



Highlights of FDA Activities – 7/1/24 – 7/31/24

FDA Drug Safety Communications & Drug Information Updates:

Disruptions in BD BACTEC Blood Culture Media Bottle Availability – MedWatch Alert 7/10/24

The FDA announced through MedWatch disruptions in the availability of BD BACTEC Blood Culture Media Bottles, which is expected to impact patient diagnosis, follow-up patient management, and antibiotic stewardship efforts. The FDA issued a letter to health care providers with information about the shortage and strategies for conserving the use of blood culture media bottles for patients at highest risk.

Compounded Injectable Semaglutide Product Dosing Errors – MedWatch Alert 7/26/24

The FDA warned compounders, providers, and patients that overdoses have occurred with compounded semaglutide injection. Causes of these errors included miscalculation of doses, patient unfamiliarity with dosing units, and multiple dose vials sent out which led to massive overdosing (5-20x). Other reported adverse events include gastrointestinal effects, fainting, headache, migraine, dehydration, acute pancreatitis, and gallstones.

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

Bausch + Lomb I-Pack Eye Injection Kits: Recall – Potential Non-Sterility 7/15/24

Bausch + Lomb and its subsidiary, Synergetics, Inc., recalled certain lots of I-Pack Injection Kits used to deliver intravitreal medications after being unable to verify the products were fully sterilized. A full list of the recalled products can be found on the FDA [site](#).

Endo USA Clonazepam Orally Disintegrating Tablets: Recall – Misabeled with Incorrect Strength 7/18/24

Endo USA recalled one lot (lot 550147301, expiration date August 2026) of clonazepam orally disintegrating tablets, USP 0.25 mg, which may appear as 0.125 mg tablets 60 count pack. Some cartons labeled 0.125 mg contain blister strips correctly labeled with the 0.25 mg strength.

Hikma Pharmaceuticals USA, Acetaminophen Injection: Recall Expanded – Misabeled 7/22/24

Hikma Pharmaceuticals USA extended its recall of one lot (lot 24070381, expiration September 2025) of acetaminophen injection 1000 mg/100 mL to the consumer level due to the presence of a bag labeled dexmedetomidine HCl 400 mcg/100 mL inside an overwrap labeled acetaminophen, presenting a serious risk for adverse reaction if dexmedetomidine is administered instead of acetaminophen. One report of an adverse event has been received by the manufacturer.

Aurobindo Pharma USA, Healthy Living Over the Counter Migraine Relief: Recall – Missing Label 7/25/24

Aurobindo Pharma USA Inc, on behalf of AuroHealth, recalled one lot (lot AC2523005A, expiration June 2025) of Healthy Living Migraine Relief Acetaminophen 250 mg, Aspirin 250 mg, and Caffeine 65 mg tablets due to the product missing the manufacturer label. Amazon customers will have received a white unlabeled bottle, with only an Amazon identifying sticker but missing required OTC labeling information, drug facts, and patient usage information.

Abbott Freestyle Libre 3 Sensors: Recall – Device Correction 7/31/24

Abbott initiated a medical device correction for some sensors from three lots (T60001948, T60001966, T60001969) of Freestyle Libre 3 sensors that were found to be malfunctioning, providing incorrect high glucose readings. Consumers with sensors from the affected lots can enter the serial number at the manufacturer's [site](#) to confirm whether their sensor is affected. Affected sensors will be replaced at no charge.

Dietary Supplement Recalls & Public Notifications

Notifications were issued regarding, safety concerns, 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>Safety Concern, Undeclared Ingredient(s) or Contaminants</u>
Gold Hard Steel Plus Liquid*	Sexual Enhancement	Sildenafil, acetaminophen
Hard Steel Capsules*	Sexual enhancement	Sildenafil, acetaminophen
Infla-650 Herbal Dietary Supplement*	Pain	Acetaminophen, diclofenac, phenylbutazone ¹
OPMS Black Liquid Kratom	Energy	Serious adverse events, including death
Umary Acido Hialuronico Suplemento Alimenticio*	Pain	Diclofenac, Omeprazole
Vail-Bon Jie Yang Wan	Skin conditions	Dexamethasone, chlorpheniramine

*Recalled

New Product Shortages

No new product shortages were reported by the FDA in July.

Brand Name or Sole Source Product Discontinuations/Withdrawals

Date Posted

Betoptic S, Ophthalmic Suspension (Novartis); betaxolol ophthalmic solution remains available from other manufacturers	7/2/24
Nascobal Spray (Endo Pharmaceuticals); alternative cyanocobalamin nasal spray products are available	7/12/24
Ziac Tablet (Teva Pharmaceuticals USA); generic bisoprolol fumarate and hydrochlorothiazide tablets remain available	7/26/24

New Drug Approvals:

Description (See Attached Drug Summaries)

Date Approved

Donanemab-azbt / Kisunla / Eli Lilly Co	Intravenous amyloid beta-directed antibody for treatment of Alzheimer's Disease in patients with mild cognitive impairment or mild dementia stage of disease	7/2/24
Deuruxolitinib phosphate / Leqselvi / Sun Pharmaceutical Industries, Inc.	JAK inhibitor for treatment of adults with severe alopecia areata	7/25/24
Benzgalantamine / Zunveyl / Alpha Cognition, Inc.	New oral (anticholinesterase) treatment for Alzheimer's disease. Zunveyl by Alpha Cognition Incorporated is a delayed-release tablet, available in three strengths: 5 mg, 10 mg, 15 mg.	7/26/24

New Indications:

Description of New Indication

Date Approved

Sucroferric oxyhydroxide / Velphoro / Fresenius Medical Care North America	Indication for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis expanded to include use in pediatric patients 9 years and older	7/1/24
IncobotulinumtoxinA / Xeomin / Merz Aesthetics	Simultaneous treatment of upper facial lines, including forehead lines, frown lines, and crow's feet	7/5/24
Vonoprazan fumarate / Voquezna / Phathom Pharmaceuticals, Inc	Treatment of heartburn associated with non-erosive gastroesophageal reflux disease in adults	7/17/24
Ribociclib succinate / Kisqali / Novartis	In combination with fulvestrant for the treatment of hormone receptor positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine therapy or with disease progression following endocrine therapy (no longer indicated only in postmenopausal women or men)	7/22/24
Cerliponase alfa / Brineura / Biomain Pharmaceuticals	Indication expanded to include patients age from birth and older with tripeptidyl peptidase 1 (TPP1) deficiency.	7/24/24

<u>New Indications: (continued)</u>	<u>Description of New Indication</u>	<u>Date Approved</u>
Peanut (<i>Arachis hypogaea</i>) Allergen Powder-dnfp / Palforzia / Aimmune Therapeutics, Inc.	Indication expanded to include the treatment of confirmed peanut allergy in patients ages 1-3 years to mitigate allergic reactions (including anaphylaxis)	7/26/24
Daratumumab and hyaluronidase-fijh / Darzalex Faspro / Janssen Research & Development	In combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant	7/30/24
Fibrinogen (human) / Fibryga / Octapharma	Expanded to include fibrinogen supplementation in bleeding adults and pediatric patients with acquired fibrinogen deficiency	7/31/24

<u>New Dosage Forms or Formulation:</u>	<u>Description</u>	<u>Date Approved</u>
Roflumilast / Zoryve / Arcutis Biotherapeutics, Inc.	Cream: 0.15%; treatment of mild to moderate atopic dermatitis in patients 6 years of age and older	7/9/24
Norethindrone acetate and ethinyl estradiol / Femlyv / Millicent U.S. Inc.	Oral disintegrating tablet: 24 ODTs containing norethindrone acetate 1 mg and ethinyl estradiol 0.02 mg and 4 inert tablets; oral contraceptive	7/22/24
Aripiprazole / Opipza / Xiamen	Oral film: 2 mg, 5 mg, 10 mg; for treatment of schizophrenia in ages 13 and older, adjunctive treatment of major depressive disorder in adults, irritability associated with autistic disorder in pediatric patient 6 years and older, and treatment of Tourette's disorder in pediatric patients 6 years and older	7/22/24
Maralixibat chloride / Livmarli / Mirum	Oral solution: 19 mg/mL; indication expanded to include treatment of pediatric patients 12 months and older with progressive familial intrahepatic cholestasis (PFIC)-related cholestatic pruritus	7/24/24
Terazosin / Tezruly / Novitium Pharma LLC	Oral solution: 1 mg/ml; for treatment of benign prostatic hyperplasia and treatment of hypertension alone or with other antihypertensive agents	7/29/24

Compiled by:

Terri Levien, Pharm.D.

Emily Hitt, Pharm.D., Drug Information Fellow

Hayden Wesley, Doctor of Pharmacy Candidate 2024

Sehr Faltin, Doctor of Pharmacy Candidate 2025

Drug Information Center

College of Pharmacy and Pharmaceutical Sciences

Washington State University

412 E. Spokane Falls Blvd.

Spokane, WA 99202-2131

(509) 358-7662

Pharmacy.druginfo@wsu.edu

Donanemab-azbt / Kisunla / Eli Lilly and Company	
Generic Name / Brand Name / Company	Donanemab-azbt / Kisunla / Eli Lilly and Company
Date of approval	7/2/24
Drug Class (Mechanism of Action if novel agent)	Anti-amyloid monoclonal antibody
Indication	Alzheimer's with mild cognitive impairment or mild dementia
Comparative agent – Therapeutic interchange?	Aducanumab, lecanemab
Dosage forms/strengths.	Injection: 350 mg/20 mL (17.5 mg/mL) (single-dose vial) for IV infusion
Common Dose/sig	Initiation: 700 mg via IV infusion over 30 minutes every 4 weeks for 3 doses. Maintenance: 1400 mg via IV infusion over 30 minutes every 4 weeks.
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Dasatinib, dabigatran, dobutamine
Clinical Use Evaluation	
Common Adverse Effects	>10%: Amyloid-related imaging abnormalities (ARIA) with edema (E), ARIA with hemosiderin deposits (ARIA-H), headache, infusion-related reactions (including chills, irritated skin, nausea, vomiting, sweating, headache, chest pain, problems breathing)
Severe Adverse Effects	Anaphylaxis, ARIA (if symptomatic), ARIA-E, ARIA-H, headache, dizziness, nausea, vomiting, difficulty walking, confusion, vision changes, seizures
Severe Drug-Drug Interactions	Increased risk of bleeding when combined with any of the following: anticoagulants, antiplatelets, thrombolytics. Risk of diminishing Fc receptor-binding agent effects (rozanolixizumab and efgartigimod alfa).
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Prior to starting: confirm presence of amyloid deposits via MRI scan plus regular MRI before 2 nd , 3 rd , 4 th , and 7 th infusions. Genetic testing of ApoE E4 status.
Used in Pediatric Areas	Not studied or intended for pediatric use.
Renal or Hepatic Dosing	Not studied and expected to undergo proteolytic degradation.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated if known hypersensitivity to any product ingredients Boxed Warnings: ARIA events can be serious and life-threatening. ApoE E4 Homozygotes are at a higher risk of ARIA reaction. Infusion related reactions - consider pretreatment
Special administration technique or considerations	Infuse over 30 minutes. Flush line only with 0.9% sodium chloride injection. Observe patient for at least 30 minutes after infusion. The infusion rate may be reduced or discontinued for infusion reactions. Consider pretreatment with antihistamines, acetaminophen, or corticosteroids prior to subsequent dosing. Missed doses should be resumed at most current dose.
Prepared by	Hayden Wesley
Source	Kisunla (donanemab-azbt)[prescribing information]. Indianapolis, IN: Eli Lilly and Company; July 2024.

Deuruxolitinib phosphate / Leqselvi / Sun Pharmaceutical Industries, Inc.	
Generic Name / Brand Name / Company	Deuruxolitinib phosphate / Leqselvi / Sun Pharm Ind, Inc.
Date of approval	7/25/24
Drug Class (Mechanism of Action if novel agent)	JAK inhibitor
Indication	Treatment of adults with severe alopecia areata
Comparative agent – Therapeutic interchange?	Baricitinib
Dosage forms/strengths.	Tablets: 8 mg
Common Dose/sig	Take 1 tablet by mouth twice a day, without regard to food.
DEA Schedule	NA
Date of market availability	Unknown
Similar Medication Names	Duragesic, duloxetine, Duracillin
Clinical Use Evaluation	
Common Adverse Effects	>1%: Headache, acne, nasopharyngitis, blood creatine phosphokinase increased, hyperlipidemia, fatigue, weight gain, lymphopenia, thrombocytosis, anemia, skin and soft tissue infections, neutropenia, herpes
Severe Adverse Effects	Gastrointestinal perforation; serious infections; hematologic abnormalities
Severe Drug-Drug Interactions	Avoid: Strong CYP3A4 inducers, moderate/strong CYP2C9 inducers Contraindicated: Moderate/strong CYP2C9 inhibitors Avoid use of live vaccines
Severe Drug-Food Interactions	None indicated.
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Genetic testing/genotyping for CYP2C9; TB evaluation; viral hepatitis screening; complete blood count before start; monitor CBC periodically
Used in Pediatric Areas	Not known, not recommended.
Renal or Hepatic Dosing	Not recommended.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: patients who are poor CYP2C9 metabolizers or using moderate/strong CYP2C9 inhibitors Box Warnings: Increased risk of infections Plus major events with other JAK inhibitors: Higher rate of all-cause mortality. Higher rates of lymphomas and lung cancers. Higher rates of MACE events. Thrombosis, especially increased risk of pulmonary embolism, venous/arterial thrombosis. Warnings: Patients at increased risk of gastric perforations, monitor and use caution. Avoid use of live vaccinations during or immediately prior to treatment.
Special administration technique or considerations	Interrupt therapy for hematologic abnormalities or serious or opportunistic infection.
Prepared by	Hayden Wesley
Source	Leqselvi (deuruxolitinib phosphate) [prescribing information]. Whippany, NJ: Sun Pharmaceutical Industries, Inc.; July 2024.

Benzgalantamine / Zunveyl / Alpha Cognition, Inc.	
Generic Name / Brand Name / Company	Benzgalantamine / Zunveyl / Alpha Cognition, Inc.
Date of approval	7/26/24
Drug Class (Mechanism of Action if novel agent)	Cholinesterase inhibitor
Indication	Treatment of Alzheimer's disease with mild/moderate dementia
Comparative agent – Therapeutic interchange?	Donepezil, galantamine
Dosage forms/strengths.	Delayed release tablets: 5 mg, 10 mg, 15 mg
Common Dose/sig	Initial: 5 mg by mouth twice a day without regard to food. Initial maintenance dosage: 10 mg by mouth twice a day starting as early as week 5, adjusted to clinical response and tolerability. After that, maximum 15 mg twice a day after minimum 4 weeks at 10 mg twice a day.
DEA Schedule	None
Date of market availability	1 st quarter 2025
Similar Medication Names	Galantamine, benazepril, Benadryl, Belrapzo, Benoxinate, benzamidine, benznidazole, benzonatate
Clinical Use Evaluation	
Common Adverse Effects	≥5%: Nausea, vomiting, diarrhea, dizziness, headache, decreased appetite
Severe Adverse Effects	Serious skin reactions, gastrointestinal bleeding
Severe Drug-Drug Interactions	Potential interference with anticholinergic effect of medications. Synergistic effect when given with succinylcholine, cholinesterase inhibitors, neuromuscular blocking agents, cholinergic agonists.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	No lab monitoring required
Used in Pediatric Areas	Safety and efficacy not assessed; not indicated in pediatric patients
Renal or Hepatic Dosing	Renal impairment with CrCl 9-59 ml/min: Do not exceed 10 mg twice a day (20 mg/day). With CrCl < 9 ml/min, use not recommended. Hepatic, Child-Pugh 7-9: Do not exceed 10 mg twice a day (20 mg/day). Child-Pugh scores 10-15, use is not recommended.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: Known hypersensitivity to benzgalantamine, galantamine, or its excipients. Warnings: Serious skin reaction events observed with galantamine, discontinue at first sign of rash; exception of non-drug related rashes. Cardiovascular conduction disorders, gastrointestinal bleeding, bladder outflow obstruction, increased seizure risk, caution in patients with severe asthma or obstructive pulmonary disease – monitor closely
Special administration technique or considerations	Do not split, crush, chew tablets. Ensure adequate fluid intake. Instruct not to take with alcohol. If therapy interrupted for more than 3 days, restart at the lowest dose.
Prepared by	Hayden Wesley
Source	Zunveyl (benzgalantamine) [prescribing information]. Grapevine, TX: Alpha Cognition, Inc.; July 2024.