WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 5/1/24 – 5/31/24

FDA Drug Safety Communications & Drug Information Updates:

Cue Health COVID-19 Tests – Avoid Use Due to Risk of False Results 5/13/24
The FDA warned patients, caregivers, and health care professionals not to use the Cue Health COVID-19 Tests due to an increased risk of false results.

Optional Autoinjector Devices Used With Glatiramer Acetate Injection – Compatibility Issues 5/16/24
The FDA alerted patients, caregivers and health care professionals of labeling updates for glatiramer acetate injection products. Updated labeling includes a new warning that using an autoinjector that is not compatible with a specific glatiramer acetate injection product may increase medication errors, such as missed dose or administration of a partial dose. Not all glatiramer products may be administered using an optional autoinjector.

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

t:connect mobile app, Tandem Diabetes Care, Inc.: Recall – Software Problem 5/8/24
Tandem Diabetes Care, Inc. recalled version 2.7 (released 2/12/24 for devices using the Apple iOS platform) of the t:connect mobile app used with the t:slim X2 insulin pump with Control-IQ technology for a product correction. The software may cause the app to crash and be automatically relaunched resulting in excessive Bluetooth communication that may result in pump battery drain and pump shutdown sooner than typically expected. Customers should be instructed to update to version 2.7.1 or later.

Plastic syringes Made in China: Recalls & Additional Alerts - Potential Device Failures 5/9, 5/16, 5/21, & 5/23
The FDA made multiple updates to recalls and communications regarding plastic syringes made in China, including additional recalls of syringes from Sol-Millennium Medical, Inc; Medline Industries, LP; and Jiangsu Shenli Medical Production Co. Ltd.; and the addition import alerts for Zhejiang Longde Pharmaceutical Co. Ltd. and Shanghai Kindly Enterprise Development Group Co. Ltd. with the recommendation to immediately transition away from the use of plastic syringes made by these manufacturers. See the updated Safety Communication for current information.

Buprenorphine Hydrochloride Injection Carpuject Units and Labetalol Hydrochloride Injection, USP, Carpuject Units, Hospira: Recall – Potential Incomplete Crimp Seals 5/22/24
Hospira recalled several lots of buprenorphine hydrochloride injection Carpuject single-dose cartridge/tube unit with Luer lock (lots HJ3965, HJ8546) and labetalol hydrochloride injection, USP Carpuject single-dose cartridge unit with Luer lock (lots HJ7566, HN8747, HN8749) after a customer complaint for a leaking unit due to the potential for incomplete crimp seals.

Docetaxel Injection USP, Sagent Pharmaceuticals: Recall – Potential Particulate Presence 5/29/24
Sagent Pharmaceuticals recalled two lots of Docetaxel Injection USP (80 mg per 8 mL multi-dose vials [lot F1030001] and 160 mg per 16 mL multi-dose vials [lot F1040001]) following a customer complaint of potential presence of particulate matter from the stopper within the drug product.

Nimbus II Infusion Pump System, OptumHealth Care Solutions: Recall – Multiple Potential Failures 5/30/24
OptumHealth Care Solutions recalled their Nimbus II Plus infusion pump in direct response to the Feb 21, 2024 InfuTronix recall of these devices due to multiple potential failure modes that may include battery failure, upstream blockage, system errors, drug product leakage, high or low flow rate, or damaged housing. The devices will not be available or supported after June 20, 2024.

New Product Shortages	***Date Initially Posted***
Mefloquine Hydrochloride	5/14/2024

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Iloprost solution (Ventavis, Actelion): Philips Respironics has discontinued the I-neb AAD system and associated supplies, including the discs required for administering the Ventavis inhalation solution. Actelion has now discontinued Ventavis iloprost solution. Patients will need to be switched to an alternative treatment for pulmonary hypertension.	5/9/24

Removed/Restricted Indications:	***Description***	***Date***
Infigratinib / Truseltiq / QED Therapeutics, Inc.	Accelerated approval for previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 fusion or other rearrangement withdrawn at sponsor's request due to difficulties recruiting and enrolling subjects for a confirmatory trial for use in first line treatment of cholangiocarcinoma and determination that continued distribution as a second line therapy was not commercially reasonable. Accelerated approval had been granted on 5/28/2021.	5/16/24

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Tarlatamab / Imdelltra / Amgen Inc.	Anti-cancer agent indicated for the treatment of adult patients with extensive-stage small cell lung cancer (ESS-SCLC) with disease progression on or after platinum-based chemotherapy.	5/16/24
mRNA-1345 / mRESVIA / Moderna ModernaTX, inc	An mRNA vaccine for the prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older.	5/31/24

New Indications:	***Description***	***Date Approved***
Lisocabtagene maraleucel / Breyanzi / Juno Therapeutics Inc.	Treatment of adults with relapsed or refractory follicular lymphoma who have received two or more prior lines of systemic therapy	5/15/24
Selpercatinib / Retevmo / Eli Lilly and Company	Treatment for pediatric patients two years of age and older with advanced or metastatic medullary thyroid cancer, advanced or metastatic thyroid cancer, or locally advanced or metastatic solid tumors, which have RET alterations	5/29/24
Lisocabtagene maraleucel / Breyanzi / Juno Therapeutics Inc.	Treatment of adults with relapsed or refractory mantle cell lymphoma who have received two or more prior lines of systemic therapy, including a Bruton tyrosine kinase inhibitor	5/30/24

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Mycophenolate mofetil / Myhibbin / Azurity Pharmaceuticals	Oral suspension: 200 mg/mL in 175 mL bottle; raspberry flavored suspension indicated for prophylaxis of organ rejection in adult and pediatric patients 3 months of age and older of allogeneic kidney, heart, or liver transplants, in combination with other immunosuppressants	5/1/24
Clonidine Hydrochloride/ Onyda XR / Tris Pharma Inc.	Extended-Release oral suspension: 0.1 mg/mL in 120 mL bottle; orange flavored suspension indicated for the treatment of attention deficit hyperactivity disorder as monotherapy or as adjunctive therapy to stimulants in pediatric patients 6 years of age and older	5/24/24

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Tarlatamab / Imdelltra / Amgen Inc.	
Generic Name / Brand Name / Company	Tarlatamab / Imdelltra / Amgen Inc.
Date of approval	5/6/24
Drug Class (Mechanism of Action if novel agent)	Antineoplastic Agent: Anti-DLL3/CD3, bispecific T-cell engager
Indication	Treatment of extensive stage small cell lung cancer in adults with disease progression on or after platinum-based chemotherapy.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Lyophilized powder in single-dose vial for injection, 1 mg & 10 mg
Common Dose/sig	Step-up dosing schedule reduces risk of cytokine release syndrome. See dosing schedule in prescribing information.
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Targretin, Imdevimab, Imdur
Clinical Use Evaluation	
Common Adverse Effects	>20%: cytokine release syndrome, fatigue, pyrexia, dysgeusia, decreased appetite, musculoskeletal pain, constipation, anemia, nausea
Severe Adverse Effects	Cytokine release syndrome, fatigue, neurologic toxicity, cytopenia, tumor lysis syndrome, decreased sodium, decreased potassium
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Complete blood count, liver enzymes, and bilirubin before each dose.
Used in Pediatric Areas	Safety and effectiveness have not been established in pediatric patients.
Renal or Hepatic Dosing	No dosage adjustments are required in mild/moderate renal impairment or mild hepatic impairment. Effect of severe renal impairment, end-stage renal disease, or moderate/severe hepatic impairment is unknown. Permanently discontinue if Grade 4 hepatotoxicity occurs.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Black box warning for cytokine release syndrome and neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome. Other warnings: cytopenias, infections, hepatotoxicity, hypersensitivity, and risk for fetal harm
Special administration technique or considerations	Must be reconstituted and diluted before administration. Should only be administered by qualified healthcare professional. Administer dexamethasone or equivalent before first 2 doses. Administer 1 L normal saline IV over 4 to 5 hours after first 3 doses; ensure patients are well hydrated before all doses. Administer as intravenous infusion over 1 hour at an infusion rate of 250 mL/hour. Flush IV catheter over 3-5 minutes with normal saline. Patients should be monitored from the start of the infusion for 22-24 hours on Cycle 1 Day 1 and Cycle 1 Day 8 in healthcare setting. Patients should remain within an hour of a healthcare setting for 48 hours from the start of the infusion and should be accompanied by a caregiver. Observe for 6-8 hours after doses on Cycle 1 Day 15 and Cycle 2, 3-4 hours after doses in Cycles 3 and 4, and 2 hours after all subsequent doses.
Prepared by	Emily Hitt, PharmD
Source	*Imdelltra* (tarlatamab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; May 2024.

Respiratory Syncytial Virus Vaccine (mRNA) / MRESVIA / Moderna US, Inc.	
Generic Name / Brand Name / Company	Respiratory syncytial virus vaccine (mRNA) / MRESVIA / Moderna US, Inc.
Date of approval	5/31/24
Drug Class (Mechanism of Action if novel agent)	Respiratory syncytial virus (RSV) vaccine containing modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F protein), which induces an immune response against RSV pre-F protein to protect against lower respiratory tract disease caused by RSV
Indication	Immunization for prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older
Comparative agent – Therapeutic interchange?	Alternative RSV vaccines: AREXVY (GSK), ABRYSVO (Pfizer)
Dosage forms/strengths.	Injectable suspension: single-dose syringes containing 1 dose of 0.5 mL
Common Dose/sig	Inject 0.5 mL intramuscularly into the deltoid once
DEA Schedule	N/A
Date of market availability	By Fall 2024
Similar Medication Names	Mesalamine, Mesalazine, Respiratory Syncytial Virus Vaccine (Recombinant), Respiratory Syncytial Virus Vaccine (Recombinant [adjuvanted])
Clinical Use Evaluation	
Common Adverse Effects	≥10%: injection site pain, fatigue, headache, myalgia, arthralgia, underarm swelling or tenderness, chills
Severe Adverse Effects	Grade 3 (preventing daily activity): fever, headache, fatigue, myalgia, arthralgia, nausea/vomiting, chills
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	Safety and effectiveness have not been established in pediatric patients
Renal or Hepatic Dosing	None
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Vaccine is contraindicated in individuals with history of anaphylaxis to any of its components. Appropriate medical treatment must be readily available to manage potential anaphylactic reactions following vaccine administration. Fainting may occur in association with vaccine administration; ensure there are procedures in place to avoid injury from fainting. Immunocompromised patients may have a diminished immune response to this vaccine.
Special administration technique or considerations	Vaccine is supplied as prefilled syringe containing a frozen suspension that must be thawed prior to administration. Do not refreeze after thawing. Thawing time depends on whether vaccine is thawed in the refrigerator or at room temperature. Vaccine thawed in the refrigerator may be stored up to 30 days; vaccine thawed at room temperature must be used within 24 hours.
Prepared by	Emily Hitt, PharmD
Source	*MRESVIA* (respiratory syncytial virus vaccine) [prescribing information]. Princeton, NJ: Moderna US, Inc; May 2024.