



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

FDA Drug Safety Communications & Drug Information Updates:

Guillain-Barre Syndrome Warning for RSV Vaccines Abrysvo and Arexvy – Labeling Change 1/7/25

The FDA is requiring addition of a statement in the Warnings and Precautions sections of the labeling for the RSV vaccines Abrysvo and Arexvy that post marketing observational studies for these vaccines suggest an increased risk of Guillain-Barre syndrome during the 42 days following vaccination.

FDA Revokes Use of FD&C Red No.3 in Foods and Drugs 1/15/25

The FDA amended color additive regulations to no longer allow the use of FD&C Red No.3 in food and ingested drugs. Drug manufacturers have until January 18, 2028 to reformulate their products. The FDA states that the color additive is found to cause cancer in male laboratory rats exposed to high levels of the dye because of a hormonal mechanism that occurs in male rats, but there is no evidence showing it causes cancer in humans. Authorization was revoked because the Delaney Clause of the Federal Food, Drug, and Cosmetic Act prohibits authorization of a food additive or color additive if it has been found to induce cancer in humans or animals.

Epinephrine Nasal Solutions, BPI Labs and Endo USA – Unapproved Products, Do Not Use 1/16/25

The FDA warned healthcare professionals not to use unapproved epinephrine nasal solutions manufactured by BPI Labs LLC and Endo USA. These products have been confused with FDA-approved intravenous epinephrine products.

Glatiramer Acetate (Copaxone, Glatopa) -- Boxed Warning for Anaphylaxis 1/22/25

A boxed warning about the risk of anaphylaxis with glatiramer acetate was added to the prescribing information and patient Medication Guide. Anaphylaxis may occur at any time while patients are receiving treatment with this agent. Symptoms of anaphylaxis appeared within one hour of the injection for most patients.

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

Infusion Pump Software Issue, Fresenius Kabi USA – Early Alert Recall Program 1/16/25

Fresenius Kabi USA issued notifications to affected health care providers recommending certain software versions of the Ivenix Infusion System Large Volume Pump (LVP-0004) software be updated due to a potentially high-risk device issue. There were anomalies reported in software versions 5.9.2 and earlier that have potential to cause serious harm or death due to being underdosed or over infused. Software should be updated to version 5.10.

Phenylephrine HCl Injection, Provepharm: Recall – Particulate Matter 1/24/25

Provepharm Inc recalled one lot (24020027, expiry date December 2025) of phenylephrine hydrochloride injection, USP, 10 mg/mL (pharmacy bulk package) due to the presence of black particulate matter in one vial.

StatStrip Glucose and Glucose/Ketone Hospital Meters, Nova Biomedical: Software Correction Due to Risk for Transmission of Incorrect Patient Results 1/30/25

Nova Biomedical issued a software correction for the StatStrip Glucose and Glucose/ketone Hospital meters due to a potential risk for a software error to cause incorrect glucose patient test results to be transmitted to hospital medical record systems. The issue would occur when the operator would visit the “review results” screen while the machine was still in the process of transmitting results to the system.

Fentanyl Transdermal System 25 mcg/h, Alvogen: Recall – Defective Delivery System 1/31/25

Alvogen Inc recalled one lot (108319, expiration date 04/2027) fentanyl transdermal system 25 mcg/h transdermal patches due to the potential that the patches could be multi-stacked, adhered one on top of the other, in a single product pouch resulting in increased risk of overdose and respiratory depression.

Dietary Supplement Recalls & Public Notifications

No new recalls or warnings for dietary supplements were announced by the FDA in January.

New Product Shortages

Peginterferon alfa-2a Injection

Date Initially Posted

1/24/25

Brand Name or Sole Source Product Discontinuations/Withdrawals

Ramipril (Altace, Pfizer): 10 mg capsule (NDC 61570-0120-01), 2.5 mg Capsule (NDC 61570-0111-01);
ramipril capsules remain available from other manufacturers

Date Posted

1/30/25

Epoprostenol Sodium Injection (Flolan, GSK): 0.5 mg injection vial (NDC 00173-0517-00), 50 mL injection
diluent (NDC 00173-0857-02), 1.5 mg injection vial (NDC 00173-0519-00); GSK will cease distribution
approximately 11/30/25; a generic remains available

1/31/25

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

Datopotamab deruxtecan-dlnk/
Datroway/Daiichi Sankyo Inc

Trop-2-directed antibody and topoisomerase inhibitor conjugate
for the treatment of adult patients with unresectable or
metastatic, hormone receptor (HR)-positive, human epidermal
growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC
2+/ISH-) breast cancer who have received prior endocrine-
based therapy and chemotherapy for unresectable or
metastatic disease

1/17/25

Treosulfan/Grafapex/Medexus
Pharma Inc

Alkylating agent that is indicated for use in combination with
fludarabine as a preparative regimen for allogeneic
hematopoietic stem cell transplantation in adult and pediatric
patients with either acute myeloid leukemia or
myelodysplastic syndrome

1/21/25

Suzetrigine/Journavx/Vertex Pharms

Sodium channel blocker indicated for the treatment of
moderate to severe acute pain in adults

1/30/25

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

Mirikizumab-mrkz/Omvoh/Lilly
Panitumumab/Vectibix/Amgen

Treatment of moderately to severely active Crohn's disease
Use in combination with sotorasib for the treatment of adult
patients with KRAS G12C-mutated metastatic colorectal cancer
who have received prior fluoropyrimidine-, oxaliplatin-, and
irinotecan-based chemotherapy

1/15/25

1/16/25

Sotorasib/Lumakras/Amgen

Use in combination with panitumumab for the treatment of
adult patients with KRAS G12C-mutated metastatic colorectal
cancer who have received prior fluoropyrimidine-, oxaliplatin-,
and irinotecan-based chemotherapy

1/16/25

Acalabrutinib/Calquence/
AstraZeneca

Use with bendamustine and rituximab in adult patients with
previously untreated mantle cell lymphoma who are ineligible
for autologous hematopoietic stem cell transplantation

1/17/25

Esketamine/Spravato/Janssen
Trastuzumab deruxtecan/Enhertu/
Daiichi Sankyo Inc.

Treatment-resistant depression in adults as monotherapy
Unresectable or metastatic hormone receptor positive, HER2-
low or HER2-ultralow breast cancer that has progressed while
on one or more endocrine therapies

1/21/25

1/27/25

Semaglutide/Ozempic/Novo Nordisk

To reduce risk of sustained estimated glomerular filtration rate
decline, end-stage kidney disease, and cardiovascular death in
adults with type 2 diabetes and chronic kidney disease

1/28/25

<u>New Dosage Forms or Formulation:</u>	<u>Description</u>	<u>Date Approved</u>
Sitagliptin/Brynovin/Azurity	Oral solution: 25 mg/mL in a 120 mL bottle; as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	1/16/25
Hydrochlorothiazide/Inzirqo/ANI Pharmaceuticals	Oral suspension: 10 mg/mL powder for suspension in an 80 mL bottle; for use in adult and pediatric patients for treatment of hypertension when used alone or in combination with other antihypertensive agents and treatment of edema associated with congestive heart failure, hepatic cirrhosis, and renal disease	1/28/25
Meloxicam and rizatriptan/Symbravo/ Axsome	Tablets: meloxicam 20 mg and rizatriptan 10 mg; for the acute treatment of migraine with or without aura in adults	1/30/25

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Datopotamab deruxtecan-dInk/Datroway/Daiichi Sankyo Inc	
Generic Name / Brand Name / Company	Datopotamab deruxtecan-dInk/Datroway/Daiichi Sankyo Inc
Date of approval	1/17/25
Drug Class (Mechanism of Action if novel agent)	Trop-2-directed antibody and topoisomerase inhibitor conjugate
Indication	Treatment of adult patients with unresectable or metastatic, HR-positive, HER2-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease
Comparative agent – Therapeutic interchange?	Sacituzumab govitecan-hziy (Trodelvy)
Dosage forms/strengths	Injection: 100 mg lyophilized powder in a single-dose vial
Common Dose/sig	6 mg/kg (up to a maximum of 540 mg for patients weighing 90 kg or more) administered as an IV infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Daratumumab, dinutuximab, fam-trastuzumab deruxtecan
Clinical Use Evaluation	
Common Adverse Effects	>10%: stomatitis, nausea, constipation, vomiting, diarrhea, abdominal pain, fatigue, alopecia, rash, dry eye, keratitis, decreased appetite, cough, COVID-19; laboratory abnormalities >30%: decreased leukocytes, decreased lymphocytes, decreased hemoglobin, decreased neutrophils, decreased calcium
Severe Adverse Effects	Interstitial lung disease/pneumonitis, stomatitis, vomiting, fatigue, rash
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.	Hematology and chemistry as clinically indicated; extensive ophthalmologic assessments required
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	No renal dose adjustment for CrCl of 30-90 mL/min but monitor for increased adverse effects; effect of severe renal impairment (under 30 mL/min) is unknown. No dosage adjustment for mild hepatic impairment; patients with moderate to severe impairment should be monitored for increased side effects.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications. Monitor for interstitial lung disease/pneumonitis, ocular adverse effects and stomatitis. It can cause embryo-fetal toxicity.
Special administration technique or considerations	Administer in a setting where cardiopulmonary resuscitation medication and equipment are available. Premedicate and treat concomitantly with preservative-free lubricant eyedrops, steroid-containing mouthwash, antihistamine, acetaminophen, and antiemetics. The first infusion should be over 90 minutes, then second and third infusion infused over 30 minutes. Monitor for infusion reactions for at least 1 hour for the first 2 cycles; if there are no reactions, monitor for at least 30 minutes for subsequent infusions. Dosage modifications recommended for adverse reactions.
Prepared by	Connor Turner
Source	Datroway (datopotamab deruxtecan-dInk) [prescribing information]. Basking Ridge, NJ: Daiichi Sankyo Company, Ltd.; January 2025.

Treosulfan/Grafapex/Medexus Pharma Inc	
Generic Name / Brand Name / Company	Treosulfan/Grafapex/Medexus Pharma Inc
Date of approval	1/21/25
Drug Class (Mechanism of Action if novel agent)	Alkylating agent
Indication	Use in combination with fludarabine as a preparative regimen for allogenic hematopoietic stem cell transplantation in adult and pediatric patients with acute myeloid leukemia or myelodysplastic syndrome
Comparative agent – Therapeutic interchange?	Busulfan
Dosage forms/strengths	Injection: 1 g/vial and 5 g/vial as a lyophilized powder in a single use vial
Common Dose/sig	10 g/m ² body surface area per day as a 2-hour IV infusion, given on three consecutive days in conjunction with fludarabine before hematopoietic stem cell infusion day
DEA Schedule	NA
Date of market availability	April 2025
Similar Medication Names	Gabapentin, Tremfya
Clinical Use Evaluation	
Common Adverse Effects	≥20%: Musculoskeletal pain, stomatitis, pyrexia, nausea, edema, infection, and vomiting; common severe laboratory abnormalities (>5%): increased GGT, increased bilirubin, increased ALT
Severe Adverse Effects	Second malignancy, cardiac failure, pericardial effusion, embolism, pneumonitis, pleural effusion, acute kidney injury, tissue necrosis, dermatitis, infection, febrile neutropenia, hypertension, hepatotoxicity
Severe Drug-Drug Interactions	Treosulfan is a CYP2C19 and CYP3A4 inhibitor, so it has interactions with CYP2C19 and CYP3A4 substrates.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Monitor blood cell counts daily
Used in Pediatric Areas	Used in patients 1 year of age and older with AML or MDS
Renal or Hepatic Dosing	No recommended dosage changes in renal or hepatic dysfunction, however, the effect of moderate or severe renal/hepatic impairment is unknown.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with hypersensitivity to any component of the drug product. Boxed warning for myelosuppression. Monitor for myelosuppression, seizures, skin disorders, injection site reactions, tissue necrosis and secondary malignancies. Don't use higher doses than recommended due to increased risk of early morbidity and mortality. There is a risk of embryo-fetal toxicity.
Special administration technique or considerations	Infuse over 2 hours. Confirm patency of IV line prior to infusion and monitor for extravasation during infusion. If extravasation occurs, stop the infusion.
Prepared by	Taylor Johnson
Source	Grafapex (treosulfan) [prescribing information]. Chicago, IL: Medexus Pharma Inc; February 2025.

Suzetrigine/Journavx/Vertex Pharmaceuticals	
Generic Name / Brand Name / Company	Suzetrigine/Journavx/Vertex Pharmaceuticals
Date of approval	1/30/25
Drug Class (Mechanism of Action if novel agent)	Selective Na _v 1.8 voltage-gated sodium channel blocker
Indication	Moderate to severe acute pain in adults
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Tablet: 50 mg
Common Dose/sig	Recommended starting dose of 100 mg orally, then 50 mg every 12 hours.
DEA Schedule	NA
Date of market availability	Late February 2025
Similar Medication Names	Sustenna, Sustiva, Susvimo, Jorveza, Jordyna, Jornay
Clinical Use Evaluation	
Common Adverse Effects	Pruritus (2%), muscle spasms (1.3%), increased blood creatine phosphokinase (1.1%), rash (1.1%)
Severe Adverse Effects	Rash, arrhythmia, decreased eGFR
Severe Drug-Drug Interactions	Strong/moderate CYP3A inhibitors and inducers: contraindicated with strong CYP3A inhibitors, reduce suzetrigine dose with moderate CYP3A inhibitors, avoid use with strong or moderate CYP3A inducers CYP3A substrates: dosage modifications may be required Hormonal contraceptives containing progestins other than levonorgestrel and norethindrone should use additional nonhormonal contraceptive or alternative hormonal contraceptive during concomitant use and for 28 days after suzetrigine discontinuation
Severe Drug-Food Interactions	Grapefruit containing food or drink should be avoided
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Creatine phosphokinase, eGFR
Used in Pediatric Areas	Safety and effectiveness have not been established
Renal or Hepatic Dosing	No renal dose adjustments but avoid use if eGFR less than 15 mL/min; has not been studied in patients with severe hepatic impairment. Those with moderate hepatic impairment may be at greater risk for side effects, those with mild impairment should receive the same dose as those with normal hepatic function. Avoid use in severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Concomitant use with strong CYP3A inhibitors is contraindicated. Avoid use in patients with severe hepatic impairment and adjust dose in moderate hepatic impairment due to potential for higher exposure to the medication and increased adverse effects. Patients may have to use alternative contraception if they currently use hormonal contraceptives.
Special administration technique or considerations	Swallow the tablets whole and do not chew or crush. Take the first dose on an empty stomach 1 hour before or 2 hours after food to avoid delay in onset of action, clear liquids may be consumed during that time frame. Subsequent doses may be taken with or without food. Avoid grapefruit juice. Take for the shortest duration possible; use beyond 14 days has not been studied.
Prepared by	Taylor Johnson
Source	Journavx (suzetrigine) [prescribing information]. Boston, MA: Vertex; January 2025.