WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 1/1/26 – 1/31/26

FDA Drug Safety Communications & Drug Information Updates:

Glucagon-Like Peptide-1 Receptor Agonists: Removal of Suicidal Ideation and Behavior Warning 1/13/26

The FDA has requested removal of the suicidal ideation and behavior information from the labeling of glucagon-like peptide-1 receptor agonist (GLP-1 RA) medications. In the initial review of GLP-1 RA clinical trial data, there was no association found between the use of GLP-1 RAs and the occurrence of suicidal ideation and behavior. However, because there were a small number of observed cases of suicidal ideation and behavior, there was uncertainty in the risk, leading to the labeled warning. The FDA conducted a retrospective cohort study with a population of 2,243,138 patients and the FDA did not find an increased risk of intentional self-harm in patients treated with GLP-1 RA medications. With the completion of this retrospective cohort study the FDA is requesting the language be removed.

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

Broselow Rainbow Tape, AirLife: Early Alert – Medication Related Errors 1/16/26

AirLife announced a recall for their Broselow Rainbow Tapes due to potentially life-threatening errors. This recall affects multiple products including pediatric and adult dosing tapes. The errors can be seen under vecuronium, flumazenil, and ketamine (IV/IO for pain/analgesia) emergency dosing. The manufacturer has recommended identifying, isolating, and stop using these tapes. The products affected include all lots of Rev. 3 for the following products: Broselow Pediatric Emergency Rainbow Tape (REF # 7700REA/UDI each 10889483588970/UDI case 30889483588974 and REF # 7700RE/UDI each 10889483588963/UDI case 30889483588967) and Broselow ALS Organizer Full (REF # 7730ALS/UDI each 10889483589151 and REF # 7730IALS/UDI each 10889483589205/UDI case 30889483589209).

FreeStyle Libre 3 and FreeStyle Libre 3 plus, Abbot: Device Correction- 1/16/26

Abbott initiated a medical device correction for certain FreeStyle Libre 3 and FreeStyle Libre 3 Plus Sensors after testing revealed some sensors may provide incorrect low glucose readings. Consumers can go to the following site to see if their sensors are affected and to get a replacement at no charge: https://www.freestylecheck.com.

MediHoney Wound and Burn Dressing, Integra LifeSciences & CVS Wound Gel Products: Early Alert 1/22/26

The FDA alerted users that Integra LifeSciences identified packaging failures related to all lots of all MediHoney Wound and Burn products and certain lots of CVS Wound Gel products (SKU CVS405406; lots 2446 and 2428) that could breach the sterile barrier and lead to patient infection. These products should be immediately removed from service and not used.

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*
Live it Up Super Greens, Superfood Inc*	Support energy & gut health	Salmonella
Modern Warrior Ready, Modern Warrior*	Nootropic	1,4 – DMAA[1], aniracetam[2], tianeptine[3]
Silintan, 123Herbals*	Joint and body aches	Meloxicam
Why Not Natural Organic Moringa*	Support energy & gut health	Salmonella

*recalled

[1]1,4 – DMAA is a synthetic stimulant drug chemically similar to amphetamine that is banned in supplements by the FDA

[2]Aniracetam is a synthetic stimulant and mental enhancer that is not approved by the FDA for any use, including dietary supplements.

[3]Tianeptine is an atypical tricyclic antidepressant that is not approved by the FDA for any use

New Product Shortages (per FDA or ASHP)	*Date Initially Posted*
Moxifloxacin injection	1/13/26
Conjugated estrogens injection	1/27/26
Iothalamate meglumine urethral solution	1/28/26
Colchicine oral liquid	1/30/26
Estradiol transdermal patch	1/30/26
Mesalamine extended-release capsules	1/30/26

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

Brand Name or Sole Source Product Discontinuations/Withdrawals	*Date Posted*
Azithromycin injection 500 mg (Zithromax IV, Pfizer); generics remain available	1/20/26
Maraviroc 20 mg/mL oral solution kit (Selzentry, GlaxoSmithKline); distribution will cease in August 2026 although tablets will remain available	1/20/26
Riboflavin 5-phosphate ophthalmic solution (Photrexa Cross-Linking Kit, Glaukos); no FDA-approved drug alternatives available	1/20/26
Fluvastatin sodium extended-release tablet (Lescol XL, Sandoz); generics remain available	1/27/26
Podofilox topical gel 0.5% (Condylox, AbbVie); generics remain available	1/28/26

New Drug Approvals:	*Description (See Attached Drug Summaries)*	*Date Approved*
Copper histidinate/Zycubo/Sentynl Therapeutics	Subcutaneous copper replacement therapy for the treatment of Menkes disease in pediatric patients	1/12/26

New Indications:	*Description*	*Date Approved*
Imiglucerase, Cerezyme, Genzyme	Treatment of Gaucher disease type 3	1/12/26
Ibuprofen/Caldalor/Cumberland Pharmaceuticals	Treatment of postoperative pain	1/23/26
Daratumumab and hyaluronidase-fihj/Darzalex Faspro/Janssen Biotech	In combination with bortezomib, lenalidomide, and dexamethasone for the treatment of adults with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant	1/27/26

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Folic acid/Quiofic/CMP Development	Oral solution: 0.2 mg/mL; for the treatment of megaloblastic anemias due to folic acid deficiency in adult and pediatric patients	1/26/26
Carbachol and brimonidine/Yuvezzi/ Tenpoint	Ophthalmic solution: carbachol 2.75% and brimonidine 0.1%; for the treatment of presbyopia	1/28/26

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Copper histidinate/Zycubo/Sentanyl Therapeutics	
Generic Name/Brand Name/Company	Copper histidinate/Zycubo/Sentanyl Therapeutics
Date of approval	1/12/26
Drug Class (Mechanism of Action if novel agent)	Bioavailable copper replacement therapy that is administered as a subcutaneous injection to bypass the impaired gastrointestinal absorption observed in patients with Menkes disease
Indication	Treatment of Menkes disease in pediatric patients
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Subcutaneous injection: 2.9 mg of copper histidinate (equivalent to 0.5 mg elemental copper) as a lyophilized powder or cake in a single-dose vial for reconstitution
Common Dose/sig	- Age < 1 year: 1.45 mg administered subcutaneously twice daily (8-12 hours between injections). - Age 1 year to < 17 years: 1.45 mg administered subcutaneously once daily.
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	None
Clinical Use Evaluation	
Common Adverse Effects	≥7%: Pneumonia, viral infection, respiratory failure, seizure, bacterial infection, hemorrhage, hypotension, vomiting, tachycardia, pyrexia, volume depletion, fracture, dyspnea, transaminase elevation, diarrhea, fungal infection, anemia, and local administration reaction.
Severe Adverse Effects	Pneumonia, dehydration, seizure, respiratory distress, respiratory syncytial virus infection, cardiopulmonary failure, upper respiratory tract infection, respiratory failure, and vomiting
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.	Monitor serum copper and ceruloplasmin levels, serum electrolytes, kidney and liver function, and complete blood count (CBC) before initiating, every 6 weeks for the first 6 months, then every 3 months for 18 months, and then every 6 months thereafter
Used in Pediatric Areas	Currently indicated in pediatric patients
Renal or Hepatic Dosing	Monitor patients during treatment. Adjust dosage if necessary.

Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling Warnings: Copper accumulation and risk of toxicity - treatment with copper histidinate may lead to further copper accumulation and has the potential to result in drug-induced kidney injury, liver dysfunction, and hematological abnormalities. Monitor patients closely and adjust dosage or temporarily withhold or permanently discontinue if necessary.
Special administration technique or considerations	Zycubo is available as a vial for reconstitution and is administered subcutaneously. Reconstitute with 0.9% sodium chloride. Once reconstituted, doses can be stored refrigerated for 24 hours and can be stored at room temperature for 4 hours. Administer using sterile disposable 1 mL syringe and ½ inch 23 to 27 gauge needle. A caregiver may administer the dose after proper training in subcutaneous injection technique. Administer in abdominal area, buttocks, or outer lateral aspect of the upper arm or thigh. Do not administer more than one dose from the vial.
Prepared by	Jason Iltz
Source	Zycubo (copper histidinate) [prescribing information]. Solana Beach, CA: Sentanyl Therapeutics; January 2026.