



## Highlights of FDA Activities – 5/1/25 – 5/31/25

### FDA Drug Safety Communications & Drug Information Updates:

#### **FDA Warns About Dangerous “Gas Station Heroin” Product Availability**

5/8/25

The FDA warned of the availability of tianeptine, a drug that is not approved by the FDA for any medical uses and may result in serious harm including but not limited to agitation, respiratory depression, confusion, and death. Products containing tianeptine may be readily available at gas stations, convenience stores, vape shops, and online retailers, and may be known as Neptune’s Fix, ZaZa, Pegasus, or TD Red. These products may also have extreme side effects with prescription medications that are FDA approved, such as MAOI’s, opioid narcotics, and other CNS depressing medications.

#### **Ixchiq (Chikungunya Vaccine, Live): Recommended Pause in Use - Adverse Events**

5/12/25

The FDA and CDC recommended a pause in the use of Ixchiq (Chikungunya vaccine, live) based on reports of serious adverse events in people 60 years and older including neurologic, cardiac, and Chikungunya-like symptoms, as well as death. The FDA recommends pausing administration of this vaccine until further notice, although a recall has not been put into effect. An alternative recombinant Chikungunya vaccine, Vimkungunya, was approved in February 2025 and is not subject to the pause.

#### **FDA to Begin Removing Prescription Ingestible Fluoride for Children from the Market**

5/13/25

The FDA has initiated action to remove concentrated ingestible fluoride prescription products from the market, with a goal date of October 31, 2025 for completion of a safety review and public comment period.

#### **Cetirizine and Levocetirizine – Long-Term Use Can Lead to Severe Itching Upon Discontinuation**

5/16/25

The FDA issued a Drug Safety Communication about cetirizine (Zyrtec) and levocetirizine (Xyzal) regarding long-term use. Using either of these medications daily for months or years for allergies and then discontinuing them shows a possible correlation to new onset pruritus. Symptoms developed within a few days of discontinuing daily use and resolved in most patients who restarted the antihistamine and in some patients who tapered off the medicine after restarting it. Overall, 209 cases were reported in the FDA Adverse Event Reporting System database, with data suggesting the number of cases increased with duration of use; median duration of use was 33 months (range 1 week to 23 years). The FDA advises patients to consult with doctors about starting either medication for long-term use. Patients taking these agents long-term should be advised of the risk. Manufacturers are also required to add a warning about pruritus after stopping these medications in the prescribing information and on the packages of OTC forms of cetirizine and levocetirizine.

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

None in May, see dietary supplement recalls below

### 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>
Endurance Boost with Horny Goat Weed* (Lot 250214PRO, Exp 02/14/27, sold exclusively on Amazon)	Male performance and energy	Sildenafil, propoxyphenylsildenafil
Umovy Acido Hialuronico, Umary-usa*	Joint health, pain	Dexamethasone, diclofenac, omeprazole
Unavy Acido Hialuronico, Umary usa*	Joint health, pain	Dexamethasone, diclofenac, omeprazole

\*recalled

**New Product Shortages (per FDA or ASHP)****Date Initially Posted**

Aminolevulinic acid powder for oral solution	5/1/25
Doxazosin extended-release tablets	5/5/25
Imatinib mesylate tablets	5/14/25
Phenytoin oral suspension	5/21/25
Conjugated estrogens injection	5/21/25
Megestrol acetate tablets	5/23/25
Meperidine HCl injection	5/30/25

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

**Brand Name or Sole Source Product Discontinuations/Withdrawals****Date Posted**

Cholestyramine powder (Prevalite, Upsher-Smith Laboratories); remains available as generic	5/14/25
Desonide cream 0.5% (Desowen, Actavis); remains available as generic	5/28/25

**New Drug Approvals:****Description (See Attached Drug Summaries)****Date Approved**

Avutometinib and defactinib/Avmapki Fakzinja Co-pack/Verastem	RAF/MEK clamp and selective FAK inhibitor for the treatment of adults with KRAS-mutated, recurrent, low-grade serous ovarian cancer who have received prior systemic therapy	5/8/25
Telisotuzumab vedotin-tllv/Emrelis/ AbbVie	Antibody drug conjugate for treatment of adult patients with locally advanced or metastatic, non-squamous non-small cell lung cancer who have previously received systemic therapy and whose tumors exhibit high c-Met protein overexpression	5/14/25
COVID-19 vaccine, adjuvanted/ Novavax/Novavax	Vaccine for active immunization to prevent COVID-19 caused by SARS-CoV-2 in adults 65 years and older or individuals 12 through 64 years who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19	5/16/25
Alcotremon/Tryptyr/Alcon	TRPM8 receptor agonist for the treatment of signs and symptoms of dry eye disease	5/28/25
COVID-19 vaccine, mRNA/mNexspike/ Moderna	Vaccine for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals who have been previously vaccinated with any COVID-19 vaccine and are adults 65 years and older or individuals 12 through 64 years who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19	5/30/25

**New Indications:****Description****Date Approved**

Perflutren Protein – Type A Microspheres/Optison/GE Healthcare	Indication expanded to include use in pediatric patients with suboptimal echocardiograms to opacify the left ventricle and improve delineation of the left ventricular endocardial borders	5/9/25
Belzutifan/Welireg/Merck	Treatment of pheochromocytoma and locally advanced, unresectable, or metastatic paraganglioma in adults and children 12 years or older	5/14/25
Retifanlimab-dlwr/Zynyz/Incyte	In combination with carboplatin and paclitaxel for first line treatment of inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC), and as a single agent for patients with locally recurrent or metastatic SCAC with disease progression on or intolerance to platinum-based chemotherapy	5/16/25

<b><u>New Indications: (continued)</u></b>	<b><u>Description</u></b>	<b><u>Date Approved</u></b>
Antihemophilic factor (recombinant), PEGylated-aucl/Jivi/Bayer	Use in previously treated pediatric patients 7 years and older with hemophilia A; not indicated for patients younger than 7 years due to greater risk for hypersensitivity reactions and/or loss of efficacy	5/19/25
Ranibizumab/Susvimo/Roche	Treatment of patients with diabetic retinopathy who have previously responded to at least two intravitreal injections of a vascular endothelial growth factor inhibitor medication	5/22/25
Mepolizumab/Nucala/GlaxoSmithKline	Add-on maintenance treatment of adults with inadequately controlled chronic obstructive pulmonary disease and an eosinophilic phenotype	5/22/25
Roflumilast foam 0.3%/Zoryve/Arcutis Biotherapeutics	Treatment of plaque psoriasis in adults and adolescents ages 12 years and older	5/22/25
Meningococcal vaccineMenQuadfi/ Sanofi	Protection against meningococcal infection in infants 6 weeks and older	

<b><u>New Dosage Forms or Formulation:</u></b>	<b><u>Description</u></b>	<b><u>Date Approved</u></b>
Dihydroergotamine mesylate/Brekiya/ Amneal Pharmaceuticals	Auto-injector: acute treatment of migraine and cluster headache	5/15/25
Rivaroxaban/Aususubar/Auson Pharmaceuticals		5/20/25
Treprostinil/Yutrepia/Liquidia	Dry powder formulation; to increase exercise ability in adults with pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease	5/27/25
Hydrocortisone/Khindivi/Eton Pharmaceuticals	Oral solution: 1 mg/mL; replacement therapy in pediatric patients 5 years and older with adrenocortical insufficiency	5/28/25

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<b>Avutometinib and defactinib/Avmapki Fakzynja Co-pack/Verastem</b>	
Generic Name / Brand Name / Company	Avutometinib and defactinib/Avmapki Fakzynja Co-pack/Verastem
Date of approval	5/8/25
Drug Class (Mechanism of Action if novel agent)	RAF/MEK clamp and selective FAK inhibitor
Indication	Treatment of adults with KRAS-mutated, recurrent, low-grade serous ovarian cancer who have received prior systemic therapy
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Avutometinib capsules: 0.8 mg Defactinib tablets: 200 mg
Common Dose/sig	Avutometinib 3.2 mg orally twice weekly (days 1 and 4) for the first 3 weeks of each 4-week cycle and defactinib 200 mg orally twice daily for the first 3 weeks of each 4-week cycle
DEA Schedule	None
Date of market availability	Late 2025
Similar Medication Names	Avycaz
<b>Clinical Use Evaluation</b>	
Common Adverse Effects	≥25%: nausea, fatigue, rash, diarrhea, musculoskeletal pain, edema, vomiting, abdominal pain, dyspepsia, dermatitis acneiform, vitreoretinal disorders, stomatitis, pruritus, visual impairment, constipation, dry skin, dyspnea, cough, urinary tract infection; increased creatinine phosphokinase, aspartate aminotransferase, alanine aminotransferase, blood bilirubin, triglycerides, alkaline phosphatase; decreased hemoglobin, lymphocyte count, platelet count, neutrophil count
Severe Adverse Effects	Diarrhea, vomiting, stomatitis, fatigue, rash, vitreoretinal disorders, dyspnea, hypertension, venous thromboembolism, urinary tract infection, increased creatine phosphokinase, decreased potassium
Severe Drug-Drug Interactions	Strong and moderate CYP3A4 inhibitors or inducers, warfarin, proton pump inhibitors, H2 antagonists: avoid concomitant use
Severe Drug-Food Interactions	None known; defactinib AUC and Cmax are increased with food
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Verify pregnancy status in females of reproductive potential; monitor liver function tests and creatine phosphokinase prior to each cycle, on day 15 of the first 4 cycles, and as clinically indicated.
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments required; effects of severe renal impairment or moderate to severe hepatic impairment are not known
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling Warnings: ocular toxicities (eye exams required), serious skin toxicities (prophylaxis advised; limit sun exposure), hepatotoxicity, rhabdomyolysis, embryo-fetal toxicity
Special administration technique or considerations	If acid-reducing agent required, administer defactinib 2 hours before or 2 hours after the locally acting antacid. Administer topical corticosteroids and systemic oral antibiotics with initiation of and during the first 2 cycles as prophylaxis for skin reactions. Take avutometinib and defactinib with food. Dosage adjustments advised for adverse reactions. Store in refrigerator.
Prepared by	Terri Levien
Source	Avmapki Fakzynja Co-Pack (avutometinib and defactinib) [prescribing information]. Needham, MA: Verastem, Inc; May 2025.

<b>Telisotuzumab vedotin-tllv/Emrelis/AbbVie</b>	
Generic Name / Brand Name / Company	Telisotuzumab vedotin-tllv/Emrelis/AbbVie
Date of approval	5/14/25
Drug Class (Mechanism of Action if novel agent)	c-Met directed antibody and microtubule inhibitor conjugate
Indication	Treatment of adults with locally advanced or metastatic non-squamous non-small cell lung cancer with high c-MET protein overexpression who have received prior systemic therapy
Comparative agent – Therapeutic interchange?	MET inhibitors
Dosage forms/strengths	Injection: 20 mg or 100 mg as a lyophilized powder in a single-dose vial
Common Dose/sig	1.9 mg/kg IV every 2 weeks (maximum 190 mg)
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Emrosi
<b>Clinical Use Evaluation</b>	
Common Adverse Effects	>20%: peripheral neuropathy, fatigue, decreased appetite, peripheral edema; >2%, grade 3 or 4: decreased lymphocytes, increased glucose, increased ALT, increased GGT, decreased phosphorus, decreased sodium, decreased hemoglobin, decreased calcium
Severe Adverse Effects	Interstitial lung disease, pneumonitis, pneumonia, noninfectious endocarditis, myocardial infarction, fatigue, peripheral edema, blurred vision
Severe Drug-Drug Interactions	Strong CYP3A inhibitors: monitor for increased adverse reactions
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Select patients based on presence of high c-Met protein overexpression; verify pregnancy status in females of reproductive potential
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	Avoid use in severe or moderate hepatic impairment; no dosage adjustment recommended in mild hepatic impairment or mild to moderate renal impairment; no data in severe renal impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling Warnings: peripheral neuropathy, interstitial lung disease/pneumonitis, ocular surface disorders, infusion-related reactions, embryo-fetal toxicity
Special administration technique or considerations	Reconstitute with sterile water for injection and further dilute in 0.9% sodium chloride injection prior to administration. Infuse over 30 minutes in dedicated line with 0.2- or 0.22-micron inline filter. Administer premedication (ie, H1 antihistamine, H2 antihistamine, antipyretic, glucocorticoid) for patients with infusion-related reactions. Adjust dose for adverse reactions.
Prepared by	Terri Levien
Source	Emrelis (telisotuzumab vedotin-tlly) [prescribing information]. North Chicago, IL: AbbVie Inc; May 2025.

<b>COVID-19 vaccine, adjuvanted/Nuvaxovid/Novavax</b>	
Generic Name / Brand Name / Company	COVID-19 vaccine, adjuvanted/ Nuvaxovid/Novavax
Date of approval	5/16/25
Drug Class (Mechanism of Action if novel agent)	Vaccine, subunit; contains recombinant spike protein of SARS-CoV-2 Omicron variant lineage JN.1 and Matrix-M adjuvant
Indication	Active immunization to prevent COVID-19 caused by SARS-CoV-2 in adults 65 years and older or individuals 12 through 64 years who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19
Comparative agent – Therapeutic interchange?	COVID-19 vaccine (mRNA)
Dosage forms/strengths	Injectable suspension: 0.5 mL in a pre-filled syringe
Common Dose/sig	0.5 mL IM as a single dose
DEA Schedule	N/A
Date of market availability	Available; previously available under Emergency Use Authorization
Similar Medication Names	COVID-19 vaccine (mRNA)
<b>Clinical Use Evaluation</b>	
Common Adverse Effects	Injection site tenderness (up to 71.7%), injection site pain (up to 64.6%), headache (up to 62.9%), fatigue (up to 57.1%), muscle pain (up to 60.4%), malaise (up to 45.1%), nausea/vomiting (up to 23.6%), fever (up to 16.9%), joint pain (up to 24.2%), injection site redness (up to 10.3%); frequency varied by age and initial vs booster injection
Severe Adverse Effects	Tenderness, pain, fatigue, headache, myalgia, malaise, joint pain, nausea/vomiting, fever, allergic reactions
Severe Drug-Drug Interactions	Immunosuppressants may reduce response to vaccines
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None required
Used in Pediatric Areas	Indicated in adolescents 12 through 17 years; safety and efficacy not established in children younger than 12 year of age
Renal or Hepatic Dosing	No dosage adjustments required
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: history of severe allergic reaction to any ingredient or severe allergic reaction following a previous dose of this vaccine Warnings: myocarditis and pericarditis; allergic reactions; syncope; reduced response in immunocompromised
Special administration technique or considerations	Store vaccine in refrigerator. If patient previously vaccinated with an COVID-19 vaccine, administer this vaccine at least 2 months after the last vaccine dose.
Prepared by	Terri Levien
Source	Nuvaxovid (COVID-19 vaccine, adjuvanted) [prescribing information]. Gaithersburg, MD: Novavax, Inc; May 2025.

<b>Alcotremon/Tryptyr/Alcon</b>	
Generic Name / Brand Name / Company	Alcotremon/Tryptyr/Alcon
Date of approval	5/28/25
Drug Class (Mechanism of Action if novel agent)	Transient receptor potential melastatin 8 (TRPM8) thermoreceptor agonist; activates trigeminal nerve signaling to increase basal tear production.
Indication	Treatment of signs and symptoms of dry eye disease
Comparative agent – Therapeutic interchange?	Cyclosporine, lifitegrast, perflurohexyloctane, varenicline
Dosage forms/strengths	Ophthalmic solution: 0.003% in single-dose vial
Common Dose/sig	Instill 1 drop in each eye twice daily (approximately 12 hours apart)
DEA Schedule	None
Date of market availability	3 <sup>rd</sup> quarter 2025
Similar Medication Names	Triptodur
<b>Clinical Use Evaluation</b>	
Common Adverse Effects	Instillation site pain (50%)
Severe Adverse Effects	None known
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 required
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments required
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling Warnings: avoid touching vial tip to eye or other surfaces, use with contact lenses
Special administration technique or considerations	Single dose vial can be used to dose both eyes. Separate administration from other topical ophthalmic drops by at least 5 minutes. Remove contact lenses before instillation of drops and reinsert after 15 minutes. Do not use vials more than 7 days after opening foil pouch.
Prepared by	Terri Levien
Source	Tryptyr (alcotremon) [prescribing information]. Fort Worth, TX: Alcon Laboratories, Inc; May 2025.

<b>COVID-19 vaccine, mRNA/mNexspike/Novavax</b>	
Generic Name / Brand Name / Company	COVID-19 vaccine, mRNA/mNexspike/Novavax
Date of approval	5/30/25
Drug Class (Mechanism of Action if novel agent)	Vaccine, mRNA encoding for domains of the Spike glycoprotein of SARS-CoV-2 Omicron variant lineage JN.1
Indication	Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals who have been previously vaccinated with any COVID-19 vaccine and are adults 65 years and older or individuals 12 through 64 years who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19
Comparative agent – Therapeutic interchange?	Spikevax; noninferiority study demonstrated generation of higher antibody levels with a lower dose in older adults compared with Spikevax
Dosage forms/strengths	Injectable suspension: 0.2 mL in prefilled syringe
Common Dose/sig	0.2 mL IM as a single dose
DEA Schedule	None
Date of market availability	Available; Spikevax will also remain available
Similar Medication Names	COVID-19 vaccine, mRNA (Spikevax); COVID-19 vaccine, adjuvanted
<b>Clinical Use Evaluation</b>	
Common Adverse Effects	Injection site pain (up to 74.8%), headache (up to 54.5%), fatigue (up to 54.3%), myalgia (up to 41.6%), axillary swelling or tenderness (up to 34.6%), chills (up to 31.6%), arthralgia (up to 32.4%), nausea/vomiting (up to 16.1%); frequency varies by age
Severe Adverse Effects	Fever
Severe Drug-Drug Interactions	Immunosuppressants may diminish immune response to vaccine
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None required
Used in Pediatric Areas	Indicated in individuals 12 through 17 years; safety and efficacy have not been established in children younger than 12 years of age
Renal or Hepatic Dosing	No dosage adjustment required
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: history of severe allergic reaction to any ingredient or severe allergic reaction to a previous dose of Spikevax or any Moderna COVID-19 vaccine authorized for emergency use Warnings: myocarditis and pericarditis, acute allergic reactions, syncope; diminished immune response in immunocompromised
Special administration technique or considerations	Stored in freezer. If frozen, thaw before use. After thawing may be stored refrigerated for up to 90 days or at room temperature for up to 24 hours. Administer at least 3 months after the last dose of COVID-19 vaccine.
Prepared by	Terri Levien
Source	mNexspike (COVID-19 vaccine, mRNA) [prescribing information]. Princeton, NJ: Moderna US, Inc; May 2025.