WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 2/1/25 – 2/28/25

FDA Drug Safety Communications & Drug Information Updates:

Missed Safety Alerts Due to Phone Settings with Smartphone-Compatible Diabetes Devices 2/5/25
The FDA alerted patients of a safety concern regarding diabetic devices that rely on smartphones to deliver critical safety alerts in which users report these alerts are not being delivered or heard, even when users thought they had configured the alerts to be delivered. The FDA recommends turning off automatic operating system updates, confirming alert settings after updating, and checking that alerts are configured at least once a month

FDA Determines Semaglutide Shortage is Resolved 2/21/25
The FDA reported that the shortage of semaglutide products has been resolved. The FDA does not intend to act against compounders for violations of the FD&C Act arising from conditions that depend on semaglutide's inclusion on the drug shortage list until April 22, 2025 for compounders acting under section 503A of the FD&C Act (state-licensed pharmacies or physician compounding) or until May 22, 2025 for compounders acting under section 503B of the FD&C Act (outsourcing facilities).

FDA Ends Clozapine REMS Program Requirement 2/24/25
The FDA announced, as of 2/24/25, that they no longer expect prescribers, pharmacies, and patients to participate in the REMS program for clozapine or to report results of absolute neutrophil count (ANC) blood tests before pharmacies dispense clozapine. ANC monitoring is still recommended at the frequency described in the prescribing information, and information on severe neutropenia will remain in a boxed warning. In the coming months labeling will be updated for all clozapine products removing the REMS.

Testosterone Labeling Updated Removing Warnings of Risk of Adverse Cardiovascular Outcomes 2/28/25
The FDA recommended changes to the labeling of all testosterone products adding information about the findings from a long-term study of vascular events with testosterone replacement therapy in hypogonadal men. Based on the results of this study, the FDA recommended retaining the "Limitation of Use" language for age-related hypogonadism and removing language from the boxed warning related to increased risk of adverse cardiovascular outcomes. The FDA is also requiring addition of product specific information on increased blood pressure for testosterone products with data from completed required ambulatory blood pressure studies and adding a new warning about increased blood pressure for testosterone products which currently do not have such a warning in their labeling.

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

Potassium Chloride Injection, 20 mEq and 10 mEq, ICU Medical: Recall - Mislabeling 2/13/25
ICU Medical recalled one lot of potassium chloride Injection 20 mEq due to incorrect overwrap labels which state potassium chloride Injection 10 mEq, but are packaged in cases of potassium chloride injection 20 mEq. The mislabeled 20 mEq 100 mL bags contain incorrect overwrap labels with the following information: NDC 0990-7074-26, 200 mEq/L POTASSIUM CHLORIDE Inj. 10 mEq. The lot 1023172 and Exp. Date 31 January 2026 are found on the primary container. The mislabeled bags are packaged in cases labeled: NDC 0990-7075-26, CASE PACK 1x24 – 100ML 20MEQ POTASSIUM CHLORIDE INJECTION LOT NO. 1023172, EXP DATE 2026-01.

ChloraPrep™ Clear 1 mL Applicators, BD: Recall - Fungal Contamination 2/18/25
BD recalled one lot of ChloraPrep Clear 1 mL applicators due to fungal contamination allowing the growth of *Aspergillus penicillioides.* Growth within the packaging can contaminate the applicator surface and may result in direct inoculation of fungus into tissues. The recalled lot (NDC 54365-400-31, Lot #3200240) was distributed globally beginning September 2023.

Phenylephrine 40 mg added to 0.9% Sodium Chloride 250 mL in 250 mL Excel Bags, Central Admixture Pharmacy Services (CAPS): Recall - Visible Black Particulate Matter 2/25/25

CAPS recalled 3 lots of Phenylephrine 40 mg added to 0.9% Sodium Chloride 250 mL in 250 mL Excel Bags (NDC 71285-6092-1) to the hospital level after notification from their raw material supplier of detection of visible black particulate matter in a sealed vial of phenylephrine hydrochloride. Lot #s 37-928390, 37-928796, and 37-928839 were distributed from December 2024 to January 2025.

SinuCleanse Soft Tip Squeeze Bottle Nasal Wash System, Ascent Consumer Products Inc: Recall - Microbial Contamination 2/25/25

Ascent Consumer Products recalled one lot (Lot # 024122661A1, expiration date 12/31/2027) of the SinuCleanse Wash System to the consumer level because of *Staphylococcus aureus* contamination. The affected lot was distributed in January 2025.

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***
Vitality Capsules (One Source Nutrition)*	Male enhancement	Sildenafil, tadalafil
Vitafer-L Gold Liquid (Natural Dior LLC)*	Male enhancement	Tadalafil
Lyons ReadyCare & Sysco Imperial (Prairie Farms Dairy, Inc)*	Frozen supplemental shakes	*Listeria monocytogenes*

*Recalled

New Product Shortages	***Date Initially Posted***
Methylphenidate, Film, Extended Release	2/28/25
Pimecrolimus topical cream	2/28/25

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Pirfenidone Capsule (Esbriet, Genentech); generics remain available	2/5/25
Idarubicin Injection (Idamycin, Pfizer); generics remain available	2/6/25
Erythromycin Topical Gel (Erygel, Mylan); generics remain available	2/14/25
Silodosin Capsules (Rapaflo, AbbVie); generics remain available	2/20/25
Tolterodine Tartrate Tablets (Detrol, Mylan); generics remain available	2/26/25
Tolterodine Tartrate Capsules, Extended Release (Detrol LA, Mylan); generics remain available	2/26/25
Pimecrolimus cream (Elidel, Bausch Health Americas); generics remain available	2/28/25

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Mirdametinib/Gomekli/ Springworks Therapeutics	Kinase inhibitor for treatment of adult and pediatric patients 2 years older with neurofibromatosis type 1 with symptomatic plexiform neurofibromas not amenable to complete resection	2/11/25
Vimseltinib/Romvimza/ Deciphera Pharms	Kinase inhibitor for treatment of adults with symptomatic tenosynovial giant cell tumor in which surgical resection may worsen functional limitation or severe morbidity	2/14/25

New Indications:	***Description***	***Date Approved***
Ranibizumab/Susvimo / Genentech	Treatment of diabetic macular edema	2/4/25
Moxidectin/Medicines Development for Global Health	Indication expanded to include pediatric patients 4 years and older and weighing at least 13 kg for the treatment of onchocerciasis due to *Onchocerca volvulus*	2/7/25
Brentuximab vedotin/Adcetris/ Seagen	In combination with lenalidomide and a rituximab product for adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy who are ineligible for autologous hematopoietic stem cell transplantation or CAR T-cell therapy	2/11/25
Tenecteplase/TNKase/Genentech	Treatment of acute ischemic stroke in adults	2/28/25
Ravulizumab-cwvz/Ultomiris/ Alexion	Treatment of generalized myasthenia gravis in pediatric patients six years of age and older who are anti-acetylcholine receptor antibody positive	2/28/25
House dust mite allergen tablet/ Odactra/ALK Inc	Treatment of house dust mite-induced allergic rhinitis, with or without conjunctivitis, in pediatric patients 5 through 11 years	2/28/25

New Dosage Form or Formulation:	***Description***	***Date Approved***
Apomorphine/Onapgo/Supernus	Injection: 98 mg/20 mL in single dose cartridges; subcutaneous infusion for treatment of motor fluctuations in adults with advanced Parkinson's disease	2/3/25
Aztreonam and avibactam/Emblaveo/ AbbVie	Injection: lyophilized powder in a single-dose vial containing aztreonam 1.5 g and avibactam 0.5 g; for use in combination with metronidazole for treatment of complicated intra-abdominal infections	2/7/25
Risdiplam/Evrysdi/Roche	Tablet: 5 mg, to be swallowed whole or dispersed in water; treatment of spinal muscular atrophy	2/12/25
Chikungunya vaccine/Vimkunya/ Bavarian Nordic	Injectable suspension: 0.8 mL single IM dose; prevention of disease caused by chikungunya virus in individuals 12 years and older	2/14/25
Meningococcal Groups A, B, C, W, and Y vaccine/Penmenvy/ GlaxoSmithKline	Injectable suspension: 0.5 mL after reconstitution; prevention of invasive disease caused by Neisseria meningitidis serogroups A, B, C, W, and Y in individuals 10 through 25 years of age	2/14/25
Chemodiol/Ctexli/Mirum	Tablet: 250 mg; treatment of cerebrotendinous xanthomatosis in adults	2/21/25
Copper intrauterine system/Miudella/ Sebela Womens Health, Inc.	Copper IUS with 175 mm^2 of exposed copper surface area indicated for pregnancy prevention for up to 3 years	2/24/25

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Mirdametinib/Gomekli/Springworks Therapeutics	
Generic Name / Brand Name / Company	Mirdametinib/Gomekli/Springworks Therapeutics
Date of approval	2/11/25
Drug Class (Mechanism of Action if novel agent)	Mitogen-activated protein kinase inhibitor
Indication	Treatment of neurofibromatosis type 1 (NF1) in adult and pediatric patients 2 years of age and older who have symptomatic plexiform neurofibromas (PN) not amenable to resection
Comparative agent – Therapeutic interchange?	Selumetinib
Dosage forms/strengths	Capsule, Oral: 1 mg, 2mg Tablet Soluble, Oral: 1 mg
Common Dose/sig	2 mg/m^2 orally twice daily for the first 21 days of each 28-day cycle
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Mirabegron, mirikizumab, mirtazapine
Clinical Use Evaluation	
Common Adverse Effects	Adults: (>25%) rash, diarrhea, nausea, musculoskeletal pain, vomiting, and fatigue; severe lab abnormalities (> 2%): increased creatine phosphokinase Pediatric: (>25%) rash, diarrhea, musculoskeletal pain, abdominal pain, vomiting, headache, paronychia, left ventricular dysfunction, & nausea; severe lab abnormalities (> 2%): decreased neutrophil count, increased creatine phosphokinase
Severe Adverse Effects	Rash, diarrhea, abdominal pain, musculoskeletal pain, headache, left ventricular dysfunction, increased creatine phosphokinase, decreased glucose, decreased neutrophils
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.	Verify pregnancy status prior to initiating treatment
Used in Pediatric Areas	Indicated for treatment of patients 2 years of age and older with NF1 who have symptomatic PN not amenable to complete resection
Renal or Hepatic Dosing	No dosage adjustment required for patients with mild to moderate renal or hepatic impairment; has not been studied in patients with severe renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Conduct comprehensive ophthalmic assessment, assess ejection fraction by echocardiogram, and verify pregnancy status prior to initiating. Monitor for any new or worsening visual changes, assess ejection fraction regularly, initiate supportive care at first signs of dermatologic adverse reactions, and adjust dosing as indicated in the prescribing information. There is risk for embryo-fetal toxicity. Advise females of reproductive potential to use effective contraception during treatment and for 6 weeks after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose.
Special administration technique or considerations	Capsules should be swallowed whole (do not open, break, or chew) and tablets may either be swallowed whole or dispersed in water and administered as an oral liquid.
Prepared by	Emily Hitt, PharmD; Hannah Choi, Doctor of Pharmacy Candidate 2025
Source	Gomekli (mirdametinib) [prescribing information]. Stamford, CT: SpringWorks Therapeutics, Inc; February 2025.

Vimseltinib/Romvimza/Deciphera Pharmaceuticals	
Generic Name / Brand Name / Company	Vimseltinib/Romvimza/Deciphera Pharmaceuticals, LLC
Date of approval	2/14/25
Drug Class (Mechanism of Action if novel agent)	Tyrosine kinase inhibitor; inhibits CSF1R autophosphorylation, signaling induced by CSF1 ligand binding, and proliferation of cells expressing CSF1R.
Indication	Treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity
Comparative agent – Therapeutic interchange?	Pexidartinib
Dosage forms/strengths	Capsules, Oral: 14 mg, 20 mg, 30 mg
Common Dose/sig	30 mg orally twice weekly with a minimum of 72 hours between doses
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Vandetanib, Romazicon
Clinical Use Evaluation	
Common Adverse Effects	≥ 20%: increased AST, periorbital edema, fatigue, rash, increased cholesterol, peripheral edema, face edema, decreased neutrophils, decreased leukocytes, pruritus, and increased ALT
Severe Adverse Effects	Edema, rash, hypertension, neuropathy
Severe Drug-Drug Interactions	Avoid concomitant use of P-gp, BCRP, and OCT substrates with vimseltinib due to risk of increased exposure to these substrates.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Verify pregnancy status; monitor AST, ALT, total and direct bilirubin, ALP, & GGT prior to initiation, twice a month for the first 2 months, once every 3 months for the first year, and as clinically indicated thereafter
Used in Pediatric Areas	Safety and effectiveness have not been established.
Renal or Hepatic Dosing	Dose modification is recommended for hepatotoxicity, but no dose adjustment is recommended for patients with mild hepatic impairment. Avoid initiation in patients with active liver or biliary tract disease, increased serum transaminases, alkaline phosphatase, or total/direct bilirubin > ULN at baseline. No dosage adjustments for renal impairment;
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Hepatotoxicity: avoid use in patients with pre-existing increased serum transaminases, total bilirubin or direct bilirubin, or active liver or biliary tract disease. Contains FD&C Yellow No. 5 (tartrazine) and No.6 (Sunset Yellow FCF) which may cause allergic reactions. Risk for embryo-fetal toxicity. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during therapy and for 1 month after the last dose. May impair fertility. Avoid breastfeeding during treatment and for 1 month after final dose. Assess renal function using measures not based on serum creatinine.
Special administration technique or considerations	Vimseltinib should be taken twice weekly with at least 72 hours between doses and should be swallowed whole (do not open, break, or chew).
Prepared by	Hannah Choi, Doctor of Pharmacy Candidate 2025
Source	Romvimza (vimseltinib) [prescribing information]. Waltham, MA: Deciphera Pharmaceuticals LLC; February 2025.