



Highlights of FDA Activities – 10/1/24 – 10/31/24

FDA Drug Safety Communications & Drug Information Updates:

Clarification for GLP-1 Compounders

10/3/24

The FDA issued a statement clarifying FDA policies related to compounding of glucagon-like peptide 1 (GLP-1) medications in response to shortages due to increased demand. FDA reminded compounders of legal restrictions on compounding during a shortage and that compounders may not make compounded drugs that are identical or nearly identical to an FDA-approved drug unless the approved drug is on the FDA's drug shortage list. At this time of this announcement, dulaglutide, semaglutide and liraglutide remained in shortage.

FDA Authorizes First Home Flu and COVID-19 Combination Test

10/7/24

The FDA granted marketing authorization for the Healgen Rapid Check COVID-19/Flu A&B Antigen Test, for use without a prescription. The test uses a nasal swab sample to deliver results in approximately 15 minutes for COVID-19 and influenza.

Baxter International Manufacturing Recovery Update

10/9/24

The FDA established a [website](#) to provide updates on the impact of Hurricane Helene on manufacturing at the Baxter International facility in Marion, North Carolina.

Temporary Policies for Compounding Parenteral Drug Products – Hurricane Recovery

10/11/24

The FDA released a guidance for compounders to fill gaps from the impact of the damage to the Baxter International facility from Hurricane Helene. The FDA does not plan to take action against a pharmacy that is not registered as an outsourcing facility for providing compounded products without first obtaining a patient-specific prescription, provided conditions stipulated in the guidance are met.

Extended Use Dates for Baxter Parenteral Drug Products

10/21 and 10/28/24

The FDA announced extended use dates for some parenteral products after review of stability data from Baxter. The [linked table](#) can be used to locate specific Baxter products by product code and lot number. Extended dates equal to 24 months from the date of manufacture are applicable for the listed products manufactured prior to 9/30/24.

Compounders Required to Use Ingredients Suitable for Sterile Compounding

10/30/24

The FDA reminded compounders to only produce sterile drugs using components that are suitable for compounding drugs intended to be sterile. The notification was prompted by reports of compounders using food-grade nicotinamide adenine dinucleotide (NAD+) to make intravenous products. Adverse events reports following use of these products have included severe chills, shaking, vomiting, and fatigue consistent with excessive levels of endotoxins. Previous FDA warnings have followed reports of compounders using the dietary ingredient glutathione to compound sterile injectables. Ingredients identified as food grade are not suitable for compounding sterile drugs.

New Opioid REMS – New Drug Disposal Option

10/31/24

The FDA approved a modification to the opioid analgesic REMS requiring companies participating in the program to begin providing free, pre-paid drug mail-back envelopes upon request to outpatient pharmacies and other dispensers of opioid analgesics by March 31, 2025, that will be provided to patients and caregivers. Updates to the Patient Guide and a Patient Education Sheet have also been made to reflect information on the importance of safe disposal.

Major Medication/Drug-Related Product Recalls Announced Through MedWatch:**Ivenix Infusion System Large Volume Pump Software, Fresenius Kabi USA: Software Correction** 10/1/24

Fresenius Kabi USA, LLC issued a software correction for the Ivenix Infusion System Large Volume Pump Software version 5.9.1 and earlier to resolve multiple software anomalies and a cybersecurity vulnerability that had the potential to result in delay or underdosage of therapy. The recall involves updating to version 5.9.2.

Zyno Medical Z-800, Z-800F, Z-800W, and Z-800WF Infusion Pumps: Recall – Software Defect 10/11/24

Zyno Medical recalled certain Z-800, Z-800F, Z-800W, and Z-800WF infusion pumps due to a defect in the air-in-line software algorithm that may allow a 1 mL air bubble to be passed on to a patient. The affected pumps should be removed from use and returned for a software update.

MiniMed 600 and 700 Series Insulin Pumps, Medtronic: Recall – Battery Life 10/17/24

Medtronic notified users of MiniMed 600 and 700 series insulin pumps of an increased risk of shortened battery life and less time until shutdown after a battery alert occurs. Units that have been dropped even once, bumped, or experienced another physical impact may have damaged electrical components causing the issue. Users should be advised to replace the battery as soon as they receive the “Low Battery Pump” alert, carry extra batteries, and contact Medtronic for a replacement if there are any changes to the pump battery life.

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>
AK Forte Tablets*	Joint pain and arthritis	Diclofenac, dexamethasone, methocarbamol
Regener-Eyes	Dry eye	Amniotic fluid
Skin-Cap	Psoriasis, seborrheic dermatitis, eczema, skin itching & irritation	High potency glucocorticosteroid
Trinity Gold	Joint and muscle pain	Acetaminophen, diclofenac, and phenylbutazone ¹

*recalled

¹Phenylbutazone is a NSAID that is no longer marketed in the US due to serious and life-threatening toxicity including bone marrow toxicity

New Product Shortages**Date Initially Posted**

Dextrose 70% IV solution	10/11/24
Lactated Ringers IV solution	10/11/24
Peritoneal dialysis solution	10/11/24

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

None reported in October

Removed/Restricted Indications:**Description****Date Announced**

Sacituzumab govitecan-hziy/Trodelyv/ Gilead	Gilead withdrew the indication for metastatic urothelial cancer following failure to demonstrate overall survival benefit in a confirmatory trial	10/18/24
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<u>New Drug Approvals:</u>	<u>Description (See Attached Drug Summaries)</u>	<u>Date Approved</u>
Inavolisib/Itovebi/Genentech USA, Inc	Kinase inhibitor for use with palbociclib and fulvestrant for 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	10/10/24
Marstacimab-hncq/ Hympavzi/Pfizer Labs	Tissue factor pathway inhibitor (TFPI) antagonist for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with hemophilia A without factor VIII inhibitors or hemophilia B without factor IX inhibitors	10/11/24
Zolbetuximab-clzb/Vyloy/Astellas Pharma US, Inc	Claudin 18.2-directed cytolytic antibody for use in combination with fluoropyrimidine- and platinum-containing chemotherapy for first-line therapy of adults with locally advanced or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma whose tumors are claudin 18.2 positive	10/18/24
Sulopenem etzadroxil and probenecid/Orlynvah/Iterum Therapeutics U.S. Limited	Penem antibacterial and renal tubular transport inhibitor for the treatment of uncomplicated urinary tract infection in adult women who have limited or no alternative oral antibacterial treatment options	10/25/24
<u>New Indications:</u>	<u>Description</u>	<u>Date Approved</u>
Nivolumab/Opdivo/Bristol-Myers Squibb Company	With platinum-doublet chemotherapy as adjuvant treatment, followed by single-agent nivolumab after surgery as adjuvant treatment, for adults with resectable non-small cell lung cancer and no known epidermal growth factor receptor mutations or anaplastic lymphoma kinase rearrangements	10/3/24
Sodium oxybate/Lumryz/Avadel CNS Pharmaceuticals	Indication expanded to include use in pediatric patients 7 years and older in the management of narcolepsy	10/16/24
OnabotulinumtoxinA/Botox Cosmetic/ AbbVie	Temporary improvement of the appearance of moderate to severe platysma bands associated with platysma muscle activity	10/18/24
Respiratory syncytial virus vaccine/ Abrysvo/Pfizer	Prevention of lower respiratory tract disease caused by RSV in individuals 18 through 59 years of age who are at increased risk for lower respiratory disease caused by RSV	10/22/24
Methotrexate/Jylamvo/Shorla Pharma	Indication expanded to include use in pediatric patients with polyarticular juvenile idiopathic arthritis and pediatric patients with acute lymphoblastic leukemia as part of a combination chemotherapy maintenance regimen	10/23/24
Asciminib/Scemblix/Novartis	First-line treatment for adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase	10/29/24
<u>New Dosage Forms or Formulation:</u>	<u>Description</u>	<u>Date Approved</u>
Pyridostigmine bromide/Amneal Pharmaceuticals	Extended-release tablets: 105 mg; for pretreatment against the lethal effects of soman nerve agent poisoning in adults	10/4/24
Foscarbidopa and foslevodopa/Vyalev/ AbbVie	Injection solution: 120 mg foscarbidopa and 2,400 mg foslevodopa per 10 mL; for continuous subcutaneous infusion for the treatment of motor fluctuations in adults with advanced Parkinson disease	10/17/24

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Inavolisib/Itovebi/Genentech USA, Inc	
Generic Name / Brand Name / Company	Inavolisib/Itovebi/Genentech USA, Inc
Date of approval	10/10/24
Drug Class (Mechanism of Action if novel agent)	Kinase inhibitor; PIK3CA inhibitor
Indication	For use with palbociclib and fulvestrant for adults with endocrine-resistant, PIK3CA-mutated, HR-positive, HER2-negative, locally advanced or metastatic breast cancer following recurrence on or after completing adjuvant endocrine therapy
Comparative agent – Therapeutic interchange?	Alpelisib
Dosage forms/strengths	Tablets: 3 mg and 9 mg
Common Dose/sig	9 mg orally once daily; dose adjustments recommended for adverse reactions
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Invokana
Clinical Use Evaluation	
Common Adverse Effects	≥20%: stomatitis, diarrhea, fatigue, nausea, rash, decreased appetite, COVID-19 infection, headache; decreased neutrophils, hemoglobin, platelets, lymphocytes, calcium, potassium, sodium, and magnesium; increased fasting glucose, creatinine, and ALT
Severe Adverse Effects	Hyperglycemia, diarrhea, stomatitis, nausea, vomiting, fatigue, decreased weight
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.	PIK3CA mutation detected in plasma specimen; evaluate fasting plasma glucose, blood glucose, and HbA1C prior to starting and at regular intervals; monitor complete blood count
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	No dose modification in mild renal impairment; reduce starting dose in moderate renal impairment; has not been studied in severe renal impairment. No dosage adjustments in hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. Monitor for hyperglycemia, stomatitis, diarrhea and adjust therapy as needed. Can cause fetal harm; advise use of effective contraception.
Special administration technique or considerations	May be taken with or without food; should be taken at approximately the same time each day. Swallow tablets whole. Administer in combination with palbociclib and fulvestrant, with palbociclib taken for 21 consecutive days followed by 7 days off to comprise a cycle.
Prepared by	Terri Levien
Source	Itovebi (inavolisib) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; October 2024.

Marstacimab-hncq/Hympavzi/Pfizer	
Generic Name / Brand Name / Company	Marstacimab-hncq/Hympavzi/Pfizer Labs
Date of approval	10/11/24
Drug Class (Mechanism of Action if novel agent)	Tissue factor pathway inhibitor (TFPI) antagonist; reduces activity of TFPI, an endogenous anticoagulant protein
Indication	For routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with hemophilia A without factor VIII inhibitors or hemophilia B without factor IX inhibitors.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Injection: 150 mg/mL in single-dose prefilled syringe or pen
Common Dose/sig	Loading dose: 300 mg by subcutaneous injection; maintenance dose: 150 mg every week, 300 mg weekly can be considered
DEA Schedule	NA
Date of market availability	By end of 2024
Similar Medication Names	Hymovis
Clinical Use Evaluation	
Common Adverse Effects	≥3%: injection site reaction, headache, pruritus
Severe Adverse Effects	Allergic reaction
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.	Pregnancy test in females of reproductive potential
Used in Pediatric Areas	Indicated in patients 12 years and older
Renal or Hepatic Dosing	No dosage adjustments in mild renal or hepatic impairment; not studied in moderate to severe renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. Thromboembolic events may occur; interrupt prophylaxis if symptoms occur. Discontinue in the event of severe allergic reaction. May cause fetal harm; advise on use of effective contraception. Temporarily discontinue before major surgery.
Special administration technique or considerations	Administered by subcutaneous injection. Maintenance dose should be given on the same day each week at any time of day. Factor VIII and factor IX products can be administered for breakthrough bleeds; do not use marstacimab-hncq for treatment of breakthrough bleeding.
Prepared by	Terri Levien
Source	Hympavzi (marstacimab-hncq) [prescribing information]. New York, NY: Pfizer Labs; October 2024.

Zolbetuximab-clzb/Vyloy/Astellas Pharma US, Inc	
Generic Name / Brand Name / Company	Zolbetuximab-clzb/Vyloy/Astellas Pharma US, Inc
Date of approval	10/18/24
Drug Class (Mechanism of Action if novel agent)	Claudin 18.2-directed cytolytic antibody
Indication	For use in combination with fluoropyrimidine- and platinum-containing chemotherapy for first-line therapy of adults with locally advanced or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma whose tumors are claudin 18.2 positive
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Injection: 100 mg lyophilized powder in single-dose vial
Common Dose/sig	800 mg/m ² IV followed by 600 mg/m ² every 3 weeks or 400 mg/m ² every 2 weeks
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	VyLibra
Clinical Use Evaluation	
Common Adverse Effects	≥15%: nausea, vomiting, fatigue, decreased appetite, diarrhea, peripheral sensory neuropathy, abdominal pain, constipation, decreased weight, hypersensitivity reaction, pyrexia; decreased neutrophils, leukocytes, albumin, hemoglobin, lymphocyte count, platelets, glucose, sodium, potassium, and magnesium; increased creatinine, glucose, AST, alkaline phosphatase, ALT, and phosphate
Severe Adverse Effects	Hypersensitivity, infusion-related reactions, nausea and vomiting, decreased appetite; decreased leukocytes, neutrophils, potassium, sodium, albumin, or glucose
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.	CLDN18.2 diagnostic test
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	No adjustments in mild to moderate renal impairment or mild hepatic impairment; no data in severe renal impairment or moderate to severe hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. Hypersensitivity and infusion-related reactions, including severe and fatal reactions, have occurred. Nausea and vomiting occurred commonly, including severe nausea and vomiting; pretreat with antiemetics and manage with antiemetic and fluid replacement.
Special administration technique or considerations	Premedicate prior to each infusion with a combination of antiemetics for the prevention of nausea and vomiting. Manage adverse reactions by reducing infusion rate, interrupting the infusion, withholding the dose, or permanently discontinuing; no dose reduction is recommended. Administer by IV infusion only. If administered on the same day as other chemotherapy, zolbetuximab-clzb must be administered first. Use an in-line filter. Begin infusion at a slower rate for 30 to 60 minutes than gradually increase rate. If the infusion time exceeds the recommended storage time, the infusion bag must be discarded and a new infusion bag prepared to continue the infusion.
Prepared by	Terri Levien
Source	Vyloy (zolbetuximab-clzb) [prescribing information]. Northbrook, IL: Astellas Pharma US, Inc.; October 2024.

Sulopenem etzadroxil and probenecid/Orlynvah/Iterum Therapeutics U.S. Limited	
Generic Name / Brand Name / Company	Sulopenem etzadroxil and probenecid/Orlynvah/Iterum Therapeutics
Date of approval	10/25/24
Drug Class (Mechanism of Action if novel agent)	Penem antibacterial and renal tubular transport inhibitor
Indication	Treatment of uncomplicated urinary tract infections (UTI) caused by <i>Escherichia coli</i> , <i>Klebsiella pneumoniae</i> , or <i>Proteus mirabilis</i> in adult women who have limited or no alternative oral antibacterial options. It is not indicated for treatment of complicated UTI or complicated intra-abdominal infections or for use as step-down treatment after IV antibacterial treatment.
Comparative agent – Therapeutic interchange?	None; reserve use for infections with no oral treatment options
Dosage forms/strengths	Tablets: sulopenem etzadroxil 500 mg and probenecid 500 mg
Common Dose/sig	One tablet orally twice daily for 5 days
DEA Schedule	NA
Date of market availability	To be determined
Similar Medication Names	Orladeyo
Clinical Use Evaluation	
Common Adverse Effects	>2%: diarrhea, nausea, vulvovaginal mycotic infections, headache, vomiting
Severe Adverse Effects	Allergic reactions
Severe Drug-Drug Interactions	Contraindicated with ketorolac tromethamine; use with ketoprofen is not recommended. Increased risk of adverse reactions due to increased concentrations with indomethacin, naproxen, methotrexate, rifampin, lorazepam, and oral sulfonyleureas.
Severe Drug-Food Interactions	None known; sulopenem absorption enhanced when administered with food (AUC increased 48% with high fat meal)
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Renal function, culture and sensitivity
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients.
Renal or Hepatic Dosing	Use is not recommended in patients with CrCl less than 15 mL/min or on hemodialysis. No dosage adjustment if CrCl is at least 15 mL/min. The effects of hepatic impairment are not known.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with a history of hypersensitivity to any product components or other beta-lactams, known blood dyscrasias, known uric acid kidney stones, or with ketorolac tromethamine. Warnings: hypersensitivity reactions, <i>Clostridioides difficile</i> -associated diarrhea, risk of uric acid kidney stone development, and exacerbation of gout. Ensure appropriate gout therapy is instituted for patients with a known history of gout.
Special administration technique or considerations	Administration with food is recommended.
Prepared by	Terri Levien
Source	Orlynvah (sulopenem etzadroxil and probenecid) [prescribing information]. Chicago, IL: Iterum Therapeutics U.S. Limited; October 2024.