WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 7/1/22 – 7/31/22

FDA Drug Safety Communications & Drug Information Updates:

FDA Authorizes Pharmacists to Prescribe Paxlovid (nirmatrelvir and ritonavir) 7/6/22
The FDA approved an Emergency Use Authorization (EUA) authorizing state-licensed pharmacists to prescribe Paxlovid to patients. Sufficient patient information must be available to assess renal and hepatic functions and a comprehensive list of medications that the patient is taking must be obtained to assess for potential drug interaction. More information about Paxlovid usage and the authorization can be found at the FDA website.

FDA Authorizes Emergency Use of Novavax COVID-19 Vaccine, Adjuvanted 7/13/22
The FDA issued an EUA for Novavax COVID-19 vaccine, Adjuvanted for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older. In a clinical trial in the US and Mexico, the vaccine proved 90.4% effective overall in preventing mild, moderate, or severe COVID-19. In a subset of participants 65 years of age and older, the vaccine was 78.6% effective. The FDA warns that clinical trial data provide evidence for increased risks of myocarditis and pericarditis following administration of Novavax COVID-19 Vaccine, especially to participants who have history of those diseases. More information of Novavax COVID-19 vaccine can be found at the FDA website.

Paxlovid (nirmatrelvir and ritonavir) Shelf-Life Extension 7/26/22
The FDA authorized extended dates for 4 lots of Paxlovid, which were labeled with 9-month expiry. These 4 lots of Paxlovid were manufactured prior to the EUA issuance, which authorized 12-month product shelf-life for EUA products. The four lots are FL4515, FL4517, FR7229, and FR9088. More information about the latest expiration dates can be found at the FDA website.

Update on FDA Response to Monkeypox Outbreak 7/29/22
The FDA provided an update on the response to the monkeypox outbreak with information on diagnostics, vaccine (Jynneos Vaccine), and therapeutics (tecovirimat, TPOXX), including the CDC expanded access program for antiviral therapy. Additional information can be found on a dedicated FDA website.

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

Insulin Glargine (insulin glargine-yfgn) Injection Pens, 100 units/mL, Mylan: Recall – Missing Labels 7/5/22
Mylan Pharmaceuticals recalled batch BF21002895 of the unbranded biosimilar Insulin Glargine (insulin glargine-yfgn) Injection, 100 units/mL (U-100), 3 mL prefilled pens due to the potential for the label to be missing on some pens. This recall does not impact the branded Semglee (insulin glargine-yfgn) injection pens.

Propofol Injectable Emulsion, USP (Containing Benzyl Alcohol), Hospira: Recall - Visible Particulate 7/14/22
Hospira recalled one lot of Propofol Injectable Emulsion, USP (containing benzyl alcohol), 100 mL Single Patient Use Glass Fliptop Vial (NDC 0409-4699-54, lot DX9067), supplied in a case of 10 units (NDC 0409-4699-24), due to a visible particulate observed in a single vial during annual examination of retained samples.

Magnesium Citrate Saline Laxative Oral Solution, Vi-Jon, LLC: Recall Expanded - Microbial Contamination 7/15/22 & 7/25/22
Vi-Jon, LLC expanded its recall to include all lots of all flavors of Magnesium Citrate Saline Laxative Oral Solution to the consumer level after third party microbial testing identified the presence of *Gluconacetobacter liquefaciens*. The recall includes Cherry Flavor, Grape Flavor, and Lemon Flavor, 10 FL OZ (296 mL). Products were labeled under a variety of brands including CVS, Equate, Kroger, Rexall, Rite Aid, Walgreens, and others. The brands and NDCs of the recalled products can be found at the FDA website.

Family Dollar Voluntary Recalls of Certain Over-the-Counter Products 7/21/22
Family Dollar initiated a retail level product recall of certain products that were stored and inadvertently shipped to certain stores on or around May 1, 2022, through June 10, 2022, due to product being stored outside of labeled temperature requirements. The information on recalled products can be found at the FDA website.

Medfusion 3500 and 4000 Syringe Infusion Pumps, Smiths Medical: Recall – Software Issues 7/20/22
Smiths Medical recalled 118,055 Medfusion 3500 and 4000 Syringe Infusion Pumps due to 8 software malfunctions that affect different serial numbers and software versions. The malfunctions could result in under- or over-infusion or delays in medication delivery. The full list of affected pumps can be found on the FDA website.

Abacus Order Entry and Calculation Software, Baxter Healthcare Corp: Recall – Medication Label Errors 7/25/22
Baxter Healthcare Corp. recalled the Abacus software application due to the risk that final printed bag labels for compounded mixtures may contain incorrect information, including incorrect values or patient names, if changes to the label template had been made. Baxter is performing a software upgrade to remove the ability of users to change label templates. All printed labels should be closely reviewed.

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***
Adam's Secret Extra Strength 3000 Platinum	Sexual enhancement	Tadalafil
Adam's Secret Extra Strength Amazing Black	Sexual enhancement	Tadalafil
Adam's Secret Extra Strength Blue	Sexual enhancement	Tadalafil
Adam's Secret Extra Strength Purple	Sexual enhancement	Sildenafil, tadalafil
Honeymoon Exclusive for Men & Women	Sexual enhancement	Sildenafil, tadalafil
Kingdom Honey – Royal Honey VIP*	Sexual enhancement	Sildenafil
Launch Sequence*	Sexual enhancement	Tadalafil
Lipopastilla + Gold Max	Weight loss	Sibutramine[1], phenolphthalein[2]
Sustango*	Sexual enhancement	Tadalafil
Vital Honey – Vital VIP*	Sexual enhancement	Tadalafil

*recalled

[1]Sibutramine has been associated with increased cardiovascular events; removed from market for safety reasons in 2010[FDA]; N-desmethylsibutramine is an active metabolite of sibutramine

[2]Phenolphthalein was an over-the-counter laxative that is no longer marketed in the US due to carcinogenicity concerns

New Product Shortages	***Date Initially Posted***
Erythromycin ophthalmic ointment	7/6/22
Streptozocin sterile powder	7/12/22
Vandetanib tablets	7/13/22
Iomeprol Injection	7/14/22

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
None in July	

New Drug Approvals:

None in July

New Indications:	***Description***	***Date Approved***
Pegloticase / Krystexxa / Horizon Pharma	Co-administration of pegloticase with methotrexate (15 mg orally once weekly, for patients for whom methotrexate is not contraindicates and clinically appropriate) in the treatment of chronic gout in adult patients refractory to conventional therapy	7/7/22
COVID-19 Vaccine, mRNA / Comirnaty / Pfizer-BioNTech	Active immunization to prevent COVID-19 in individuals 12 through 15 years of age	7/8/22
Indigotindisulfonate sodium / Bludigo / Provepharm Sas Previously marketed without approved NDA	Visualization aid in the cystoscopic assessment of the integrity of the ureters in adults following urological and gynecological open, robotic, or endoscopic surgical procedures	7/8/22
Crizotinib / Xalkori / PF Prism CV	Treatment of adult and pediatric patients 1 year of age and older, with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) that is ALK-positive	7/14/22
Adalimumab-FKJP / Hulio / Mylan Pharmaceuticals Inc.	Indication of polyarticular Juvenile Idiopathic Arthritis expanded to include patients 2 years of age and older, and the indication of Crohn's Disease expanded to include patients 6 years of age and older	7/14/22
Steripentol / Diacomit / Biocodex SA	Indication of seizures associated with Dravet syndrome in patients taking clobazam expanded to include pediatric patients who are 6 months to less than 2 years of age and weighing 7 kg or more	7/14/22
Ruxolitinib / Opzelura/ Incyte Corp	Topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older	7/18/22
Adalimumab-ADAZ / Hyrimoz / Sandoz Inc.	Indication of polyarticular Juvenile Idiopathic Arthritis expanded to include patients 2 years of age and older, and the indication of Crohn's Disease expanded to include patients 6 years of age and older	7/18/22
Belimumab / Benlysta / Human Genome Sciences Inc.	Indication for treatment of active lupus nephritis expanded to include patients 5 17 years of age.	7/26/22
Adalimumab-ATTO / Amjevita / Amgen, Inc.	Indication of polyarticular Juvenile Idiopathic Arthritis expanded to include patients 2 years of age and older, and the indication of Crohn's Disease expanded to include patients 6 years of age and older	7/28/22
Adalimumab-AFZB / Abrilada / Pfizer Inc	Indication of polyarticular Juvenile Idiopathic Arthritis expanded to include patients 2 years of age and older, and the indication of Crohn's Disease expanded to include patients 6 years of age and older	7/29/22
Ustekinumab / Stelara / Centocor Ortho Biotech Inc	Treatment of active psoriatic arthritis expanded to include pediatric patients 6 years and older	7/29/22

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Zonisamide/ Zonisade/ Azurity	Oral suspension: 100 mg/5 mL; for adjunctive therapy in the treatment of partial-onset seizures in patients 16 years and older	7/15/22
Ravulizumab-CWVZ / Ultomiris / Alexion Pharm	Subcutaneous injection solution: 245 mg/3.5 mL, in on-body delivery system; for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria and atypical hemolytic uremic syndrome	7/22/22
Testosterone undecanoate / Kyzatrex / Marius Pharmaceuticals	Oral capsules: 100 mg, 150 mg, 200 mg; for testosterone replacement therapy in adult males with conditions associated with a deficiency of absence of endogenous testosterone	7/27/22
Roflumilast / Zoryve / Arcutis Biotherapeutics, Inc.	Cream: 0.3%; topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older (see attached drug summary)	7/29/22

Compiled by:

Terri Levien, Pharm.D.
Brittney Kessel, Pharm.D., PGY1 Drug Information Resident
Dang Huynh, 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

Roflumilast / Zoryve / Arcutis Biotherapeutics, Inc.	
Generic Name / Brand Name / Company	Roflumilast / Zoryve / Arcutis Biotherapeutics, Inc.
Date of approval	7/29/22
Drug Class (Mechanism of Action if novel agent)	PDE-4 inhibitor
Indication	Topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.
Comparative agent – Therapeutic interchange?	Topical corticosteroids, vitamin D analogues, tazarotene, tapinarof, pimecrolimus, tacrolimus
Dosage forms/strengths.	Cream, 0.3%: 3 mg of roflumilast per gram in 60-gram tubes
Common Dose/sig	Apply once daily to affected areas and rub in completely.
DEA Schedule	N/A
Date of market availability	Anticipated Mid-August 2022
Similar Medication Names	Roflumilast systemic, Zorbtive
Clinical Use Evaluation	
Common Adverse Effects	≥1%: Diarrhea, headache, insomnia, application site pain, upper respiratory tract infections, and urinary tract infections.
Severe Adverse Effects	None known
Severe Drug-Drug Interactions	The coadministration of roflumilast with systemic CYP3A4 inhibitors or dual inhibitors that inhibit both CYP3A4 and CYP1A2 simultaneously (e.g., erythromycin, ketoconazole, fluvoxamine, enoxacin, cimetidine) may increase roflumilast systemic exposure and may result in increased adverse reactions. The coadministration of roflumilast with oral contraceptives containing gestodene and ethinyl estradiol may increase roflumilast systemic exposure and may result in increased side effects.
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 efficacy not established in patients younger than 12 years of age.
Renal or Hepatic Dosing	No dosage adjustment in renal impairment. Contraindicated in patients with hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C) Do not use during labor and delivery, as animal studies showed oral roflumilast disrupted the labor and delivery process in mice.
Special administration technique or considerations	Apply to the affected areas once daily. Rub the cream in completely. Patients should be instructed to wash hands after applying, unless hands are being treated. If someone else applies the cream, they should wash their hands after applying.
Prepared by	Dang Huynh
Source	Zoryve (Roflumilast) [prescribing information]. Westlake Village, CA: Arcutis Biotherapeutics, Inc; July 2022.