



Highlights of FDA Activities – 4/1/25 – 4/30/25

FDA Drug Safety Communications & Drug Information Updates:

Counterfeit Ozempic (semaglutide) Found in US Drug Supply Chain 4/14/25

The FDA became aware of and seized several hundred units of counterfeit Ozempic (semaglutide) 1 mg injection in the US drug supply chain; testing of the seized product is underway. The FDA advises patients, wholesalers, retail pharmacies, and health care professionals to check Ozempic products they have received and not use, distribute, or sell products labeled with lot #PAR0362 and a serial number starting with the first eight digits: 51746517. The FDA recommends pharmacies only purchase Ozempic through authorized distributors of Novo Nordisk and to confirm the legitimacy of their shipments. The FDA also advises patients to only obtain Ozempic with a valid prescription through state-licensed pharmacies.

Risks Associated with Compounded Topical Finasteride Products 4/22/25

The FDA alerted health care providers, compounders, and consumers regarding potential risks associated with compounded topical finasteride products marketed to treat hair loss. There is no FDA-approved topical formulation of finasteride. The FDA has received reports of adverse events associated with the use of compounded topical finasteride consistent with effects associated with systemic absorption including erectile dysfunction, anxiety, suicidal ideation, brain fog, depression, fatigue, insomnia, decreased libido, and testicular pain. Additional risks include local reactions and inadvertent exposure to others through transfer of applied product, which carries particular risk with exposure to pregnant females. The FDA advises health care providers educate patients on potential risks of using compounded finasteride and consumers should consult with health care providers regarding potential risks prior to initiation of treatment with topical finasteride. Adverse events or quality problems associated with compounded finasteride should be reported to the MedWatch Adverse Event Reporting program.

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

Ropivacaine hydrochloride injection USP 500 mg/100 mL, Amneal: Recall – Particulate Matter 4/18/25

Amneal Pharmaceutical recalled two lots of ropivacaine hydrochloride injection USP 500 mg/100 mL following detection of particulate matter identified as inert polypropylene fibers. Affected products include the 12x100 mL single dose IV bags (NDC 70121-17343), lots AL240003 (exp 01/2026) and AL240004 (exp 01/2026), distributed between 4/23/24 and 11/8/24.

PowerPICC Intravascular Catheter, Bard Access Systems: Recall Early Alert – Cracks 4/21/25

Bard Access Systems, a subsidiary of Becton Dickinson, issued a letter recommending unused PowerPICC Intravascular Catheters not be used and updating use instructions for those currently in use. An increase in material fatigue leaks associated with the catheters resulting in transverse/circumferential cracks in the catheter body has been observed. Ten serious injuries have resulted from this issue.

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. Products marked with * were recalled.

<u>Product</u>	<u>Promoted Use</u>	<u>Undeclared Ingredient(s) or Contaminants</u>
Male Ultra, Malextra, Electro Buzz, Ultra Armor, Male Ultra Pro, from Health Fixer*	Male enhancement	Chloropretadalafil, propoxyphenylsildenafil, sildenafil
Painflex Forte, NaTerra	Joint pain	Dexamethasone and diclofenac
Spermidine Maximum Strength 10 mg, Dorado Nutrition*	Supports healthy aging	Wheat (unlabeled allergen)

New Product Shortages (per FDA or ASHP)

	<u>Date Initially Posted</u>
Lanthanum carbonate	4/2/25
Morphine sulfate immediate-release tablets	4/6/25
Hydroxyethyl starch	4/9/25
Fluorescein sodium ophthalmic strips	4/9/25
Dexamethasone oral solution/elixir	4/16/25
Erythromycin lactobionate injection	4/21/25
Ephedrine injection	4/21/25

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

Brand Name or Sole Source Product Discontinuations/Withdrawals

	<u>Date Posted</u>
Haloperidol decanoate injection (Haldol, Janssen); generic remain available	4/7/25
Zileuton tablet (Zyflo, Chiesi USA); no alternative zileuton formulations available	4/1/25
Topiramate extended-release capsule (Qudexy XR, Upsher-Smith); generic remains available	4/24/25

New Drug Approvals:

<u>Description (See Attached Drug Summaries)</u>	<u>Date Approved</u>
Atrasentan/Vanrafia/Novartis	4/2/25
Endothelin receptor antagonist to reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk of rapid disease progression	
Penpulimab-kcqx/Anniko/Akeso	4/23/25
Programmed death receptor (PD-1) blocking antibody for use with cisplatin or carboplatin and gemcitabine for first-line treatment of recurrent or metastatic non-keratinizing nasopharyngeal carcinoma (NPC) or as a single agent in patients with NPC with disease progression on or after platinum-based chemotherapy and with at least one other prior line of therapy	
Prademagene zamikeracel/Zevaskyn/Abeona Therapeutics	4/29/25
Gene therapy for treatment of dystrophic epidermolysis bullosa	
Nipocalimab-aahu/Imaavy/Johnson & Johnson	4/29/25
Neonatal Fc receptor blocker for the treatment of generalized myasthenia gravis in patients 12 years and older who are anti-acetylcholine receptor or anti-muscle-specific kinase antibody positive	

New Indications:

<u>Description</u>	<u>Date Approved</u>
Tedizolid phosphate/Sivextro/Merck	4/4/25
Indication expanded to include treatment of acute bacterial skin and skin structure infections in pediatric patients at least 26 weeks gestational age and weighing at least 1 kg	
Dexamethasone ophthalmic insert/Dextenza/Ocular Therapeutix	4/7/25
Indication expanded to include use in pediatric patients for the treatment of ocular inflammation and pain following ophthalmic surgery and in pediatric patients 2 years and older for the treatment of ocular itching associated with allergic conjunctivitis	
Diazepam/Valtoco/Neurelis	4/15/25
Indication expanded to include use for acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern in patients 2 years and older with epilepsy	
Osilodrostat/Isturisa/Recordati	4/16/25
Treatment of endogenous hypercortisolemia in adults with Cushing syndrome for whom surgery is not an option or has not been curative	

<u>New Indications: (continued)</u>	<u>Description</u>	<u>Date Approved</u>
Palonosetron/Posfrea/Avyxa Pharma	Indication expanded to include use for the prevention of acute nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy in pediatric patients 1 month to less than 17 years of age	4/16/25
Dupilumab/Dupixent/Sanofi	Treatment of chronic spontaneous urticaria in patients 12 years and older	4/18/25
Upadacitinib/Rinvoq/AbbVie	Treatment of giant cell arteritis	4/29/25

<u>New Dosage Forms or Formulation:</u>	<u>Description</u>	<u>Date Approved</u>
Diazepam/Libervant/Aquestive	Buccal film: 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg; acute treatment of intermittent, stereotypical episodes of frequent seizure activity that are distinct from the patient's usual seizure pattern in patients 2 to 5 years of age with epilepsy (status subsequently changed to tentative approval)	4/2/25
Metoprolol tartrate/Lopressor/Advagen	Oral solution: 10 mg/mL; for the treatment of hypertension, angina pectoris, or myocardial infarction	4/10/25
Maralixibat/Livmarli/Mirum	Tablets: 10 mg, 15 mg, 20 mg, 30 mg; treatment of cholestatic pruritus in patients 3 months and older with Alagille syndrome and treatment of cholestatic pruritus in patients 12 months and older with progressive familial intrahepatic cholestasis	4/14/25
Aripiprazole/Mezofy/CMG Pharmaceutical	Oral film: 5 mg, 10 mg, 15 mg; treatment of schizophrenia	4/15/25
Apixaban/Eliquis/Bristol-Myers Squibb	Tablets for oral suspension: 0.5 mg tablet in packet Powder for oral suspension (Eliquis Sprinkle): 0.15 mg capsule; indication expanded for 2.5 mg and 5 mg tablets and these formulations to include use for the treatment of venous thromboembolism (VTE) and reduction in the risk of recurrent VTE in pediatric patients from birth and older after at least 5 days of initial anticoagulant treatment	4/17/25
Meloxicam/Qamzova/Nanjing Delova Biotech	Injection: 30 mg/mL single dose vial; for use in adults for management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics	4/22/25
Dihydroergotamine/Atzumi/Satsuma Pharmaceuticals	Nasal powder: 5.2 mg; acute treatment of migraine with or without aura in adults	4/30/25

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Atrasentan/Vanrafia/Novartis	
Generic Name / Brand Name / Company	Atrasentan/Vanrafia/Novartis
Date of approval	4/2/25
Drug Class (Mechanism of Action if novel agent)	Endothelin receptor antagonist
Indication	Reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk of rapid disease progression, generally a urine protein-to-creatinine ratio of 1.5 g/g or greater; granted accelerated approval, data demonstrating slowed kidney function decline necessary for continued approval.
Comparative agent – Therapeutic interchange?	Iptacopan, budesonide, sparsentan
Dosage forms/strengths	Tablets: 0.75 mg
Common Dose/sig	0.75 mg orally once daily
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Vafseo
Clinical Use Evaluation	
Common Adverse Effects	≥5%: peripheral edema, anemia
Severe Adverse Effects	Hepatotoxicity has been observed with other drugs in this class, but not with atrasentan at this time
Severe Drug-Drug Interactions	Strong or moderate CYP3A inducers: avoid concomitant use OATP1B1/1B3 inhibitors (eg, cyclosporine): avoid concomitant use
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Pregnancy test; liver function tests before initiating and as clinically indicated.
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment in mild to severe renal impairment or mild to moderate hepatic impairment. Avoid use in severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in pregnancy and patients with history of hypersensitivity to atrasentan or any product ingredient. Warnings: hepatotoxicity, fluid retention, and decreased sperm counts. May cause fetal harm. Advise use of effective contraception before initiation, during treatment, and for 2 weeks after discontinuation. Advise not to breastfeed.
Special administration techniques or considerations	Store and dispense in the original container. Administer with or without food. Swallow tablets whole.
Prepared by	Terri Levien
Source	Vanrafia (atrasentan) [prescribing information]. East Hanover, NJ: Novartis; April 2025.

Penpulimab-kcqx/Anniko/Akeso	
Generic Name / Brand Name / Company	Penpulimab-kcqx/Anniko/Akeso
Date of approval	4/23/25
Drug Class (Mechanism of Action if novel agent)	PD-1 blocking antibody
Indication	Use with cisplatin or carboplatin and gemcitabine for first-line treatment of recurrent or metastatic non-keratinizing nasopharyngeal carcinoma (NPC) or as a single agent in patients with NPC with disease progression on or after platinum-based chemotherapy and with at least one other prior line of therapy
Comparative agent – Therapeutic interchange?	Toripalimab-tpzi
Dosage forms/strengths	Injection: 100 mg/10 mL (10 mg/mL) single-dose vial
Common Dose/sig	In combination with chemotherapy: 200 mg IV every 3 weeks Single agent: 200 mg IV every 2 weeks
DEA Schedule	N/A
Date of market availability	To be determined
Similar Medication Names	Anakinra
Clinical Use Evaluation	
Common Adverse Effects	In combination with chemotherapy ($\geq 20\%$): nausea, vomiting, hypothyroidism, constipation, decreased appetite, decreased weight, cough, COVID-19 infection, fatigue, rash, pyrexia Single agent ($\geq 20\%$): anemia, hypothyroidism
Severe Adverse Effects	Immune-mediated adverse reactions, infusion reactions
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.	Liver enzymes, creatinine, thyroid function at baseline and periodically during treatment; verify pregnancy status prior to initiating therapy
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment in mild or moderate hepatic or renal impairment; the effects of severe hepatic or renal impairment on the pharmacokinetics of penpulimab-kcqx are not known. Withhold or discontinue use in patients with immune-mediated hepatic or renal adverse reactions.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Warnings: immune-mediated adverse reactions, infusion reactions, increased risk of complications in patients receiving allogeneic HSCT before or after PD-1 blocking antibody; embryo-fetal harm
Special administration technique or considerations	Dilute in 0.9% sodium chloride injection prior to administration. Infuse over 60 minutes through an IV line containing a 0.2 micron or 0.22 micron in-line or add-on filter. Adjust dosage or discontinue therapy for severe adverse reactions (see product labeling).
Prepared by	Terri Levien
Source	Penpulimab-kcqx [prescribing information]. Zhongshan, Guangdong, China: Akeso Biopharma Co, Ltd; April 2025.

Prademagene zamikeracel/Zevaskyn/ Abeona Therapeutics	
Generic Name / Brand Name / Company	Prademagene zamikeracel/Zevaskyn/ Abeona Therapeutics
Date of approval	4/29/25
Drug Class (Mechanism of Action if novel agent)	Autologous cell sheet-based gene therapy, functional copies of the COL7A1 gene expressing collagen 7 protein
Indication	Treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa
Comparative agent – Therapeutic interchange?	Beremagene geperpavec
Dosage forms/strengths	Cellular sheets (5.5 x 7.5 cm): containing patient's gene-modified cells; up to 12 sheets may be manufactured from the patient biopsies and supplied for potential use
Common Dose/sig	Apply topically to wounds
DEA Schedule	None
Date of market availability	Third quarter 2025
Similar Medication Names	Zevalin, Zevtera,
Clinical Use Evaluation	
Common Adverse Effects	≥5%: procedural pain, pruritus
Severe Adverse Effects	Hypersensitivity reactions
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.	None required
Used in Pediatric Areas	Safety and efficacy have been established in pediatric patients; clinical studies included pediatric patients 6 years and 16 years of age
Renal or Hepatic Dosing	No dose adjustment required in renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Warnings: hypersensitivity reactions to vancomycin, amikacin, or product excipients may occur; retroviral vector-mediated insertional oncogenesis may potentially occur (monitor lifelong for development of malignancies); transmission of infectious agents from use of human- and bovine-derived reagents in manufacturing
Special administration technique or considerations	Application is a surgical procedure; following debridement under anesthesia the sheets are applied onto the wound bed and affixed with resorbable sutures. Do not overlap sheets Do not suture sheets onto healthy skin. All sheets should be applied in a single session. Applied sheets should be covered with non-adhesive dressings and topical antibiotic ointment. Treated area should be left undisturbed for 5 to 10 days and the treated area should not be submerged in water until the gauze of the product falls of the site (within 2 to 3 weeks).
Prepared by	Terri Levien
Source	Zevaskyn (prademagene zamikeracel) [prescribing information]. Cleveland, OH: Abeona Therapeutics Inc; April 20.

Nipocalimab-aahu/Imaavy/Johnson & Johnson	
Generic Name / Brand Name / Company	Nipocalimab-aahu/Imaavy/Johnson & Johnson
Date of approval	4/29/25
Drug Class (Mechanism of Action if novel agent)	Neonatal Fc receptor blocker
Indication	Treatment of generalized myasthenia gravis in adult and pediatric patients 12 years and older who are anti-acetylcholine receptor or anti-muscle-specific tyrosine kinase antibody positive
Comparative agent – Therapeutic interchange?	Rozanolixizumab
Dosage forms/strengths	Injection: 300 mg/1.62 mL (185 mg/mL) or 1200 mg/6.5 mL (185 mg/mL) in single-dose vials
Common Dose/sig	30 mg/kg once via IV infusion; two weeks after the initial dose initiate maintenance dosage of 15 mg/kg IV every 2 weeks
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Imatinib
Clinical Use Evaluation	
Common Adverse Effects	>10%: respiratory tract infections, peripheral; edema, muscle spasms
Severe Adverse Effects	Infections, hypersensitivity reactions, infusion-related reactions
Severe Drug-Drug Interactions	Effectiveness of medications that bind the human neonatal Fc receptor may be reduced with concomitant use. Vaccination with live vaccines is not recommended during nipocalimab-aahu treatment.
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	No dosage adjustment in patients 12 years and older; safety and effectiveness not established in patients younger than 12 years
Renal or Hepatic Dosing	No dose adjustment in renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with a history of serious hypersensitivity reaction to nipocalimab-aahu or any product ingredients. Warnings: infections, hypersensitivity reactions, infusion-related reactions
Special administration technique or considerations	Evaluate the need to administer age-appropriate vaccines prior to initiation. Dilute with 0.9% sodium chloride injection prior to administration. Administer as an IV infusion through an IV line including a 0.2 micron in-line or add-on filter. Administer first dose via IV infusion over at least 30 minutes; subsequent doses may be administered over at least 15 minutes.
Prepared by	Terri Levien
Source	Imaavy (nipocalimab-aahu) [prescribing information]. Horsham, PA: Janssen Biotech Inc; April 2025.