



Highlights of FDA Activities – 10/1/25 – 10/31/25

FDA Drug Safety Communications & Drug Information Updates:

Ciltacabtagene Autoleucl (Carvykti): Updated Boxed Warning - Enterocolitis 10/10/25

Reports of immune effector cell-associated enterocolitis (IEC-EC) in patients treated with Carvykti have prompted labeling changes including an update to the boxed warning, warnings, and adverse events sections. IEC-EC presents with severe or prolonged diarrhea, abdominal pain, and weight loss requiring total parenteral nutrition. It can occur weeks to months after Carvykti infusion. Supportive care and immunosuppressive therapy, including corticosteroids, have been required. Fatal outcomes have been reported. The FDA determined overall benefit, including increased overall survival, continues to outweigh the potential risks associated with Carvykti therapy.

Tranexamic Acid Injection: Boxed Warning – Inadvertent Spinal Administration 10/21/25

The FDA is requiring labeling changes to strengthen warnings that tranexamic acid injection should not be administered intrathecally or as an epidural injection. Medication errors with inadvertent neuraxial administration in place of the intended local anesthetic have been reported and have resulted in prolonged hospitalization and death. Changes to the labeling include addition of a boxed warning regarding the risk of medication errors involving inadvertent neuraxial administration, a statement that tranexamic acid injection is contraindicated as a neuraxial injection, and an update to the Dosage and Administration section to clarify tranexamic acid injection is only to be administered intravenously. The FDA is also recommending the container labels prominently display the product name and intravenous route of administration.

Restrictions on Sale of Ingestible Fluoride Prescription Products 10/31/25

The FDA announced they would be taking enforcement action against companies marketing ingestible fluoride products labeled for use in children under the age of 3 years or older children at low or moderate risk for tooth decay. Ingestible fluoride products are not FDA-approved as they have been used since the 1940s. The FDA advises ingestible fluoride (oral chewable tablets and oral drops) may not be labeled for use in children under 3 years of age or that does not limit use to children at high risk for dental caries, such as those with a history of tooth decay and lack of access to fluoridated drinking water.

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

TRUE METRIX Blood Glucose Meters, Trividia Health: Recall – Defective LCD Displays 10/7/25

Trividia Health recalled TRUE METRIX Self-Monitoring blood glucose meters co-branded under the Good Neighbor Pharmacy® brand. The recalled meters with lot number KD0746 manufactured 9/4/25 and distributed 9/8/25 through 9/16/25 may have defective LCD displays that affect product performance.

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.

<u>Product</u>	<u>Promoted Use</u>	<u>Undeclared Ingredient(s) or Contaminants</u>
Ashfiat Alharamain Energy Support	Sexual enhancement	Tadalafil
Black Thai Honey	Sexual enhancement	Sildenafil, tadalafil, diclofenac
Contra Reumas	Joint pain	Dexamethasone, diclofenac, methocarbamol
Mojo Max Fusion XXX	Sexual enhancement	Sildenafil, tadalafil

<u>Product (continued...)</u>	<u>Promoted Use</u>	<u>Undeclared Ingredient(s) or Contaminants</u>
Monarch Premium Kratom Powder (Bali Gold, Red Bali, Green Maeng Da, and White Elephant)*	Various	Salmonella
MyBladder, Purity Products (Lot 030425176)	Bladder control	<i>Escherichia coli</i> O7:K1 and 1303
OsteoSin Max	Joint pain	Dexamethasone, methocarbamol, phenylbutazone ¹
SPARTAN	Sexual enhancement	Sildenafil
Super Greens, Member's Mark (moringa leaf powder)	Dietary supplement	<i>Salmonella</i>
vROX	Sexual enhancement	Sildenafil

*recalled

¹Phenylbutazone is a NSAID that was discontinued for human use in the U.S. due to risk of serious adverse events including aplastic anemia and agranulocytosis.

New Product Shortages (per FDA or ASHP)

Date Initially Posted

Fludarabine injection	10/15/25
Ascorbic acid injection	10/16/25
Sterile talc intrapleural powder	10/27/25

[ASHP Drug Shortages List](#) contains up to-date information on drug shortages

Brand Name or Sole Source Product Discontinuations/Withdrawals

Date Posted

Quinapril HCl tablet (Accupril, Pfizer): generics remain available	10/1/25
Quinapril HCl and hydrochlorothiazide tablet (Accuretic, Pfizer): generics remain available	10/1/25
Paricalcitol capsule (Zemplar, AbbVie); generics remain available	10/7/25
Cobicistat tablet (Tybost, Gilead); planned distribution through the end of February 2026, cobicistat will remain available as a component of some combination products but not as a single agent	10/7/25
Adalimumab-afzb injection (Abrilada Injection Kit, Pfizer); branded adalimumab and other biosimilars remain available	10/9/25
Pemetrexed injection (Alimta, Eli Lilly & Co); generics remain available	10/16/25
Vigabatrin oral solution (Vigpoder, Pyros Pharmaceuticals); other branded and generic products remain available	10/16/25
Voriconazole injection (Vfend, Pfizer); generics remain available	10/16/25
Elbasvir/Grazoprevir tablet (Zepatier, Merck); to be discontinued 12/1/25 – alternative antivirals for the treatment of hepatitis C genotypes 1 and 4 are available	10/17/25
Tranylcypromine sulfate (Parnate, Teva); supply to be depleted by 12/31/25, generics remain available	10/21/25
Insulin lispro (Humalog U-100 Tempo Pen, Eli Lilly & Co); alternative dosage forms remain available	10/24/25
Insulin glargine (Basaglar U-100 Tempo Pen, Eli Lilly & Co); alternative dosage forms remain available	10/24/25
Pramlintide acetate injection (SymlinPen 60, Symplint Pen 120; AstraZeneca); patients will need to be converted to an alternative therapy	10/27/25

New Drug Approvals:

Description (See Attached Drug Summaries)

Date Approved

Nerandomilast/Jascayd/Boehringer Ingelheim	Phosphodiesterase 4B inhibitor for the treatment of idiopathic pulmonary fibrosis	10/7/25
Elinzanetant/Lynkuet/Bayer HealthCare Pharmaceuticals Inc	Neurokinin 1 and neurokinin 3 receptor antagonist for the treatment of moderate to severe vasomotor symptoms due to menopause	10/24/25

<u>New Indications:</u>	<u>Description</u>	<u>Date Approved</u>
Atezolizumab/Tecentriq/Genentech	With lurbinectedin for the maintenance treatment of adult patients with extensive-stage small cell lung cancer (SCLC) whose disease has not progressed after first-line induction therapy with atezolizumab and hyaluronidase-tqis or intravenous atezolizumab, and carboplatin plus etoposide	10/2/25
Atezolizumab and hyaluronidase-tqis/Tecentriq Hybreza/Genentech	With lurbinectedin for the maintenance treatment of adult patients with extensive-stage SCLC whose disease has not progressed after first-line induction therapy with atezolizumab or atezolizumab and hyaluronidase-tqis, carboplatin, and etoposide	10/2/25
Lurbinectedin/Zepzelca/Jazz Pharmaceuticals	With atezolizumab or atezolizumab and hyaluronidase-tqis for the maintenance treatment of adults patients with extensive-stage SCLC whose disease has not progressed after first-line induction therapy with atezolizumab or atezolizumab and hyaluronidase-tqis, carboplatin, and etoposide	10/2/25
Pemetrexed/Axle/Avyxa Pharma	With pembrolizumab and platinum chemotherapy for initial treatment of patients with metastatic non-squamous non-small cell lung cancer without EGFR or ALK genomic tumor aberrations	10/3/25
Golimumab/Simponi/Janssen Biotech	Indication expanded to include treatment of pediatric patients weighing at least 15 kg with moderately to severely active ulcerative colitis	10/7/25
Cemiplimab-rwlc/Libtayo/Regeneron Pharmaceuticals Inc	Adjuvant treatment of patients with cutaneous squamous cell carcinoma at high risk of recurrence after surgery and radiation	10/8/25
Iopamidol/Isovue/Bracco Diagnostics	To delineate the gastrointestinal tract on computed tomography of the abdomen and pelvis in adults and pediatric patients	10/10/25
Sodium phenylbutyrate/Olpruva/Acer Therapeutics	Indicated expanded to include use in pediatric patients 1 year and older who weight 7 kg or more as adjunctive therapy to standard of care for chronic management of urea cycle disorders involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase, or argininosuccinic acid synthetase	10/10/25
Risperidone/Uzedy/Teva	Monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar 1 disorder in adults	10/14/25
Ferumoxytol/Ferabright/Covis	For magnetic resonance imaging of the brain in adults with known or suspected malignant neoplasms in the brain to visualize lesions with a disrupted blood-brain barrier	10/16/25
Tofacitinib/Xeljanz/Pfizer Labs	Treatment of active psoriatic arthritis in patients 2 years and older who have had an inadequate response or intolerance to one or more tumor necrosis factor blockers	10/16/25
Tezepelumab-ekko/Tezspire/Amgen & AstraZeneca	Add-on maintenance treatment of inadequately controlled chronic rhinosinusitis with nasal polyps in patients 12 years and older	10/17/25
Obinutuzumab/Gazyva/Roche	Treatment of adults with active lupus nephritis who are taking standard therapy	10/17/25
Adalimumab-aaty/Yuflyma/Celltrion	Treatment of hidradenitis suppurativa in adolescents 12 years and older and uveitis in children 2 years and older	10/17/25

<u>New Indications (continued):</u>	<u>Description</u>	<u>Date Approved</u>
Semaglutide/Rybelsus/Novo Nordisk Inc	To reduce risk of major cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes who are at high risk for these events	10/17/25
Belantamab mafodotin/Blenrep/GlaxoSmithKline	With bortezomib and dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory drug; returning to market with new indication	10/23/25
Revumenib/Revuforj/Syndax	Treatment of adult and pediatric patients at least 1 year of age with relapsed or refractory acute myeloid leukemia with a susceptible NPM1 mutation who do not have satisfactory alternative treatment options	10/24/25

<u>New Dosage Forms or Formulation:</u>	<u>Description</u>	<u>Date Approved</u>
Roflumilast/Zoryve/Arcutis	Cream 0.05%; new strength with indication expanded to include treatment of mild-to-moderate atopic dermatitis in patients 2 to 5 years of age	10/4/25
Furosemide/Lasix ONYU/SQ Innovation	Injection: 80 mg/2.67 mL in a single-dose prefilled cartridge co-packaged with a single-use disposable unit infuser; for the treatment of edema in adults with chronic heart failure; device preprogrammed to deliver 30 mg of furosemide over the first hour and then 12.5 mg per hour for the subsequent 4 hours; not for chronic use, replace with oral diuretic	10/8/25
Riboflavin 5' Phosphate/Epioxa/Glaukos	Ophthalmic solution: 0.239% and 0.177% supplied in single-dose glass syringes copackaged in an Epithelium-on Cross-Linking Kit; photoenhancer for the treatment of keratoconus used in conjunction with the O2n System and Boost Goggles	10/20/25
Fosfomycin/Contepo/Meitheal Pharmaceuticals	Injection: 6 g powder for reconstitution and dilution in a single-dose vial; for treatment of complicated urinary tract infections including acute pyelonephritis caused by susceptible isolates of <i>Escherichia coli</i> and <i>Klebsiella pneumoniae</i> in adults	10/22/25
Clonidine hydrochloride/Javadin/Azurity	Oral solution: 0.02 mg/mL supplied in bottles of 250 mL; indicated for lowering blood pressure in adults with hypertension.	10/23/25

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Nerandomilast/Jascayd/Boehringer Ingelheim	
Generic Name/Brand Name/Company	Nerandomilast/Jascayd/Boehringer Ingelheim
Date of approval	10/7/25
Drug Class (Mechanism of Action if novel agent)	Phosphodiesterase 4 (PDE4) inhibitor; exerts anti-fibrotic and immunomodulatory effects
Indication	Treatment of idiopathic pulmonary fibrosis
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Tablets: 9 mg and 18 mg
Common Dose/sig	18 mg orally twice daily; dose may be reduced for intolerability to 9 mg twice daily unless the patient is also taking pirfenidone
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Neratinib maleate
Clinical Use Evaluation	
Common Adverse Effects	At 18 mg twice daily dose: diarrhea (42%), COVID-19 (13%), upper respiratory tract infection (13%), depression (12%), weight decreased (11%), decreased appetite (9%), nausea (8%), fatigue (7%), headache (7%), vomiting (6%), back pain (6%), dizziness (5%)
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	Reduce dose with strong CYP3A inhibitors. Avoid concomitant use of nerandomilast with moderate or strong CYP3A inducers. If used concomitantly with pirfenidone, do not reduce nerandomilast dose to 9 mg, due to potential loss of efficacy.
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	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment in mild, moderate or severe renal impairment or mild or moderate hepatic impairment; use is not recommended in patients with end stage renal disease or severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications or warnings
Special administration technique or considerations	Administered twice daily approximately 12 hours apart with or without food. Swallow tablets whole or may disperse in 100 mL of non-carbonated, room temperature water. Stir tablet in water without crushing for approximately 15 to 20 minutes until dispersed; tablet will not completely dissolve.
Prepared by	Terri Levien
Source	Jascayd (nerandomilast) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; October 2025.

Elinzanetant/Lynkuet/Bayer HealthCare Pharmaceuticals Inc	
Generic Name/Brand Name/Company	Elinzanetant/Lynkuet/Bayer HealthCare Pharmaceuticals Inc
Date of approval	10/24/25
Drug Class (Mechanism of Action if novel agent)	Neurokinin 1 and neurokinin 3 receptor antagonist
Indication	Treatment of moderate to severe vasomotor symptoms due to menopause
Comparative agent – Therapeutic interchange?	Fezolinetant (Veoza), a neurokinin 3 receptor antagonist
Dosage forms/strengths	Capsules: 60 mg
Common Dose/sig	120 mg (two capsules) orally once daily at bedtime with or without food
DEA Schedule	N/A
Date of market availability	November 2025
Similar Medication Names	Eliglustat, fezolinetant
Clinical Use Evaluation	
Common Adverse Effects	Headache (9.6%), fatigue (7.3%), dizziness (6.1%), somnolence (5.1%), abdominal pain (4.5%), rash (4.2%), diarrhea (3.8%), muscle spasms (3.2%)
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	Avoid concomitant use with strong CYP3A4 inhibitors, and strong or moderate CYP3A4 inducers; reduce elinzanetant dosage to 60 mg once daily with moderate CYP3A4 inhibitors
Severe Drug-Food Interactions	Avoid grapefruit juice
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Pregnancy test prior to initiation in females of reproductive potential. Hepatic function tests prior to initiation and 3 months after initiation.
Used in Pediatric Areas	Not indicated; safety and efficacy not established
Renal or Hepatic Dosing	No dosage adjustment in mild to severe renal impairment or mild hepatic impairment. Not recommended in patients with end stage renal disease with or without hemodialysis or patients with moderate to severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: pregnancy Warnings: CNS depressant effect and daytime impairment Hepatic transaminase elevations Seizure risk
Special administration technique or considerations	Swallow capsules whole with water. May take with or without food. Take at bedtime at about the same time each day.
Prepared by	Terri Levien
Source	Lynkuet (elinzanetant) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; October 2025.