WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 4/1/22 – 4/30/22

FDA Drug Safety Communications & Drug Information Updates:

FDA Updates Sotrovimab Emergency Use Authorization 4/5/22
Sotrovimab is no longer authorized to treat Covid-19 in any US region due to an increase in the percentage of Covid-19 cases caused by the Omicron BA.2 sub-variant, which data shows the authorized dose of sotrovimab is unlikely to be effective against. More information, including the current health care provider fact sheet for sotrovimab can be found at the FDA website.

FDA Considers New Approach to Improve Safe Disposal of Prescription Opioid Analgesics 4/20/22
FDA announced it is seeking public comment on a potential change that would require opioid analgesics used in outpatient settings to be dispensed with prepaid mail-back envelopes and that pharmacists provide patient education on safe disposal of opioids. This potential modification to the existing Opioid Analgesic REMS would provide a convenient, additional disposal option for patients beyond those already available such as flushing, commercially available in-home disposal products, collection kiosks, and takeback events.

FDA Approves Bosentan REMS Modifications – Drug Information Update 4/29/22
The FDA approved modifications to the bosentan REMS program to take effect June 27, 2022. All stakeholders should document their enrollment/certification ID, username, and password, and confirm email prior to June 24 in order to login to the new platform. Under the new REMS, prescribers will be able to delegate some REMS administrative activities to member of their staff. Pharmacists will be required to obtain a pre-dispense authorization (PDA) by accessing the REMS website or calling the Bosentan Contact Center prior to dispensing. Pharmacists will be able to confirm patient testing results and enter or confirm patient counseling information through the website before obtaining a PDA. Additional information can be found on the Bosentan REMS website.

Counterfeit At-Home OTC COVID-19 Diagnostic Tests 4/29/22
The FDA advised healthcare professionals and consumers that counterfeit at-home diagnostic tests are being distributed or used in the US. These tests have not been authorized for use and may be associated with false-negative or false-positive results. The tests closely resemble authorized tests. Additional information for identifying counterfeit tests can be found on the FDA website. The FDA will continue to update this page.

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

Mickey Mouse and Mandalorian Hand Sanitizers, Best Brand Consumer Products: Recall – Presence of Methanol and Benzene 4/1/22
Best Brands Consumer Products recalled one lot each of The Mandalorian Hand Sanitizer Ethyl Alcohol 68% (MFG Lot 20D21, Expire Date 6/30/2022, NDC 74530-013-02) available in green and blue formulations and Mickey Mouse Hand Sanitizer Ethyl Alcohol 68% (MFG Lot 20E21, Expire Date 9/30/2022, NDC 74530-012-02) blue formulation to the consumer level after FDA testing found the presence of benzene in The Mandalorian Hand Sanitizer product and methanol in the Mickey Mouse Hand Sanitizer product.

Insulin Glargine-yfgn Injection, 100 units/mL, Mylan Pharmaceuticals: Recall – Potential Missing Label 4/12/22
Mylan recalled one batch of Insulin glargine-yfgn, 100 units/mL (NDC 49502-393-80; Batch BF21002800; Expiry Aug 2023), packaged in a 10 mL vial inside a carton. This product is not the branded *Semglee* vial but the unbranded Insulin Glargine-yfgn vial. This batch is being recalled due to potentially missing vial labels on some vials. The product information, batch number and expiry date information are present on the carton.

Accupril (Quinapril) Tablets, Pfizer: Recall – Presence of a Nitrosamine 4/22/22

Pfizer recalled five lots of *Accupril* (quinapril) tablets to the patient level due to the presence of N-nitroso-quinapril observed in recent testing above the Acceptable Daily Intake level. Affected lot numbers and expiration dates can be found at the FDA website.

Compounded Drugs, Drug Depot LLC (APS Pharmacy): Recall – Sterility Issues 4/26/22

The FDA alerted health care professionals, patients, and animal owners of a recall by Drug Depot LLC, doing business as APS Pharmacy, of compounded drugs for human and animal use due to a lack of sterility assurance. The compounded products for human use included gonadorelin acetate, testosterone cypionate in grapeseed oil, testosterone cypionate/anastrozole in grapeseed oil, testosterone cypionate/DHEA in grapeseed oil, and testosterone cypionate/propionate in sesame seed oil. Those for animal use included cyclosporine and tacrolimus for animal ophthalmic use. A list of recalled products can be found at the FDA website.

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" – products containing "Artri" in name (eg, Artri Ajo Kin)	Arthritis, muscle pain, osteoporosis, bone cancer	Dexamethasone, diclofenac, methocarbamol
Artri King	Joint pain, arthritis	Dexamethasone, diclofenac
Cougar Secret Honey VIP	Sexual enhancement	Sildenafil
Erkexin	Sexual enhancement	Sildenafil
ETUMAX VIP Royal Honey for Him	Sexual enhancement	Sildenafil, tadalafil
Helmi's Honey VIP	Sexual enhancement	Tadalafil
HoneyGizer™	Sexual enhancement	Sildenafil
Kingdom Honey Royal Honey VIP	Sexual enhancement	Sildenafil
Medcare Golden Royal Honey	Sexual enhancement	Tadalafil
Ortiga – products containing "Ortiga" in name (eg, Ortiga Mas Ajo Rey)	Arthritis, muscle pain, osteoporosis, bone cancer	Dexamethasone, diclofenac, methocarbamol
Ortiga Mas Ajo Rey	Joint pain, arthritis	Dexamethasone, diclofenac, methocarbamol
Ortiga Mas Ajo Rey Extra Forte	Joint pain, arthritis	Dexamethasone, diclofenac, methocarbamol
Pink Pussycat Capsules*	Sexual Enhancement	Sildenafil
Royal Honey VIP	Sexual enhancement	Tadalafil
Secret Miracle Honey	Sexual enhancement	Sildenafil
Vital Honey	Sexual enhancement	Tadalafil
X Rated Honey for Men	Sexual enhancement	Tadalafil

*recalled

New Product Shortages	***Date Initially Posted***
Sodium Chloride 14.6% Injection	4/5/22
Ibutilide fumarate injection	4/29/22

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Naratriptan tablets (Amerge; GlaxoSmithKline); naratriptan tablets remain available from other manufacturers.	4/7/22
Dorzolamide ophthalmic solution (Trusopt, Merck Sharp & Dohme Corp); dorzolamide ophthalmic solution remains available from other manufacturers.	4/11/22

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Oteseconazole / Vivjoa / Mycovia Pharmaceuticals	Azole antifungal indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential	4/26/22
Mavacamten / Camzyos / Bristol Myers Squibb	Cardiac myosin inhibitor indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms	4/28/22

New Indications:	***Description***	***Date Approved***
Axicabtagene ciloleucel / Yescarta / Kite Pharma	For adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemotherapy; not indicated for the treatment of patients with primary central nervous system lymphoma	4/1/22
Alpelisib / Vijoice / Novartis	For the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy	4/5/22
Dapagliflozin and metformin extended-release / Xigduo XR / AstraZeneca	To reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression	4/11/22
Ceftolozane and tazobactam / Zerbaxa / Merck	Indications expanded to include use in pediatric patients from birth to less than 18 years of age for all approved indications: complicated urinary tract infections including pyelonephritis and complicated intra-abdominal infections	4/21/22
Remdesivir / Veklury / Gilead	Approval expanded to include pediatric patients 28 days of age and older weighing at least 3 kg with positive SARS-CoV-2 test who are hospitalized or not hospitalized but have mild-to-moderate COVID-19 and are at high risk for progression to severe disease	4/25/22
Ravulizumab-cwvz / Ultromiris / Alexion	Treatment of adult patients with generalize myasthenia gravis who are anti-acetylcholine receptor (AChR) antibody-positive	4/27/22

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Dexmedetomidine / Igalmi / BioXcel Therapeutics	Sublingual film: 120 mcg and 180 mcg; for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults	4/6/22
Benzoyl peroxide / Epsolay / Sol-Gel Technologies	Topical cream: 5%; for the treatment of rosacea in adults	4/22/22
Trientine tetrahydrochloride / Cuvrior / Orphalan	Tablets: 300 mg of trientine tetrahydrochloride, functionally scored; for the treatment of adult patients with stable Wilson's disease who are de-coppered and tolerant to penicillamine	4/28/22
Levothyroxine sodium / Ermeza / Mylan	Oral solution: 150 mcg/5 mL; for use in adults and pediatric patients for thyroid replacement therapy or pituitary thyrotropin suppression in the management of thyroid cancer	4/29/22

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Oteseconazole / Vivjoa / Mycovia Pharmaceuticals	
Generic Name / Brand Name / Company	Oteseconazole / Vivjoa / Mycovia Pharmaceuticals
Date of approval	4/26/22
Drug Class (Mechanism of Action if novel agent)	Azole antifungal
Indication	To reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history RVVC who are NOT of reproductive potential
Comparative agent – Therapeutic interchange?	Fluconazole
Dosage forms/strengths.	Capsules: 150 mg
Common Dose/sig	Oteseconazole monotherapy regimen: • Day 1, oteseconazole 600 mg as a single dose • Day 2, oteseconazole 450 mg as a single dose • Starting on day 14, oteseconazole 150 mg every 7 days for 11 weeks (weeks 2 through 12) Fluconazole/oteseconazole regimen: • Days 1, 4, and 7, fluconazole 150 mg • Days 14-20, oteseconazole 150 mg once daily for 7 days • Starting on day 28, oteseconazole 150 mg every 7 days for 11 weeks (weeks 4 through 14)
DEA Schedule	None
Date of market availability	Late 2022
Similar Medication Names	Fluconazole, itraconazole, Vijoice, voriconazole
Clinical Use Evaluation	
Common Adverse Effects	> 2%: headache, nausea
Severe Adverse Effects	None specified in labeling
Severe Drug-Drug Interactions	BCRP transporter substrates (eg, rosuvastatin): oteseconazole is a BCRP inhibitor. Concurrent use with BCRP substrates may increase the risk of adverse effects associated with these drugs.
Severe Drug-Food Interactions	Administration of this drug with a high-fat, high-calorie meal increased Cmax and AUC by 45% and 36%. No significant differences when taken with a low-fat, low-calorie meal.
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 pre-menarchal pediatric females.
Renal or Hepatic Dosing	No dosage adjustment is recommended in patients with mild/moderate renal impairment; use is not recommended in severe renal impairment or end-stage renal disease. No dosage adjustment is recommended in patients with mild hepatic impairment; use is not recommended in patients with moderate or severe hepatic impairment.

Oteseconazole continued…	
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications • Females of reproductive potential • Pregnant and lactating women • Known hypersensitivity to oteseconazole Warnings • Embryo-fetal toxicity: Animal studies show that this drug may cause fetal harm, specifically a range of ocular abnormalities.
Special administration technique or considerations	Oteseconazole capsules should be given orally with food. The capsules should be swallowed whole and not chewed, crushed, dissolved, or opened. Fluconazole for the combination regimen is not supplied in the oteseconazole carton.
Prepared by	Emily Hitt
Source	*VIVJOA* (oteseconazole) [prescribing information]. Durham, NC: Mycovia Pharmaceuticals; April 2022.

Mavacamten / Camzyos / MyoKardia (Bristol Myers Squibb)	
Generic Name / Brand Name / Company	Mavacamten / Camzyos / MyoKardia (Bristol Myers Squibb)
Date of approval	4/28/22
Drug Class (Mechanism of Action if novel agent)	Cardiac myosin inhibitor
Indication	For the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Capsules: 2.5 mg, 5 mg, 10 mg, and 15 mg
Common Dose/sig	The recommended starting dose is 5 mg orally once daily without regard to food; allowable subsequent doses with titration are 2.5, 5, 10, or 15 mg once daily based on clinical response and Valsalva left ventricular outflow tract (LVOT) gradient assessment.
DEA Schedule	None
Date of market availability	Available, only through a REMS program
Similar Medication Names	Mevacor, Mavenclad
Clinical Use Evaluation	
Common Adverse Effects	>5% and more often than placebo: dizziness (27% vs 18%) and syncope (6% vs 2%).
Severe Adverse Effects	Heart failure due to systolic dysfunction
Severe Drug-Drug Interactions	Moderate to strong CYP2C19 inducers or inhibitors; strong CYP3A4 inhibitors; moderate to strong CYP3A4 inducers. Concomitant disopyramide, ranolazine, verapamil with a concurrent beta-blocker, diltiazem with a concurrent beta-blocker. Combination hormonal contraceptives (CHCs)
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Pregnancy testing in females of reproductive potential prior to initiation
Used in Pediatric Areas	Safety and effectiveness not established in patients less than 18 years old.
Renal or Hepatic Dosing	No dose adjustments required for mild-to-moderate renal or hepatic impairment. The effects of severe renal or hepatic impairment and of renal failure are unknown.

Mavacamten continued…	
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: Concomitant moderate to strong CYP2C19 inducers or inhibitors, strong CYP3A4 inhibitors, and moderate to strong CYP3A4 inducers. Warnings and precautions: Mavacamten reduces systolic function and can cause heart failure or total blockade of ventricular function; initiation of mavacamten in patients with LVEF <55% is not recommended. Concomitant use of mavacamten with CYP2C19 and CYP3A4 inducers or inhibitors may lead to life-threatening heart failure or loss of effectiveness. Mavacamten may cause embryo-fetal toxicity when administered to a pregnant woman. Because mavacamten can reduce the effectiveness of hormonal contraceptives, patients taking hormonal contraceptives should be advised to use an alternative method of contraception that is not affected by CYP enzyme induction or to add a nonhormonal method.
Special administration technique or considerations	Genetic variation in CYP2C19 and CYP3A4 activity can cause large differences in mavacamten exposure. The initial dose and subsequent titration are based on LVEF, Valsalva LVOT, and clinical status. The dosing algorithms in the mavacamten prescribing information are recommended to guide initiation and maintenance dosing of mavacamten. Dose interruption is recommended if LVEF decreases to <50%. Dose reduction or discontinuation may be recommended for patients taking concomitant weak or moderate CYP2C19 or CYP3A4 inhibitors or inducers.
Prepared by	Regan Smith
Source	Camzyos (mavacamten) [prescribing information]. Brisbane, CA: Bristol Myers Squibb; April 2022.