Highlights of FDA Activities – 6/1/26 – 6/30/26

FDA Drug Safety Communications & Drug Information Updates:

Product	Description	Date of Update
OTC Skin Lightening Products: Drug Safety/Health Fraud – Mercury	The FDA advised consumers not to use over-the-counter (OTC) skin lightening products due to high levels of mercury and/or hydroquinone. There are no FDA-approved or legally marketed OTC skin lightening products. A recent round of laboratory testing found high levels of mercury and/or hydroquinone in some products.	6/1/26
Orlistat: Drug Safety Communication – Risk of Kidney Stones and Kidney Injury	The FDA approved changes to the OTC labeling for the weight loss drug orlistat (alli) to warn of risks of acute kidney injury. Consumers are advised to ask a health care provider before using OTC orlistat if they have ever had kidney disease or kidney stones, and advised to stop using the drug and ask a doctor if they develop symptoms of acute kidney injury such as back or groin pain, painful urination, blood in the urine, feet and leg swelling, or less frequent urination. Labeling for the OTC product now contains the same cautions regarding kidney injury as those in the prescription higher strength orlistat product.	6/10/26
Implementation of Isotretionoin iPLEDGE REMS Modifications Delayed	The FDA announced implementation of iPLEDGE REMS modifications scheduled to go into effect 8/8/26 have been delayed until 11/15/26 to allow additional time for system updates and to ensure patients have uninterrupted access to isotretinoin. Until the modifications are fully implemented, the FDA will continue to exercise enforcement discretion regarding pregnancy testing.	6/16/26
Isotretinoin Labeling Updates	The FDA has requested manufacturers of generic Accutane (isotretinoin) capsules update the labeling to convert the format to the Physician Labeling Rule format to meet current requirements, be consistent with other drugs containing the drug or in the same class, have enhanced clarity in the Warnings and Precautions and Drug Interactions sections, and have updated adverse reaction descriptions.	6/17/26

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

Product	Description	Date Announced
BD Spinal Trays Containing Bupivacaine Ampules, Becton Dickinson: Recall – Kit Correction due to Drug Ineffectiveness	Becton Dickenson issued an anesthesia kit correction for BD spinal trays containing bupivacaine ampules due to quality issues and reports of drug ineffectiveness. The kits are not recalled, but bupivacaine ampules should be removed from BD Spinal Tray with BD Whitacre Needle, BDF Spinal Tray with BD Quincke Needle, and BD Spinal Tray with Sprotte Needle. The remaining components within the kits may continue to be used.	6/3/26
Omnipod Insulin Pumps, Insulet: Recall – Early Alert due to Tubing Tears and Insulin Leaks	Insulet notified users that certain Omnipod 5 Automated Insulin Delivery System, Omnipod Dash Insulin Management System, and Omnipod Insulin Management System (Omnipod Eros) lots may have tubing tears than could result in insulin leakage. All Pods should be checked to see if they are in the list of affected lots. If a Pod is from an affected lot, it should not be used.	6/4/26
Gas-X Extra Strength Softgels, Haleon: Recall – Potential Chemical Contamination	Haleon recalled 4 lots of Gas-X Extra Strength Softgels 125 mg, 120 count and 72 count due to potential contamination with a diluted propylene glycol-based coolant from a machine leakage during the packaging process. The recalled products are 120 count packages (lots TL8K, YH9X, YH9Y, with expiration 30 Nov 2028) distributed from 4/13/26 to 5/5/26 and 72 count packages (lot X78N, expiration 30 Nov 2028) distributed from 5/5/26 to 5/14/26.	6/4/26
ChloraPrep Clear and FREPP Clear Applicators, BD: Recall – Microbial Contamination	BD recalled lot 4032183 of ChloraPrep Clear 1 mL Single Sterile and lot 4073005 of FREPP Clear 1.5 mL applicators with paper lidding due to fungal contamination allowing growth of *Aspergillus penicillioides*. The two lots were distributed between March 2024 and June 2024 and have an expiry date in 2027.	6/8/26
Beekeeper's Naturals Saline Nasal Spray: Recall – Microbial Contamination	Beekeeper's Naturals recalled lot #5950 of Beekeeper's Naturals Saline Nasal Spray, expiration date 02/2028, sold through Amazon to the consumer level due to microbial contamination with *Aspergillus* spp.	6/12/26
Convenience Kits Containing Bupivacaine HCl in Dextrose Injection, USP, Medline: Recall – Kit Correction due to Quality Issues	Medline recommended certain convenience kits containing Bupivacaine HCl in Dextrose Injection, USP, manufactured by Huons Co., Ltd, be corrected prior to continued use by removing the included bupivacaine injection. A link to the complete list of affected kits can be found on the	6/12/26

Product	Description	Date Announced
	FDA website. An FDA inspection of the Huons manufacturing facility revealed quality issues.	
Nara Organics Whole Milk Infant Formula: Recall – *Clostridium botulinum* Contamination	Nara Organics recalled all lots of Nara Organics Powdered Whole Milk Infant Formula (400 g and 700 g) due to potential risk of *Clostridium botulinum* contamination. The infant formula was distributed nationally across Target retail stores, Target.com, and Nara.com between July 2025 and June 2026. Three cases of infant botulism in infants who consumed the formula have been reported in California, Washington, and Pennsylvania; the three specific product lots these infants were exposed to are: 70912528oE, 709125288E14F2, and 708125174E14F2. Customers should stop using the formula immediately. Infants who have consumed the product should be closely observed for symptoms of infant botulism. Additional information can be found on the FDA site.	6/23/26
Convenience Kits Containing Webcol Large Alcohol Prep Pads, Windstone Medical Packaging: Recall – Kit Correction due to Contamination -	Windstone Medical Packaging Inc issued an alert advising customers with convenience kits containing Cardinal Health Webcol Large Alcohol Prep Pads to remove the pads from use due to potential contamination with *Paenibacillus phoenicis*. Affected kits are DSAEK Pack – RX, Thyroid FNA Pack – RX, Preop Kit – NS, and Dr. Lewin Pack. The remaining kit components may be used after removing and discarding the pads.	6/16/26

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
Branch Manager for Men	Sexual enhancement	Yohimbine[1]
Business Pill	Sexual enhancement	Yohimbine[1]
Doctor's Pride Ultra Potent Complete Green Superfood Moringa Capsules*	Herbal supplement	Salmonella
juicy af!	Sexual enhancement	Sildenafil
Lipofit Extreme 2.0 Fat Burner	Weight loss	Fluoxetine, 2,4-dinitrophenol (DNP)[2]
Pink Pussycat brand products	Sexual enhancement	Sildenafil, tadalafil
Pre-Formance Black	Increase performance	1,4-dimethylamylamine (DMAA)[3]
TNVitamins 100% Organic Moringa 1,200 mg Capsules*	Herbal supplement	Salmonella

Product	Promoted Use	Undeclared Ingredient(s) or Contaminants
TNVitamins 100% Organic Moringa Powder*	Herbal supplement	Salmonella
TNVitamins Ultra Potent Complete Green Superfood Moringa Capsules*	Herbal supplement	Salmonella

**recalled*

[1]yohimbine is a plant-derived chemical once used as a prescription erectile dysfunction medication but since replaced by safer medications; the listed products contain high levels of yohimbine which can cause severe high blood pressure, irregular heartbeat, seizures, mania or psychosis, and drug interactions with caffeine, ADHD medications, and other medications

[2]DNP is a toxic substance commonly used as a pesticide, dye, wood preservative, and herbicide that is not FDA-approved for any use; short-term exposure can cause nausea, vomiting, sweating, dizziness, headaches and long-term exposure can damage the eyes, skin, bone marrow, nervous system and heart. Toxicity can cause dangerous high body temperature, rapid heart rate and breathing, cardiac arrest, and death.

[3]DMAA or "geranium extract" is an amphetamine derivative that can elevate blood pressure, and can cause cardiovascular effects as well as seizures and other neurological and psychological conditions.

New Product Shortages (per FDA or ASHP)

Product	Date Initially Posted
Estradiol vaginal cream	6/6/26
Ifosfamide injection	6/12/26
Fluorescein sodium and benoxinate hydrochloride ophthalmic solution	6/16/26
Aluminum chloride hexahydrate topical solution	6/23/26
Activated charcoal oral suspension	6/23/26

ASHP Drug Shortages List contains up-to-date information on drug shortages

Brand Name or Sole Source Product Discontinuations/Withdrawals

Product	Date Posted
Clindamycin phosphate injection (Cleocin, Pfizer); generics remain available	6/1/26
Semaglutide tablet (Rybelsus, Novo Nordisk); Rybelsus will be replaced by Ozempic (semaglutide) tablets.	6/4/26
Dacomitinib tablet (Vizimpro, Pfizer); patients will need to be switched to an alternative therapy	6/8/26
Leflunomide tablet (Arava, Sanofi-Aventis US); generics remain available	6/8/26
Lorlatinib tablet 25 mg in bottles of 120 (Lorbrena, Pfizer); bottles of 30 will continue to be manufactured	6/15/26
Emtricitabine capsule (Emtriva, Gilead); generics remain available	6/17/26

New Drug Approvals

Product	Description (See Attached Drug Summaries)	Date Approved
Bemotrizinol/Parasol Shield/DSM-Firmenich	New active sunscreen ingredient added to the over-the-counter sunscreen drug products monograph at concentrations up to 6%; to be included in sunscreen products starting 8/9/26	6/10/26
Tebipenem pivoxil/Utebzi/GSK	Oral carbapenem for the treatment of complicated urinary tract infections in adults who have limited or no alternative treatment options	6/17/26
Veligrotug-vvze/Lumvoa/Viridian Therapeutics	Insulin-like growth factor-1 receptor inhibitor for treatment of thyroid eye disease	6/26/26
Allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq/Tregzi/Orca Bio	T-cell based immunotherapy with hematopoietic stem and progenitor cells and T cells for use in matched donor hematopoietic stem cell transplantation (HSCT) with myeloablative preparative regimen, for hematopoietic and immunologic reconstitution and to improve chronic graft-versus-host (GVHD) disease-free survival in the treatment of adults with hematologic malignancies	6/30/26

New Indications

Product	Description	Date Approved
Marstacimab-hncq/Hympavzi/Pfizer	Treatment of hemophilia A or B with or without inhibitors in patients 6 years and older	6/8/26
Belzutifan/Welireg/Merck	In combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for the adjuvant treatment of adults with clear cell renal cell carcinoma at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions	6/12/26
Pembrolizumab/Keytruda/Merck and berahyaluronidase alfa-pmph/ Keytruda Qlex/Merck	In combination with belzutifan for the adjuvant treatment of adults with clear cell renal cell carcinoma at intermediate-high or high risk at intermediate or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions	6/12/26
Capivasertib/Truqap/AstraZeneca	For use in combination with abiraterone and prednisone for the treatment of adults with PTEN-deficient metastatic androgen pathway modulation-naïve or sensitive prostate cancer	6/12/26
Teplizumab/Tzield/Provention Bio Inc	To delay the decline in endogenous insulin production in pediatric patients 8 to 17 years of age recently diagnosed with Stage 3 type 1 diabetes	6/12/26

Product	Description	Date Approved
Hyaluronic acid/Skinvive by Juvederm/Allergan Aesthetics	To reduce neck lines for the improvement of neck appearance in adults over the age of 21	6/16/26
Afamitresgene autoleucel/Tecelra/ USWM CT LLC	Treatment of pediatric patients 12 years and older with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive, and whose tumor expresses the MAGE-A4 antigen	6/18/26
Pneumococcal 21-valent conjugate vaccine/Capvaxive/Merck	Active immunization for the prevention of invasive pneumococcal disease caused by *Streptococcus pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F and 35B in individuals 2 through 17 years of age who are at increased risk for pneumococcal disease	6/18/26
Olezarsen/Tryngolza/Ionis Pharmaceuticals	With diet to reduce triglycerides and the risk of acute pancreatitis in adults with severe hypertriglyceridemia	6/24/26
Palbociclib/Ibrance/Pfizer	In combination with trastuzumab, with or without pertuzumab, and endocrine therapy for the maintenance treatment of adults with hormone receptor-positive, HER2-positive locally advanced or metastatic breast cancer following induction treatment	6/24/26
Pembrolizumab/Keytruda/Merck and berahyaluronidase alfa-pmph/ Keytruda Qlex/Merck	In combination with Sacituzumab govitecan-hziy for the first line treatment of adults with unresectable locally advanced or metastatic triple-negative breast cancer whose tumors express PD-L1	6/24/26
Sacituzumab govitecan-hziy/ Trodelvy/Gilead Sciences	As monotherapy for the first-line treatment of adults with unresectable locally advanced or metastatic triple-negative breast cancer who are not candidates for PD-1 or PD-L1 inhibitor-based therapy	6/24/26
Sacituzumab govitecan-hziy/ Trodelvy/Gilead Sciences	With pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for the first-line treatment of adults with unresectable locally advanced or metastatic triple-negative breast cancer whose tumors express PD-L1	6/24/26
Risankizumab-rzaa/Skyrizi/AbbVie	Children 6 years and older with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy or with active psoriatic arthritis	6/26/26
IncobotulinumtoxinA/Xeomin/Merz Therapeutics	To treat increased muscle stiffness in the arm because of upper limb spasticity in children and adolescents 2 years and older with cerebral palsy	6/26/26

Product	Description	Date Approved
Roflumilast/Zoryve/Arcutis	Cream 0.3% indicated for treatment of plaque psoriasis in children 2 years and older	6/30/26

New Dosage Forms or Formulation

Product	Description	Date Approved
Naloxone/Rextovy/International Medication Systems Ltd	Nasal spray: 4 mg; now available OTC for emergency treatment of opioid overdose	6/16/26

Compiled by:

Terri Levien, Pharm.D.

Dr Danial Baker Drug Information and Telehealth 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

New Drug Approvals: Drug Summaries

Tebipenem pivoxil/Utebzi/GSK

Date of approval	6/17/26
Drug Class/Mechanism of Action	Oral penem antibiotic
Indication	Treatment of complicated urinary tract infections, including pyelonephritis, caused by susceptible *Escherichia coli*, *Klebsiella pneumonia*, *Enterobacter cloacae* species complex, *Klebsiella oxytoca*, and *Enterococcus faecalis* in adults who have limited or no alternative oral treatment options
Comparative agent	Ertrapenem
Dosage forms/strengths	Tablets: 300 mg
Common Dose/sig	600 mg orally every 6 hours for 7 to 10 days (if eGFR 60-150 mL/min)
DEA Schedule	N/A
Date of market availability	By end of 2026
Similar Medication Names	None identified

Clinical Use Evaluation

Common Adverse Effects	Diarrhea (8%), headache (3%), nausea (1%), abdominal pain (1%), hepatic enzyme increased (1%), *Clostridioides difficile* infection (1%)
Severe Adverse Effects	None reported – see warnings for potential severe events
Severe Drug-Drug Interactions	Valproic acid or divalproex sodium: serum concentrations may be reduced increasing the risk of seizures OAT1 and OAT3 inhibitors: increased tebipenem concentrations
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Culture and sensitivity; renal function to determine dosing
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	300 mg every 6 hours for eGFR 30-59 mL/min and every 12 hours for eGFR 15-29 mL/min; not recommended if eGFR > 150 mL/min due to decreased exposure/reduced efficacy. No dosing adjustments in hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: hypersensitivity to tebipenem or other beta-lactams; patients with carnitine deficiency or inborn error of metabolism that may result in clinically significant carnitine deficiency Warnings: Hypersensitivity reactions Seizures Concomitant use with valproic acid or divalproex sodium Secondary carnitine deficiency *C. difficile* infection Interference with newborn screening test for isovaleric acidemia
Special administration technique	May take with or without food. Do not use for more than 10 days.
Source	Utebzi (tebipenem pivoxil) [prescribing information]. Durham, NC: GlaxoSmithKline; June 2026.

Veligrotug-vvze/Lumvoa/Viridian Therapeutics

Date of approval	2/26/26
Drug Class/Mechanism of Action	Insulin-like growth factor-1 receptor inhibitor
Indication	Treatment of thyroid eye disease regardless of thyroid eye disease activity or duration
Comparative agent	Teprotumumab-trbw (Tepezza)
Dosage forms/strengths	Injection: 500 mg/10 mL solution in single-dose vial
Common Dose/sig	10 mg/kg by IV infusion every 3 weeks for a total of 5 infusions
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	None identified

Clinical Use Evaluation

Common Adverse Effects	Muscle spasms (40%), menstrual disorders (29%), headache (17%), hearing impairment (15%), hyperglycemia (13%), fatigue (13%), diarrhea (11%), ear discomfort (10%), infusion reaction (9%), nausea (8%), nasopharyngitis (7%), increased creatine phosphokinase (6%), dry skin (6%), hypertension (6%)
Severe Adverse Effects	Severe hearing impairment and hearing loss
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Blood glucose
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments necessary in renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindication: none in prescribing information Warnings: Infusion reactions Inflammatory bowel disease Hyperglycemia Hearing impairment and hearing loss Embryo-fetal toxicity – advise use of contraception during & 6 months after the last dose
Special administration technique or considerations	Infuse over 45 minutes for first infusion; if well tolerated subsequent infusions can be administered over a minimum of 30 minutes.
Source	Lumvoa (veligrotug-vvze) [prescribing information]. Waltham, MA: Viridian Therapeutics Inc; June 2026.

Allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq/Tregzi/Orca Bio

Date of approval	6/30/26
Drug Class/Mechanism of Action	T-cell based immunotherapy
Indication	Use in matched donor HSCT with myeloablative preparative regimen, for hematopoietic and immunologic reconstitution and to improve chronic GVHD-free survival in treatment of adults with hematologic malignancies
Comparative agent	None
Dosage forms/strengths	Suspension for IV infusion, supplied in 4 patient specific infusion bags: hematopoietic stem and progenitor cells (HSPCs), regulatory T cells (Tregs), conventional T cells (Tcons), and Tcon diluent
Common Dose/sig	HSPCs IV once on day 0 (at least 1 x 106 cells per kg), Tregs IV once on day 0 immediately after HSPCs (1.3 x 106 to 3.5 x 106 cells per kg), Tcons IV once on day +2 and +3 (1.3 x 106 to 6.9 x 106 cells per kg)
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Trelegy

Clinical Use Evaluation

Common Adverse Effects (rates and nature were similar to control group)	Mucositis (85%), diarrhea (69%), rash (65%), viral infections (51%), unspecified infections (45%), abdominal pain (45%), vomiting (44%), nausea (41%), bacterial infections (40%), hemorrhage (39%), acute GVHD (38%), edema (30%), fungal infection (20%)
Severe Adverse Effects	Mucositis, infections, hemorrhage, Grade 3-4 laboratory abnormalities (decreased lymphocytes, platelets, leukocytes, neutrophils, hemoglobin)
Severe Drug-Drug Interactions	None known; corticosteroids not recommended for premedication
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Complete blood counts
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	Contraindications: none in prescribing information Warnings: Graft failure – monitor closely for hematopoietic recovery GVHD – treat with a calcineurin inhibitor as prophylaxis Infusion reactions – monitor during and after administration Secondary malignancies and malignancies of donor origin – monitor Transmission of infectious agents – monitor for serious infection
Special administration technique or considerations	Confirm patient identifiers. Premedicate with diphenhydramine and/or acetaminophen approximately 30 minutes before HSPC and Tcon infusions. Central venous catheter access is recommended. Do not use a leukodepleting filter. Prime tubing and flush after administration with NS.
Source	Tregzi (allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq) [prescribing information]. Sacramento, CA: Orca; June 2026.