WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 2/1/24 – 2/29/24

FDA Drug Safety Communications & Drug Information Updates:

Cardinal Health Monoject Luer-Lock and Enteral Syringes: Safety Communication – Do Not Use 2/2/24
The FDA issued a safety communication warning consumers, health care providers, and health care facilities not to use certain Cardinal Health Monoject Luer-Lock and enteral syringes that were recently recalled (see below).

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

Cardinal Health Monoject Luer-Lock and Enteral Syringes, Cardinal Health: Recall – Size Difference 2/2/24
Cardinal Health recalled all sizes of Cardinal Health brand Monoject Luer-Lock Soft Pack Sterile Syringes (1, 3, 6, 12, 20, 35, and 60 mL) and Cardinal Health brand Monoject Enteral Sterile Syringes with the ENFit connection (1, 3, 6, 12, 35, and 60 mL). A complete list of the recalled syringes can be found on the link from the FDA site. Covidien brand Monoject syringes are not impacted by this recall.

TING 1% Tolnaftate Athlete's Foot Spray, Insight Pharmaceuticals: Recall – Benzene 2/2/24
Insight Pharmaceuticals recalled two lots of TING 1% Tolnaftate Athlete's Foot Spray Antifungal Spray Liquid 4.5 ounce package (lots 0H50545 and 1G50645) to the consumer level after detection of elevated levels of benzene in samples from the two lots.

Saline and Sterile Water Medical Products, Nurse Assist LLC: Recall – Lack of Sterility 2/7/24
Nurse Assist LLC issued a recall on 11/6/2023 due to sterility issues in water-based products (0.9% sodium chloride for irrigation and sterile water for irrigation). Additional products were added to this recall in February, including feeding tube kits marketed by Avanos Medical Inc. Information on all recalled Nurse Assist products and related recalls can be found on the FDA site. All recalled products other than part number 1030A have an expiration date from 11/1/23 to 9/18/25. For the recalled 1030A product (USP Sterile water syringe), the expiration dates are between 11/1/23 to 09/18/28. This includes kits and trays which contain these products.

Medfusion Model 4000 Syringe Pump Due: Recall – Software Issues 2/14/24
Smiths Medical ASD Inc. recalled Medfusion model 4000 syringe pump due to issues associated with earlier versions of software which may affect the alarm system, the pump, the control screen, and other components of the pump. These issues may cause the device to deliver therapy inappropriately. Versions affected in differing capacities include: v1.0.0, v1.1.0, v1.1.1, v1.1.2, v1.5.0, v1.5.1, v1.6.0, v1.6.1, v1.6.4, v1.6.5, v2.3, v2.4, and v2.5.

Baby's Vitamin D3 Liquid, Nordic Naturals: Recall – Elevated Vitamin D3 2/21/24
Nordic Naturals recalled one lot of Nordic Naturals Baby's Vitamin D3 Liquid 400 IU (lot 234909, expiration December 2025) due to a manufacturing error resulting in an elevated vitamin D3 dosage.

Eye Ointments by Brassica Pharma Pvt. Ltd.: Recall - Lack of Sterility Assurance 2/26/24
Brassica Pharma Pvt. Ltd. recalled multiple eye ointment products due to lack of sterility assurance which was noted during an FDA inspection. Products include Equate Lubricant Eye Ointment, Equate Stye Lubricant Eye Ointment, CVS Health Lubricant Eye Ointment, and Lubricant PM Ointment.

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***
Alipotec Raiz de Tejocote "Alipotec King"	Weight loss	Yellow oleander, a poisonous plant
Arize Herbal Dietary Supplement*	Sexual enhancement	Nortadalafil
Brazil Seed Pure Natural Semilla de Brasil & Tejo Root, Raiz de Tejocte*	Weight loss	Yellow oleander
H&N Natural Brazil Seed*	Weight loss	Yellow oleander
H&N Natural TejoRoot*	Weight loss	Yellow oleander
Neptune's Fix, by Super Chill*	Kratom alternative	Tianeptine[1]
Schwinnng*	Sexual enhancement	Nortadalafil and tadalafil
Sustain*	Sexual enhancement	Nortadalafil and tadalafil

*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 Initially Reported in February

Coagulation Factor VIIa (recombinant) (NovoSeven RT)
Naltrexone hydrochloride tablets
Rho(D) Immune Globulin (Human) (WinRho SDF)
Rocuronium Bromide, Injection

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Melphalan (Alvogen): 2 mg tablets (NDC 47781-0200-50). Oral melphalan tablets will no longer be available from any manufacturer	2/23/24

Removed/Restricted Indications:	***Description***	***Date***
Melphalen flufenamide / Pepaxto / Oncopeptides	FDA withdrawing drug following failure of confirmatory study to confirm clinical benefit in multiple myeloma	2/23/24

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Lifileucel / Amtagvi / Iovance Biotherapeutics	Tumor-derived aulogous T cell immunotherapy for adults with previously treated unresectable or metastatic melanoma	2/16/24
Cefepime and enmetazobactam / Exblifep / Allerca Therapeutics SAS	Cephalosporin antibacterial and beta-lactamase inhibitor for treatment of complicated urinary tract infections including pyelonephritis	2/22/24

New Indications:	***Description***	***Date Approved***
Irinotecan liposome / Onivyde / Ipsen Biopharmaceuticals	With oxaliplatin, fluorouracil, and leucovorin for the first-line treatment of metastatic pancreatic adenocarcinoma	2/13/24
Omalizumab / Xolair / Genentech	In conjunction with food allergen avoidance for IgE-mediated food allergy in adults and pediatric patients 1 year and older for the reduction of allergic reactions, including anaphylaxis, that may occur with accidental exposure to one or more foods	2/16/24

New Indications (continued)	***Description***	***Date Approved***
Osimertinib / Tagrisso / AstraZeneca Pharmaceuticals LP	In combination with pemetrexed and platinum-based chemotherapy as first-line treatment in adult patients with locally advanced or metastatic NSCLC whose tumors have EFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA approved test	2/16/24
Bictegravir, Emtricitabine, and Tenofovir Alafenamide / Biktarvy / Gilead Sciences INC.	Indication to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen modified to include use in patients with no known or suspected substitutions associated with resistance to bictegravir or tenofovir and no longer requires patients have no history of treatment failure	2/23/24
Remdesivir / Veklury / Gilead	Indication expanded to include use in pediatric patients from birth to less than 28 days of age weighing at least 1.5 kg to less than 3 kg	2/28/24

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Budesonide / Eohilia / Takeda Pharmaceuticals America, Inc.	Oral suspension: 2 mg/10 mL single-dose stick packs; for treatment in adult and pediatric patients 11 years and older with eosinophilic esophagitis at a recommended dose of 2 mg orally twice daily for 12 weeks	2/9/24
Acetylcysteine / Legubeti / Galephar Pharmaceutical Research	Oral powder for solution: supplied in 500 mg and 2.5 g packets to be dissolved in diet cola or other diet soft drink; indicated as an antidote to prevent or lessen hepatic injury following ingestion of potentially hepatotoxic quantities of acetaminophen in adults and pediatric patients	2/13/24
Iloprost / Aurlymyn / Eicos Sciences Inc.	Injection solution: 100 mcg in 1 mL single dose vial; administered as an IV infusion in 0.9% sodium chloride injection for the treatment of severe frostbite in adults to reduce the risk of digit amputations	2/13/24
Pantopazole sodium / Baxter Healthcare	Injection solution: single-dose containers of 40 mg/100 mL, 40 mg/50 mL, 80 mg/100 mL; for short term treatment of gastroesophageal reflux or pathological hypersecretions conditions including Zollinger-Ellison (SE) syndrome	2/14/24

Compiled by:

Terri Levien, Pharm.D.
Emily Hitt, Pharm.D., PGY1 Drug Information Resident
Andrew Staten, Doctor of Pharmacy Candidate

Drug Information 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

Lifileucel / Amtagvi / Iovance Biotherapeutics	
Generic Name / Brand Name / Company	Lifileucel / Amtagvi / Iovance Biotherapeutics
Date of approval	2/16/24
Drug Class (Mechanism of Action if novel agent)	Autologous T-cell immunotherapy
Indication	Unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 positive, a BRAF inhibitor with or without a MEK inhibitor
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Cell suspension: 7.5×10^9 to 72×10^9 cells in patient-specific bag(s)
Common Dose/sig	Infuse single dose (contained in 1 to 4 patient-specific IV bags)
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Sipuleucel-T
Clinical Use Evaluation	
Common Adverse Effects	>20%: chills, pyrexia, fatigue, tachycardia, diarrhea, febrile neutropenia, edema, rash, hypotension, alopecia, infection, hypoxia, dyspnea
Severe Adverse Effects	Death, severe infection, abdominal hemorrhage, intracranial hemorrhage, renal failure, acute respiratory failure, cardiac arrythmia, liver injury, bone marrow failure, anaphylaxis
Severe Drug-Drug Interactions	Avoid prophylactic use of systemic corticosteroids.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Blood counts,
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	Monitor renal function, withhold or discontinue if severe acute renal injury or patient is deemed ineligible for aldesleukin infusion.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Monitor for hypersensitivity during infusion. Monitor for prolonged severe cytopenia and internal organ hemorrhage. Treat severe infections. Monitor cardiopulmonary and renal function throughout therapy.
Special administration technique or considerations	Administered after a lymphodepleting regimen. Premedicate with acetaminophen and diphenhydramine. Do not use a leukocyte depleting filter when infusing. Follow lifileucel dose with aldesleukin.
Prepared by	Terri Levien
Source	Amtagvi (lifileucel) [prescribing information]. Philadelpha, PA: Iovance Biotherapeutics Manufacturing LLC; February 2024

Cefepime and Enmetazobactam / Exblifep / Allecra Therapeutics	
Generic Name / Brand Name / Company	Cefepime and Enmetazobactam / Exblifep / Allecra Therapeutics
Date of approval	2/22/24
Drug Class (Mechanism of Action if novel agent)	B-lactam-β-lactamase inhibitor
Indication	Complicated urinary tract infections, including pyelonephritis
Comparative agent – Therapeutic interchange?	Ceftazidime-avibactam, ceftolozane-tazobactam
Dosage forms/strengths	Powder for reconstitution in single-dose vials containing cefepime 2 g and enmetazobactam 0.5 g
Common Dose/sig	Infuse 2.5 g (cefepime 2 g and enmetazobactam 0.5 g) intravenously over 2 hours every 8 hours for 7 to 14 days
DEA Schedule	None
Date of market availability	To be determined
Similar Medication Names	Cefepime, piperacillin-tazobactam, ceftolozane-tazobactam
Clinical Use Evaluation	
Common Adverse Effects	≥1%: transaminases increased (20%), bilirubin increased (7%), headache (5%), phlebitis/infusion site reactions (5%), diarrhea (4%), anemia (3%), vomiting (2%), nausea (1%)
Severe Adverse Effects	Hypersensitivity, nausea, increased transaminases.
Severe Drug-Drug Interactions	Aminoglycosides: monitor renal function when co-administered with aminoglycosides due to increased potential nephrotoxicity. Diuretics: monitor renal function when co-administered with potent diuretics.
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Renal function to guide dosing, monitor regularly and adjust dosage accordingly
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	eGFR > 130 mL/min: 2.5 g every 8 hours via a 4-hour IV infusion. eGFR 60 to 129 mL/min: 2.5 g every 8 hours via a 2-hour IV infusion. eGFR 30 to 59 mL/min: 1.25 g every 8 hours via a 2-hour IV infusion. eGFR 15 to 29 mL/min: 1.25 g every 12 hours via a 2-hour IV infusion. eGFR < 15 mL/min or receiving intermittent hemodialysis: Loading dose of 1.25 g on day 1 of treatment followed by 0.625 g via IV infusion every 24 hours
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: known history of serious hypersensitivity reactions to any of its components. Warnings: Hypersensitivity reactions, neurotoxicity, *Clostridioides difficile*-associated diarrhea (CDAD), Positive direct Coombs' test, prolonged prothrombin time, development of drug-resistant bacteria.
Special administration technique or considerations	Prepare using aseptic technique and reconstitute with 10 mL of 0.9% sodium chloride, 5% dextrose, or 2.5% dextrose and 0.4% sodium chloride injection from a 250 mL bag. The solution should be diluted further in a 250 mL bag using the same solution that was utilized during the reconstitution step.
Prepared by	Andrew Staten
Source	Exblifep (cefepime and enmetazobactam) [prescribing information]. France: Allecra Therapeutics SAS; February 2024.