
Dupixent The Food and Drug Administration (FDA) approved Dupixent® (dupilumab subcutaneous injection) to include add-on maintenance treatment of adolescents aged 12 to 17 years with	Expanded Indication	09-12-2024

Drug Name	Drug Reason	Date
inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP). Source: FDA website		
Boruzu The Food and Drug Administration (FDA) approved BoruzuTM (bortezomib ready-to-use subcutaneous injection) for the treatment of adults with multiple myeloma and for the treatment of adults with mantle cell lymphoma. Source: FDA website	New Formulation	09-05-2024
Tecentriq Hybreza The Food and Drug Administration (FDA) approved Tecentriq HybrezaTM (atezolizumab and hyaluronidase-tqjs subcutaneous injection) for all the adult indications as the intravenous formulation including non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), hepatocellular carcinoma (HCC), melanoma, and alveolar soft part sarcoma (ASPS). Source: FDA website	New Formulation	09-12-2024
Ocrevus Zunovo The Food and Drug Administration (FDA) approved Ocrevus ZunovoTM (ocrelizumab & hyaluronidase-ocsq subcutaneous injection) for the treatment of relapsing multiple sclerosis (RMS) and primary progressive multiple sclerosis (PPMS). Source: FDA	New Formulation	09-13-2024
Lazcluze The Food and Drug Administration (FDA) approved LazcluzeTM (lazertinib tablets) in combination with Rybrevant (amivantamab-vmjw injection) for the first-line treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test. Source: FDA website	New Drug	08-19-2024
Ebglyss^{TM} The Food and Drug Administration (FDA) approved Ebglyss (lebrikizumab subcutaneous injection) for the treatment of adults and children age 12 years and older who have moderate-to-severe atopic dermatitis (AD) that is not well controlled, despite treatment with topical prescription therapies. Source: FDA website	New Drug	09-13-2024
Veozah The Food and Drug Administration (FDA) issued a warning that Veozah® (fezolinetant tablets), a medicine used to treat hot flashes due to menopause, can cause rare but serious liver injury. The FDA has added a warning about this risk to the existing warning about elevated liver function test values and required liver function testing in the prescribing information. Contact your health care provider with questions. More details may be viewed at: https://www.fda.gov/safety/medical-product-safety-information/fda-adds-warning-about-rare-occurrence-serious-liver-injury-use-veozah-fezolinetant-hot-flashes-due Source: FDA website	Drug Warning	09-12-2024
Cimzia The Food and Drug Administration (FDA) approved Cimzia® (certolizumab pegol injection) for the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) for individuals 2 years of age and older. Source: FDA website	Expanded Indication	09-13-2024
Kisqali The Food and Drug Administration (FDA) approved Kisqali® (ribociclib tablets) with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence. The Food and Drug Administration (FDA) also approved the Kisqali Femara® Co-Pack (ribociclib and letrozole) for the same indication. Source: FDA website	Expanded Indication	09-17-2024
Rybrevant The Food and Drug Administration (FDA) approved Rybrevant® (amivantamab-vmjw injection) with carboplatin and pemetrexed for adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations whose disease has progressed on or after treatment with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor. Source: FDA website	Expanded Indication	09-19-2024
Sarclisa The Food and Drug Administration (FDA) approved Sarclisa® (isatuximab-irfc injection) for use with bortezomib, lenalidomide, and dexamethasone for adults with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant (ASCT). Source: FDA website	Expanded Indication	09-20-2024
Flumist The Food and Drug Administration (FDA) approved Flumist® (influenza vaccine live intranasal) for self- or caregiver-administration for the prevention of influenza disease caused by influenza virus subtypes A and B in individuals 2 through 49 years of age. Source: FDA website	Expanded Indication	09-20-2024

Drug Name	Drug Reason	Date
Tagrisso The Food and Drug Administration (FDA) approved Tagrisso® (osimertinib tablets) for adults with locally advanced, unresectable (stage III) non-small cell lung cancer (NSCLC) whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy and whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by a Food and Drug Administration (FDA)-approved test. Source: FDA website	Expanded Indication	09-13-2024
Opdivo The Food and Drug Administration (FDA) approved Opdivo® (nivolumab injection) with platinum-doublet chemotherapy as neoadjuvant treatment, followed by single-agent nivolumab after surgery as adjuvant treatment, for adults with resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements. Source: FDA website	Expanded Indication	10-03-2024
Fasenra The Food and Drug Administration (FDA) approved Fasenra® (benralizumab injection) to treat adults with eosinophilic granulomatosis with polyangiitis (EGPA), a type of rare immune-mediated vasculitis. Source: FDA website	New Indication	09-17-2024
Keytruda The Food and Drug Administration (FDA) approved Keytruda® (pembrolizumab injection) with pemetrexed and platinum chemotherapy as first-line treatment of unresectable advanced or metastatic malignant pleural mesothelioma (MPM). Source: FDA website	New Indication	09-17-2024
Bimzelx The Food and Drug Administration (FDA) approved Bimzelx® (bimekizumab-bkzx injection) for adults with active psoriatic arthritis (PsA), active nonradiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation, and active ankylosing spondylitis (AS). Source: FDA website	New Indication	09-20-2024
Dupixent The Food and Drug Administration (FDA) approved Dupixent® (dupilumab injection) as add-on maintenance treatment of adults with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype. Source: FDA website	New Indication	09-27-2024
Bynfezia The Food and Drug Administration (FDA) approved Bynfezia Pen® (octreotide subcutaneous injection) for acromegaly, carcinoid tumors, and vasoactive intestinal peptide tumors. Source: FDA website	New Formulation	09-27-2024
Aqneursa The Food and Drug Administration (FDA) approved AqneursaTM (levacetylleucine for oral suspension) for the treatment of neurological manifestations of Niemann-Pick Disease Type C (NPC) in individuals weighing 15 kg or more. Source: FDA website	New Drug	09-24-2024
Miplyffa The Food and Drug Administration (FDA) approved MiplyffaTM (arimoclomol capsules) in combination with miglustat oral for the treatment of neurological manifestations of Niemann-Pick Disease Type C (NPC) in individuals 2 years and older. Source: FDA website	New Drug	09-20-2024
Cobenfy The Food and Drug Administration (FDA) approved CobenfyTM (xanomeline and trospium chloride) for the treatment of schizophrenia in adults. Source: FDA website	New Drug	09-26-2024
Atovaquone BionPharma announced a voluntary recall of one batch of atovaquone oral suspension 750 mg per mL due to bacterial contamination. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bionpharma-inc-issues-voluntary-nationwide-recall-atovaquone-oral-suspension-due-bacterial Source: FDA website	Drug Recall	09-19-2024
Veklury Gilead Sciences announced a voluntary recall of one lot of Veklury® (remdesivir) for injection 100 mg/vial due to the presence of a glass particle. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/gilead-issues-voluntary-nationwide-recall-one-lot-veklury-remdesivir-injection-100-mgvial-due Source: FDA website	Drug Recall	09-24-2024
Lumryz The Food and Drug Administration (FDA) approved LumryzTM (sodium oxybate extended-release oral suspension) to include treatment of cataplexy or excessive daytime sleepiness (EDS) in adults 7 years of age and older with narcolepsy. Source: FDA website	Expanded Indication	10-17-2024
Abrysvo	Expanded Indication	10-23-2024

Drug Name	Drug Reason	Date
The Food and Drug Administration (FDA) approved Abrysvo® (respiratory syncytial virus vaccine intramuscular injection) to include active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV. Source: FDA website		
Bimzelx		
The Food and Drug Administration (FDA) approved Bimzelx® (bimekizumab-bkzx subcutaneous injection) for adults with active psoriatic arthritis (PsA), active nonradiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation, and active ankylosing spondylitis (AS). Source: FDA website	New Indication	10-11-2024
Jylamvo		
The Food and Drug Administration (FDA) approved Jylamvo (methotrexate oral solution) for the treatment of pediatric individuals with polyarticular juvenile idiopathic arthritis (pJIA) and for the treatment of pediatric individuals with acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen. Source: FDA website	New Indication	10-23-2024
Scemblix		
The Food and Drug Administration (FDA) approved Scemblix® (asciminib tablets) for adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP). Source: FDA website	New Indication	10-29-2024
Vyalev		
The Food and Drug Administration (FDA) approved VyalevTM (foscarbidopa/foslevodopa injection for subcutaneous use) for the treatment of motor fluctuations in adults with advanced Parkinson’s disease. Source: FDA website	New Drug	10-16-2024
Itovebi		
The Food and Drug Administration (FDA) approved ItovebiTM (inavolisib tablets) for use in combination with Ibrance® (palbociclib tabets and capsules) and fulvestrant to treat adults with endocrine-resistant, PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer following recurrence on or after completing adjuvant endocrine therapy. Source: FDA website	New Drug	10-10-2024
Hympavzi		
The Food and Drug Administration (FDA) approved HympavziTM (marstacimab-hncq injection for subcutaneous use) for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and pediatrics 12 years of age and older with hemophilia A without factor VIII inhibitors or hemophilia B without factor IX inhibitors. Source: FDA website	New Drug	10-11-2024
Vyloy		
The Food and Drug Administration (FDA) approved VyloyTM (zolbetuximab-clzb injection for intravenous use) in combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of adults with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction adenocarcinoma whose tumors are claudin (CLDN) 18.2 positive. Source: FDA website	New Drug	10-18-2024
Orlynvah		
The Food and Drug Administration (FDA) approved OrlynvahTM (sulopenem etzadroxil and probenecid tablets) for the treatment of uncomplicated urinary tract infections (uUTI) caused by the designated microorganisms Escherichia coli, Klebsiella pneumoniae, or Proteus mirabilis in adult women who have limited or no alternative oral antibacterial treatment options. Source: FDA website	New Drug	10-25-2024
Ascorbic acid		
Staska Pharmaceuticals announced a voluntary recall of one lot of ascorbic acid solution for injection due to the presence of glass particulates. Contact your health care provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/staska-pharmaceuticals-inc-issues-voluntary-nationwide-recall-ascorbic-acid-solution-injection Source: FDA website	Drug Recall	10-17-2024
Emrosi		
The Food and Drug Administration (FDA) approved EmrosiTM (minocycline hydrochloride extended-release capsules) for the treatment of inflammatory lesions (papules and pustules) of rosacea in adults. Source: FDA website	New Formulation	11-1-2024
Danziten	New Formulation	11-7-2024
The Food and Drug Administration (FDA) approved DanzitenTM (nilotinib tartrate tablets) for the treatment of adults with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. Also approved for the treatment of adults with chronic phase and accelerated phase Philadelphia chromosome positive chronic		

Drug Name	Drug Reason	Date
myelogenous leukemia (Ph+ CML) resistant or intolerant to prior therapy that included imatinib. Source: FDA website		
Aucatzyl The Food and Drug Administration (FDA) approved Aucatzyl® (obecabtagene autoleucel suspension for intravenous infusion) for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). Source: FDA website	New Drug	11-8-2024
Kebilidi The Food and Drug Administration (FDA) approved Kebilidi (eladocagene exuparvovec-tneq suspension for intraputaminal infusion) for the treatment of adult and pediatric individuals with aromatic L-amino acid decarboxylase (AADC) deficiency. Source: FDA website	New Drug	11-13-2024
Fullerton Wellness The Food and Drug Administration (FDA) is warning consumers and health care providers not to use drugs compounded and distributed by Fullerton Wellness LLC in Ontario, California due to sterility issues. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-patients-and-health-care-professionals-not-use-compounded-drugs-fullerton-wellness Source: FDA website	Drug Warning	11-1-2024
Bimzelx The Food and Drug Administration (FDA) approved Bimzelx® (bimekizumab injection) to treat active moderate-to-severe hidradenitis suppurativa (HS) in adults responding inadequately to conventional systemic therapy. Source: FDA website	New Indication	11-19-2024
Imfinzi The Food and Drug Administration (FDA) approved Imfinzi® (durvalumab injection) for adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy. Source: FDA website	New Indication	12-4-2024
Imkeldi The Food and Drug Administration (FDA) approved Imkeldi (imatinib oral solution) to treat chronic myeloid leukemia, acute lymphoblastic leukemia, myelodysplastic/myeloproliferative diseases, and gastrointestinal stromal tumors as well as aggressive systematic mastocytosis, hypereosinophilic syndrome, chronic eosinophilic leukemia, and dermatofibrosarcoma protuberans. Source: FDA website	New Indication	11-22-2024
Rapiblyk The Food and Drug Administration (FDA) approved Rapiblyk (landiolol injection) for the short-term reduction of ventricular rate in adults with supraventricular tachycardia including atrial fibrillation and atrial flutter. Source: FDA website	New Drug	11-22-2024
Attruby The Food and Drug Administration (FDA) approved Attruby® (acoramidis tablets) for the treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular death and cardiovascular-related hospitalization. Source: FDA website	New Drug	11-22-2024
Ziihera The Food and Drug Administration (FDA) approved Ziihera® (zanidatamab-hrii injection) for the treatment of adults with previously treated, unresectable or metastatic HER2-positive biliary tract cancer. Source: FDA website	New Drug	11-20-2024
Revuforj The Food and Drug Administration (FDA) approved Revuforj® (revumenib tablets) for relapsed or refractory acute leukemia lysine methyltransferase 2A gene (KMT2A) translocation in adult and pediatric individuals aged 1 year and older. Source: FDA website	New Drug	11-15-2024
Bizengri The Food and Drug Administration (FDA) approved Bizengri® (zenocutuzumab-zbco injection) for adults with advanced, unresectable or metastatic non-small cell lung cancer (NSCLC) or pancreatic adenocarcinoma harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy. Source: FDA website	New Drug	12-4-2024
Clonazepam Endo is expanding a previously announced voluntary recall of clonazepam orally disintegrating tablets due to potential product carton strength mislabeling. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/endo-expands-voluntary-recall-clonazepam-orally-disintegrating-tablets-usp-c-iv-due-potential Source: FDA website	Drug Recall	11-19-2024
Ocaliva	Drug Warning	12-12-2024

Drug Name	Drug Reason	Date
The Food and Drug Administration (FDA) identified cases of serious liver injury among individuals being treated for primary biliary cholangitis (PBC) with Ocaliva® (obeticholic acid tablets) who did not have liver cirrhosis. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/medical-product-safety-information/ocaliva-obeticholic-acid-intercept-pharmaceuticals-drug-safety-communication-serious-liver-injury?utm_medium=email&utm_source=govdelivery Source: FDA website		
Vtama		
The Food and Drug Administration (FDA) approved Vtama® (tapinarof topical cream) for the treatment of atopic dermatitis (AD) in adults and pediatric individuals 2 years of age and older. Source: FDA website	New Indication	12-12-2024
Nemluvio		
The Food and Drug Administration (FDA) approved Nemluvio® (nemolizumab injection) for the treatment of individuals 12 years and older with moderate-to-severe atopic dermatitis, in combination with topical corticosteroids (TCS) and/or calcineurin inhibitors (TCI) when the disease is not adequately controlled with topical prescription therapies. Source: FDA website	New Indication	12-13-2024
Gemtesa		
The Food and Drug Administration (FDA) approved Gemtesa® (vibegron tablets) for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adult males on pharmacological therapy for benign prostatic hyperplasia (BPH). Source: FDA website	New Indication	12-18-2024
Invokana; Invokamet; Invokamet XR		
The Food and Drug Administration (FDA) approved Invokana® (canagliflozin tablets), Invokamet® (canagliflozin/metformin tablets), and Invokamet® XR (canagliflozin/metformin extended-release) as an adjunct to diet and exercise to improve glycemic control in pediatric individuals aged 10 years and older. Source: FDA website	New Indication	12-18-2024
Braftovi		
The Food and Drug Administration (FDA) approved Braftovi® (encorafenib capsules) with cetuximab and mFOLFOX6 for individuals with metastatic colorectal cancer (mCRC) with a BRAF V600E mutation, as detected by a FDA-approved test. Source: FDA website	New Indication	12-20-2024
Zepbound		
The Food and Drug Administration (FDA) approved Zepbound® (tirzepatide injection) in combination with a reduced-calorie diet and increased physical activity to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity. Source: FDA website	New Indication	12-20-2024
Tevimbra		
The Food and Drug Administration (FDA) approved Tevimbra® (tislelizumab-jsgr injection) for use in combination with platinum and fluoropyrimidine-based chemotherapy in adults for the first-line treatment of unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma (G/GEJ) whose tumors express programmed death-ligand 1 (PD-L1) ≥1. Source: FDA website	New Indication	12-26-2024
Imcivree		
The Food and Drug Administration (FDA) approved Imcivree® (setmelanotide injection) to include children as young as 2 years old with obesity due to Bardet-Biedl syndrome (BBS) or pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency. Source: FDA website	Expanded Indication	12-20-2024
Trikafta		
The Food and Drug Administration (FDA) approved Trikafta® (elexacaftor/tezacaftor/ivacaftor tablets and oral granules) for the treatment of people with cystic fibrosis (CF) ages 2 and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation that is responsive to Trikafta based on clinical and/or in vitro data. With this approval, 94 additional non-F508del CFTR mutations have been added to the Trikafta label. Source: FDA website	Expanded Indication	12-20-2024
Xromi		
The Food and Drug Administration (FDA) approved Xromi (hydroxyurea oral solution) to reduce the frequency of painful crises and to reduce the need for blood transfusions in pediatric individuals 2 years of age and older with sickle cell anemia with recurrent moderate to severe painful crises. Source: FDA website	Expanded Indication	12-23-2024
Arixtra		
The Food and Drug Administration (FDA) approved Arixtra (fondaparinux sodium injection) for the treatment of venous thromboembolism in pediatric individuals aged 1 year or older weighing at least 10 kg. Source: FDA website	Expanded Indication	12-23-2024
Unloxcyt	New Drug	12-13-2024
The Food and Drug Administration (FDA) approved UnloxcytTM (cosibelimab-ipdl injection for intravenous use) for the treatment of adults with metastatic cutaneous squamous cell		

Drug Name	Drug Reason	Date
carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation. Source: FDA website		
Crenessity The Food and Drug Administration (FDA) approved CrenessityTM (crinecerfont capsules and oral solution) as adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric individuals 4 years of age and older with classic congenital adrenal hyperplasia (CAH). Source: FDA website	New Drug	12-13-2024
Ensacove The Food and Drug Administration (FDA) approved EnsacoveTM (ensartinib capsules) for the treatment of adults with anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) who have not previously received an ALK inhibitor. Source: FDA website	New Drug	12-18-2024
Tryngolza The Food and Drug Administration (FDA) approved Tryngolza (olezarsen subcutaneous injection) as adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS). Source: FDA website	New Drug	12-19-2024
Alhemo The Food and Drug Administration (FDA) approved Alhemo® (concizumab-mtci subcutaneous injection) for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric individuals 12 years of age and older with hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors and hemophilia B (congenital factor IX deficiency) with FIX inhibitors. Source: FDA website	New Drug	12-20-2024
Alyftrek The Food and Drug Administration (FDA) approved Alyftrek (vanzacaftor/ tezacaftor/ deutivacaftor tablets) for the treatment of cystic fibrosis (CF) in individuals aged 6 years and older who have at least one F508del mutation or another responsive mutation in the CFTR gene. Source: FDA website	New Drug	12-20-2024
Opdivo Qvantig The Food and Drug Administration (FDA) approved Opdivo QvantigTM (nivolumab and hyaluronidase-nvhy subcutaneous injection) for renal cell carcinoma, melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, urothelial carcinoma, colorectal cancer, hepatocellular carcinoma, esophageal carcinoma, gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma. Source: FDA website	New Formulation	12-27-2024
Veozah The Food and Drug Admistration (FDA) added a Boxed Warning to the Veozah labeling to highlight the risk of rare but serious liver injury associated with use. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-warning-about-rare-occurrence-serious-liver-injury-use-veozah-fezolinetant-hot-flashes-due Source: FDA website	Drug Warning	12-16-2024
Tacrolimus Astellas Pharma announced a voluntary recall of one lot of Prograf 0.5 mg (tacrolimus) and one lot of Astagraf XL 0.5 mg (tacrolimus extended-release) because bottles may contain empty capsules. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/astellas-pharma-us-inc-issues-voluntary-nationwide-recall-one-lot-prografr-05mg-tacrolimus-and-one Source: FDA website	Drug Recall	12-25-2024
Respiratory syncytial virus (RSV) vaccines The Food and Drug Administration (FDA) has approved labeling changes for AbrysvoTM (respiratory syncytial virus vaccine intramuscular injection) and Arexvy (respiratory syncytial virus vaccine, adjuvanted intramuscular injection) to include a warning about the risk for Guillain-Barré syndrome (GBS). Contact your healthcare provider. More details may be viewed at: https://www.fda.gov/safety/medical-product-safety-information/fda-requires-guillain-barre-syndrome-gbs-warning-prescribing-information-rsv-vaccines-abrysvo-and Source: FDA website	Drug Warning	1-07-2025
Enhertu The Food and Drug Administration (FDA) approved Enhertu® (fam-trastuzumab deruxtecan-nxki injection for intravenous use) for the treatment of adults with unresectable or metastatic hormone receptor (HR)-positive, HER2-low or HER2-ultralow breast cancer that has progressed on one or more endocrine therapies in the metastatic setting. Source: FDA website	Expanded Indication	1-27-2025
Susvimo The Food and Drug Administration (FDA) approved SusvimoTM (ranibizumab injection for ocular implant) for the treatment of diabetic macular edema (DME). Source: FDA website	New Indication	2-4-2025
Ozempic	New Indication	1-28-2025

Drug Name	Drug Reason	Date
The Food and Drug Administration (FDA) approved Ozempic® (semaglutide injection for subcutaneous use) to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease. Source: FDA website		
Symbravo The Food and Drug Administration (FDA) approved Symbravo (meloxicam/rizatriptan oral tablets) for acute migraine treatment with or without aura. Source: FDA website	New Formulation	1-30-2025
Onapgo The Food and Drug Administration (FDA) approved OnapgoTM (apomorphine hydrochloride subcutaneous infusion device) for the treatment of motor fluctuations in adults with advanced Parkinson's disease. Sourc: FDA website	New Formulation	2-4-2025
Journavx The Food and Drug Administration (FDA) approved JournavxTM (suzetrigine oral tablets) to treat moderate-to-severe acute pain in adults. Source: FDA website	New Drug	1-30-2025
Phenylephrine hydrochloride Provepharm Inc. announced a voluntary recall of one lot of phenylephrine hydrochloride injection 10 mg/mL due to the presence of particulate matter. Contact your healthcare provider with questions. More details may be available at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/provepharm-inc-issues-voluntary-nationwide-recall-one-lot-phenylephrine-hydrochloride-injection-usp Source: FDA website	Drug Recall	1-24-2025
Fentanyl transdermal system Alvogen announced a voluntary recall of one lot of fentanyl transdermal system 25 mcg/h due to a defective delivery system. Contact your healthcare provider with questions. More details may be available at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/alvogen-issues-voluntary-nationwide-recall-one-lot-fentanyl-transdermal-system-25-mcgh-due-defective Source: FDA website	Drug Recall	1-31-2025
Adcetris The Food and Drug Administration (FDA) approved Adcetris® (brentuximab vedotin injection for intravenous use) in combination with lenalidomide and a rituximab product for adults with relapsed or refractory large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS), DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma (HGBL), after two or more lines of systemic therapy who are ineligible for autologous hematopoietic stem cell transplantation (auto-HSCT) or chimeric antigen receptor (CAR) T-cell therapy. Source: FDA website	Expanded Indication	02-11-2025
Odefsey The Food and Drug Administration (FDA) approved Odefsey® (emtricitabine/rilpivirine/tenofovir alafenamide tablets) label expansion to include pediatric individuals weighing at least 25 kg to less than 35 kg for the treatment of human immunodeficiency virus-1 (HIV-1) infection as initial therapy in those with no antiretroviral treatment history with HIV-1 RNA less than or equal to 100,000 copies per mL and pediatric individuals weighing at least 25 to less than 35 kg for the treatment of HIV-1 infection to replace a stable antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies/mL). Source: FDA website	Expanded Indication	02-19-2025
Evrysdi The Food and Drug Administration (FDA) approved Evrysdi® (risdiplam tablets) 5 mg tablet formulation for the treatment of spinal muscular atrophy (SMA) in individuals 2 years of age and older weighing at least 20 kg. Source: FDA website	New Formulation	02-11-2025
Emblaveo The Food and Drug Administration (FDA) approved Emblaveo (aztreonam/avibactam injection for intravenous use) in combination with metronidazole for individuals 18 years and older who have limited or no alternative options for the treatment of complicated intra-abdominal infections (cIAI), including those caused by the following susceptible Gram-negative microorganisms: Escherichia coli, Klebsiella pneumoniae, Klebsiella oxytoca, Enterobacter cloacae complex, Citrobacter freundii complex, and Serratia marcescens. Source: FDA website	New Formulation	02-07-2025
Vimkunya The Food and Drug Administration (FDA) approved VimkunyaTM (chikungunya vaccine, recombinant injection for intramuscular use) for the prevention of disease caused by chikungunya virus in individuals 12 years of age and older. Source: FDA website	New Formulation	02-14-2025
Penmenvy The Food and Drug Administration (FDA) approved Penmenvy (meningococcal groups A, B, C, W, and Y vaccine injection for intramuscular use) for active immunization to prevent	New Formulation	02-14-2025

Drug Name	Drug Reason	Date
invasive disease caused by Neisseria meningitidis serogroups A, B, C, W, and Y in individuals 10 through 25 years of age. Source: FDA website		
Romvimza The Food and Drug Administration (FDA) approved RomvimzaTM (vimseltinib capsules) for the treatment of adults with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity. Source: FDA website	New Drug	02-14-2025
Gomekli The Food and Drug Administration (FDA) approved GomekliTM (mirdametinib capsules and tablets for oral suspension) for adult and pediatric individuals 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN) not amenable to complete resection. Source: FDA website	New Drug	02-11-2025
Potassium chloride ICU Medical announced a voluntary recall of one lot each of potassium chloride injection 20 mEq and potassium chloride injection 10 mEq due to mislabeling. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/icu-medical-issues-nationwide-recall-potassium-chloride-injection-20-meq-and-potassium-chloride Source: FDA website	Drug Recall	02-13-2025
Odactra The Food and Drug Administration (FDA) approved Odactra® (house dust mite [Dermatophagoides farinae and Dermatophagoides pteronyssinus] allergen) to include the treatment of house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, in pediatric individuals aged 5 to 11 years. Source: FDA website	Expanded Indication	2/27/2025
Soliris The Food and Drug Administration (FDA) approved Soliris® (eculizumab injection for intravenous use) for the treatment of generalized myasthenia gravis (gMG) in pediatric individuals six years of age and older who are anti-acetylcholine receptor (AChR) antibody positive. Source: FDA website	Expanded Indication	2/28/2025
Livmarli	Expanded Indication	07-24-2024
Neffy The Food and Drug Administration (FDA) approved Neffy® (epinephrine intranasal spray) for emergency treatment of type I allergic reactions, including anaphylaxis, in individuals who weigh between 15 and 30 kilograms. Source: FDA website	Expanded Indication	3/5/2025
Furoscix The Food and Drug Administration (FDA) approved Furoscix® (furosemide injection for subcutanous use) for the treatment of edema in individuals with chronic kidney disease (CKD).Source: FDA website	Expanded Indication	3/6/2025
Tevimbra The Food and Drug Administration (FDA) approved Tevimbra® (tislelizumab-jsgr injection for intravenous use) in combination with platinum-containing chemotherapy for the first-line treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (≥1). Source: FDA website	New Indication	3/4/2025
Phenylephrine Central Admixture Pharmacy announced the voluntary recall of three lots of phenylephrine 40 mg added to 0.9% sodium chloride 250 mL due to visible black particular matter in a single-sealed vial. Contact your health care provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/central-admixture-pharmacy-services-caps-issues-nationwide-recall-phenylephrine-40-mg-added-09 Source: FDA website	Drug Recall	2/27/2025
Miudella The Food and Drug Administration (FDA) approved Miudella® (copper intrauterine device) for the prevention of pregnancy in females of reproductive potential for up to 3 years. Source: FDA website	New Formulation	2/24/2025
Ctexli The Food and Drug Administration (FDA) approved CtexliTM (chenodiol tablets) for treatment of cerebrotendinous xanthomatosis (CTX) in adults. Source: FDA website	New Drug	2/21/2025
Baqsimi The Food and Drug Administration (FDA) approved Baqsimi (glucagon nasal powder for intranasal use) to include the treatment of severe hypoglycemia in individuals aged 1 year and older with diabetes. Source: FDA website	Expanded Indication	3/17/2025
Synjardy; Synjardy XR The Food and Drug Administration (FDA) approved Syndardy® (empagliflozin/metformin hydrochloride) and Syndardy® XR (empagliflozin/metformin hydrochloride extended-release tablets) in adults with type 2 diabetes mellitus to reduce the risk of sustained decline in	New Indication	3/17/2025

Drug Name	Drug Reason	Date
estimated glomerular filtration rate (eGFR), end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression. Source: FDA website		
Iluvien The Food and Drug Administration (FDA) approved Iluvien® (fluocinolone acetonide intravitreal implant) for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. Source: FDA website	New Indication	3/12/2025
Gvoke Vialdx The Food and Drug Administration (FDA) approved Gvoke Vialdx (glucagon injection for intravenous use) for use as a diagnostic aid during radiologic examinations to temporarily inhibit movement of the gastrointestinal tract in adults. A new 1 mg/0.2 mL single-dose vial and carton and container labeling for the intravenous use were also approved. Source: FDA website	New Indication	3/14/2025
Amvuttra The Food and Drug Administration (FDA) approved AmvuttraTM (vutrisiran injection for subcutaneous use) for cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality, cardiovascular hospitalizations and urgent heart failure visits. Source: FDA website	New Indication	3/20/2025
Tremfya The Food and Drug Administration (FDA) approved Tremfya® (guselkumab injection for subcutaneous or intravenous use) to treat adults with moderately-to-severely active Crohn's disease (CD), with both subcutaneous (SC) and intravenous (IV) induction options. Source: FDA website	New Indication	3/20/2025
Fabhalta The Food and Drug Administration (FDA) approved Fabhalta® (iptacopan capsules) for the treatment of adults with complement 3 glomerulopathy (C3G) to reduce proteinuria. Source: FDA website	New Indication	3/20/2025
Arbli The Food and Drug Administration (FDA) approved Arbli (losartan potassium oral suspension) for the treatment of hypertension in adults and children greater than 6 years old, reduction of the risk of stroke in individuals with hypertension and left ventricular hypertrophy, and treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria in individuals with type 2 diabetes and a history of hypertension. Source: FDA website	New Formulation	3/13/2025
Hemiclor The Food and Drug Administration (FDA) approved HemiclorTM (chlorthalidone tablets) for the treatment of hypertension in adults. Source: FDA website	New Formulation	3/17/2025
Immune globulin intravenous (IGIV); Immune globulin subcutaneous (IGSC) Selected lots of IGIV and IGSC products have been withdrawn by the manufacturers due to a higher rate of allergy/hypersensitivity type reactions. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/voluntary-lot-withdrawals-immune-globulin-intravenous-igiv-and-immune-globulin-subcutaneous-igsc-0?utm_medium=email&utm_source=govdelivery Source: FDA website	Drug Recall	3/11/2025
Levetiracetam Dr. Reddy’s Laboratories announced a voluntary recall of one lot of levetiracetam in 0.75% sodium chloride injection due to mislabeling of infusion bag. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/dr-reddys-issues-nationwide-recall-levetiracetam-075-sodium-chloride-injection-1000-mg100-ml-us-due Source: FDA website	Drug Recall	3/14/2025
Prezcobix The Food and Drug Administration (FDA) approved Prezcobix® (darunavir/cobicistat tablets) for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in treatment-naïve and treatment-experienced adults and pediatric individuals weighing at least 25 kg to less than 40 kg. A new fixed dose tablet containing 675 mg of darunavir and 150 mg of cobicistat is also approved. Source: FDA website	Expanded Indication	3/25/2025
Pluvicto The Food and Drug Administration (FDA) approved Pluvicto® (lutetium Lu 177 vipivotide tetraxetan injection for intravenous use) to include adults with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibitor (ARPI) therapy and are considered appropriate to delay taxane-based chemotherapy. Source: FDA website	Expanded Indication	3/28/2025
Imvinzi	Expanded Indication	3/28/2025

Drug Name	Drug Reason	Date
The Food and Drug Administration (FDA) approved Imfinzi® (durvalumab injection for intravenous use) with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent durvalumab as adjuvant treatment following radical cystectomy, for adults with muscle invasive bladder cancer (MIBC). Source: FDA website		
Rivfloza The Food and Drug Administration (FDA) approved Rivfloza® (nedosiran injection for subcutaneous use) expansion to lower urinary oxalate levels in children 2 to < 9 years of age with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function. Source: FDA website	Expanded Indication	3/27/2025
Cabometyx The Food and Drug Administration (FDA) approved Cabometyx® (cabozantinib tablets) for adult and pediatric individuals 12 years of age and older with previously treated, unresectable, locally advanced or metastatic, well-differentiated pancreatic neuroendocrine tumors (pNET) and well-differentiated extra-pancreatic neuroendocrine tumors (epNET). Source: FDA website	New Indication	3/26/2025
Uplizna The Food and Drug Administration (FDA) approved Uplizna® (inebilizumab-cdon injection for intravenous use) for the treatment of immunoglobulin G4-related disease (IgG4-RD) in adults. Source: FDA website	New Indication	4/3/2025
Vykat XR The Food and Drug Administration (FDA) approved Vykat XRTM (diazoxide choline extended-release tablets) for the treatment of hyperphagia (chronic overeating) in adults and pediatrics 4 years of age and older with Prader-Willi syndrome (PWS). Source: FDA website	New Formulation	3/26/2025
Blujepa The Food and Drug Administration (FDA) approved Blujepa (gepotidacin tablets) for the treatment of female adult and pediatric individuals 12 years of age and older weighing at least 40 kg with uncomplicated urinary tract infections (uUTIs) caused by the following susceptible microorganisms: Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii complex, Staphylococcus saprophyticus, and Enterococcus faecalis. Source: FDA website	New Drug	3/25/2025
Qfitlia The Food and Drug Administration (FDA) approved QfitliaTM (fitusiran injection for subcutaneous use) for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and pediatrics aged 12 years and older with hemophilia A or B with or without factor VIII or IX inhibitors. Source: FDA website	New Drug	3/28/2025
Vanrafia The Food and Drug Administration (FDA) approved VanrafiaTM (atrasentan tablets) to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression. Source: FDA website	New Drug	4/2/2025
Isturisa The Food and Drug Administration (FDA) approved Isturisa® (osilodrostat tablets) for the treatment of endogenous hypercortisolemia in adults with Cushing syndrome for whom surgery is not an option or has not been curative. Source: FDA website	New Indication	4/16/2025
Dupixent The Food and Drug Administration (FDA) approved Dupixent® (dupilumab injection for subcutanous use) for the treatment of chronic spontaneous urticaria (CSU) in individuals aged 12 years and older who remain symptomatic despite H1 antihistamine treatment. Source: FDA website	New Indication	4/18/2025
Opdivo The Food and Drug Administration (FDA) approved Opdivo® (nivomulab injection for intravenous use) with Yervoy® (ipilimumab injection for intravenous use) for the first-line treatment of adults with unresectable or metastatic hepatocellular carcinoma (HCC). Source: FDA website	New Indication	4/11/2025
Opdivo The Food and Drug Administration (FDA) approved Opdivo® (nivomulab injection for intravenous use) with Yervoy® (ipilimumab injection for intravenous use) for adult and pediatric individuals 12 years of age and older with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC). Source: FDA website	Expanded Indication	4/8/2025
Dextenza The Food and Drug Administration (FDA) approved Dextenza® (dexamethasone ophthalmic insert for intracanalicular use) for the treatment of ocular inflammation and pain following ophthalmic surgery in pediatric individuals and the treatment of ocular itching	Expaned Indication	4/7/2025

Drug Name	Drug Reason	Date
associated with allergic conjunctivitis in pediatric individuals aged 2 years and older. Source: FDA website		
Valtoco The Food and Drug Administration (FDA) approved Valtoco® (diazepam nasal spray) to include the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (ie, seizure clusters, acute repetitive seizures) that are distinct from an individual's usual seizure pattern in individuals with epilepsy as young as 2 years old. Source: FDA website	Expanded Indication	4/16/2025
Vyvgart Hytrulo The Food and Drug Administration (FDA) approved Vyvgart Hytrulo® (efgartigimod alfa and hyaluronidase-qvfc injection for subcutaneous use) pre-filled syringe formulation for self-administration in the treatment of adults with generalized myasthenia gravis (MG) who are anti-acetylcholine receptor antibody positive and for adults with chronic inflammatory demyelinating polyneuropathy (CIDP). Source: FDA website	New Dosage Form	4/11/2025
Livmarli The Food and Drug Administration (FDA) approved Livmarli® (maralixibat tablets and oral solution) tablet formulation for the treatment of cholestatic pruritus in individuals 3 months of age and older with Alagille syndrome (ALGS), and for the treatment of cholestatic pruritus in individuals 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC). Source: FDA website	New Dosage Form	4/14/2025
Ropivacaine hydrochloride Amneal Pharmaceuticals announced a voluntary recall of two lots of ropivacaine hydrochloride injection 500 mg/100 mL infusion bags due to the potential presence of particulate matter. Contact your healthcare provider with questions. More details may be viewed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceutical-llc-issues-nationwide-recall-ropivacaine-hydrochloride-injection-usp Source: FDA website	Drug Recall	4/18/2025
Rinvoq The Food and Drug Administration (FDA) approved Rinvoq® (upadacitinib extended-release tablets) for the treatment of giant cell arteritis in adults. Source: FDA website	New Indication	4/28/2025
Eliquis; Eliquis Sprinkle The Food and Drug Administration (FDA) approved Eliquis® (apixaban tablets for oral use and tablets for oral suspension) and Eliquis® Sprinkle (apixaban capsules for oral suspension) for the treatment of venous thromboembolism (VTE) and reduction in the risk of recurrent VTE in pediatric individuals from birth and older after at least 5 days of initial anticoagulant treatment, and for the addition of 0.5 mg tablets for oral suspension. Source: FDA website	Expanded Indication	4/17/2025
Mezofy The Food and Drug Administration (FDA) approved MezofyTM (aripiprazole oral film) for the treatment of schizophrenia. Source: FDA website	New Formulation	4/15/2025
Qamzova The Food and Drug Administration (FDA) approved QamzovaTM (meloxicam injection for intravenous use) for use in adults for the management of moderate-to-severe pain alone or in combination with non-NSAID analgesics. Source: FDA website	New Formulation	4/22/2025
Atzumi The Food and Drug Administration (FDA) approved AtzumiTM (dihydroergotamine nasal powder) for the acute treatment of migraine with or without aura in adults. Source: FDA website	New Formulation	4/30/2025
Penpulimab-kcqx The Food and Drug Administration (FDA) approved Penpulimab-dcqx injection with cisplatin or carboplatin and gemcitabine for the first-line treatment of adults with recurrent or metastatic non-keratinizing nasopharyngeal carcinoma (NPC). It was also approved as a single agent for adults with metastatic non-keratinizing NPC with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy. Source: FDA website	New Drug	4/23/2025
Zevaskyn The Food and Drug Administration (FDA) approved ZevaskynTM (prademagene zamikeracel gene-modified cellular sheets) for the treatment of wounds in adult and pediatric individuals with recessive dystrophic epidermolysis bullosa (RDEB). Source: FDA website	New Drug	4/29/2025
Imaavy The Food and Drug Administration (FDA) approved ImaavyTM (nipocalimab-aahu injection for intravenous use) for the treatment of generalized myasthenia gravis (gMG) in adults and pediatrics 12 years of age and older who are anti-acetylcholine receptor (AChR+) or anti-muscle-specific tyrosine kinase (MuSK+) antibody positive. Source: FDA website	New Drug	4/29/2025

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