WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 1/1/24 – 1/31/24

FDA Drug Safety Communications & Drug Information Updates:

Glucagon-Like Peptide-1 Receptor Agonist: Drug Safety Communication—Suicidal Thoughts or Actions 1/11/24
The FDA has been assessing the reports of suicidal ideation and action in patients taking GLP-1 RAs. They have not found a clear relationship in the reports on FAERS, as well as the clinical trials. Although there appears to be no link between the two, the small number of reports do not allow the FDA to definitively rule out a small risk and the FDA is continuing to research this issue. Health care professionals should monitor for and advise patients to report new or worsening depression, suicidal thoughts, or any unusual changes in mood or behavior.

Naloxone (Narcan): Drug Information Update—Extended Shelf Life 1/17/24
The FDA announced that naloxone (Narcan) 4 mg nasal spray products had their shelf-life extended from 3 years to 4 years. This update is only applicable to 4 mg Narcan nasal sprays produced on and after 1/17/2024.

Denosumab (Prolia): Drug Safety Communication—Risk of Severe Hypocalcemia 1/20/24
The FDA has reviewed available information, concluding that denosumab has an increased risk of severe hypocalcemia in people with advanced chronic kidney disease (CKD). This is truer for patients on dialysis, and common amongst patients with CKD mineral and bone disorder. A boxed warning is being added to the labeling advising appropriate patient selection and increased monitoring of blood calcium levels.

Contaminated Copycat Eye Drops: Drug Safety Communication 1/31/24
The FDA advised consumers not to purchase or use South Moon, Rebright, or FivFivGo eye drops due to the risk of eye infection. These are unapproved drugs marketed in packaging resembling Bausch + Lomb Lumify brand eye drops and promoted for the treatment of eye conditions such as glaucoma. Some of the tested products were found to be contaminated with *Burkholderia cepacia* complex; none contained brimonidine, the active ingredient in Lumify.

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

Monoject Disposable Syringes, Cardinal Health: Recall—Incompatible with Syringe Pumps 1/8/24
Cardinal Health recalled multiple lines of Monoject disposable syringes (1 mL Tuberculin Syringe, 6 mL Syringe, 12 mL Syringe, 20 mL Syringe, 35 mL Syringe, and 60 mL Syringe. All Luer-Lock tip soft packs) as these are incompatible for use with syringe pumps. The syringes have different dimensions than previously branded "Covidien Monoject Syringes" and can lead to pump performance issues when used.

Vancomycin IV Bags, Phenylephrine IV Bags, Fentanyl IV Bags, Leiter Health: Recall — Superpotency 1/8/24
Leiter Health recalled 33 lots of vancomycin, phenylephrine, and fentanyl IV bags due to them potentially having superpotency, containing twice the labeled amount of drug. Item number are: F33555, F3342, F3360, F3352, F3206, and F3208.

Kits/Trays, Busse Hospital Disposables: Recall — Sterility Concerns 1/11/24
Busse Hospital Disposables recalled their Tracheostomy Care Tray, Dressing Change Tray, and Tracheostomy Care Set in response to the Nurse Assist LLC's recall of 0.9% sodium chloride irrigation USP and sterile water for irrigation USP due to sterility concerns.

Ivenix Infusion Pumps, Fresenius Kabi USA LLC: Recall—Mechanical Interference 1/12/24
Fresenius Kabi USA, LLC., recalled Ivenix Infusion Pumps due to mechanical interference of the fluid valve pins, impacting the side of the sensor. This will cause the alarm to go off and stop an ongoing infusion or delay treatment. Affected model number is LVP-0004, which had been distributed from 10/1/2021 to 7/31/2023.

Regard Operative Lap P&S Surgical Kit, ROi CPS LLC: Recall — Lack of Sterility 1/16/24
ROi CPS, LLC recalled Regard Operative Lap P&S Surgical Kit due to possible lack of sterility of the 0.9% sodium chloride and sterile water irrigation USP as this is a previously recalled item that had been produced by Nurse Assist. These kits have been distributed from 1/12/22 to 7/10/23, and the model number is 800943001.

Eye Drops, Kilitch Healthcare India Limited: Recall – Safety Concerns 1/22/24
Kilitch Healthcare India Limited updated information on products recalled in November during a national eye drop recall. NDC numbers were improperly listed for two products in the original recall. The recalled products, distributed nationwide by Velocity Pharma LLC and labeled Rite Aid, were Lubricant Gel Drops (NDC 11822-4540-5) and Lubricant Eye Drops (NDC 11822-4811-5) with expiration dates through September 2025.

Robitussin Honey CF Max Cough Syrups, Haleon: Recall — Microbial Contamination 1/24/24
Haleon recalled 8 lots of Robitussin Honey CF Max Day and Nighttime Adult cough syrups (lot #s T10810; T08730, T08731, T08732, T08733, T10808; T08740, T08742) due to possible microbial/fungal contamination.

Local Lower Extremity Pack 1, In House Ocular Pack, and Closure Kit, Aligned Medical Solutions: Recall—Lack of Sterility 1/23/24
Aligned Medical Solutions recalled AMS10833 Local Lower Extremity Pac 1, AMS12947 In House Ocular Pack, AMS12947A In House Ocular Pack, and AMS13043 Closure Kit due to 0.9% sodium chloride irrigation piggybacked to the packs lacking proper sterility assurance, from a previously recalled product produced by Nurse Assist.

Dextroamphetamine Sulfate (Zenzedi) 30 mg tablets, Azurity Pharmaceuticals: Recall — Mislabeled 1/25/24
Azurity Pharmaceuticals, Inc. recalled 1 lot (F230169A; NDC 24338-0856-03) of Zenzedi (light yellow, hexagonal; side1 = 30, side2 = MIA) 30 mg tablets due to a report of a bottle containing the antihistamine carbinoxamine maleate (white, round; side1 = GL, side2 = 211) 4 mg tablets.

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***
Arize	Sexual enhancement	Nortadalafil
ENDUREA	Sexual enhancement	Sildenafil, tadalafil
ForeverMen	Sexual enhancement	Sildenafil
Neptune's Fix Elixir and Tablets*	Improve brain function, treat anxiety, depression, pain, opioid use disorder and other conditions	Tianeptine[1]
Schwinnng	Sexual enhancement	Nortadalafil
Seraphim Z	Sexual enhancement	Sildenafil
Sustain	Sexual enhancement	Avanafil, tadalafil
Tejocote root dietary supplements	Weight loss	Yellow oleander, a poisonous plant

*recalled

[1]Tianeptine is not FDA approved for any indication; its use has been associated with severe adverse events including seizures, loss of consciousness, and death

New Product Shortages	***Date Initially Posted***
Riluzole Oral Suspension	1/26/24

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Berdazimer sodium / Zelsuvmi / EPIH SPB, LLC.	Nitric oxide releasing agent for the topical treatment of molluscum contagiosum in patients 1 year old or older	1/5/24

New Indications:	***Description***	***Date Approved***
Pembrolizumab / Keytruda / Merck Sharp & Dohme LLC	In combination with chemoradiotherapy for the treatment of patients with FIGO 2014 Stage III-IVA cervical cancer	1/12/24
Immune Globulin Infusion 10% Human with Recombinant Human Hyaluronidase / Hyqvia / Takeda Pharmaceuticals USA Inc	Treatment of chronic inflammatory demyelinating polyneuropathy as maintenance therapy to prevent relapse of neuromuscular disability and impairment in adults	1/12/24
Exagamglogene autotemcel / Casgevy / Vertex Pharmaceuticals Inc	Treatment of transfusion-dependent beta-thalassemia in patients aged 12 years and older	1/16/24
Alpelisib / Piqray / Novartis	Indication expanded to include pre- and perimenopausal women in the current breast cancer indication	1/18/24
Erdafitinib / Balversa / Janssen Products	Indication updated for treatment of urothelial carcinoma with susceptible FGFR3 genetic alterations whose disease has progressed on or after at least one line of systemic therapy; use is not recommended for patients who are eligible for and have not received prior PD-1 or PD-L1 inhibitor therapy	1/19/24
Bupivacaine and meloxicam extended-release solution / Zynrelef / Heron Therapeutics	Indication expanded to use in adults for instillation to produce postsurgical analgesia for up to 72 hours after soft tissue and orthopedic surgical procedures	1/23/24
Dupilumab / Dupixent / Regeneron Pharmaceuticals	Indication expanded to include treatment of eosinophilic esophagitis in pediatric patients aged 1 year and older weighing at least 15 kg	1/25/24
Ceftazidime and avibactam / Avycaz / AbbVie Inc	Indication expanded to include use in pediatric patients from birth (at least 31 weeks gestational age) to less than 3 months of age for treatment of complicated intra-abdominal infections, complicated urinary tract infections, and hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia	1/26/24

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Berdazimer / Zelsuvmi / EPIH SPV, LLC	
Generic Name / Brand Name / Company	Berdazimer / Zelsuvmi / EPIH SPV, LLC
Date of approval	1/5/24
Drug Class (Mechanism of Action if novel agent)	Nitric Oxide Releasing Agent
Indication	For the topical treatment of molluscum contagiosum in adults and pediatric patients at least 1 year old
Comparative agent – Therapeutic interchange?	Cantharidin, podophyllotoxin
Dosage forms/strengths.	Topical gel (10.3% berdazimer) supplied as two tubes, with tube A containing berdazimer gel and Tube B containing hydrogel
Common Dose/sig	Mix 0.5 mL of gel from both tube A and B on the dosing guide, mix, and immediately apply to lesions in an even thin layer, applying once daily to each lesion for up to 12 weeks
DEA Schedule	None
Date of market availability	Second half of 2024
Similar Medication Names	Zelapar, Vidaza, Berinert, Xeljanz
Clinical Use Evaluation	
Common Adverse Effects	≥1%: application site reactions or pain [including burning or stinging sensations (18.7%)], erythema (11.7%), pruritus (5.7%), exfoliation (5.0%), dermatitis (4.9%), swelling (3.5%), erosion (1.6%), discoloration (1.5%), vesicles (1.5%), irritation (1.2%), and infection (1.1%)
Severe Adverse Effects	Application site reactions, including allergic contact dermatitis
Severe Drug-Drug Interactions	None
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Approved for use in pediatric patients aged 1 year and older
Renal or Hepatic Dosing	No dose adjustments for renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Warning: allergic contact dermatitis has occurred and should be suspected if pain, pruritus, swelling, or erythema at application site last longer than 24 hours. Discontinue use and initiate appropriate therapy if contact dermatitis occurs.
Special administration technique or considerations	This drug comes in two tubes (A & B) which need to be mixed before application and not premixed. Use equal amount (0.5 ml) of tube A and B and mix together based on dosing guide. Immediately after preparation, apply a thin layer of this gel on molluscum contagiosum lesions and do not store premixed gel. Allow to dry for 10 minutes after application. Avoid washing treated areas for 1 hour after application. It is intended for topical use only and not for oral, intravaginal, or ophthalmic use.
Summary prepared by	Kyle Fay and Ghazal Meratnia
Source	Zelsuvmi (berdazimer) prescribing information. Wilmington, DE: EPIH SPV, LLC; January 2024.