



Highlights of FDA Activities – 11/1/24 – 11/30/24

FDA Drug Safety Communications & Drug Information Updates:

Compounded Drugs, Fullerton Wellness: Warning – Lack of Sterility 11/1/24

The FDA warned against use of drugs compounded and distributed by Fullerton Wellness LLC of Ontario California following inspections by California regulatory authorities and the FDA and a report of particulate in distributed product. The company used non-sterile ingredients to make injectable drugs and took no steps to sterilize them. Products compounded by Fullerton Wellness include semaglutide and tirzepatide injections.

Skysona (elivaldogene autotemcel): FDA Investigating Risk of Hematologic Malignancy 11/27/24

The FDA is investigating the risk of hematologic malignancy following additional reports of malignancies, including life-threatening cases of myelodysplastic syndrome and acute myeloid leukemia, after treatment of cerebral adrenoleukodystrophy with Skysona (elivaldogene autotemcel). Cases were reported from patients treated in clinical trials, with cases diagnosed between 14 to 92 months post-treatment. Alternative therapies, including allogeneic hematopoietic stem cell transplant when possible, should be considered prior to deciding to treat a child with Skysona. Treated patients should be monitored lifelong for hematologic malignancy.

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

CADD-Solis Li-ion Rechargeable Battery, Smiths Medical: Recall – Instruction Correction 11/19/24

Smiths Medical issued updated instructions for the CADD-Solis Li-ion Rechargeable Battery Pack due to a potential issue where battery back damage may cause a short within the battery resulting in melting of the battery case which prevents the battery from being able to charge. Damaged battery packs should be replaced with another rechargeable pack or with four AA batteries.

Clonazepam Orally Disintegrating Tablets USP, Endo: Recall Expansion – Mislabeling 11/19/24

Endo USA expanded a previously announced recall of clonazepam orally disintegrating tablets USP (0.125 mg, 0.25 mg, 1 mg, and 2 mg) due to potential carton strength mislabeling. The affected [lot numbers](#) may contain some cartons printed with the incorrect strength and NDC. The blister strips and tablets inside the product pack reflect the correct strength for the lot.

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>
Force Forever	Joint pain	Diclofenac, dexamethasone
HON-E-LING	Sexual enhancement	Sibutramine ¹ , sildenafil
LipoFit Turbo	Weight loss	Sibutramine ¹ , metformin, fluoxetine, furosemide
Nhan Sam Tuyet Lien Truy Phong Hoan	Gout, arthritis	Chlorpheniramine, dexamethasone, furosemide
PeakMax*	Sexual enhancement	Sildenafil, diclofenac
THERMO SHOCK	Weight loss	1,3-mitheylylamylamine (1,3-DMAA) ² , synephrine ³
Umary acid hyaluronic	Joint health	Diclofenac, omeprazole
VITAFER-L Gold	Sexual enhancement	Tadalafil
VitalityXtra*	Sexual enhancement	Sildenafil
ZapMax*	Sexual enhancement	Sildenafil, diclofenac
ZoomMax*	Sexual enhancement	Sildenafil, diclofenac

*recalled; ¹Sibutramine has been associated with increased cardiovascular events; removed from market for safety reasons in 2010^{FDA}; ²1,3-DMAA can elevate blood pressure and associated cardiovascular complications; ³Synephrine can increase heart rate and blood pressure

New Product Shortages

Hydroxocobalamin injection

Date Initially Posted

11/4/24

Brand Name or Sole Source Product Discontinuations/Withdrawals

Daprodustat tablets (Jesduvroq, GlaxoSmithKline); vadadustat (Vafseo, Akebia Therapeutics) in the same class anticipated to be available in January 2025, or erythropoietin products

Date Posted

11/21/24

Memantine HCl tablets (Namenda, Actavis Pharma); remains available from generic manufacturers

11/21/24

Removed/Restricted Indications:Sacituzumab govitecan-hziy/Trodelyv/
Gilead Sciences**Description**

Withdrawal of indication for treatment of patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and either PD-1 or PD-L1 inhibitor

Date Approved

11/22/24

New Drug Approvals:Obecabtagene autoleucel/Aucatzyl/
Autolus Inc.**Description (See Attached Drug Summaries)**

CD19-directed genetically modified autologous T cell immunotherapy for treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia

Date Approved

11/8/24

Eladocagene exuparvovec-
tneq/Kebilidi/PTC Therapeutics, Inc.

Gene therapy for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency

11/13/24

Revumenib/Revuforj/Syndax
Pharmaceuticals, Inc.

A menin inhibitor for the treatment of relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation in adult and pediatric patients 1 year and older

11/15/24

Zanidatamab-hrii/Ziihera/Jazz
Pharmaceuticals, Inc.

HER2-targeted bispecific antibody for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer

11/20/24

Acoramidis/Attruby/BridgeBio
Pharma, Inc.

Transthyretin stabilizer to treat adults with cardiomyopathy of wild-type or variant (hereditary) transthyretin-mediated amyloidosis to reduce death and hospitalization

11/22/24

Landiolol/Rapiblyk/AOP Orphan
Pharmaceuticals GmbH

Beta blocker for short-term reduction of ventricular rate in adults with supraventricular tachycardia including atrial fibrillation and atrial flutter

11/22/24

Iomeprol/Iomervu/Bracco Diagnostics
Inc.Radiographic contrast agent for intra-arterial or intravenous use in multiple imaging types (see [labeling](#) for additional information)

11/27/24

New Indications:

	<u>Description</u>	<u>Date Approved</u>
Fludarabine phosphate/Sandoz	Indication updated as part of Project Renewal, an initiative aimed at updating labeling for older oncology drugs. Added indication is for use as a component of a combination regimen for the treatment of adults with B-cell chronic lymphocytic leukemia.	11/19/24
Bimekizumab-bkzx/Bimzelx/UCB	Treatment of adults with moderate to severe hidradenitis suppurativa	11/20/24

New Dosage Forms or Formulation:

	<u>Description</u>	<u>Date Approved</u>
Minocycline HCl / Emrosi / Journey Medical Corp.	Extended-release capsules: 40 mg; treatment of inflammatory lesions (papules and pustules) of rosacea in adults	11/1/24
Nilotinib tartrate/Danziten/Azurity Pharmaceuticals, Inc.	Tablets: 71 mg and 95 mg; treatment of newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia and chronic phase and accelerated phase Ph+ CML resistant to or intolerant to prior therapy that included imatinib	11/7/24
Imatinib/Imkeldi/Shorla Oncology Inc	Oral solution: 80 mg/mL; for administration of imatinib in cancer therapy for patients with difficulty swallowing or requiring specific dosing based on body surface area	11/22/24

Compiled by:

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Obecabtagene autoleucel/Aucatzyl/Autolus Inc.	
Generic Name / Brand Name / Company	Obecabtagene autoleucel/Aucatzyl/Autolus Inc.
Date of approval	11/8/24
Drug Class (Mechanism of Action if novel agent)	CD19-directed genetically modified autologous T cell immunotherapy
Indication	Treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia
Comparative agent – Therapeutic interchange?	Brexucabtagene autoleucel (Tecartus)
Dosage forms/strengths	Cell suspension, dose supplied in 3 to 5 infusion bags
Common Dose/sig	410 x 10 ⁶ CD19 CAR-positive viable T cells as a split dose infusion on day 1 and day 10
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Austedo, obeticholic acid
Clinical Use Evaluation	
Common Adverse Effects	≥20%: cytokine release syndrome (CRS), infections, musculoskeletal pain, fever, nausea, diarrhea, febrile neutropenia, immune effector cell-associated neurotoxicity syndrome (ICANS), hypotension, pain, fatigue, headache, encephalopathy, hemorrhage
Severe Adverse Effects	CRS, ICANS, pulmonary or cardiac toxicities, infection
Severe Drug-Drug Interactions	Avoid use of prophylactic systemic corticosteroids.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Screen for HBV, HCV, and HIV before collecting cells for manufacturing. Pregnancy test. Monitor blood counts, immunoglobulin levels; monitor for CRS, ICANS, and other acute toxicities for at least 14 days at healthcare facility.
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	Not studied; no routine dosage adjustments recommended.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. Boxed warnings: cytokine release syndrome, neurologic toxicities, secondary hematologic malignancies Warnings: prolonged cytopenias, infections, hypogammaglobulinemia, hemophagocytic lymphohistiocytosis/macrophage activation syndrome, hypersensitivity reactions, secondary malignancies, effects on ability to drive and use machinery
Special administration technique or considerations	Autologous use only; patient's identify must match the patient identifiers on the infusion bag. Follow the recommended split dose regimen based on bone marrow assessment. Only administer after completion of lymphodepleting chemotherapy regimen. Premedicate with acetaminophen approximately 30 minutes before CAR-T infusion. Infuse entire infusion bag within 60 minutes post-thaw.
Prepared by	Terri Levien
Source	Aucatzyl (obecabtagene autoleucel) [prescribing information]. Gaithersburg, MD: Autolus Inc.; November 2024.

Eladocagene exuparovec-tneq/Kebilidi/PTC Therapeutics, Inc.	
Generic Name / Brand Name / Company	Eladocagene exuparovec-tneq/Kebilidi/PTC Therapeutics, Inc.
Date of approval	11/13/24
Drug Class (Mechanism of Action if novel agent)	Adeno-associated virus vector gene therapy resulting in expression of AADC and subsequent increase in dopamine production
Indication	Treatment of adult and pediatric patients with AADC deficiency
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Suspension for intraputaminial administration: 2.8x10 ¹¹ vector genomes (vg) in an extractable volume of 0.5 mL in a single-dose vial
Common Dose/sig	1.8 x 10 ¹¹ vg (0.32 mL) delivered as four 0.08 mL intraputaminial infusions
DEA Schedule	NA
Date of market availability	Available, administered only in centers specializing in stereotactic neurosurgery
Similar Medication Names	Elacestrant, etranacogene dezaparovec
Clinical Use Evaluation	
Common Adverse Effects	≥15%: dyskinesia, pyrexia, hypotension, anemia, salivary hypersecretion, hypokalemia, hypophosphatemia, insomnia, hypomagnesemia, procedural complications
Severe Adverse Effects	Potential for procedural complications
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.	Confirm AADC deficiency due to biallelic mutations of the DDC gene
Used in Pediatric Areas	Safety and effectiveness established in trials enrolling pediatric patients 16 months to 10 years who had achieved skull maturity. Safety and effectiveness not established in patients younger than 16 months.
Renal or Hepatic Dosing	No dosage adjustments
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients who have not achieved skull maturity. Warnings: procedural complications, dyskinesia. Dyskinesia occurred in 77% of patients; use of dopamine antagonists may be considered.
Special administration technique or considerations	Administered only as a single-dose intraputaminial infusion in a single stereotactic surgery. Infusion takes 4 hours; maximum time from product thaw to completion of infusion should be no more than 10 hours. Thaw at room temperature; takes approximately 15 minutes. Infuse during surgical procedure at 4 sites (2 in anterior putamen and 2 in posterior putamen) at a rate of 0.003 mL/min at each target. Dose duration at each target point is 27 minutes.
Prepared by	Terri Levien
Source	kebilidi (eladocagene exuparovec-tneq) [prescribing information]. Warren, NJ: PTC Therapeutics, Inc.; November 2024.

Revumenib/Revuforj/Syndax Pharmaceuticals, Inc.	
Generic Name / Brand Name / Company	Revumenib/Revuforj/Syndax Pharmaceuticals, Inc.
Date of approval	11/15/24
Drug Class (Mechanism of Action if novel agent)	Menin inhibitor
Indication	Treatment of relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation in adult and pediatric patients 1 year and older
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Tablets: 25 mg, 110 mg, 160 mg
Common Dose/sig	Based on weight or BSA and concomitant use of strong CYP3A4 inhibitors; for patient weighing 40 kg or more without concomitant strong CYP3A4 inhibitor, the recommended initial dose is 270 mg orally twice daily
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Revlimid
Clinical Use Evaluation	
Common Adverse Effects	≥20%: hemorrhage, nausea, musculoskeletal pain, infection, febrile neutropenia, bacterial infection, diarrhea, differentiation syndrome, QT prolongation, decreased appetite, constipation, edema, viral infection, fatigue; increased phosphate, AST, ALT, parathyroid hormone, triglycerides, alkaline phosphatase; decreased phosphate, potassium
Severe Adverse Effects	Differentiation syndrome, hemorrhage, infection, thrombosis
Severe Drug-Drug Interactions	Avoid concomitant use with strong or moderate CYP3A4 inducers or QT prolonging drugs; reduce dose when administered with strong CYP3A4 inhibitors
Severe Drug-Food Interactions	Not known; studied when taken in fasted condition or with low-fat meal
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Assess pregnancy status prior to initiation; assess blood counts, electrolytes, and liver enzymes prior to initiation and monthly
Used in Pediatric Areas	Approved for use in patients 1 year and older
Renal or Hepatic Dosing	No dosage adjustments for mild to moderate renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. Boxed warning: differentiation syndrome (immediately initiation corticosteroid therapy and hemodynamic monitoring) Warnings: QTc interval prolongation (monitor, embryo-fetal toxicity)
Special administration technique or considerations	Administer orally twice daily fasted or with a low-fat meal at approximately the same time each day. Swallow whole but may crush and disperse in water if taken within 2 hours of preparation.
Prepared by	Terri Levien
Source	Revuforj (revumenib) [prescribing information]. Waltham, MA: Syndax Pharmaceuticals, Inc.; November 2024.

Zanidatamab-hrii/Ziihera/Jazz Pharmaceuticals, Inc.	
Generic Name / Brand Name / Company	Zanidatamab-hrii/Ziihera/Jazz Pharmaceuticals, Inc.
Date of approval	11/20/24
Drug Class (Mechanism of Action if novel agent)	HER2-targeted bispecific antibody
Indication	Treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer
Comparative agent – Therapeutic interchange?	Trastuzumab plus pertuzumab, trastuzumab plus tucatinib, fam-trastuzumab deruxtecan
Dosage forms/strengths	Injection: 300 mg as lyophilized powder in single-dose vial
Common Dose/sig	20 mg/kg as an IV infusion every 2 weeks
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Zanubrutinib
Clinical Use Evaluation	
Common Adverse Effects	≥20%: diarrhea, infusion-related reaction, abdominal pain, fatigue
Severe Adverse Effects	Diarrhea, infusion-related reactions, left-ventricular dysfunction
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 testing
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments based on renal or hepatic function.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. Boxed warning: embryo-fetal toxicity Warnings: left ventricular dysfunction (assess left ventricular ejection fraction prior to initiation and at regular intervals), infusion-related reactions, diarrhea
Special administration technique or considerations	Premedicate with acetaminophen, an antihistamine, and a corticosteroid, 30 to 60 minutes prior to each administration. Administer as IV infusion with 0.2- or 0.22-micron filter. Infusion duration of 120 to 150 minutes for first and second dose, 90 minutes for third and fourth infusion, and 60 minutes for subsequent infusions. Dosage and infusion rate reductions advised for severe adverse reactions.
Prepared by	Terri Levien
Source	Ziihera (zanidatamab-hrii) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; November 2024.

Acoramidis/Attruby/BridgeBio Pharma, Inc.	
Generic Name / Brand Name / Company	Acoramidis/Attruby/BridgeBio Pharma, Inc.
Date of approval	11/22/24
Drug Class (Mechanism of Action if novel agent)	Transthyretin stabilizer
Indication	Treatment of adults with cardiomyopathy of wild-type or variant (hereditary) transthyretin-mediated amyloidosis to reduce death and hospitalization
Comparative agent – Therapeutic interchange?	Tafamidis
Dosage forms/strengths	Tablets: 356 mg
Common Dose/sig	712 mg (two tablets) twice daily
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Altuviio
Clinical Use Evaluation	
Common Adverse Effects	Diarrhea (11.6%), upper abdominal pain (5.5%)
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	Avoid concomitant use with UGT inducers or strong CYP3A inducers; monitor when co-administered with sensitive CYP2C9 substrates
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 adjustments recommended in renal impairment; the effect of hepatic impairment on acoramidis pharmacokinetics is not known.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications or warnings
Special administration technique or considerations	Administered with or without food. Tablets should be swallowed whole, without cutting, crushing or chewing.
Prepared by	Terri Levien
Source	Attruby (acoramidis) [prescribing information]. Palo Alto, CA: BridgeBio Pharma, Inc.; November 2024.

Landiolol/Rapiblyk/AOP Orphan Pharmaceuticals GmbH	
Generic Name / Brand Name / Company	Landiolol/Rapiblyk/AOP Orphan Pharmaceuticals GmbH
Date of approval	11/22/24
Drug Class (Mechanism of Action if novel agent)	Beta-blocker with a 4-minute elimination half-life
Indication	Short-term reduction of ventricular rate in adults with supraventricular tachycardia including atrial fibrillation and atrial flutter
Comparative agent – Therapeutic interchange?	Esmolol
Dosage forms/strengths	Injection: 280 mg as lyophilized powder in single-dose vial
Common Dose/sig	If normal cardiac function, start at 9 mcg/kg/min; adjust dose in 10-minute intervals as need in increments of 9 mcg/kg/min to a maximum of 36 mcg/kg/min; if impaired cardiac function, start at 1 mcg/kg/min and adjust in 10-minute intervals as needed in increments of 1 mcg/kg/min to a maximum of 36 mcg/kg/min
DEA Schedule	NA
Date of market availability	To be determined
Similar Medication Names	Rapivab
Clinical Use Evaluation	
Common Adverse Effects	Hypotension (10%)
Severe Adverse Effects	None reported; consider warnings and risk factors for severe reactions
Severe Drug-Drug Interactions	Avoid concomitant use with negative inotropes and medications that slow heart rate or cardiac conduction
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Serum electrolytes
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients.
Renal or Hepatic Dosing	More conservative dose titration is recommended in patients with mild hepatic impairment; avoid use in moderate or severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with severe sinus bradycardia, sick sinus syndrome, heart block greater than first degree, decompensated heart failure, cardiogenic shock, pulmonary hypertension, or history of hypersensitivity to any product ingredients. Warnings: hypotension, bradycardia, cardiac failure, infusion site reactions, abrupt discontinuation, hyperkalemia, use in patients with reactive airways disease, diabetes mellitus and hypoglycemia, Prinzmetal's angina, pheochromocytoma, peripheral circulatory disorders, metabolic acidosis, hyperthyroidism, patients at risk of severe acute hypersensitivity reactions
Special administration technique or considerations	Administer by continuous IV infusion, titrating for heart rate control. Avoid infusion into small veins or through a butterfly catheter. Reconstitute with 0.9% sodium chloride injection or 5% dextrose injection. Data is limited beyond 24 hours of use. When switching to an oral beta-blocker, reduced the infusion rate by 50% ten minutes after administration of the oral beta-blocker. If satisfactory control is maintained for at least one hour, discontinue landiolol infusion.
Prepared by	Terri Levien, PharmD
Source	Rapiblyk (landiolol) [prescribing information]. Vienna, Austria: AOP Orphan Pharmaceuticals GmbH; November 2024.