WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 2/1/26 – 2/28/26

FDA Drug Safety Communications & Drug Information Updates:

Capecitabine and Fluorouracil Safety Labeling Update – Dihydropyrimidine Dehydrogenase Deficiency 2/5/26
Updates to the product labeling of capecitabine and fluorouracil have been made related to risks associated with dihydropyrimidine dehydrogenase (DPD) deficiency. Healthcare professionals should be aware of the risks of DPD deficiency, inform patients prior to treatment about the potential for serious and life-threatening toxicities due to DPD deficiency, and test patients for genetic variants of DPYD prior to initiating treatment with capecitabine or fluorouracil unless immediate treatment is necessary. A boxed warning has been added to the labeling of capecitabine and fluorouracil products highlighting the risks and advising DPYD testing. Use of these agents should be avoided in patients with certain homozygous or compound heterozygous PYPD variants that result in complete DPD deficiency.

Isotretinoin iPLEDGE Risk Evaluation and Mitigation Strategy Modification Approved 2/10/26
The FDA approved modifications to the isotretinoin iPLEDGE REMS effective 180 days after the 2/9/26 approval. Prescribers must continue to complete pre-treatment pregnancy tests in a medical setting prior to starting isotretinoin treatment. If permitted by the prescriber, patients may complete subsequent pregnancy tests outside of a medical setting (eg, at-home pregnancy test) during and after treatment. If a person who can get pregnant does not pick up their prescription within the 7-day window, a repeat pregnancy test may be done immediately without an additional waiting period; this must be in a medical setting if the patient had not picked up their first dose. Patients who cannot get pregnant must be counseled at enrollment and counseling should be reinforced throughout the course of treatment but must no longer be documented monthly. For pharmacies, there is no longer a 30-day prescription window for patients who cannot get pregnant. Pharmacy staff training is required annually; records of training completion should be maintained by the pharmacy's authorized representative.

Menopausal Hormone Therapies – Labeling Changes 2/12/26
Following the FDA's November 2025 label change announcement, the FDA has approved drug labeling changes for the following 6 products: Prometrium, Divigel, Cenestin, Enjuvia, Estring, Bijuva. For each product risk statements related to cardiovascular disease, breast cancer, and probable dementia were removed from the boxed warnings. To date 29 drug companies have submitted proposed labeling changes with additional FDA approved labeling changes anticipated.

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

FreeStyle Libre 3 and FreeStyle Libre 3 plus, Abbott: Recall – Incorrect Low Glucose Readings 2/4/26
Abbott recalled certain FreeStyle Libre 3 and FreeStyle Libre 3 Plus Sensors due to incorrect low glucose readings that are lower than the actual blood glucose reading. As of January 7, 2026, Abbott had reported 860 serious injuries and seven deaths associated with the incorrect readings. Instructions for locating the sensor serial number and a complete list of affected products/lots can be found on the FDA site or at https://www.freestylecheck.com/. For potentially affected sensors as identified on the list or via a customer service representative, patients should immediately discontinue use and dispose of the affected sensor(s). Replacement sensors will be provided at no cost.

TRUE METRIX Blood Glucose Monitoring Systems, Trividia Health: Labeling Correction 2/10/26

Trividia Health Inc. initiated a labeling correction requiring modification of the Owner's Booklets/System Instructions for Use for all TRUE METRIX, TRUE METRIX AIR, and TRUE METRIX GO Self-Monitoring, and TRUE METRIX PRO Professional Monitoring Blood Glucose Systems. The E-5 Error Code in the "Messages" section of the instructions is updated to emphasize that users must seek medical attention immediately if they receive an E-5 error code and are experiencing symptoms of high glucose. The E-5 code is displayed for either a very high blood glucose or when there is a test strip error. A delay in seeking care following an E-5 code could result in serious injury for users with very high glucose levels. There have been 114 reports of serious injuries and one death associated with the E-5 error code since the product was introduced in August 2014.

Ivenix Large Volume Pump Software, Fresenius Kabi: Software Correction 2/25/26

Fresenius Kabi issued a letter recommending all Ivenix Large Volume Pump Software (versions 5.10.1 and earlier) be corrected prior to continued use. Abnormalities that may cause delays or interruptions to infusion were identified, and have been associated with two serious injuries.

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***
Alkaloids Chewable Tablets—White Vein (Lot B# AAW.501.3), Shaman Botanicals*	Energy	7-Hydroxymitragynine (7-OH) exceeding declared 7.5 mg content
Ashfiat Alharamain Energy Support, Akkarco LLC*	Energy support	Tadalafil
Boner Bears Chocolate Syrup*	Sexual enhancement	Sildenafil
DTF Sexual Chocolate	Sexual enhancement	Sildenafil and tadalafil
Fantasy Aphrodisiac Chocolate	Sexual enhancement	Sildenafil
Green Lumber (LOT308EXP03/28)*	Sexual enhancement	Counterfeit product contains tadalafil
Ilum Male Sexual Enhancement Chocolate	Sexual enhancement	Tadalafil
LOVION Chocolate with Ginseng for Men	Sexual enhancement	Sildenafil and tadalafil
Pink Pussycat Aphrodisiac Chocolate	Sexual enhancement	Tadalafil
Rhino Choco VIP Chocolate 10X*	Sexual enhancement	Tadalafil
Rosabella Moringa, Ambrosia Brands*	Sleep, joints, energy	Salmonella
ULTRA ADVANC3	Joint pain	Dexamethasone, diclofenac, methocarbamol
ULTRA ADVANC3 GOLD	Joint pain	Dexamethasone, diclofenac, methocarbamol
Umary products	Pain	Diclofenac

*recalled

New Product Shortages (per FDA or ASHP)	***Date Initially Posted***
Disopyramide phosphate controlled-release capsules (Norpace CR, Pfizer)	2/5/26
Trimethobenzamide injection (Tigan, Par Pharmaceuticals)	2/19/26
Epoprostenol injection	2/23/26
Furosemide oral solution	2/25/26

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

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Chlorothiazide (Diuril, Salix Pharmaceuticals) oral suspension; convert patients to an alternative diuretic	2/10/26
Gemfibrozil (Lopid, Pfizer) tablet 600 mg; generics remain available	2/10/26
Frovatriptan succinate (Frova, Endo) tablets; generics remain available	2/24/26
Lincomycin HCl (Lincocin, Pfizer) injection; generics remain available	2/25/26
Clindamycin HCl (Cleocin, Pfizer) capsules; generics remain available	2/25/26
Itraconazole (Sporanox, Janssen) capsuels; generics remain available	2/27/26

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Difamilast/Adquey/Acrotech Biopharma	Topical phosphodiesterase 4 inhibitor for the treatment of adults and pediatric patients 2 years and older with mild to moderate atopic dermatitis	2/12/26
Milsaperidone/Bysanti/Vanda Pharmaceuticals	Atypical antipsychotic for the acute treatment of manic or mixed episodes associated with bipolar I disorder and for the treatment of schizophrenia in adults	2/20/26
Pegzilarginase-nbln/Loargys/ Immedica	Enzyme replacement therapy for the treatment of arginase 1 deficiency in patients 2 years and older	2/23/26
Navepegritide/Yuviwel/Ascendis Pharma	C-type natriuretic peptide analog to increase linear growth in children 2 years and older with achondroplasia with open epiphyses	2/27/26

New Indications:	***Description***	***Date Approved***
Pembrolizumab/Keytruda/Merck	In combination with paclitaxel, with or without bevacizumab, for treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1 and who have received one or two prior systemic therapies	2/10/26
Pembrolizumab and berahyaluronidase/Keytruda Qlex/ Merck	In combination with paclitaxel, with or without bevacizumab, for treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1 and who have received one or two prior systemic therapies	2/10/26
Inclisiran/Leqvio/Novarti	Indication expanded to include pediatric patients 12 years and older with heterozygous familial hypercholesterolemia	2/12/26
Landiolol/Rapiblyk/AOP	For the short term reduction of ventricular rate in pediatric patients with supraventricular tachycardia	2/13/26
Pitolisant/Wakix/Harmony	Indication expanded to include treatment of cataplexy in pediatric patients 6 years and older with narcolepsy	2/13/26
Acalabrutinib/Calquence/AstraZeneca	With venetoclax for the treatment of adult patients with chronic lymphocytic leukemia/small lymphocytic leukemia	2/19/26
Venetoclax/Veclexta/AbbVie	With acalabrutinib for the treatment of adult patients with previously untreated chronic lymphocytic leukemia/small lymphocytic leukemia	2/19/26
Gadopiclenol/Elucirem/Guerbet	Indication expanded to include term neonates and older	2/20/26
Dupilumab/Dupixent/	Treatment of adults and pediatric patients 6 years and older with allergic fungal rhinosinusitis with a history of sino-nasal surgery	2/23/26
Zongertinib/Hernexeos/Boehringer Ingelheim Pharmaceuticals	Treatment of adults with unresectable or metastatic non-squamous non-small cell lung cancer whose tumors have HER2 tyrosine kinase domain activating mutations	2/26/26
Rizatriptan/RizaFilm/Gensco Pharma	Acute treatment of migraine with or without aura to include pediatric patients 6 to 11 years of age	2/26/26
Pegvaliase-pqpz/Palynziq/BioMarin Pharmaceutical	Indication expanded to include pediatric patients with phenylketonuria ages 12 years and older	2/27/26
Somapacitan-beco/Sogroya/Novo Nordisk	Treatment of pediatric patients 2.5 years and older with short stature for gestational age and with no catch-up growth by 2 years of age, growth failure associated with Noonan syndrome, or idiopathic short stature	2/27/26

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Leucovorin calcium/Vykoura/Avyxa Pharma	Injection: 50 mg/5 mL, 350 mg/30 mL, 500 mg/50 mL in single-dose vial; injection for subcutaneous administration for rescue after high-dose methotrexate therapy, reducing toxicity of methotrexate in patients with impaired elimination or folic acid antagonists or dihydrofolate reductase inhibitors following overdose, treatment of megaloblastic anemias due to folic acid deficiency when oral therapy is not feasible, and treatment of patients with metastatic colorectal cancer in combination with 5-fluorouracil	2/3/26
Etoposide/Avopef/Avyxa	Multidose vial: 100 mg/5 mL; for use in combination with other chemotherapy or immunotherapy for the treatment of adult patients with refractory testicular cancer or small cell lung cancer	2/13/26
5-Fluorouracil/Favlyxa/Avyxa	Injection: 250 mg/10 mL single-dose vial; for the treatment of adenocarcinoma of the colon and rectum, adenocarcinoma of the breast, gastric adenocarcinoma, pancreatic adenocarcinoma	2/20/26
Desmopressin acetate/Desmoda/Eton Pharmaceuticals	Oral solution: 0.05 mg/mL; for the management of central diabetes insipidus as antidiuretic replacement therapy in adults and pediatric patients	2/25/26
Darunavir and cobicistat/Prezcobix/ Janssen Products	Tablet for oral suspension: 800 mg/150 mg, 675 mg/150 mg, 600 mg/90 mg; for the treatment of HIV-1 infection in pediatric patients aged 3 years and older and weighing at least 15 kg	2/27/26

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Difamilast/Adquey/Acrotech Biopharma	
Generic Name/Brand Name/Company	Difamilast/Adquey/Acrotech Biopharma
Date of approval	2/12/26
Drug Class (Mechanism of Action if novel agent)	Phosphodiesterase-4 (PDE4) inhibitor
Indication	Treatment of adults and pediatric patients 2 years and older with mild to moderate atopic dermatitis
Comparative agent – Therapeutic interchange?	Crisaborole, roflumilast
Dosage forms/strengths	Ointment, 1%; 27 g and 85 g tubes
Common Dose/sig	Apply thin layer twice daily to affected areas and run in completely
DEA Schedule	N/A
Date of market availability	Unknown
Similar Medication Names	Apremilast, diflunisal
Clinical Use Evaluation	
Common Adverse Effects	Nasopharyngitis (6% vs 4% with vehicle placebo)
Severe Adverse Effects	None known
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Indicated for use in patients 2 years and older
Renal or Hepatic Dosing	No unique dosing or cautions
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications or warnings
Special administration technique or considerations	Topical use only. Rub in completely and wash hands after application. Avoid infected areas of skin when applying.
Prepared by	Terri Levien
Source	Adquey (difamilast) [prescribing information]. East Windsor, NJ: Acrotech Biopharma Inc; February 2026.

Milsaperidone/Bysanti/Vanda Pharmaceuticals	
Generic Name/Brand Name/Company	Milsaperidone/Bysanti/Vanda Pharmaceuticals
Date of approval	2/20/26
Drug Class (Mechanism of Action if novel agent)	Iloperidone prodrug, atypical antipsychotic
Indication	Acute treatment of manic or mixed episodes associated with bipolar I disorder and for the treatment of schizophrenia in adults
Comparative agent – Therapeutic interchange?	Iloperidone
Dosage forms/strengths	Tablets: 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg
Common Dose/sig	Initiate with 1 mg twice daily. Follow titration schedule to titrate to recommended maintenance dose over 5 to 7 days: Schizophrenia: 6 to 12 mg twice daily Bipolar mania: 12 mg twice daily
DEA Schedule	N/A
Date of market availability	Third quarter 2026
Similar Medication Names	Iloperidone, milnacipran, risperidone
Clinical Use Evaluation	
Common Adverse Effects	Schizophrenia (>5%): dizziness, dry mouth, fatigue, nasal congestion, orthostatic hypotension, somnolence, tachycardia, increased weight Bipolar mania (>5%): tachycardia, dizziness, dry mouth, hepatic enzymes increased, nasal congestion, increased weight, hypotension, somnolence

Severe Adverse Effects	Hyperglycemia, neuroleptic malignant syndrome,
Severe Drug-Drug Interactions	Strong CYP2D6 inhibitors and/or strong CYP3A4 inhibitors: reduce dose Drugs that lower blood pressure: avoid use with alpha-adrenergic blocking agents and consider lowering dose of other drugs that lower blood pressure
Severe Drug-Food Interactions	None known; not studied with grapefruit (moderate CYP3A4 inhibitor)
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Consider CYP2D6 genetic testing. Monitor fasting plasma glucose before or soon after initiation and periodically. Monitor serum potassium and magnesium at baseline and during treatment in patients at risk for electrolyte disturbances; complete blood count in patients with pre-existing low white blood cell count, absolute neutrophil count, or history of drug-induced leukopenia or neutropenia;
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment in patients with renal impairment or mild hepatic impairment. Consider lower maintenance dosage in patients with moderate hepatic impairment. Not recommended in patients with severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: hypersensitivity Warnings: Boxed warning – elderly patients with dementia-related psychosis QTc interval prolongation CYP2D6 poor metabolizers (reduce dose) Neuroleptic malignant syndrome Tardive dyskinesia Metabolic changes – monitor Orthostatic hypotension and syncope Seizures Leukopenia, neutropenia, and agranulocytosis Hyperprolactinemia Body temperature regulation Dysphagia Priapism Potential for cognitive or motor impairment Intraoperative floppy iris syndrome
Special administration technique or considerations	Administer orally twice daily with or without food. Titrate to reduce risk of orthostatic hypotension.
Prepared by	Terri Levien
Source	Bysanti (milsaperidone) [prescribing information]. Washington, DC: Vanda Pharmaceuticals Inc; February 2026.

Pegzilarginase-nbln/Loargys/ Immedica	
Generic Name/Brand Name/Company	Pegzilarginase-nbln/Loargys/Immedica
Date of approval	2/23/26
Drug Class (Mechanism of Action if novel agent)	Arginine specific enzyme replacement therapy
Indication	Treatment of arginase 1 deficiency in patients 2 years and older
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Injection: 2 mg/0.4 mL, 5 mg/mL; single-dose vial
Common Dose/sig	Starting dose: 0.1 mg/kg IV once weekly; maximum recommended dose is 0.2 mg/kg once weekly. May switch to subcutaneous administration after 8 weeks of IV therapy.
DEA Schedule	N/A
Date of market availability	April 2026
Similar Medication Names	Pegaspargase
Clinical Use Evaluation	
Common Adverse Effects	Vomiting (33%), pyrexia (19%), infusion-associated reactions (14%), constipation (14%), hypersensitivity (2%)
Severe Adverse Effects	Anaphylaxis
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.	Obtain baseline plasma arginine concentration prior to initiating treatment.
Used in Pediatric Areas	Indicated for use in patients 2 years and older
Renal or Hepatic Dosing	No dosage adjustments required
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications Boxed warning: hypersensitivity reactions including anaphylaxis
Special administration technique or considerations	Administer under supervision of health care provider knowledgeable in the management of severe hypersensitivity reactions. Initiate therapy in a healthcare setting with appropriate monitoring and support measures. Consider pre-medication with antihistamines and corticosteroids. Dilute in 0.9% sodium chloride injection for IV administration. Administer IV over at least 30 minutes. Flush line with 0.9% sodium chloride injection. After 8 weeks may switch to subcutaneous administration. Administer undiluted solution subcutaneously in the abdomen, lateral thigh, or side or back of the upper arms. After establishing tolerability, maintenance subcutaneous doses may be self-administered at home.
Prepared by	Terri Levien
Source	Loargys (pegzilarginase-nbln) [prescribing information]. City, ST: Manufacturer; January 2026.

Navepegritide/Yuviwel/Ascendis Pharma	
Generic Name/Brand Name/Company	Navepegritide/Yuviwel/Ascendis Pharma
Date of approval	2/27/26
Drug Class (Mechanism of Action if novel agent)	C-type natriuretic peptide analog
Indication	To increase linear growth in pediatric patients 2 years and older with achondroplasia with open epiphyses
Comparative agent – Therapeutic interchange?	Vosoritide
Dosage forms/strengths	Injection: 1.3 mg, 2.8 mg, 5.5 mg as lyophilized powder in single-dose vial
Common Dose/sig	Weight based dose administered subcutaneously once weekly; consult prescribing information dosage table
DEA Schedule	N/A
Date of market availability	Second quarter 2026
Similar Medication Names	Yuvezzi
Clinical Use Evaluation	
Common Adverse Effects	Vomiting (21%), injection-site reaction (19%), pain in extremity (12%), nausea (6%), hypertrichosis (3%)
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Pediatric patients 2 years and older, until epiphyseal closure
Renal or Hepatic Dosing	No dosage adjustments in mild renal impairment. Not recommended in patients with moderate or severe renal impairment. Not studied in hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications Warnings: transient blood pressure reductions
Special administration technique or considerations	Administer subcutaneously in abdomen, thigh, buttocks, or back of upper arms. Monitor growth and adjust dose according to body weight. Discontinue upon epiphyseal closure.
Prepared by	Terri Levien
Source	Yuviwel (navepegritide) [prescribing information]. Princeton, NJ: Ascendis Pharma Endocrinology Inc; February 2026.