



Highlights of FDA Activities – 4/1/26 – 4/30/26

FDA Drug Safety Communications & Drug Information Updates:

Product	Description	Date
TRUE METRIX Blood Glucose Monitoring Systems, Trividia Health: Safety Communication – Risks	The FDA is alerting consumers and healthcare providers of risks associated with use of the TRUE METRIX Blood Glucose Monitoring Systems that were recalled in February 2026. The FDA recommends all TRUE METRIX users transition to an alternative method of blood glucose monitoring, although they should not stop using the meter until they have an alternative method available for testing. Users at highest risk, including those who rely on intensive insulin therapy, sulfonylureas, or who have frequent hyper- or hypo-glycemic events, are particularly urged to transition to an alternative glucose monitoring system as soon as possible. Patients who continue to use a TRUE METRIX device prior to switching should be aware that an E-5 Error Code may mean that they have a very high glucose (>600 mg/dL) or that they have a test strip error in which case their blood glucose could be normal, high, or low. Any patient receiving an E-5 Error Code while experiencing symptoms of low or high blood glucose should immediately contact their healthcare provider.	4/28/26

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

Product	Description	Date Announced
Revitaderm and Tridergel Wound Care Gels (0.1% Benzalkonium Chloride), Blaine Labs Inc: Recall – Microbial Contamination	Blaine Labs Inc recalled three lots of Wound Care Gel products, 1 oz and 3 oz (0.1% benzalkonium chloride) to the consumer level due to detection of contamination with <i>Lysinibacillus fusiformis</i> . The recalled products are Revitaderm Wound Care Antiseptic Gel (1 oz and 3 oz, lots BL3608 and BL3525) and Tridergel Wound Care (1 oz, lot BL3435).	4/10/26
IVSTATION SYRINGE Sterile Label, Omnicell: Early Alert – Mislabeling Due to Inconsistent Label Detection	Omicell alerted customers to remove IVSTATION SYRINGE sterile label (40MMx40MM), part number 258920028, and IVSTATION SYRINGE sterile label (20 MMx40MM), part number 258920029, from use. Inconsistent label detection across i.v.STATION printers has been observed when using these sterile labels resulting in unlabeled or mislabeled syringes after compounding completion.	4/24/26

Product	Description	Date Announced
Lactated Ringer's Injection, B. Braun Medical: Recall – Particulate Matter	B. Braun Medical recalled two lots of Lactated Ringer's Injection, E7500 1 L (NDC 0264-7750-07, lots J4P756 and J4S843, expiration date 31May2027) due to the presence of particulate matter identified as cellulose and stearates with extremely low levels of inorganic matter such as copper.	4/28/26
Omnipod 5 Pods, Insulet Co.: Recall Update to Previous Early Alert	The FDA has posted an update to an Early Alert announced in March 2026, for Insulet's Omnipod 5 Pods (insulin delivery system; UDI 10385083000527). The affected pods contain tears in their internal mechanism, causing leakage of insulin within the pods and underdosing of insulin. A link to the full list of affected products can be found on the FDA website . Patients who have pods from lot numbers listed should discontinue use of those pods and ensure when changing pods that the replacement pod is not also affected by this recall. Patients may need alternative methods of insulin delivery while waiting for pods to be replaced.	4/29/26

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.

Product	Promoted Use	Undeclared Ingredient(s) or Contaminants
Addall XL 30 capsules	Focus	2-amino-6-methylheptane (DMHA), 1,4-dimethylamylamine (1,4-DMAA)
Addall XR orange-flavored shot	Focus	Phenibut (β -phenyl-GABA), 1,4-DMAA
Aller-C, Vital Nutrients*	Allergies	Egg, hazelnut, soy
Circuflex	Joint pain	Dexamethasone, diclofenac
DINA Acido Hialurónico	Joint pain	Dexamethasone, methocarbamol, meloxicam, phenolphthalein ²
DTF Sexual Chocolate*	Sexual enhancement	Sildenafil, tadalafil
Good Brain Tonic*	Memory and focus	<i>Botulism</i> potential
Kian Pee Wan*	Allergies	Dexamethasone, cyproheptadine
KUKA FLEX CBD	Joint pain	Diclofenac
RM Joe	Joint pain	Dexamethasone phosphate, diclofenac
UMARY products	Joint pain	Dexamethasone, diclofenac, omeprazole

Product	Promoted Use	Undeclared Ingredient(s) or Contaminants
WAP Sensual Enhancement	Sexual enhancement	Flibanserin, sildenafil, tadalafil
YEICOB Ácido Hialurónico	Joint pain	Dexamethasone phosphate, diclofenac

*recalled

¹DMHA, an unlawful ingredient in dietary supplements, and DMAA, an undeclared ingredient, can elevate blood pressure; phenibut, an unlawful ingredient in dietary supplements can cause neurocognitive side effects, addiction, and withdrawal symptoms

²Phenolphthalein was an over-the-counter laxative that is no longer marketed in the US due to carcinogenicity concerns

New Product Shortages (per FDA or ASHP)

Product	Date Initially Posted
Benzphetamine HCl tablets	4/7/26
Oxaliplatin injection	4/15/26
Ifosfamide injection	4/17/26
Morphine sulfate extended-release tablets	4/23/26
Romidepsin injection kits	4/28/26
Ioversol injection	4/30/26

[ASHP Drug Shortages List](#) contains up-to-date information on drug shortages

Brand Name or Sole Source Product Discontinuations/Withdrawals

Product	Date Posted
Idelalisib tablet (Zydelig, Gilead) – a generic remains available	4/7/26
Aprepitant oral powder for suspension (Emend, Merck Sharp & Dohme) – capsules remain available	4/8/26
Azithromycin tablet (Zithromax, Pfizer) – generics remain available	4/9/26
Leucovorin calcium tablets (Wellcovorin, GlaxoSmithKline) – FDA withdrew approval of the new drug application (NDA) at GSK's request; generics remain available	4/10/26
Nitroglycerin ointment 0.4% (Rectiv, AbbVie) – generic remains available	4/14/26
Rifampin injection (Rifadin, Sanofi-Aventis US) – generic remains available	4/20/26
Palbociclib capsule (Ibrance, Pfizer) – tablets continue to be available	4/22/26
Etravirine tablet (Intelence, Janssen) – generics remain available	4/28/26
Crinecerfont capsule 25 mg (Crenessity, Neurocrine Biosciences) – the 50 mg and 100 mg capsules and 50 mg/mL oral solution remain available	4/28/26

Removed/Restricted Indications

Product	Description	Date Announced
Selinexor/Xpovio/Karyopharm Therapeutics	Treatment of relapsed or refractory diffuse large B-cell lymphoma indication removed	4/30/26

New Drug Approvals

Product	Description (See Attached Drug Summaries)	Date Approved
Orforglipron/Foundayo/Eli Lilly & Co	Oral glucagon-like peptide-1 receptor agonist for use in combination with a reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long-term in adults with obesity or adults with overweight in the presence of at least one weight-related chronic condition	4/1/26
Doravirine and islatravir/Idvynso/Merck	HIV-1 nonnucleoside reverse transcriptase inhibitor and nucleoside analog reverse transcriptase inhibitor combination for the treatment of adults with HIV-1 who are virologically suppressed, as a replacement for their current antiretroviral regimen	4/21/26
Lunsotogene parvec-cwha/Otarmeni/Regeneron Pharmaceuticals	Gene therapy for the treatment of pediatric and adult patients with severe-to-profound and profound sensorineural hearing loss (any frequency >90 dB HL) associated with molecularly confirmed biallelic variants in the OTOF gene, preserved outer hair cell function, and no prior cochlear implant in the same ear	4/23/26

New Indications

Product	Description	Date Approved
Calcium hydroxylapatite/Radiesse/Merz Aesthetics	Dermal filler for the treatment of wrinkles in the décolleté area in patients 22 years and older	4/8/26
Faricimab-svoa/Vabysmo/Genentech	Removed limited six month duration specified for monthly dosing for the treatment of macular edema caused by retinal vein occlusion	4/9/26
Sparsentan/Filspari/Traverse Therapeutics	Treatment of focal segmental glomerulosclerosis	4/13/26
Landiolol/Rapiblyk/AOP Health US	Treatment of supraventricular tachycardia in pediatric patients from birth to 18 years	4/15/26
Ustekinumab/Stelara/Janssen Biotech	Treatment of moderately to severely active Crohn's disease in pediatric patients 2 years and older	4/15/26
Secukinumab/Cosentyx/Novartis	Treatment of ankylosing spondylitis in patients 12 years and older	4/17/26

Product	Description	Date Approved
Teplizumab-mzwv/Tzield/Provention Bio	To delay the onset of Stage 3 type 1 diabetes in pediatric patients 1 to 8 years of age with Stage 2 type 1 diabetes	4/20/26
Dupilumab/Dupixent/Regeneron Pharmaceuticals	Treatment of chronic spontaneous urticaria in pediatric patients 2 to 11 years of age who remain symptomatic despite treatment with histamine-1 antihistamines	4/22/26
Budesonide and formoterol fumarate/Symbicort Aerosphere/AstraZeneca	Treatment of asthma in adult and pediatric patients 12 years and older	4/27/26
Budesonide, formoterol fumarate, and glycopyrrolate/Breztri Aerosphere/AstraZeneca	Maintenance treatment of asthma in adult and pediatric patients 12 years and older	4/27/26
Dextromethorphan hydrobromide and bupropion hydrochloride (extended release)/Auvelity/Axome Therapeutics	First non-antipsychotic medication used to treat agitation associated with dementia due to Alzheimer's Disease.	4/30/26

New Dosage Forms or Formulation

Product	Description	Date Approved
Thrombin, Topical (Bovine) USP/Thrombin-JMI Liquid/Pfizer	Liquid thrombin formulation: 5,000 IU/vial and 20,000 IU/vial	4/10/26
Anifrolumab-fnia/Saphnelo/AstraZeneca Pharmaceuticals	Subcutaneous injection: 120 mg/0.8 mL in single-dose prefilled syringe or autoinjector; administered subcutaneously once weekly for treatment of moderate to severe systemic lupus erythematosus in patients receiving standard therapy	4/24/26

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New Drug Approvals: Drug Summaries

Orforglipron / Foundayo / Lilly USA

Date of approval	4/1/26
Drug Class/Mechanism of Action	Glucagon-like peptide-1 (GLP-1) receptor agonist
Indication	With a reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition
Comparative agent	Semaglutide
Dosage forms/strengths	Tablets: 0.8 mg, 2.5 mg, 5.5 mg, 9 mg, 14.5 mg, 17.2 mg
Common Dose/sig	Initiate therapy with 0.8 mg once daily. Dosage may be increased to next dosage level after at least 30 days on the current dose based on response and tolerability. Maximum dose is 17.2 mg once daily.
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	None identified

Clinical Use Evaluation

Common Adverse Effects (≥5%)	Nausea, constipation, diarrhea, vomiting, dyspepsia, abdominal pain, headache, abdominal distension, fatigue, eructation, gastroesophageal reflux disease, flatulence, hair loss
Severe Adverse Effects	Gastrointestinal reactions
Severe Drug-Drug Interactions	Strong CYP3A4 inhibitors – maximum orforglipron dose of 9 mg; avoid use with strong CYP3A4 inhibitors that also inhibit OATP1B CYP3A4 inducers – avoid concomitant use with strong inducers and monitor and escalate dose as needed with moderate inducers Simvastatin – do not exceed simvastatin 20 mg daily Gastric emptying – may be slowed and impact absorption of concomitant medications
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Monitor renal function in patients with adverse reactions that could lead to volume depletion. Monitor blood glucose in patients with diabetes.
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment recommended in renal impairment or in mild or moderate hepatic impairment. Not recommended in patients with severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2); known serious hypersensitivity to any product ingredient Boxed warning: risk of thyroid C-cell tumors

	<p>Warnings: acute pancreatitis, severe gastrointestinal reactions, acute kidney injury due to volume depletion, hypoglycemia, hypersensitivity reactions, diabetic retinopathy complications in patients with type 2 diabetes, acute gallbladder disease, pulmonary aspiration during general anesthesia or deep sedation.</p> <p>May cause fetal harm; discontinue when pregnancy recognized. Females using oral contraceptives should switch to non-oral contraceptive or add barrier method of contraception for 30 days after initiation and for 30 days after each dose escalation.</p>
Special administration technique or considerations	Take once daily with or without food. Swallow tablets whole. Do not take more than one tablet per day.
Source	Foundayo (orforglipron) [prescribing information]. Indianapolis, IN: Lilly USA LLC; April 2026.

Doravirine and Islatravir / Idvynso / Merck

Date of approval	4/21/26
Drug Class/Mechanism of Action	HIV-1 nonnucleoside reverse transcriptase inhibitor and nucleoside analog reverse transcriptase inhibitor
Indication	As a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically-suppressed on a stable antiretroviral regimen with no history of virologic treatment failure and no known substitutions associated with resistance to doravirine
Comparative agent	Demonstrated noninferiority to bicitgravir/emtricitabine/ tenofovir alafenamide
Dosage forms/strengths	Tablets: 100 mg doravirine/0.25 mg islatravir
Common Dose/sig	One tablet orally once daily
DEA Schedule	N/A
Date of market availability	After 5/11/26
Similar Medication Names	Doravirine, lamivudine, and tenofovir disoproxil

Clinical Use Evaluation

Common Adverse Effects (1-3%)	Diarrhea, dizziness, fatigue, abdominal distension, headache, increased weight
Severe Adverse Effects	Skin reactions including Stevens-Johnson syndrome/toxic epidermal necrolysis and Drug Rash with Eosinophilia and Systemic Symptoms (DRESS); immune thrombocytopenia
Severe Drug-Drug Interactions	Contraindicated with CYP _{3A} enzyme inducers, or with lamivudine or emtricitabine; additional doravirine 100 mg dose daily recommended if taken with rifabutin
Severe Drug-Food Interactions	None known
Important Labs Monitoring	HIV-1 RNA

Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments in mild to moderate renal or hepatic impairment; use not recommended in severe renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: with concomitant CYP ₃ A inducers, lamivudine, or emtricitabine Warnings: discontinue immediately if signs or symptoms of severe skin reactions
Special administration technique or considerations	Taken at a regularly scheduled time daily with or without food.
Source	Idvynso (doravirine/islatravir) [prescribing information]. Rahway, NJ: Merck Sharp & Dohme LLC; April 2026.

Lunsotogene parvec-cwha / Otarmeni / Regeneron Pharmaceuticals

Date of approval	4/23/26
Drug Class/Mechanism of Action	Adeno-associated virus vector-based gene therapy results in expression of the otoferlin protein (OTOF) gene facilitating production of functional otoferlin protein and restoring synaptic transmission to the auditory nerve
Indication	Gene therapy treatment for pediatric and adult patients with severe-to-profound and profound sensorineural hearing loss (any frequency >90 dB HL) associated with molecularly confirmed biallelic variants in the OTOF gene, preserved outer hair cell function, and no prior cochlear implant in the same ear
Comparative agent	None
Dosage forms/strengths	For intracochlear infusion only; 2 mL vial with 0.63 extractable volume
Common Dose/sig	7.2×10^{12} vector genomes (vg) in a total volume of 0.24 mL infused intracochlearly at 0.9 mL/hr
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Lunsumio Velo

Clinical Use Evaluation

Common Adverse Effects	Otitis media (38%), vomiting (33%), nausea (29%), dizziness (21%), procedural pain (17%), gait disturbance (8%), nystagmus (8%)
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	NA
Severe Drug-Food Interactions	NA
Important Labs Monitoring	Monitor patients for surgical (procedure-related) adverse reactions.
Used in Pediatric Areas	Use in ages 10 months to 16 years has been established as safe and effective.
Renal or Hepatic Dosing	NA

Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. Not recommended in patients in whom preoperative imaging demonstrates access to the inner ear is not feasible. Procedure-related (surgical) risks may include vertigo, tinnitus, cerebral spinal fluid leak, ipsilateral facial paresis, ipsilateral change in taste, meningitis, wound infection, mastoiditis, numbness around ear, blood or fluid at surgical site, labyrinthitis.
Special administration technique or considerations	Administer under general anesthesia by surgeon experienced in intracochlear surgery. Bilateral administration should be in the same, single session, if applicable. Each vial is one dose (unilateral). Use oral corticosteroids (at equivalent strength of prednisone 1 mg/kg/day not to exceed 60 mg/day) the day of infusion and for two weeks and taper for following two weeks. Administer antibiotic prophylaxis prior to incision. Patients must get appropriate vaccinations including anti-meningitis-associated microorganisms at a minimum of 1 month prior to receiving corticosteroid use, and at a minimum of 1 month after the cessation of corticosteroid use. Follow detailed instructions for product preparation and administration using the supplied administration kit.
Source	Otarmeni (lunsotogene parvec-cwha) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals; April 2026.