WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 5/1/22 – 5/31/22

FDA Drug Safety Communications & Drug Information Updates:

Janssen COVID-19 Vaccine Use Limits 5/5/22
The FDA limited the authorized use of the Janssen COVID-19 vaccine to individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Janssen vaccine because they would not otherwise receive a COVID-19 vaccine. These limits were added due to the risk of thrombosis with thrombocytopenia syndrome associated with the vaccine.

Labcorp Seasonal Respiratory Virus RT-PCR DTC Test Authorized 5/16/22
The FDA authorized the Labcorp Seasonal Respiratory Virus RT-PCR DTC Test for use without a prescription by individuals with symptoms of respiratory viral infection consistent with COVID-19. The test allows individuals to self-collect or collect with assistance a nasal swab sample that is sent to Labcorp for testing. The test can identify and differentiate influenza A and B, respiratory syncytial virus, and SARS-CoV-2. It is authorized for use in individuals 2 years and older.

Pfizer-BioNTech COVID-19 Vaccine Booster Dose Expanded to Children 5 through 11 Years 5/17/22
The FDA amended the emergency use authorization for the Pfizer-BioNTech COVID-19 vaccine authorizing a single booster dose in individuals 5 through 11 years of age, with administration at least 5 months after completion of the primary series with the Pfizer-BioNTech vaccine. The updated Fact Sheet can be found on the FDA website.

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

SyrSpend SF Cherry, Fagron Inc.: Recall – Microbial Contamination 5/3/22
Fagron Inc. recalled two lots of SyrSpend SF Cherry (lot A67185, 500 mL, NDC 51552-1123-5, expiration 08/31/2024; lot A67186, 4 L, NDC 51551-1123-9, expiration 08/31/2024) to the hospital, pharmacy, and distributor level due to potential contamination with *Burkholderia gladioli*.

Skippack Medical Lab SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold): Recall – Not Approved 5/10/22
SML Distribution LLC recalled the Skippack Medical Lab SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) and the FDA warned people not to use this test as it has not been authorized or approved by the FDA for distribution or use in the United States. The FDA is concerned about the risk of false results with the test because SML Distribution LLC has not provided the FDA with adequate data to show the test works correctly.

Accula SARS-CoV-2 Tests, Mesa Biotech: Recall – False Positives due to Contamination 5/10/22
Mesa Biotech recalled the Accula SARS-CoV-2 Test because certain lots have an increased risk of false positive results due to contamination at the manufacturing facility. The Accula test is a polymerase chain reaction test authorized for use in point of care settings.

Oral Rapid SARS-CoV-2 Antigen Rapid Test Kits and Joysbio SARS-CoV-2 Antigen Rapid Test Kits (Colloidal Gold), Woodside Acquisitions: Recall – Not Approved 5/17/22
Woodside Acquisitions recalled Oral Rapid SARS-CoV-2 Antigen Rapid Test Kits and Joysbio SARS-CoV-2 Antigen Rapid Test Kits (Colloidal Gold) because they have not been authorized or approved by the FDA for distribution or use in the United States. The FDA is concerned about the risk of false results with the test because Woodside Acquisitions has not provided the FDA with adequate validation data to show accurate test performance.

Anagrelide Capsules, 0.5 mg, Teva USA: Recall - Failed Dissolution Test 5/23/22

Teva ISA recalled one lot of anagrelide capsules (lot GD01090, 100 capsules, NDC 0172-5241-60, expiration 05/31/22) to the consumer/user level due to delayed dissolution that may result in decreased effectiveness in platelet lowering ability.

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***
Artri Ajo King Joint Supplements*	Joint health	Diclofenac
Botanic Choice Prune & Senna Softgels*	Constipation	Peanuts
NaturesPlus Keto Living Sugar Control*	Glucose control	Gluten (labeled as gluten free)

*recalled

New Product Shortages	***Date Initially Posted***
Fluorescein injection	5/2/22
Sufentanil citrate injection	5/3/22
Fludarabine phosphate injection	5/6/22
Iodixanol (Visipaque) injection	5/9/22
Iohexol (Omnipaque) injection	5/9/22
Iopromide (Ultravist) injection	5/26/22

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Risedronate 30 mg tablets (Actonel, Allergan): NDC 0430-0470-15, 30-count bottles; Actonel remains available in other strengths; risedronate 30 mg remains available from generic manufacturers.	5/9/22
Nedocromil Sodium Ophthalmic 2% solution (Alocril, Allergan): NDC 0023-8842—05; a generic remains available	5/18/22
Umbralisib tosylate 200 mg tablets (Ukoniq, TG Therapeutics): NDC 73150-200-12); this product was withdrawn from sale by the manufacturer and the FDA withdrew its approval. No equivalent is available. Patients should be switched to alternative treatments.	5/18/22

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Vonoprazan tablets; amoxicillin capsules; clarithromycin tablets / Voquezna Triple Pak / Phathom Pharmaceuticals	Co-packaged product containing vonoprazan, a potassium competitive acid blocker (PCAB), for the treatment of Helicobacter pylori (H. pylori) infection in adults.	5/3/22
Vonoprazan tablets; amoxicillin capsules / Voquenza Dual Pak / Phathom Pharmaceuticals	Co-packaged product containing vonoprazan, a PCAB, for the treatment of Helicobacter pylori (H. pylori) infection in adults.	5/3/22
Tirzepatide / Mounjaro / Eli Lilly and Company	For the treatment of type 2 diabetes mellitus.	5/13/22
Tapinarof / Vtama / Dermavant Sciences Inc.	An aryl hydrocarbon receptor agonist for the topical treatment of plaque psoriasis in adults	5/23/22

New Indications:	***Description***	***Date Approved***
Fam-trastuzumab deruxtecan-nxi / Enhertu / AstraZeneca	Indication modified to treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received a prior anti-HER2-based regimen either in the metastatic setting or in the neoadjuvant or adjuvant setting in those with disease recurrence	5/4/22
Baricitinib / Olumiant / Lilly	Treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, noninvasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation; approval also provided for addition of a 4 mg tablet strength for this indication	5/10/22
Azacitidine / Vidaza / Celgene Corporation	For the treatment of pediatric patients one month and older with newly diagnosed juvenile myelomonocytic leukemia	5/20/22
Dupilumab / Dupixent / sanofi-aventis U.S. LLC and Regeneron Pharmaceuticals Inc.	For the treatment of adult and pediatric patients 12 years and older weighing at least 40 kg with eosinophilic esophagitis	5/20/22
Ivosidenib / Tibsovo / Servier Pharmaceuticals LLC	In combination with azacitidine or as monotherapy in the treatment of newly diagnosed acute myeloid leukemia with susceptible isocitrate dehydrogenase-1 (IDH1) mutation in patients age 75 years or older or with comorbidities that preclude use of intensive induction chemotherapy	5/25/22
Brolucizumab-dbll / Beovu / Novartis	Treatment of diabetic macular edema	5/27/22
Risdiplam / Evrysdi / Genentech Inc	Expanded indication to patients with spinal muscular atrophy (SMA) younger than 2 months old	5/27/22
Ipilimumab / Yervoy / Bristol Myers Squibb	In combination with nivolumab for treatment of unresectable advanced or metastatic esophageal squamous cell carcinoma	5/27/22
Nivolumab / Opdivo / Bristol-Myers Squibb Company	In combination with ipilimumab for treatment of unresectable advanced or metastatic esophageal squamous cell carcinoma	5/27/22
Nivolumab / Opdivo / Bristol-Myers Squibb Company	In combination with fluoropyrimidine- and platinum-based chemotherapy for treatment of unresectable advanced or metastatic esophageal squamous cell carcinoma	5/27/22
Tisagenlecleucel / Kymriah / Novartis	Treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy	5/27/22

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Edaravone / Radicava Ors / Mitsubishi Tanabe Pharma America Inc	Oral suspension: 105 mg/5 ml in a multi-dose amber glass bottle, supplied in 14-day and 10-day treatment cycle kits including dosing syringes and bottle adapter; for the treatment of amyotrophic lateral sclerosis (ALS)	5/12/22
Tecovirimat / TPOXX / Catalent Pharma Solutions, Patheon Manufacturing Services LLC	Injection, 200 mg/20 ml for dilution prior to IV infusion; for the treatment of human smallpox disease in adults and pediatric patients weighing at least 3 kg	5/18/22
Treprostinil / Tyvaso DPI / United Therapeutics	Dry powder inhaler: 16, 32, 48, or 64 mcg per cartridge; for the treatment of pulmonary hypertension.	5/23/22

Compiled by:

Terri Levien, Pharm.D.
Tristan Hilton, Doctor of Pharmacy Candidate 2023
Ashley Rittenhouse, Doctor of Pharmacy Candidate 2023

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

Vonoprazan co-packaged products / Voquezna Triple Pak and Dual Pak / Phathom Pharmaceuticals	
Generic Name / Brand Name / Company	Vonoprazan tablets; amoxicillin capsules; clarithromycin tablets / Voquezna Triple Pak / Phathom Pharmaceuticals Vonoprazan tablets; amoxicillin capsules / Voquezna Dual Pak / Phathom Pharmaceuticals
Date of approval	5/3/22
Drug Class (Mechanism of Action if novel agent)	Potassium-competitive acid blocker (PCAB) + amoxicillin +/- clarithromycin
Indication	Treatment of *H. pylori* infection in adults
Comparative agent – Therapeutic interchange?	PPI + clarithromycin + amoxicillin or metronidazole
Dosage forms/strengths. Common Dose/sig	One vonoprazan 20 mg tablet by mouth twice daily for 14 days (with co-packaged antibiotic(s)).
DEA Schedule	NA
Date of market availability	Anticipated 3rd quarter 2022
Similar Medication Names	-
Clinical Use Evaluation	
Common Adverse Effects	>2% (Voquezna Triple Pak): dysgeusia, diarrhea, vulvovaginal candidiasis, headache, abdominal pain, hypertension; >2% (Voquezna Dual Pak): diarrhea, abdominal pain, vulvovaginal candidiasis, nasopharyngitis
Severe Adverse Effects	Hypersensitivity, cutaneous reactions
Severe Drug-Drug Interactions	Consider clarithromycin's drug-drug interactions when prescribing Voquezna Triple Pak
Severe Drug-Food Interactions	None known
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	Avoid use if eGFR <30 ml/min and in moderate to severe hepatic impairment (Child-Pugh B or C). No other renal or hepatic dosage adjustment recommended.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Avoid use in patients with known hypersensitivity to vonoprazan or other product ingredients. Contraindicated with use or rilpivirine-containing products. Consider contraindications and cautions associated with the antibiotic ingredients.
Special administration technique or considerations	With or without food
Prepared by	Ashley Rittenhouse
Source	Voquezna Triple Pak and Voquezna Dual Pak [prescribing Information]. Buffalo Grove, Il: Phathom Pharmaceuticals; May 2022

Tirzepatide / Mounjaro / Lilly USA LLC	
Generic Name / Brand Name / Company	Tirzepatide / Mounjaro / Lilly USA LLC
Date of approval	5/13/22
Drug Class (Mechanism of Action if novel agent)	Glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) receptor agonist
Indication	Adults with type 2 diabetes mellitus
Comparative agent – Therapeutic interchange?	Once weekly injectable GLP-1 receptor agonists (liraglutide, dulaglutide, or exenatide)
Dosage forms/strengths. Common Dose/sig	Injection with single-use autoinjector pen: 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg per 0.5 mL. Starting dose of 2.5 mg. Inject 0.5 mL (2.5 mg) subcutaneously once weekly with or without food. May increase by 2.5 mg per week after at least 4 weeks on a dose.
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Monjuvi (tafasitamab)
Clinical Use Evaluation	
Common Adverse Effects	>5%: nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, abdominal pain
Severe Adverse Effects	Black Box Warning for thyroid c-cell tumors observed in rats and contraindicated in personal or family history of medullary thyroid carcinoma and Multiple Endocrine Neoplasia syndrome type 2; hypoglycemia (when combined with sulfonylureas or basal insulin); hypersensitivity reactions; injection site reactions; acute gallbladder disease
Severe Drug-Drug Interactions	Sulfonylureas / insulin / potential impact on oral absorption due to delaying gastric emptying (monitor narrow therapeutic drugs like warfarin and advise non-oral contraceptive methods or add barrier methods for 4 weeks after initiation/dose increase)
Severe Drug-Food Interactions	None, can take with or without regard to food
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Monitor renal function (potential acute kidney injury due to risk of severe dehydration from nausea/vomiting)
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	No renal or hepatic dose adjustments
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Black Box Warning for thyroid c-cell tumors observed in rats and contraindicated in personal or family history of medullary thyroid carcinoma and Multiple Endocrine Neoplasia syndrome type 2 or known hypersensitivity to tirzepatide or excipients Cautions consistent with GLP-1 receptor agonists including pancreatitis, hypoglycemia with concomitant insulin or insulin secretagogues, hyperemotivity reactions, acute kidney injury, severe gastrointestinal disease, and acute gallbladder disease.
Special administration technique or considerations	Only inject once weekly; maximum dose 15 mg weekly. Administer missed dose within 4 days or skip if longer; minimum 72 hours between doses. Rotate injection site each dose. Never mix or inject directly adjacent to insulin.
Prepared by	Tristan Hilton
Source	Mounjaro (tirzepatide) [prescribing information]. Indianapolis, IL: Lilly USA LLC; May 2022

Tapinarof / Vtama / Dermavant	
Generic Name / Brand Name / Company	Tapinarof cream / Vtama / Dermavant
Date of approval	5/23/22
Drug Class (Mechanism of Action if novel agent)	Aryl hydrocarbon receptor agonist
Indication	Plaque psoriasis in adults
Comparative agent – Therapeutic interchange?	Calcipotriene / calcitriol / tacalcitol / tazarotene / pimecrolimus, tacrolimus / topical steroids
Dosage forms/strengths. Common Dose/sig	1% topical cream. Apply a thin layer to affected area once daily.
DEA Schedule	NA
Date of market availability	Mid-2022
Similar Medication Names	Tapentadol / tacalcitol / tacrolimus / Veltassa (Patiromer)
Clinical Use Evaluation	
Common Adverse Effects	>1%: folliculitis, nasopharyngitis, contact dermatitis, headache, pruritis, influenza
Severe Adverse Effects	Urticaria, drug eruption
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
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments recommended
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications
Special administration technique or considerations	Do not use in or around the eyes, mouth, or vagina. Wash hands after application unless treating hands.
Prepared by	Ashley Rittenhouse and Tristan Hilton
Source	Vtama (tapinarof) [prescribing information]. Long Beach, CA: Dermavant Sciences Inc.; May 2022