WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 4/1/23 – 4/30/23

FDA Drug Safety Communications & Drug Information Updates:

Mail-back Envelopes to be Available for Opioid Analgesics Dispensed in Outpatient settings 4/3/23

The FDA announced it is requiring manufacturers of opioid analgesics dispensed in the outpatient setting to make prepaid mail-back envelopes available to outpatient pharmacies and other dispensers as an additional opioid analgesic disposal option for patients.

Abbott Issued Safety Notification for FreeStyle Libre Family of Readers 4/4/23

Abbott initiated a medical device correction to emphasize proper instructions for FreeStyle Libre readers following reports of the device's lithium-ion battery malfunctioning. No specific products are being recalled.

Gohibic (vilobelimab) Injection Authorized for the Treatment of COVID-19 4/4/23

The FDA issued an Emergency Use Authorization (EUA) for the use of Gohibic (vilobelimab) injection for treating COVID-19 in hospitalized adults when initiated within 48 hours of invasive mechanical ventilation or extracorporeal membrane oxygenation. Vilobelimab is a monoclonal anti-human complement factor C5a antibody demonstrated to reduce all-cause mortality 23.9% compared with placebo in patients critically ill with COVID-19 and invasively mechanically ventilated.

FDA Withdraws Approval of Makena (Hydroxyprogesterone Caproate) and Generics 4/6/23

The FDA announced the final decision to withdraw approval of Makena (hydroxyprogesterone caproate) and its generics. The drug was approved via the accelerated approval pathway in 2011 to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of spontaneous preterm birth. Approval included a requirement that the sponsor conduct a post-marketing confirmatory study. The confirmatory study did not verify clinical benefit of the drug, prompting withdrawal of approval of Makena and generic versions of Makena.

Quinacrine Hydrochloride Added to the List of Bulk Drug Substances that May Be Used in Compounding 4/6/23

The FDA added quinacrine hydrochloride to the list of bulk drug substances that may be used in compounding by outsourcing facilities (503B Bulks List) to meet the need for drug products used in the treatment of some patients with cutaneous lupus erythematosus.

Risk of Protection Failure with Certain O&M Halyard Surgical N95 Respirators, Surgical Masks, and Pediatric Face Masks: FDA Safety Communication 4/12/23 and 4/21/23

The FDA issued a safety communication recommending consumers, healthcare providers, and facilities not use certain surgical N95 Respirators by O&M Halyard and use caution with certain surgical masks and pediatric face masks made by O&M Halyard. Additional information on specific respirators and masks can be found on the FDA site.

Labeling Updates for All Opioid Pain Medications. 4/13/23

The FDA is requiring several updates to the prescribing information for both the immediate-release (IR) and extended-release (ER)/long-acting (LA) opioids. These updates include a new warning about opioid-induced hyperalgesia, and statements that: the risk for overdose increases as the dose increases for all opioid medications, IR opioids should not be used for an extended period of time unless a patient's pain remains severe enough to require them and alternate treatment options remain inadequate, many acute pain conditions treated in the outpatient setting require no more than a few days of an opioid pain medicine, and ER/LA opioid pain medicines should be reserved for severe and persistent pain that requires an extended treatment period with daily opioid pain medicine and for which alternate treatment options are inadequate.

Bivalent mRNA COVID-19 Vaccine Recommendations 4/18/23

The FDA amended the EUAs for the Moderna and Pfizer bivalent mRNA COVID-19 vaccines to simplify the regimen for most individuals. The EUAs were updated authorizing the bivalent vaccines to be used for all doses administered to individuals 6 months of age and older. The monovalent vaccines are no longer authorized for use in the US.

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

Ivenix Infusion System, Fresenius Kabi USA, LLC: Recall - Fluid Leaks that Delay or Interrupt Treatment 4/20/23

Fresenius Kabi USA recalled the Ivenix Infusion System, a large volume pump that is used in hospitals to deliver blood products to adults and pediatric patients, due to a leak that allows fluid to damage the electrical system, leading to loss of power and system failure.

Human and Animal Drug Products, Akorn: Recall - Company Shutdown 4/26/23

Akorn Operating company LLC has filed for chapter 7 bankruptcy on February 23, 2023. In connection with that filing, the company has ceased and shut down all operations. The Akorn Trustee is initiating a voluntary recall of within-expiry human and animal products as a result of the closure and discontinuation of the quality activity of these marketed products. Links to the lists of recalled products can be found on the FDA site.

Fentanyl Buccal Tablets, Teva: Recall - Labelling Error 4/27/23

Teva Pharmaceuticals USA recalled specific lots of fentanyl buccal lots manufactured and labeled for Mayne Pharmaceuticals Inc. The recall was initiated because some updated safety information regarding the use of the products was not included in the package insert or the medication guide. A complete list of recalled lots can be found on the FDA site.

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***
AK Forte*	Arthritis and joint pain	Diclofenac, dexamethasone, methocarbamol
American Bangster Black Label Optimum Formula 4000	Sexual enhancement	tadalafil
American Bangster Optimum Formula 3000	Sexual enhancement	Sildenafil, tadalafil
Dr. Rico Perez Super Kids Colostrum	Dietary supplement	Undeclared milk allergen
DYNAMITE SUPER*	Sexual enhancement	Tadalafil, sildenafil
EuroMedica Active B Complex	Vitamin	Undeclared milk allergen
NORF 20	Weight loss	Acetaminophen, salicylic acid, theophylline
Nose Slap	Energy Booster	Ammonia
NU·X Male Enhancement*	Sexual enhancement	Tadalafil, sildenafil
Pro Power Knight Plus*	Sexual enhancement	Tadalafil, sildenafil
Soul Slap	Energy booster	Ammonia
Tantra Jelly Herbal Jelly for Him	Sexual enhancement	Sildenafil, tadalafil
Terry Naturally Bioactive Vitamin B	Vitamin	Undeclared milk allergen
Truvy or TruVision Health branded products (eg, truCONTROL, reFORM, truWeight, Truvy boost, truBoost)*	Energy and weight loss	Hordenine and/or octodrine/1,5-dimethylhexylamine (DHMA)[1]

*recalled

[1]Hordenine and octodrine/DHMA have been associated with stimulant-like properties, rapid heart rate, high blood pressure, and are not approved dietary ingredients; use in pregnant patients, patients with cardiovascular disease, and during exercise may be potentially dangerous.

New Product Shortages	***Date Initially Posted***
Chloramphenicol sodium succinate injection	4/5/23
Penicillin G benzathine injectable suspension	4/26/23
0.9% Sodium chloride irrigation	4/28/23
Sterile water for irrigation	4/28/23
Carboplatin injection	4/28/23

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Glycopyrrolate inhalation solution (Lonhala Magnair, Sunovion): this product had no approved generics; alternative anticholinergic bronchodilators for inhalation remain available	4/3/23
Ethinyl estradiol / norethindrone acetate and ferrous fumarate tablets (Minastrin 24 Fe, Allergan): this chewable formulation had no approved generic	4/5/23
Albuterol sulfate inhalation aerosol, metered (Proventil HFA, Sandoz); generic formulations remain available	4/13/23
Nicotine (Nicotrol) Inhaler (Pfizer); alternative nicotine dosage forms (nasal spray, transdermal, lozenges, gum remain available	4/26/23
Prazosin capsules (Minipress, Pfizer); generics remain available from other manufacturers	4/28/23

New Drug Approvals:	***Description***	***Date Approved***
Omidubicel-onlv / Omisirge / Gamida Cell Ltd.	Modified allogeneic cord blood-based cell therapy to quicken recovery of neutrophils and reduce infection risk in patients 12 years and older with blood cancers planned for umbilical cord blood transplantation following myeloablative conditioning	4/17/23
Tofersen / Qalsody / Biogen	An antisense oligonucleotide indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS) associated with a mutation in the superoxide dismutase (SOD1) gene *(See Attached Drug Summary)*	4/25/23

New Indications:	***Description***	***Date Approved***
Pembrolizumab / Keytruda / Merck & Co	In combination with enfortumab vedotin-ejfv for adults with locally advanced or metastatic urothelial carcinoma, who are not eligible for cisplatin-containing therapy.	4/3/23
Enfortumab vedotin-ejfv / Padcev / Astellas Pharma	In combination with pembrolizumab for adults with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing therapy	4/3/23
Atogepant / Qulipta / AbbVie	Preventive treatment of migraine in adults with chronic migraine	4/17/23
Polatuzumab vedoti-piiq / Polivy / Genentech	Use in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the treatment of adult patients who have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index score of 2 or greater	4/19/23
20-Valent Pneumococcal Conjugate Vaccine / Prevnar 20 / Pfizer	For the active immunization of infants 6 weeks and older for prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F and in infants and children 6 weeks through 5 years of age for prevention of otitis media cause by *S. pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F.	4/27/23

Somapacitan-beco / Sogroya / Novo Nordisk Inc.	Treatment of pediatric patients who have growth failure due to inadequate secretion of endogenous growth hormone	4/28/23

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Rizatriptan / Rizafilm / Intelgenx Corp	Oral film: 10 mg; for acute treatment of migraine with or without aura in adults and pediatric patients 12 to 17 years of age and weighing at least 40 kg	4/14/23
Niraparib / Zejula / GlaxoSmithKline, LLC	Oral tablets: 100mg, 200mg, 300mg; same indications as the 100 mg capsules	4/26/23
Elexacaftor, Tezacaftor, Ivacaftor / Trikafta / Vertex Pharmaceuticals, Inc	Oral granules: unit-dose packets of elexacaftor, tezacaftor and ivacaftor co-packaged with unit-dose packets of ivacaftor; for the treatment of cystic fibrosis in patients aged 2 years and older who have at least one F5089del mutation in the CFTR gene or a mutation in the CFTR gene that is response based on in vitro data	4/26/23
Aripiprazole / Abilify Asimtufii / Otsuka America Pharmaceutical, Inc.	Extended-release injectable suspension: 960 mg/3.2 mL and 720 mg/2.4 mL in single-dose pre-filled syringes; for the treatment of schizophrenia in adults and maintenance monotherapy treatment of bipolar I disorder in adults administered as an intramuscular injection once every 2 months	4/27/23
Budesonide and formoterol fumarate / Symbicort Aerosphere / AstraZeneca	Inhalation aerosol: pressurized metered dose inhaler delivering budesonide 160 mcg and formoterol fumarate 4.8 mcg per actuation; maintenance treatment of COPD with dose of 2 actuations twice daily by oral inhalation	4/28/23
Risperidone / Uzedy / Teva	Extended-release suspension for subcutaneous administration: 50 mg/0.14 mL, 75 mg/0.21 mL, 100 mg/0.28 mL, 125 mg/0.35 mL, 150 mg/0.41 mL, 200 mg/0.56 mL, 250 mg/0.7 mL in single-dose prefilled syringes; for the treatment of schizophrenia in adults administered as a subcutaneous injection by a healthcare professional once monthly or once every 2 months	4/28/23
Sildenafil / Liqrev / CMP Pharma	Oral suspension: 10 mg/mL; for treatment of pulmonary arterial hypertension in adults at a dose of 20 mg orally three times daily	4/28/23

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Tofersen / QALSODY / Biogen, Inc.	
Generic Name / Brand Name / Company	Tofersen / QALSODY / Biogen, Inc.
Date of approval	4/25/23
Drug Class (Mechanism of Action if novel agent)	Antisense oligonucleotide
Indication	Amyotrophic lateral sclerosis (ALS) in adults with mutation in the superoxide dismutase 1 (SOD1) gene.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Injection: 100 mg/15 mL single-dose vial
Common Dose/sig	100 mg administered intrathecally; initiate with 3 doses administered at 14-day intervals and follow with a maintenance dose every 28 days
DEA Schedule	n/a
Date of market availability	May 2023
Similar Medication Names	Tofisopam, Tofranil, Inotersen
Clinical Use Evaluation	
Common Adverse Effects	>10%: pain, fatigue, arthralgia, increased CSF WBCs, myalgia.
Severe Adverse Effects	Myelitis, radiculitis, papilledema and elevated intracranial pressure, aseptic meningitis.
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.	None required
Used in Pediatric Areas	Safety and effectiveness have not been established in pediatric patients.
Renal or Hepatic Dosing	Pharmacokinetics in patients with renal or hepatic impairment have not been evaluated.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications. Myelitis and/or radiculitis – monitor for symptoms Papilledema and elevated intracranial pressure – monitor for symptoms Aseptic meningitis – monitor for symptoms
Special administration technique or considerations	Prior to administration, remove approximately 10 mL of CSF using a lumbar puncture needle. Administer as an intrathecal bolus injection over 1-3 minutes. Administer by, or under direction of, healthcare professionals experienced in performing lumbar punctures.
Prepared by	Stephen Mealey
Source	*Qalsody* (tofersen) [prescribing information]. Cambridge, MA: Biogen, Inc.; April 2023.