WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 9/1/23 – 9/30/23

FDA Drug Safety Communications & Drug Information Updates:

FDA Eliminates REMS for Lotronex (Alosetron HCl) 9/8/23
The FDA has determined the REMS for Lotronex and alosetron HCl generics was no longer necessary to ensure the benefits outweigh the risks of ischemic colitis and complications of constipation. Prescribing can continue following the recommendations in the prescribing information and Medication Guide to mitigate risks.

Updated mRNA COVID-19 Vaccines Approved by the FDA 9/11/23
The FDA approved 2023-2024 mRNA vaccines from ModernaTX Inc. and Pfizer Inc including a monovalent component corresponding to the Omicron variant XBB 1.5. Subjects aged 5 years and older can receive one updated dose after 2 months from any COVID-19 vaccine. Kids aged 6 months to 4 years are eligible based on their vaccine history and can receive one or two doses of the updated vaccine. Unvaccinated kids in this age group can receive three doses of the updated Pfizer-BioNTech vaccine or two doses of the updated Moderna vaccine.

Oral Phenylephrine Determined to be Ineffective in Treatment of Congestion 9/12/23
The FDA held a Non-prescription Drug Advisory Committee meeting on September 11-12, 2023, to discuss the effectiveness of oral phenylephrine in over the counter for temporary relief of congestion. After discussing new data on the effectiveness, the advisory committee determined that scientific data does not support the recommended dosage of oral phenylephrine as a nasal decongestant. No safety concerns were raised. The FDA will consider the input and evidence before taking any action against the status of oral phenylephrine.

Tacrolimus Oral Capsule, Accord Healthcare Inc. – Therapeutic Equivalence Changed from AB to BX 9/18/23
The FDA changed the therapeutic equivalence rating for tacrolimus capsules manufactured by Accord Healthcare Inc., from AB to BX due to new data raising concerns about its equivalency to Prograf oral capsules. The primary concern lies in the potential for these generic capsules to induce elevated blood concentrations of tacrolimus, which creates a higher risk for adverse effects. At present, the FDA is not withdrawing Accord Healthcare Inc.'s tacrolimus oral capsules from the market; it remains approved and can still be prescribed. However, it is not recommended to be automatically substituted by a pharmacist for the brand-name drug. Other generic tacrolimus oral capsules manufactured by companies other than Accord Healthcare Inc are not affected by this issue.

Invasive Disease in Preterm Infants Given Probiotics 9/30/23
The FDA warned that preterm infants given probiotics are at risk of invasive, potentially fatal disease caused by the bacteria or fungi contained in probiotics and cited cases of bacteremia, fungemia, sepsis, and death. The FDA has not approved any probiotic product for use in infants, and the FDA reminds healthcare providers who administer probiotics containing live bacteria or yeast to treat, mitigate, cure, or prevent a disease or condition are required to submit an Investigational New Drug Application to the agency. The FDA also cited the American Academy of Pediatrics caution that current evidence does not support the routine use of probiotics, particularly in preterm infants with a birth weight less than 1000 g.

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

Cyclosporine (Sandimmune) Oral Solution 100 mg/mL by Novartis: Recall - Crystallization 9/12/23
Novartis recalled one lot (FX001691) of Sandimmune Oral solution (cyclosporine oral solution). The solution is subject to crystallization which results in non-uniform distribution in the product which may result in inconsistent dosing.

TheraBreath Kids Strawberry Splash, Church & Dwight: Recall - Contamination 9/8/23
Church & Dwight Co. recalled of one lot of TheraBreath Kids Strawberry Splash 16 oz (Lot #PA3083011) sold on Amazon from May 31 through September 2, 2023. The product is being recalled due to contamination from *Candida parapsilosis* which could pose a potential health risk for immune compromised children.

Hudson RCI Addipak Unit Dose Vial, 0.9% Full Normal Saline Solution, Medline Industries: Recall – Non-Sterile 9/20/23
Medline Industries recalled Lot 3B085 of Hudson RCI Addipak Unit Dose Vial, 0.9% Full Normal Saline Solution due to being non-sterile. It passed sterility testing but another lot in the same cleaning cycle failed sterility testing exposing the recalled lot to potential contamination.

Allergenic Extract – Pecan Nut (*Carya illinoinensis*), ALK-Abelló: Recall – False Negative Test Results 9/22/23
ALK-Abelló recalled Lot #0003963971 of Allergenic Extract – Pecan nut (*Carya illinoinensis*) – For Diagnostic Use Only, due to increased postmarketing adverse events reporting of false negative skin test results, including one case of life-threatening anaphylaxis resulting from a subsequent pecan nut exposure.

Sucralfate Oral Suspension 1 g/10 mL, VistaPharm: Recall – Microbial Contamination 9/22/23
VistaPharm recalled lot #810300 of sucralfate oral suspension 1 g/10 mL packaged in 16 oz bottles with NDC 66689-305-16 due to *Bacillus cereus* contamination.

Brexafemme (ibrexafungerp tablets), Scynexis: Recall – Cross Contamination with Beta Lactam 9/28/23
Scynexis recalled 2 lots of Brexafemme (ibrexafungerp) tablets due to potential cross contamination with a non-antibacterial beta lactam drug substance which could result in hypersensitivity reactions. The affected products were lots LF21000008 (expiration date 11/2023) and LF22000051 (expiration date 11/2025) distributed nationwide beginning in December 2022.

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***
Kuka Flex Forte	Joint pain, arthritis	Diclofenac
Nut Diet Max Nuez de la India Seeds and Capsules*	Weight loss	Yellow oleander[1]
Reumo Flex	Joint pain, arthritis	Diclofenac
Todorganic Natural Nuez de la India Seeds*	Weight loss	Yellow oleander[1]
WEFUN Capsules	Sexual Enhancement	Sildenafil

*recalled

[1]Ingestion of yellow oleander can cause neurologic, gastrointestinal, and cardiovascular adverse health effects that may be severe, or even fatal

New Product Shortages	***Date Initially Posted***
Vinblastine sulfate injection	9/14/23

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Cisatracurium Besylate Injection (Nimbex, Abbvie Inc.): generics remain available	9/11/23
Desvenlafaxine Succinate Tablet, Extended Release (Pristiq, Pfizer): 25 mg; discontinuation of the 50 mg and 100 mg previously announced; generics remain available	9/11/23

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Motixafortide / Aphexda / BioLineRx USA Inc.	Hematopoietic stem cell mobilizer used in combination with filgrastim to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma	9/8/23
Momelotinib / Ojjaara / GlaxoSmithKline	Kinase inhibitor for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia	9/15/23
Gepirone / Exxua / Mission Pharmacal	Serotonin 5HT1A agonist for the treatment of major depressive disorder (MDD) in adults	9/22/23
Cipaglucosidase alfa-atga / Pombiliti / Amicus Therapeutics	Hydrolytic lysosomal glycogen-specific enzyme indicated in combination with miglustat (Opfolda) for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy	9/28/23
Nedosiran / Rivfloza / Novo Nordisk Inc.	LDHA-directed small interfering RNA to lower urinary oxalate levels in children 9 years and older and adults with primary hyperoxaluria type 1 and relatively preserved kidney function (eGFR ≥ 30 mL/min/1.73 m^2)	9/29/23

New Indications:	***Description***	***Date Approved***
Avelumab / Bavencio / EMD Serono Inc	For the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma	9/6/23
Temozolomide / Temodar / Merck Sharp Dohme	Adjuvant treatment of adults with newly diagnosed anaplastic astrocytoma	9/14/23
Empagliflozin / Jardiance / Boehringer Ingelheim	To reduce the risk of sustained decline in eGFR, end stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression	9/21/23
Bosutinib Monohydrate / Bosulif / Pf Prism Cv	For the treatment of pediatric patients 1 year of age and older with chronic phase (CP) Philadelphia chromosome positive chronic myelogenous leukemia (Ph+ CML), newly diagnosed or resistant or intolerant to prior therapy	9/26/23

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Crizotinib / Xalkori / Pfizer	Oral pellets: 20, 50, and 150 mg; administered by opening shell and emptying contents directly into patient's mouth or into a dosing aid (eg, spoon, medicine cup) and then directly into the patient's mouth in adults with non-small cel lung cancer and adults or pediatric patients with anaplastic large cell lymphoma or inflammatory myofibroblastic tumor	9/7/23
Metronidazole/ Likmez / Saptalis Pharmaceuticals LLC	Oral suspension: 500 mg/5 mL in 200 mL bottle; for treatment of trichomoniasis in adults, amebiasis in adults and pediatric patients, and anaerobic bacterial infections in adults	9/22/23

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Phentolamine / Ryzumvi / Ocuphire Pharma Inc.	Ophthalmic solution 0.75% in single-patient-use vial; for the treatment of pharmacologically-induced mydriasis produced by adrenergic agonists (e.g.,phenylephrine) or parasympatholytic (e.g.tropicamide) agents	9/25/23
Bosutinib Monohydrate / Bosulif / Pf Prism Cv	Capsules: 50 mg, 100 mg; may be swallowed whole or opened and the contents mixed with applesauce or yogurt for patients unable to swallow whole capsules	9/26/23
Miglustat / Opfolda / Amicus Therapeutics US	Capsules: 65 mg; used in conjunction with cipaglucosidase alfa-atga for treating adult patients with late-onset Pompe disease who weigh 40 kg or more and don't respond to their current enzyme therapy	9/28/23
Vedolizumab / Entyvio / Takeda Pharmaceuticals USA	Subcutaneous injection: 108 mg/0.68 mL single-dose prefilled syringe and 108 mg/0.68 mL single-dose pen; for the treatment of adults with moderately to severely active ulcerative colitis	9/27/23
Tocilizumab-bavi / Tofidence / Biogen	Injection: 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL in single-dose vials for further dilution prior to IV infusion; biosimilar to Actemra for treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, and systemic juvenile idiopathic arthritis	9/30/23

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Motixafortide / Aphexda / BioLineRx, Ltd.	
Generic Name / Brand Name / Company	**Motixafortide / Aphexda / BioLineRx, Ltd.**
Date of approval	9/8/23
Drug Class (Mechanism of Action if novel agent)	Hematopoietic stem cell mobilizer
Indication	Used in combination with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma
Comparative agent – Therapeutic interchange?	Plerixafor
Dosage forms/strengths.	Injection: 62 mg as a lyophilized powder in a single-dose vial
Common Dose/sig	1.25 mg/kg actual body weight by subcutaneous injection 10 to 14 hours prior to initiation of apheresis. A second dose can be administered 10 to 14 hours prior to a third apheresis.
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	NA
Clinical Use Evaluation	
Common Adverse Effects	Injection site reactions (73%), general itching (38%), flushing (33%), back pain (21%)
Severe Adverse Effects	Anaphylaxis, tumor cell mobilization, leukocytosis, vomiting, injection site reactions, injection site cellulitis, hypokalemia, hypoxia
Severe Drug-Drug Interactions	Patients on beta-blockers may be at increased risk for hypotension in case of hypersensitivity reactions; replace with non-chronotropic agents.
Severe Drug-Food Interactions	NA
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Verify pregnancy status prior to treatment. Monitor white blood cell counts during motixafortide use.
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments recommended
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated if history of serious hypersensitivity to the drug. Premedicate before each dose and monitor for hypersensitivity. Administer in a facility with immediate access to treatment for allergies. Avoid use in leukemia patients as motixafortide may cause mobilization of leukemic cells and contamination of apheresis product.
Special administration technique or considerations	Administer filgrastim 10 mcg/kg subcutaneously once daily for four days prior to first dose of motixafortide and on each day prior to each apheresis. Premedicate all patients before each motixafortide dose with diphenhydramine (12.5 mg intravenously or 25 mg to 50 mg orally or another antihistamine), an H2 blocker, and a leukotriene inhibitor 30-60 minutes before injection. Rotate injection sites across abdomen, back or side of upper arm, or the thigh. Each injection volume should not exceed 2 mL; divided doses greater than 2 mL. Monitor patients for one hour after administration.
Prepared by	Adian Maloney
Source	Aphexda (motixafortide) [prescribing information]. Waltham, MA: BioLineRx USA Inc.; September 2023.

Momelotinib / Ojjaara / GlaxoSmithKline	
Generic Name / Brand Name / Company	Momelotinib / Ojjaara / GlaxoSmithKline
Date of approval	09/15/23
Drug Class (Mechanism of Action if novel agent)	Inhibits wild type Janus Kinase 1 and 2 (JAK1/JAK2), mutant JAK2V617F, and activin A receptor type 1 (ACVR1)
Indication	For the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF in adults with anemia.
Comparative agent – Therapeutic interchange?	Ruxolitinib
Dosage forms/strengths.	Tablets: 100 mg, 150 mg, 200 mg
Common Dose/sig	200 mg once daily until disease progression or unacceptable toxicity
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Mometasone
Clinical Use Evaluation	
Common Adverse Effects	≥20%: Thrombocytopenia, neutropenia, hypotension, peripheral edema, pruritus, skin rash, abdominal pain, diarrhea, nausea, urinary tract infection, hemorrhage, increased serum alanine aminotransferase, increased serum aspartate aminotransferase, increased serum bilirubin, dizziness, fatigue, headache, limb pain, cough, and fever
Severe Adverse Effects	Bacterial infection, viral infection, hemorrhage, acute kidney injury, pneumonia, pyrexia, thrombosis, syncope, thrombocytopenia, renal and urinary tract infection
Severe Drug-Drug Interactions	Organic Anion Transporting Polypeptide (OATP)1B1/B3 inhibitors: Monitor for adverse reactions and consider momelotinib dose reduction. Breast Cancer Resistance Protein (BCRP) substrates: Reduce rosuvastatin (BCRP substrate) dosage
Severe Drug-Food Interactions	Unknown
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Complete blood count (CBC) with platelets, hepatic panel
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment is necessary for renal impairment. In severe hepatic impairment (Child-Pugh class C) reduce initial dose to 150 mg once daily.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Do not initiate momelotinib in patients with an active infection Thrombocytopenia, neutropenia: manage by dose reduction/interruption Hepatotoxicity: monitor, manage with dose reduction/interruption
Special administration technique or considerations	Administer with or without food. Swallow tablets whole; do not cut, crush, or chew.
Prepared by	Adian Maloney
Source	Ojjaara (momelotinib) [prescribing information]. Durham, NC: GlaxoSmithKline; September 2023.

Gepirone / Exxua / Mission Pharmacal	
Generic Name / Brand Name / Company	Gepirone / Exxua / Mission Pharmacal
Date of approval	9/22/23
Drug Class (Mechanism of Action if novel agent)	Serotonin modulator; 5HT1A receptor selective agonist
Indication	Treatment of major depressive disorder
Comparative agent – Therapeutic interchange?	Other SSRIs
Dosage forms/strengths.	Extended-release tablets: 18.2 mg, 36.3 mg, 54.5 mg, and 72.6 mg
Common Dose/sig	18.2 mg once daily. The dosage can be increased to 36.3 mg orally once daily on day 4 and further titrated to 54.5 mg once daily after day 7 and 72.6 mg orally once daily after an additional week. The maximum daily dosage is 72.6 mg one daily
DEA Schedule	NA
Date of market availability	Early 2024
Similar Medication Names	Gepants (class), Exubera
Clinical Use Evaluation	
Common Adverse Effects	≥5% and twice the incidence of placebo: dizziness, nausea, insomnia, abdominal pain, dyspepsia
Severe Adverse Effects	Suicidal thought and behaviors in adolescents and young adults, QT prolongation, serotonin syndrome, and activation of mania or hypomania
Severe Drug-Drug Interactions	CYP3A4 moderate inhibitors: reduce gepirone dose CYP3A4 strong inhibitors: contraindicated Monoamine oxidase inhibitors: separate use by at least 14 days Drugs that prolong QTc interval: increase cardiac arrhythmias. Other serotonergic drugs increase risk of serotonin syndrome
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Electrolytes
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	Creatinine clearance < 50 mL/min: 18.2 mg orally once daily. Maximum recommended dosage of 36.3 mg orally once daily after Day 7. In moderate (Child-Pugh B) hepatic impairment: 18.2 mg once daily; contraindicated in patients with severe (Child-Pugh C) hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: hypersensitivity, prolonged QTc interval, congenital long QT syndrome, receiving strong CYP3A4 inhibitors, severe hepatic impairment, within 14 days of a MAOI Boxed warning for increased risk of suicidal thinking and behavior in pediatric and young adult patients QT prolongation: correct electrolyte abnormalities prior to initiating; perform ECG and monitor frequently in patients at risk of QTc prolongation Activation of mania or hypomania: screen for personal or family history of bipolar disorder, mania, or hypomania before initiating
Special administration technique or considerations	Take orally with food at the same time each day. Do not split, crush, or chew.
Prepared by	Adian Maloney
Source	Exxua (gepirone) [prescribing information]. San Antonio, TX: Mission Pharmacal Company; September 2023.

Cipaglucosidase alfa-atga / Pombiliti / Amicus Therapeutics	
Generic Name / Brand Name / Company	Cipaglucosidase alfa-atga / Pombiliti / Amicus Therapeutics
Date of approval	9/28/23
Drug Class (Mechanism of Action if novel agent)	Hydrolytic lysosomal glycogen-specific enzyme
Indication	Indicated in combination with miglustat (Opfolda) for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing at least 40 kg and who are not improving on their current enzyme replacement therapy
Comparative agent – Therapeutic interchange?	Nexviazyme (avalglucosidase alfa); Myozyme (alglucosidase alfa); Lumizyme (alglucosidase alfa)
Dosage forms/strengths.	For injection: 105 mg of cipaglucosidase alfa-atga as a lyophilized powder in a single-dose vial for reconstitution
Common Dose/sig	20 mg/kg administered every other week as an IV infusion over four hours
DEA Schedule	NA
Date of market availability	2024
Similar Medication Names	avalglucosidase alfa, alglucosidase alfa
Clinical Use Evaluation	
Common Adverse Effects	≥5%: headache, diarrhea, fatigue, nausea, abdominal pain, and pyrexia
Severe Adverse Effects	Hypersensitivity, infusion-related reactions
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.	Verify pregnancy prior to initiating treatment
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosing adjustments recommended
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindication: pregnancy Black Box Warning: Severe hypersensitivity reaction, infusion associated reactions, and risk of acute cardiorespiratory failure in susceptible patients
Special administration technique or considerations	Must be administered in combination with miglustat (Opfolda). Initiate infusion approximately 1 hour after oral miglustat. Consider administering antihistamines, antipyretics, and/or corticosteroids prior to administration. Completely infuse within 6 hours.
Prepared by	Adian Maloney
Source	Pombiliti (cipaglucosidase alfa-atga) [prescribing information]. Philadelphia, PA: Amicus Therapeutics US, LLC; September 2023.

Nedosiran / Rivfloza / Novo Nordisk Inc.			
Generic Name / Brand Name / Company	Nedosiran / Rivfloza / Novo Nordisk Inc		
Date of approval	9/29/23		
Drug Class (Mechanism of Action if novel agent)	Lowers hepatic lactate dehydrogenase levels by breaking down LDHA messenger ribonucleic acid in liver cells through RNA interference		
Indication	To lower urinary oxalate levels in children 9 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and preserved kidney function, e.g., eGFR ≥ 30 mL/min/1.73 m2		
Comparative agent – Therapeutic interchange?	Lumasiran (Oxlumo)		
Dosage forms/strengths.	Injection: 160 mg/mL in 80 mg single-dose vial, 128 mg single-dose prefilled syringe, and 160 mg single-dose prefilled syringe		
Common Dose/sig	Adults and adolescents 12 years and older	≥ 50 kg	160 mg subcutaneously once monthly
		< 50kg	128 mg subcutaneously once monthly
	Children 9-11 years old	≥ 50 kg	169 mg subcutaneously once monthly
		< 50 kg	3.3 mg/kg subcutaneously once monthly, not to exceed 128 mg
DEA Schedule	NA		
Date of market availability	Early 2024		
Similar Medication Names	Nedocromil		
Clinical Use Evaluation			
Common Adverse Effects	Mild injection site reactions (39%) included skin redness, pain, bruising, and rash		
Severe Adverse Effects	None known		
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 known		
Used in Pediatric Areas	Indicated for use in pediatric patients 9 years old and older		
Renal or Hepatic Dosing	No dose adjustment is recommended for patients with mild hepatic impairment or in patients with an estimated glomerular filtration rate (eGFR) of ≥ 30 mL/min/1.73 m^2. Has not been studied in PH1 patients with severe renal impairment (eGFR < 30 mL/min/1.73 m^2) or patients with moderate or severe hepatic impairment.		
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications and warnings: none in labeling		
Special administration technique or considerations	Administer by subcutaneous injection to the abdomen (at least 2 inches from the navel) or the upper thigh. Do not inject it into a vein or into scarred or bruised skin.		
Prepared by	Adian Maloney		
Source	Rivfloza (nedosiran) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; September 2023.		