



Highlights of FDA Activities – 9/1/24 – 9/30/24

FDA Drug Safety Communications & Drug Information Updates:

Warning – Rare Occurrence of Serious Liver Injury with use of Veozah (fezolinetant) 9/12/24

The FDA has added a warning that Veozah (fezolinetant), a medication used for the treatment of hot flashes due to menopause, can cause rare but serious liver injury. It is now recommended that healthcare providers conduct liver function testing before starting patients on the medication, and conduct testing monthly for the first two months after starting therapy, and then at months 3, 6, and 9 of therapy as was previously recommended. Patients should stop taking fezolinetant immediately and contact a health care professional if they experience signs and symptoms that suggest liver problems.

Pemgarda SARS-CoV-2 Variant Susceptibility Data Updated 9/26/24

The FDA revised the Pemgarda (pemivibart) fact sheet with new SARS-CoV-2 variant susceptibility data. The most frequently reported SARS-CoV-2 viral variant in the US at this time is KP.3.1.1, comprising about 53% of circulating variants as of September 14. New data suggests pemivibart is likely to retain adequate neutralization activity against KP.3.1.1 and may be effective for pre-exposure prophylaxis of COVID-19 caused by this variant.

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

FreeStyle Libre 3 Sensors, Abbott Diabetes Care Inc: Recall – Inaccurate High Glucose Readings 9/5/24

Abbott Diabetes Care Inc. has recalled FreeStyle Libre 3 continuous glucose monitor sensors after finding some sensors may provide incorrect high glucose readings. The recalled products have the Unique Device Identifier (UDI)/Model UDI-DI 00357599818005/Model No 72081-01. The lot numbers are T60001948, T60001966, and T60001969.

Ivenix Large Volume Pump Primary Administration Sets, Fresenius Kabi USA: Recall – Defect 9/16/24

Fresenius Kabi USA recalled one lot of Ivenix LVP Primary Administration Sets Dual-Inlet, Low-Sorbing, Needle-Free Port, Y-Site (UDI/Product Code 20811505030058/SET-0013-25; lot 3010538) after identifying a manufacturing defect that may allow uncontrolled medication flow.

Infusomat Space Infusion System and Large Volume Pump, B. Braun Medical: Recall – Faulty Alarm 9/17/24

B. Braun Medical Inc. issued a correction for the Infusomat Space Infusion System/Large Volume Pump, Infusomat Space Large Volume Pump Wireless, and Infusomat Space Large Volume Pump Non-Wireless Battery Pack due to a faulty occlusion alarm. The upstream occlusion sensor will need to be replaced before the devices should be used. A complete list of UDIs and serial numbers can be found on the FDA [site](#).

Atovaquone Oral Suspension, Bionpharma: Recall – Bacterial Contamination 9/19/24

Bionpharma recalled 1 batch (2310083) of atovaquone oral suspension, 750 mg/mL due to contamination with *Cohnella* bacteria.

Veklury (remdesivir) for Injection 100 mg/vial, Gilead: Recall – Glass Particle 9/23/24

Gilead Sciences recalled one lot of Veklury (remdesivir) for Injection 100 mg/vial due to confirmation of a glass particle in a vial. The recalled product (NDC 61958-2901-02, Lot # 47035CFA, Exp. date 11/2025) was distributed to wholesalers between 7/16/24 and 8/7/24.

ExactaMix Automated Compounding Device Inlets, Baxter: Recall/Correction – Particulate Matter 9/24/24

Baxter Healthcare Corporation issued a device correction with updated use instructions for the Automated Compounding Device Inlets (disposable inlet) used with the ExactaMix and ExactaMix Pro due to reports of particulate matter found within the primary packaging for the inlet components, including within the sterile fluid path tubing. The issue only affects the disposable inlets and not the compounder devices. The list of affected devices can be found on the FDA [site](#). All disposable inlets should be closely inspected prior to use, including the inlet primary packaging, tubing, connectors, and spikes. If particulate matter is observed, the inlet should not be used. If no particulate matter is observed, the inlet can be used, and the finished solution should be visually inspected by more than one health care professional. A minimum of 1.2 micron in-line filter should be used during product administration.

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>
Umary* and Amazy	Treat pain and other conditions	Diclofenac and omeprazole
SnoreStop nasal spray	Relieve congestion	Microbial contamination
Vail-Bon Jie Yang Wan capsules*	Skin disease, eczema, itch	Dexamethasone, chlorpheniramine

*recalled

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

Transmucosal immediate-release fentanyl medicines: all production will be discontinued 9/30/24; patients may continue use under the REMS while supplies remain available, but no new patients will be accepted under the REMS and patients should begin transition to other treatments	9/16/24
Voxelotor (Oxbryta, Pfizer) withdrawn by manufacturer over safety concerns; patients should be started on another treatment option	9/26/24

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

Lebrikizumab-lbkz / Ebglyss / Eli Lilly and Company	Interleukin-13 antagonist for the treatment of adult and pediatric patients 12 years and older and weighing at least 40 kg with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable	9/13/24
Arimoclomol / Miplyffa / Zevra Therapeutics Inc.	For use in combination with miglustat for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adult and pediatric patients 2 years of age and older	9/20/24
Levacetylleucine / Aqneursa / IntraBio Inc.	For the treatment of neurological manifestations of NPC in adult and pediatric patients weighing at least 15 kg	9/24/25
Xanomeline and trospium chloride / Cobenfy / Bristol-Myers Squibb	A muscarinic agonist and muscarinic antagonist for the treatment of schizophrenia in adults	9/27/24
Flurpiridaz F18 / Flyrcado / GE Healthcare	A radioactive diagnostic for positron emission tomography (PET) myocardial perfusion imaging under rest or stress in adult patients with known or suspected coronary artery disease to evaluate for myocardial ischemia and infarction	9/27/24

<u>New Indications:</u>	<u>Description</u>	<u>Date Approved</u>
Sparsentan / Filspari / Travele Therapeutics, Inc.	To slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression	9/5/24
Guselkumab / Tremfya / Janssen	Treatment of adult patients with moderately to severely active ulcerative colitis	9/11/24
Dupilumab / Dupixent / Regeneron Pharmaceuticals, Inc.	As add-on maintenance treatment in adult and pediatric patients 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps	9/12/24
Certolizumab pegol / Cimzia / UCB Inc.	Treatment of active polyarticular Juvenile Idiopathic Arthritis for patients 2 years of age and older	9/13/24
Lanreotide / InvaGen Pharmaceuticals	Treatment of adults with carcinoid syndrome to reduce the frequency of short-acting somatostatin analog rescue therapy	9/16/24
Pembrolizumab / Keytruda / Merck	In combination with pemetrexed and platinum chemotherapy as first line treatment of adult patients with unresectable advanced or metastatic malignant pleural mesothelioma	9/17/24
Ribociclib / Kisqali / Novartis	In combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence	9/17/24
Ribociclib tablets and letrozole tablets / Kisqali Femara Co-Pack / Novartis	Adjuvant treatment of adults with HR-positive, HER2-negative stage II and III early breast cancer at high risk of recurrence	9/17/24
Benralizumab / Fasenra / AstraZeneca	Treatment of adult patients with eosinophilic granulomatosis with polyangiitis	9/17/24
Amivantamab-vmjw / Rybrevant / Janssen Biotech Inc.	With carboplatin and pemetrexed for adults with locally advanced or metastatic non-small cell lung cancer with epidermal growth factor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor	9/19/24
Influenza Vaccine Live, Intranasal / FluMist / MedImmune LLC	For self- or caregiver-administration for the prevention of influenza disease caused by influenza virus subtypes A and B in individuals 2 through 49 years of age	9/20/24
Bimekizumab-bkzx / Bimzelx / UCB Inc.	Treatment of adults with active psoriatic arthritis, adults with active non-radiographic axial spondyloarthritis with signs of inflammation, and adults with active ankylosing spondylitis	9/20/24
Isatuximab-irfc / Sarclisa / sanofi-aventis U.S. LLC	In combination with bortezomib, lenalidomide, and dexamethasone for the treatment of adults with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant	9/20/24
Osimertinib / Tagrisso / AstraZeneca Pharmaceuticals	Treatment of adult patients with locally advanced, unresectable (stage III) non-small cell lung cancer whose disease has not progressed or following concurrent or sequential platinum-based chemoradiation therapy and whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations	9/25/24
Dupilumab / Dupixent / Regeneron Pharmaceuticals, Inc.	As add-on maintenance treatment in adult patients with inadequately controlled chronic obstructive pulmonary disease and an eosinophilic phenotype	9/27/24
Fibrin sealant (human) / Vistaseal / Ethicon, Inc.	Indication expanded to include use in pediatric patients (neonate to age 18) as an adjunct to hemostasis for mild to moderate bleeding in patients undergoing surgery when control of bleeding by standard techniques is ineffective or impractical.	9/27/24

<u>New Dosage Forms or Formulation:</u>	<u>Description</u>	<u>Date Approved</u>
Atezolizumab-Hyaluronidase-tqjs / Tecentriq Hybreza / Genentech, Inc.	For the treatment of all the adult indications as the intravenous formulation of atezolizumab including non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), hepatocellular carcinoma (HCC), melanoma, and alveolar soft part sarcoma (ASPS).	9/12/24
Ocrelizumab and hyaluronidase-ocsq / Ocrevus Zunovo / Genentech, Inc.	Injection: 920 mg ocrelizumab and 23,000 units hyaluronidase per 23 mL solution in a single dose vial; for subcutaneous injection for the treatment of relapsing forms of multiple sclerosis and primary progressive multiple sclerosis	9/13/24

Compiled by:

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Lebrikizumab-ibkz / Ebglyss / Eli Lilly and Company	
Generic Name / Brand Name / Company	Lebrikizumab-ibkz / Ebglyss / Eli Lilly and Company
Date of approval	9/13/24
Drug Class (Mechanism of Action if novel agent)	Interleukin-13 antagonist
Indication	Treatment of adult and pediatric patients 12 years and older and weighing at least 40 kg with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable
Comparative agent – Therapeutic interchange?	Tralokinumab
Dosage forms/strengths	Injection: 250 mg/2 mL in single dose prefilled pen or syringe
Common Dose/sig	500 mg (two 250 mg injections) at week 0 and week 2, followed by 250 mg every 2 weeks until week 16 or later, when adequate clinical response is achieved. Maintenance dose is 250 mg every 4 weeks.
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Engerix, tildrakizumab
Clinical Use Evaluation	
Common Adverse Effects	>1%: conjunctivitis, injection site reactions, herpes zoster
Severe Adverse Effects	Hypersensitivity reactions
Severe Drug-Drug Interactions	Avoid use of live vaccines during treatment
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	Patients 12 years and older and weighing at least 40 kg
Renal or Hepatic Dosing	No dosage adjustments required
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with prior serious hypersensitivity reaction to drug or any product excipients Warnings: hypersensitivity reactions including angioedema and urticaria; new or worsening conjunctivitis and keratitis; avoid use of live vaccines during treatment; treat parasitic helminth infections prior to use
Special administration technique or considerations	Complete all age appropriate vaccinations before beginning therapy. Can be used with or without topical corticosteroids. May be used with topical calcineurin inhibitors, but only in sensitive areas (ie, face, neck, intertriginous and genital areas). Administered subcutaneously; may be self-administered following training. Administer in abdomen, thigh, or back of upper arm. Alternative sites and avoid injection within 2 inches of the navel or areas of the skin that are tender, bruised, red, hard, or affected by atopic dermatitis or skin lesions. Remove from refrigerator 45 minutes prior to injection; do not warm with use of a heat source.
Prepared by	Terri Levien
Source	Ebglyss (lebrikizumab-ibkz) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; September 2024.

Arimoclomol / Miplyffa / Zevra Therapeutics Inc.	
Generic Name / Brand Name / Company	Arimoclomol / Miplyffa / Zevra Therapeutics Inc.
Date of approval	9/20/24
Drug Class (Mechanism of Action if novel agent)	Pharmacologic chaperone, heat shock protein inducer; mechanism in NPC is unknown but arimoclomol amplifies the heat shock response to target NPC protein misfolding and improves lysosomal function (Mengel et al, 2021)
Indication	Use in combination with miglustat for the treatment of neurological manifestations of NPC in patients 2 years of age and older
Comparative agent – Therapeutic interchange?	Levacetylleucine
Dosage forms/strengths	Capsules: 47 mg, 62 mg, 93 mg, 124 mg
Common Dose/sig	Administered orally based on actual body weight: 8 to 15 kg: 47 mg three times a day >15 to 30 kg: 62 mg three times a day >30 to 55 kg: 93 mg three times a day >55 kg: 124 mg three times a day
DEA Schedule	NA
Date of market availability	November 2024
Similar Medication Names	Arimidex, aripiprazole
Clinical Use Evaluation	
Common Adverse Effects	>15%: upper respiratory tract infection, diarrhea, decreased weight
Severe Adverse Effects	Hypersensitivity
Severe Drug-Drug Interactions	OCT2 substrates: monitor for adverse events and reduce substrate dose
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 in patients 2 years and older
Renal or Hepatic Dosing	Dosage adjustment for eGFR 15 to <50 mL/min: same weight-based dose but administered two times a day. No dosage adjustments in mild to moderate hepatic impairment; not studied in severe hepatic impairment or with eGFR < 15 mL/min.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. Warnings: Hypersensitivity reactions (urticaria and angioedema have been reported) Embryofetal toxicity and impaired fertility Increases serum creatinine without affecting glomerular function: use alternative measures to assess renal function such as BUN, cystatin C, or measured GFR.
Special administration technique or considerations	Administer with or without food. Swallow tablets whole, or if difficulty swallowing, may open the capsule and sprinkle contents into 15 mL of water, apple juice or soft food (eg, applesauce, pudding, yogurt). May be administered via nasogastric or gastric tube after mixing capsule contents with 20 mL water.
Prepared by	Terri Levien
Sources	Mengel E, Patterson MC, Da Riolo RM, et al. Efficacy and safety of arimoclomol in Niemann-Pick disease type C: results from a double-blind, randomised, placebo-controlled, multinational phase 2/3 trial of a novel treatment. <i>J Inher Metab Dis.</i> 2021;44(6):1463-1480.doi:10.1002/jimd.12428. Miplyffa (arimoclomol) [prescribing information]. Celebration, FL: Zebra Therapeutics, Inc.; September 2024.

Levacetylleucine / Aqneursa / IntraBio Inc.	
Generic Name / Brand Name / Company	Levacetylleucine / Aqneursa / IntraBio Inc.
Date of approval	9/24/24
Drug Class (Mechanism of Action if novel agent)	Amino acid derivative
Indication	Treatment of neurological manifestations of NPC in adult and pediatric patients weighing at least 15 kg. In clinical trials 85% of subjects were on miglustat at baseline and continued miglustat during the levacetylleucine trial.
Comparative agent – Therapeutic interchange?	Arimoclomol
Dosage forms/strengths	Granules for oral suspension: 1 g in unit-dose packet
Common Dose/sig	Weight-based dosing: 15 to <25 kg: 1 g twice daily, morning and evening 25 to <35 kg: 1 g three times daily, morning, afternoon, and evening 35 kg or more: 2 g in the morning, 1 g afternoon and evening
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Acetylcysteine, leucine,
Clinical Use Evaluation	
Common Adverse Effects	≥5%: abdominal pain, dysphagia, upper respiratory tract infection, vomiting
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	N-acetyl-DL-leucine or N-acetyl-D-leucine: avoid concomitant use P-glycoprotein transporter substrates: monitor for adverse reactions
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Verify patient is not pregnant.
Used in Pediatric Areas	Indicated in patients weighing 15 kg or greater; studied in patients 5 years and older. Has not been studied in patients weighing less than 15 kg or younger than 5 years.
Renal or Hepatic Dosing	No dosage adjustments recommended; not studied in renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. May cause fetal harm: females of reproductive potential should use effective contraception during treatment and for 7 days after the last dose if treatment is discontinued.
Special administration technique or considerations	Can be taken with or without food. Mix contents of one packet with 40 mL of water, orange juice, or almond milk and administer immediately. For doses requiring two packets, the process should be repeated. May be administered via gastrostomy tube when mixed with 40 mL water.
Prepared by	Terri Levien
Source	Aqneursa (levacetylleucine) [prescribing information]. Austin, TX: IntraBio Inc.; September 2024.

Xanomeline and trospium chloride / Cobenfy / Bristol-Myers Squibb	
Generic Name / Brand Name / Company	Xanomeline and trospium chloride / Cobenfy / Bristol-Myers Squibb
Date of approval	9/27/24
Drug Class (Mechanism of Action if novel agent)	Muscarinic agonist and muscarinic antagonist; action of xanomeline in schizophrenia is believed to be due to agonist activity at M1 and M4 muscarinic acetylcholine receptors in the CNS; trospium, a muscarinic antagonist, antagonizes the muscarinic receptors in the peripheral tissues
Indication	Treatment of schizophrenia in adults
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Capsules: 50 mg/20 mg, 100 mg/20 mg, 125 mg/30 mg
Common Dose/sig	Starting dose: 50 mg/20 mg orally twice a day for at least 2 days, then increase to 100 mg/20 mg twice daily for at least 5 days. The dose may be increased to 125 mg/30 mg twice daily based on tolerability and response. Consider slower titration in geriatric patients, with maximum dose of 100 mg/20 mg twice daily.
DEA Schedule	None
Date of market availability	October 2024
Similar Medication Names	Trospium
Clinical Use Evaluation	
Common Adverse Effects	≥5%: nausea, dyspepsia, constipation, vomiting, hypertension, abdominal pain, diarrhea, tachycardia, dizziness, gastrointestinal reflux disease
Severe Adverse Effects	Liver injury, urinary retention, allergic reactions
Severe Drug-Drug Interactions	Drugs eliminated by active tubular secretion, strong CYP2D6 inhibitors, sensitive substrates of CYP3A4 or P-gp, and antimuscarinic drugs– monitor for adverse reactions
Severe Drug-Food Interactions	Trospium absorption is reduced when taken with food
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Liver enzymes and bilirubin prior to initiation and as clinically indicated during treatment
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients.
Renal or Hepatic Dosing	Avoid use in mild hepatic impairment; contraindicated in moderate or severe hepatic impairment. Not recommended in patients with moderate or severe renal impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: urinary retention, moderate or severe hepatic impairment, gastric retention, history of hypersensitivity to the product or trospium, untreated narrow-angle glaucoma. Warnings: urinary retention, liver injury, decreased gastric motility, risk of angioedema, increased heart rate (assess heart rate at baseline and as clinically indicated, CNS effects.
Special administration technique or considerations	Take at least 1 hour before a meal or at least 2 hours after a meal. Do not open capsules.
Prepared by	Terri Levien
Source	Cobenfy (xanomeline and trospium) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; September 2024.