WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 6/1/25 – 6/30/25

FDA Drug Safety Communications & Drug Information Updates:

Scopolamine Transdermal (Transderm Scōp): Hyperthermia Warning 6/18/25
The FDA required addition of a new warning to the transdermal scopolamine prescribing information and patient information leaflet regarding the risk of hyperthermia. Use of transdermal scopolamine can increase body temperature and cause heat-related complications including hospitalization and death. Most cases occurred in children 17 years and younger and adults 60 years and older. Risk may be exacerbated by exposure to external heat sources or high environmental temperatures. Patients are instructed to remove the patch and contact a health care professional if their body temperature increases or they are not sweating in warm environmental temperatures.

Acute Liver Failure Following Elevidys Treatment 6/24/25
The FDA is investigating two deaths due to acute liver failure following treatment with Elevidys (delandistrogene moxeparvovec-rokl), a gene therapy indicated for use in patients with Duchenne muscular dystrophy. Both cases appeared related to treatment and occurred in non-ambulatory pediatric male patients. Risk of acute serious liver injury is described in the prescribing information, although current warnings do not include liver failure or death.

mRNA COVID-19 Vaccines Labeling Change: Myocarditis and Pericarditis 6/26/25
The FDA required and approved a change to the prescribing information for the mRNA COVID-19 vaccines Comirnaty and Spikevax to include updated safety information regarding the risks of myocarditis and pericarditis following administration of mRNA COVID-19 vaccines.

BCMA- and CD19-Directed CAR-T Therapies: REMS Eliminated 6/27/25
The FDA eliminated the REMS for BCMA- and CD19-directed CAR-T therapies (Abecma [idacabtagene vicleucel], Breyanzi [lisocabtagene maraleucel], Carvykti [ciltacabtagene autoleucel], Kymriah [tisagenlecleucel], Tecartus [brexucabtagene autoleucel], and Yescarta [axicabtagene ciloleucel]. The FDA noted safe and effective use of these CAR-T agents can be assured without a REMS based on established management guidelines and extensive experience in diagnosing and managing the risks of cytokine release syndrome and neurologic toxicities across products in this class. Aucatzyl (obecabtagene autoleucel) was approved in November without a REMS.

Maralixibat and Odevixibat Labeling Change: Hepatotoxicity and Vitamin Deficiency 6/27/25
The FDA notified health care professionals of safety-related changes to the prescribing information for maralixibat and odevixibat, ileal bile acid transporter (IBAT) inhibitors used in the treatment of cholestatic pruritus in patients with Alagille syndrome or progressive familial intrahepatic cholestasis. Both agents are now contraindicated in patients with prior or active hepatic decompensation and labeling contains additional information describing cases of hepatotoxicity, monitoring recommendations, and guidance for when to discontinue these agents. In addition, these agents can exacerbate fat-soluble vitamin deficiency, and cases of bleeding have been reported in association with vitamin deficiency. The updated labeling contains increased discussion of bleeding in the Warnings section.

Extended-Release Stimulants Labeling Change: Limitation of Use in Children Younger than 6 Years Old 6/30/25
The FDA is requiring a "limitation of use" section in the prescribing information of all extended-release formulations of amphetamines and methylphenidate used to treat attention deficit hyperactivity disorder (ADHD) to include a statement regarding higher rates of adverse reactions in children younger than 6 years. None of the extended-release stimulants are FDA approved for use in the treatment of ADHD in children younger than 6 years. Studies have shown higher levels of the drugs and higher rates of weight loss and other adverse effects in younger children compared with older children.

Major Medication/Drug-Related Product Recalls Announced Through MedWatch:

CADD-Solis Infusion Pumps, Smiths Medical: Recall – Corrections Needed 6/4/25
Smiths Medical issued letters notifying pump users to corrections for certain CADD-Solis Ambulatory Infusion Pumps and CADD-Solis VIP Ambulatory Infusion Pumps due to false occlusion alarms, thermal damage, and intermittent communication connection issues. Additional information can be found on the FDA site. The affected pumps do not have to be removed from use, but corrections must be applied.

Sulfamethoxazole/Trimethoprim 400mg/80 mg Tablets, Amneal Pharmaceutical LLC: Nationwide Recall – Microbial Contamination 6/4/25
Amneal Pharmaceutical, LLC recalled three lots of sulfamethoxazole/trimethoprim 400 mg/80 mg tablets (NDC 65162-271-10, lot # AM241019; NDC 65162-271-50, lot # AM241019A; and NDC 65162-271-10, lot # AM241020) due to microbial contamination observed as black spots on tablet surface, as reported in a product quality complaint, and identified as *Aspergillus*. Affected products were distributed between the dates of 12/4/2024 and 5/15/2025 and have a 06/2027 expiration date.

Novum IQ Large Volume Pump, Baxter: Recall – Corrections Needed 6/6/25
Baxter issued a letter updating operating instructions for the Novum IQ large volume pump due to potential for underinfusion following use of the "standby mode" feature. Customers are advised not to exceed the programmed standby time of 2 hours and 30 minutes for flow rates greater than 50 mL/hour, monitor patients frequently to ensure the appropriate infusion is being delivered, and remove the set upon powering off the device. The pump does not have to be removed from use.

Zicam Cold Remedy Nasal Swabs, Zicam Nasal AllClear Swabs, Orajel Baby Teething Swabs, Church & Dwight Co.: Recall – Microbial Contamination 6/9/25
Church & Dwight Co. recalled all lots of Zicam Cold Remedy Nasal Swabs, Zicam Nasal AllClear Swabs (discontinued in December 2024), and Orajel Baby Teething Swabs due to fungal contamination of the cotton swabs.

MedicaLyte Liquid Bicarbonate Concentrate, Nipro: Recall – Contamination 6/13/25
Nipro recalled all lots of MedicaLyte Liquid Bicarbonate Concentrate (dialysate; unique device identifier: 00817411022824) due to bacterial and fungal contamination.

Z-800 Infusion Pumps, Zyno Medical: Recall – Incorrect Software Installed 6/16/25
Zyno Medical recommended select units of certain Z-800 infusion pumps (Z-800, Z-800F, Z-800W, and Z-800WF) be removed from use or sale, as they were released to customers with the incorrect software version installed which may result in issues with essential functions and risk measures. A complete list of affected serial numbers for each affected model can be found on the FDA site.

Ivenix LVP Blood Products Administration Set, Fresenius Kabi: Recall – Incorrectly Assembled 6/17/25
Fresenius Kabi recalled one lot of the Ivenix LVP Blood Products Administration Set (UDI 20811505030034, lot FA24K05015) that was incorrectly assembled.

Little Remedies Honey Cough Syrup, Medtech Products Inc.: Recall – Contamination 6/18/25
Medtech Products Inc., a subsidiary of Prestige Consumer Health Inc., recalled five lots of their Little Remedies Honey cough syrup due to the presence of *Bacillus cereus*, which can cause food-borne gastrointestinal illness, and loss of shelf-stability. The affected lots of UPC 7-56184-10737-9) are 0039 (exp. 11/2025), 0545 (exp. 01/2026), 0640 (exp. 02/2026), 0450 (exp. 05/2026), and 1198 (exp. 12/2026).

Cefazolin for Injection, Sandoz Inc.: Recall – Product Mispackaging 6/27/25
One lot of cefazolin for injection USP (1 gram per vial) from Sandoz has been identified as mispackaged. The 25-vial carton of Cefazolin for injection contains several vials of Penicillin G Potassium for injection, USP (20 million units per vial) in place of some cefazolin vials. The affected product is lot #PG4360 (exp. 2027-NOV) of Cefazolin for injection NDC: 0781-3451-96 (carton); Penicillin G NDC: 0781-6136-94 (vial). The proper vials should have NDC: 0781-3451-70.

Dietary Supplement Recalls & Public Notifications

Notifications were issued regarding undeclared active ingredients or contaminants in the following products. Patients are advised not to purchase or use these products.

Product	*Promoted Use*	*Undeclared Ingredient(s) or Contaminants*
Aldi Welby Vitamin B12 Energy Support gummy (lot# 248046601)*	Vitamin B12 supplement	Peanuts
Berkely Jensen Vitamin B12 Gummies (lot# 248046601)*		
VitaGlobe Vitamin B12 Extra Strength Gummies (lot #248046601)*		

*recalled

New Product Shortages (per FDA or ASHP)	*Date Initially Posted*
Octreotide intramuscular injection kits	6/4/25
Scopolamine transdermal system	6/9/25

ASHP Drug Shortages List contains up to-date information on drug shortages

Brand Name or Sole Source Product Discontinuations/Withdrawals	*Date Posted*
Atazanavir sulfate capsules (Reyataz, Bristol Myers Squibb); generics remain available	6/4/25
Bosentan tablets (Tracleer, Actelion); generics remain available	6/9/25
Tbo-filgrastim injection (Granix, Cephalon); alternative filgrastim products are available	6/13/25
Phentermine HCl tablet (Adipex-P, Teva); generics remain available	6/13/25
Fluticasone propionate/salmeterol xinafoate inhalation powder (AirDuo RespiClick, Teva); generic fluticasone/salmeterol products are available	6/13/25
Amlodipine besylate/benazepril HCl capsules (Lotrel, Novartis): generics remain available	6/24/25

Removed/Restricted Indications:	*Description*	*Date Approved*
Niraparib/Zejula/GlaxoSmithKline	Indication for maintenance treatment of adult patients with advanced ovarian cancer in the first-line setting narrowed to only those with homologous recombination deficiency (HRD)-positive tumors defined by either a deleterious or suspected deleterious BRCA mutation and/or genomic instability	6/18/25

New Drug Approvals:	*Description (See Attached Drug Summaries)*	*Date Approved*
Clesrovimab-cfor/Enflonsia/Merck	Monoclonal antibody for prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season	6/9/25
Taletrectinib/Ibtrozi/Nuvation Bio	ROS1 tyrosine kinase inhibitor for the treatment of locally advanced or metastatic ROS1-positive non-small cell lung cancer	6/11/25
Garadacimab-gxii/Andembry/CSL	Inhibitor of activated factor XIIa for the prophylaxis of hereditary angioedema	6/16/25

New Indications:	*Description*	*Date Approved*
Xenon Xe 129 hyperpolarized/ Xenoview/Polarean	Use with magnetic resonance imaging for evaluation of lung ventilation in patients 6 years and older	6/2/25
Darolutamide/Nubeqa/Bayer	Monotherapy for metastatic castration-sensitive prostate cancer	6/3/25

New Indications: (continued)	***Description***	***Date Approved***
Glecaprevir, pibrentasvir/Mavyret/ AbbVie Inc	Treatment of acute hepatitis C virus infection in adults and pediatric patients ages 3 years and older	6/10/25
Nitisinone/Harliku/Cycle Pharmaceuticals Ltd	Reduction of urine homogentisic acid in adult patients with alkaptonuria	6/10/25
Pembrolizumab/Keytruda/Merck	Treatment of adults with resectable locally advanced head and neck squamous cell carcinoma whose tumors express PD-L1, as a single agent as neoadjuvant treatment, continued as adjuvant treatment in combination with radiotherapy with or without cisplatin after surgery, and then as a single agent	6/12/25
Talazoparib/Talzenna/Pfizer Inc	In combination with enzalutamide for treatment of metastatic castration-resistant prostate cancer unselected for HRR mutation status	6/12/25
Respiratory syncytial virus vaccine, mRNA/mResvia/Moderna Inc	Indication expanded to include use for prevention of lower respiratory tract disease caused by RSV in individuals 18-59 years of age who are increased risk for the disease	6/12/25
Tafasitamab-cxix/Monjuvi/Incyte Corp	In combination with lenalidomide and rituximab for the treatment of relapsed or refractory follicular lymphoma	6/18/25
Belimumab/Benlysta/GlaxoSmithKline	Indication expanded to include treatment of pediatric lupus nephritis in patients 5 years and older	6/20/25
Cobicistat/Tybost/Gilead	Indication expanded to include use with atazanavir in combination with other antiretroviral agents, except tenofovir alafenamide, for the treatment of HIV infection in pediatric patients weighing at least 14 kg to less than 35 kg, and use with darunavir in combination with other antiretroviral agents in pediatric patients weighing at least 15 kg to less than 40 kg	6/20/25
Dupilumab/Dupixent/Sanofi and Regeneron	Treatment of bullous pemphigoid	6/20/25
Emtricitabine and tenofovir alafenamide/Descovy/Gilead	Indication expanded to include use in pediatric patients with HIV-1 weighing at least 14 kg to less than 35 kg in combination with other antiretroviral agents, including darunavir and cobicistat but not other protease inhibitors that require a CYP3A inhibitor	6/20/25
Datopotamab deruxtecan-dlnk/ Datroway/Daiichi Sankyo Inc	Treatment of adults with locally advanced or metastatic epidermal growth factor receptor (EGFR)-mutated non-small cell lung cancer who have received prior EGFR-directed therapy and platinum-based chemotherapy	6/23/25
Florbetaben F 18/Neuraceq/Life Molecular Imaging	For positron emission tomography (PET) of the brain to estimate amyloid beta neuritic plaque density in adults with cognitive impairment to select patients who are indicated for amyloid beta-directed therapy	6/23/25
Florbetapir F 18/Amyvid/Eli Lilly	For PET of the brain to estimate amyloid beta neuritic plaque density in adults with cognitive impairment to select patients who are indicated for amyloid beta-directed therapy	6/23/25
Flutemetamol F 18/Vizamyl/GE Healthcare	For PET of the brain to estimate amyloid beta neuritic plaque density in adults with cognitive impairment to select patients who are indicated for amyloid beta-directed therapy	6/23/25
Emapalumab-lzsg/Gamifant/Swedish Orphan Biovitrum AB	Treatment of patients with hemophagocytic lympho-histiocytosis/macrophage activation syndrome (MAS) in known or suspected Still's disease, including systemic Juvenile Idiopathic Arthritis, with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS	6/27/25

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Meloxicam/Xifyrm/Azurity Pharmaceuticals	Injection: 30 mg/mL; management of moderate-to-severe pain in adults, used alone or in combination with non-NSAID analgesics	6/5/25
Telmisartan, amlodipine, indapamide/Widaplik/George Medicines	Tablet (telmisartan/amlodipine/indapamide): 10 mg/1.25 mg/0.625 mg, 20 mg/2.5 mg/1.25 mg, 40 mg/5 mg/2.5 mg; treatment of hypertension	6/5/25
Zanubrutinib/Brukinsa/BeOneMedicines USA Inc	Tablet: 160 mg; alternative to 80 mg capsules for treatment of Waldenstrom's macroglobulinemia, chronic lymphocytic leukemia or small lymphocytic lymphoma, mantle cell lymphoma, and follicular lymphoma	6/10/25
Mitomycin/Zusduri/UroGen Pharma	Intravesical solution: kit containing two 40 mg single-dose vials and one 60 mL vial of sterile hydrogel for reconstitution; treatment of adults with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer	6/12/25
Lenacapavir/Yeztugo/Gilead	Tablets: 300 mg, and Injection 463.5 mg; for preexposure prophylaxis to reduce risk of sexually acquired HIV-1, therapy is initiated with subcutaneous injection and oral tablets, followed by subcutaneous injection every 6 months	6/18/25
Immune globulin infusion (human) 10%/Gammagard Liquid ERC/Takeda	Solution: 10%; for replacement therapy for primary humoral immunodeficiency in adults and pediatric patients 2 years and older; Takeda plans to discontinue Gammagard S/D at the end of 2027	6/27/25

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Clesrovimab-cfor/Enflonsia/Merck	
Generic Name / Brand Name / Company	Clesrovimab-cfor/Enflonsia/Merck
Date of approval	6/9/25
Drug Class (Mechanism of Action if novel agent)	Monoclonal antibody with anti-respiratory syncytial virus (RSV) activity; provides passive immunity by targeting the extracellular domain of the RSV F protein to prevent fusion of the viral and cellular membranes and viral entry.
Indication	Prevention of RSV lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season
Comparative agent – Therapeutic interchange?	Nirsevimab (Beyfortus)
Dosage forms/strengths	Injection: 105 mg/0.7 mL in a single-dose prefilled syringe
Common Dose/sig	105 mg as a single intramuscular injection
DEA Schedule	N/A
Date of market availability	Available for ordering in July
Similar Medication Names	N/A
Clinical Use Evaluation	
Common Adverse Effects	Injection site erythema (3.8%), injection site swelling (2.7%), rash (2.3%)
Severe Adverse Effects	Hypersensitivity
Severe Drug-Drug Interactions	None known; can be given concomitantly with childhood vaccines at a separate site
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Neonates and infants born during the RSV season: administer once starting from birth; for infants born outside RSV season consider administering once prior to the start of their first RSV season. Safety and efficacy have not been established in children older than 12 months.
Renal or Hepatic Dosing	No dosage modifications necessary
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in infants with a history of serious hypersensitivity reactions to any product ingredient. Warnings: hypersensitivity reactions, including anaphylaxis, have occurred with other IgG1 monoclonal antibodies. Clesrovimab-cfor may interfere with some immunologically based RSV diagnostic assays; confirmation using a reverse transcriptase polymerase chain reaction assess is recommended when rapid antigen assay results are negative and clinical observations are consistent with RSV infection.
Special administration technique or considerations	Syringes should be stored refrigerated and in the original carton to protect from light until use. Allow injection solution to come to room temperature for approximately 15 minutes prior to administration. The syringes may be kept at room temperature for a maximum of 48 hours. Administer intramuscularly in the anterolateral aspect of the thigh; do not inject in the gluteal area or areas where there may be a major nerve trunk or blood vessel. For infants undergoing cardiac surgery with cardiopulmonary bypass during or entering their first RSV season, an additional 105 mg dose is recommended as soon as the infant is stable after surgery.
Prepared by	Terri Levien
Source	Enflonsia (clesroviamb-cfor) [prescribing information]. Rahway, NJ: Merck Sharp & Dohme LLC; June 2025.

Taletrectinib/Ibtrozi/Nuvation Bio	
Generic Name / Brand Name / Company	Taletrectinib/Ibtrozi/Nuvation Bio
Date of approval	6/11/25
Drug Class (Mechanism of Action if novel agent)	ROS1 tyrosine kinase inhibitor
Indication	Treatment of locally advanced or metastatic ROS1-positive non-small cell lung cancer
Comparative agent – Therapeutic interchange?	Entrectinib (Rozlytrek), Repotrectinib (Augtyro)
Dosage forms/strengths	Capsules: 200 mg
Common Dose/sig	600 mg orally once daily
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Talquetamab, Talazoparib, Tafasitamab
Clinical Use Evaluation	
Common Adverse Effects	≥20%: diarrhea, nausea, vomiting, dizziness, rash, constipation, fatigue; grade 3 or 4 lab abnormalities (≥5%): increased ALT increased AST, decreased neutrophils, increased creatine phosphokinase (CPK)
Severe Adverse Effects	Diarrhea, nausea, vomiting, rash, prolonged QT, pneumonia, pleural effusion, interstitial lung disease, hepatotoxicity
Severe Drug-Drug Interactions	Strong and moderate CYP3A inhibitors and inducers: avoid use Gastric acid reducing agents: avoid proton pump inhibitors and H2 receptor antagonists; separate from antacid dosing by 2 hours Drugs that prolong QTc interval: avoid use
Severe Drug-Food Interactions	Taken on an empty stomach; avoid grapefruit during treatment
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Monitor liver function tests prior to initiating, every 2 weeks during the first 2 months, then monthly thereafter as clinically indicated with more frequent monitoring if transaminase is elevated. Monitor electrolytes and serum uric acid levels prior to initiating and periodically during treatment. Monitor CPK as clinically indicated.
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments in renal impairment; dosage reductions, withholding therapy, or discontinuation advised in patients developing hepatoxicity
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. Warnings: hepatotoxicity (monitor liver function tests), interstitial lung disease (monitor for pulmonary symptoms), QTc interval prolongation (monitor ECG and electrolytes), hyperuricemia (monitor serum uric acid levels and initiate urate-lowering medication as clinically indicated), myalgia with CPK elevation (monitor serum CPK in patients with unexplained muscle pain, tenderness, or weakness), skeletal fractures, embryo-fetal toxicity. Advise patients to minimize sun exposure and use sun protection
Special administration technique or considerations	Taken on an empty stomach at the same time each day. No food or antacid intake at least 2 hours before and 2 hours after administration. Reduce dose, withhold therapy or discontinue for hepatotoxicity, interstitial lung disease/pneumonitis, QTc interval prolongation, hyperuricemia, CPK elevation, and other Grade 3 or 4 reactions.
Prepared by	Terri Levien
Source	Ibtrozi (taletrectinib) [prescribing information]. Burlington, MA: Nuvation Bio Inc; June 2025.

Garadacimab-gxii/Andembry/CSL Behring LLC	
Generic Name / Brand Name / Company	Garadacimab-gxii/Andembry/CSL Behring LLC
Date of approval	6/16/25
Drug Class (Mechanism of Action if novel agent)	Factor XIIa inhibitor
Indication	Prevention of hereditary angioedema (HAE) attacks in patients 12 years and older
Comparative agent – Therapeutic interchange?	Lanadelumab (a kallikrein inhibitor), berotralstat (kallikrein inhibitor), C1 inhibitor concentrates
Dosage forms/strengths	Injection: 200 mg/1.2 mL solution in single-dose prefilled autoinjector or syringe with needle safety device
Common Dose/sig	400 mg (two 200 mg injections) subcutaneously once (loading dose); 200 mg subcutaneously each month thereafter (maintenance)
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Andexanet, Androgel, Anectine, Anexsia, Gadavist, Garamycin
Clinical Use Evaluation	
Common Adverse Effects	(≥7%): nasopharyngitis, abdominal pain, injection site reactions, prolonged INR
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Indicated for patients 12 years and older with no clinical differences between pediatric patients 12 years and older and adults found. Safety and efficacy are not established in patients younger than 12 years.
Renal or Hepatic Dosing	No dosage adjustments. There is no difference in pharmacokinetics in patients with mild to moderate renal impairment; no data in severe renal impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications or warnings Garadacimab-gxii can prolong activated partial thromboplastin time (aPTT) and prothrombin time (PT) laboratory testing (no bleeding events observed in trials)
Special administration technique or considerations	Subcutaneous administration only into the thigh or abdomen (at least 1 inch away from the navel); caregiver may administer in upper arm. Do not shake. Patients may self-administer. Store refrigerated; allow to sit for 30 minutes at room temperature before use. Keep the autoinjector and syringe in the original carton to protect from light.
Prepared by	Hayden Wesley
Source	Andembry (garadacimab-gxii) [prescribing information]. Kankakee, IL: CSL Behring LLC.; June 2025.