WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 7/1/23 – 7/31/23

FDA Drug Safety Communications & Drug Information Updates:

Delayed Onset Inflammation, Dermal Fillers – FDA MedWatch Alert 7/6/23

The FDA updated information on dermal fillers with information on reports of delayed onset inflammation, swelling and redness that can develop near the dermal filler injection site following viral or bacterial illnesses or infections, vaccinations, or dental procedures. Such inflammation typically responds to treatment or resolves on its own.

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

Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 Metered Inhalations) by Cipla: Recall – Due to Container Defect 7/6/23

Cipla recalled 6 batches of albuterol sulfate inhalation aerosol due to a container defect resulting in leakage through the inhaler valve. The products were manufactured in November 2021 and have an expiry date of November 2023. The recalled batches are IB20045, IB20055, IB20056, IB20057, IB20059, and IB20072.

Tydemy, Lupin Pharmaceuticals: Recall – Out of Specification Stability Results 7/31/23

Lupin recalled lots L200183 and L201560 of Tydemy oral contraceptive (drospirenone, ethinyl estradiol and levomefolate calcium tablets 3 mg/0.03 mg/0.451 mg and levomefolate calcium tablets 0.451 mg) due to out of specification test results at the 12-month stability time point. Although the out of specification results were low for an inactive ingredient (ascorbic acid) and high for a known impurity, there is concern effectiveness of the product could be impacted. Products were distributed June 2022 to May 2023. The recall is to the patient/consumer level.

Spectrum V8 and Spectrum IQ Infusion Pumps, Baxter: Recall and Correction – Alarms 7/31/23

Baxter issued an urgent correction followed by a recall of Spectrum Infusion Pumps with Master Drug Library (Version 8; V8) and Spectrum IQ Infusion Systems with Dose IQ Safety Software (Version 9) that have been upgraded to software versions v8.01.01 and v9.02.01 due to an increase in reported false upstream occlusion alarms following the software upgrade. Pumps can continue to be used with appropriate cautions until a software reversion is completed.

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" or "Ortiga" products	Arthritis, muscle pain, osteoporosis, bone cancer	Dexamethasone, diclofenac sodium, methocarbamol; following an initial warning in April 2022 the FDA has received more than 30 additional reports of serious health effects following use of these medications

New Product Shortages	*Date Initially Posted*
Lisdexamfetamine Dimesylate Capsules	7/14/23
Methotrexate tablets	7/21/23
Methylphenidate HCl extended-release tablets	7/26/23

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Memantine hydrochloride extended-release capsules (Namenda XR, AbbVie Inc.); memantine hydrochloride extended-release capsules remain available from other manufacturers	7/11/23
Memantine hydrochloride tablet (Namenda, AbbVie Inc); memantine hydrochloride tablets remain available from other manufacturers	7/11/23
Beclomethasone dipropionate monohydrate nasal spray (Beconase AQ, GlaxoSmithKline); another nasal formulation of beclomethasone remains available	7/18/23

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Nirsevimab-alip / Beyfortus / AstraZeneca	Intramuscular monoclonal antibody for the prevention of RSV in neonates, infants, and children up to 24 months of age	7/17/23
Anthrax vaccine adsorbed, adjuvanted / Cyfendus / Emergent BioSolutions	Vaccine for post-exposure prophylaxis for anthrax	7/20/23
Quizartinib / Vanflyta / Daiichi Sankyo	Tyrosine kinase FLT3 inhibitor for treatment of newly diagnosed FLT3 ITD (internal tandem duplication) positive acute myeloid leukemia	7/20/23
Cantharidin / Ycanth / Verrica Pharmaceuticals Inc	Topical vesicant for the treatment of molluscum contagiosum in patients 2 years and older	7/21/23
Lotilaner / Xdemvy / Tarsus	Anti-parasitic for the treatment of Demodex blepharitis	7/24/23

New Indications:	***Description***	***Date Approved***
Adalimumab-bwwd / Hadlima / Samsung Bioepis Co.	Treatment of noninfectious intermediate, posterior, and panuveitis in adults	7/11/23
Leuprolide acetate for injectable suspension / Eligard / Tolmar, Inc.	Indication revised to treatment of advanced prostate cancer rather than palliative treatment of advanced prostate cancer	7/20/23
Ebola Zaire vaccine, live / Ervebo / Merck Sharp & Dohme LLC	Prevention of Ebola virus disease caused by Zaire ebolavirus in individuals 12 months through 17 years of age	7/27/23
Dostarlimab / Jemperli / GlaxoSmithKline	In combination with carboplatin and paclitaxel, followed by use as a single agent for the treatment of primary advanced or recurrent endometrial cancer that is mismatch repair deficient or microsatellite instability-high	7/31/23

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Norgestrel / Opill / Perrigo	Tablets: 0.075 mg in box of 28 tablets; over-the-counter daily oral contraceptive	7/13/23
4-factor prothrombin complex concentrate / Balfaxar / Octapharma	Lyophilized powder for reconstitution for IV use: 500 Factor IX units/20 mL or 1000 Factor IX units/40 mL; coagulation factor replacement for urgent reversal of vitamin K antagonist therapy	7/26/23
Naloxone / RiVive / Harm Reduction Therapeutics	Nasal spray: 3 mg; over-the-counter availability for emergency treatment of known or suspected opioid overdose	7/28/23

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Nirsevimab-alip / Beyfortus / Sanofi Pasteur, Inc.	
Generic Name / Brand Name / Company	Nirsevimab-alip / Beyfortus / Sanofi Pasteur, Inc.
Date of approval	7/17/23
Drug Class (Mechanism of Action if novel agent)	Recombinant human IgG1k monoclonal antibody that targets the RSV F protein
Indication	RSV prevention in neonates or infants who are born during or entering their first RSV season as well as children up to 24 months who are still vulnerable to severe RSV disease through their second RSV season.
Comparative agent – Therapeutic interchange?	Palivizumab
Dosage forms/strengths.	Injection: 50 mg/0.5 mL or 100mg/mL pre-filled syringes
Common Dose/sig	Inject intramuscularly 50 mg in neonates or infants less than 5 kg or 100 mg in infants or neonates greater than 5 kg. Children up to 24 months who are at increased risk into their second RSV season should receive a 200 mg dose (two 100 mg injections).
DEA Schedule	None
Date of market availability	Available Fall 2023
Similar Medication Names	Nivolumab
Clinical Use Evaluation	
Common Adverse Effects	Rash (0.9%) and injection site reactions (0.3%)
Severe Adverse Effects	None
Severe Drug-Drug Interactions	None
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safe in neonates, infants, and children up to 24 months. Safety and effectiveness beyond 24 months of age are unknown.
Renal or Hepatic Dosing	None
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with hypersensitivity to nirsevimab and its excipients. IM injection should be given with caution in infants and children with thrombocytopenia, any coagulation disorder, or on anticoagulants.
Special administration technique or considerations	Can be given with other childhood vaccines but both products must be administered in separate syringes and at different injection sites. Palivizumab should not be administered if the patient received nirsevimab-alip in the same season.
Prepared by	Hagop Margossian
Source	*Beyfortus* (nirsevimab-alip) [Prescribing information] Swiftwater, PA: Sanofi Pasteur, Inc.; July 2023.

Anthrax vaccine adsorbed, adjuvanted / Cyfendus / Emergent BioSolutions	
Generic Name / Brand Name / Company	Anthrax vaccine adsorbed, adjuvanted / Cyfendus / Emergent BioSolutions
Date of approval	7/20/23
Drug Class (Mechanism of Action if novel agent)	Inactivated vaccine made from avirulent, non-encapsulated strain of *Bacillus anthracis* and adjuvanted with aluminum hydroxide.
Indication	Post-exposure prophylaxis of disease following suspected or confirmed exposure to *Bacillus anthracis* in persons between 18 and 65 years old when administered in conjunction with recommended antibacterial drugs.
Comparative agent – Therapeutic interchange?	BioThrax
Dosage forms/strengths.	Suspension for injection: 0.5 mL
Common Dose/sig	0.5 ml dose IM followed by another 0.5 ml dose two weeks later
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Anthrax vaccine adsorbed
Clinical Use Evaluation	
Common Adverse Effects	≥10%: tenderness (88%), pain (86%), arm motion limitation (64%), warmth (51%), induration, itching, swelling, erythema/redness, muscle aches (75%), tiredness (67%), headache (58%)
Severe Adverse Effects	Injection site reactions, muscle ache, tiredness, headache, fever
Severe Drug-Drug Interactions	None reported
Severe Drug-Food Interactions	None reported
Important Labs Values to assess prior to order entry or at point of clinical follow up.	N/A
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	None
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Can cause fetal harm when administered to pregnant individual, Contraindicated in patients with a severe allergic reaction after a previous dose of BioThrax, this vaccine, or any product ingredients.
Special administration technique or considerations	Gently swirl, do not shake vial
Prepared by	Gaige Felix
Source	*Cyfendus* (Anthrax Vaccine Adsorbed, Adjuvanted) [prescribing information] Lansing, MI: Emergent BioDefense Operations LLC; July 2023

Quizartinib / Vanflyta / Daiichi Sankyo, Inc.	
Generic Name / Brand Name / Company	Quizartinib / Vanflyta / Daiichi Sankyo, Inc.
Date of approval	7/20/23
Drug Class (Mechanism of Action if novel agent)	Small molecule inhibitor of tyrosine kinase FLT3
Indication	With standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy in newly diagnosed FLT3 internal tandem duplication (ITD) positive acute myeloid leukemia
Comparative agent – Therapeutic interchange?	Midostaurin (Rydapt) or Gilteritinib (Xospata)
Dosage forms/strengths.	Tablets: 17.7mg or 26.5 mg
Common Dose/sig	35.4 mg orally once daily starting on day 8 of induction (7 + 3 regimen) and on day 6 of consolidation therapy. 26.5 mg orally once daily maintenance dose is started during Day 1 to 14 of the first cycle and can be increased to 53 mg once daily on day 15 if the QT < 450 ms. Can be lowered to 26.5 mg once daily if QT > 500 ms was recorded during induction or consolidation. Continue once daily dose with no breaks between the 2-week cycles.
DEA Schedule	None
Date of market availability	Available through a REMS program
Similar Medication Names	None identified
Clinical Use Evaluation	
Common Adverse Effects	>20%: decreased levels of lymphocytes, potassium, albumin, phosphorus, magnesium, calcium; increased levels of alkaline phosphatase and creatine phosphokinase, febrile neutropenia, nausea/vomiting/diarrhea, mucositis, abdominal pain, sepsis, neutropenia, headache, and upper respiratory tract infection
Severe Adverse Effects	Febrile neutropenia, sepsis, fungal infections, brain edema, pneumonia, ARDS, pulmonary embolism, QT prolongation, cardiac arrest, ventricular dysfunction, and cerebral infarction.
Severe Drug-Drug Interactions	Concurrent use with CYP3A inhibitor can increase quizartinib levels as the drug is a CYP3A substrate. Using a CYP3A inducer decreases quizartinib levels and should be avoided. Since quizartinib prolongs the QT interval, it should be used cautiously alongside other QT-prolonging drugs.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	An ECG as well as neutrophil, platelet, and lymphocyte counts should be assessed at baseline and each visit. Baseline values of potassium, albumin, phosphorus, alkaline phosphatase, magnesium, sodium, calcium, and creatine phosphokinase should be established. Potassium and magnesium levels should be assessed for each visit.
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	Dosing adjustments are not required in those with mild to moderate renal or hepatic impairment. Effects of severe renal or hepatic impairment on dosing are unknown.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with severe hypokalemia and/or hypomagnesemia or with history of long QT syndrome, ventricular arrythmias or torsades de pointes. Boxed warning regarding QT prolongation and cardiac arrest risks. Quizartinib may cause fetal harm and should be avoided in pregnant patients.
Special administration technique or considerations	Can be taken with or without food.
Prepared by	Hagop Margossian
Source	*Vanflyta* (quizartinib) [prescribing information] Basking Ridge, NJ: Daiichi Sankyo, Inc.; July 2023.

Cantharidin / Ycanth / Verrica Pharmaceuticals Inc	
Generic Name / Brand Name / Company	Cantharidin / Ycanth / Verrica Pharmaceuticals Inc
Date of approval	7/21/23
Drug Class (Mechanism of Action if novel agent)	Keratolytic agent
Indication	Topical treatment of molluscum contagiosum in adults and pediatric patients 2 years of age and older
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Topical solution: 0.7%, single-dose applicator
Common Dose/sig	Apply single application to cover lesion, can administer every 3 weeks as needed
DEA Schedule	None
Date of market availability	September 2023
Similar Medication Names	Canthacur
Clinical Use Evaluation	
Common Adverse Effects	>1%: vesiculation, pain, pruritis, scabbing, erythema, discoloration, application site dryness, edema, and erosion
Severe Adverse Effects	Vesicles, pain, pruritus, erythema, discoloration
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 effectiveness have been studied in patients 2 years of age and older
Renal or Hepatic Dosing	No adjustment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Life threatening toxicities if administered orally. It is flammable even after drying so keep away from fire or smoking near lesion.
Special administration technique or considerations	For application by a healthcare professional; instruction and training are required before preparation and administration. Use gloves and eye protection during preparation and administration. Do not use more than two applicators during a single treatment session. Remove with soap and water 24 hours after treatment. Instruct patient/caregiver to avoid contact with treatment area to avoid toxicities, but do not cover treated lesions with bandages.
Prepared by	Gaige Felix
Source	*Ycanth* (cantharidin) [prescribing information] Clinton, TN: Verrica pharmaceuticals Inc.; July 2023

Lotilaner / Xdemvy / Tarsus Pharmaceuticals, Inc.	
Generic Name / Brand Name / Company	Lotilaner / Xdemvy / Tarsus Pharmaceuticals, Inc.
Date of approval	7/24/23
Drug Class (Mechanism of Action if novel agent)	Ectoparasiticide (anti-parasitic); GABA-gated chloride channel inhibitor selective for mites, leading to their death.
Indication	Treatment of Demodex blepharitis
Comparative agent – Therapeutic interchange?	Oral ivermectin
Dosage forms/strengths.	Ophthalmic solution: 0.25% (2.5 mg/mL)
Common Dose/sig	Instill one drop in each eye approximately every 12 hours for 6 weeks
DEA Schedule	None
Date of market availability	Available by the end of August 2023
Similar Medication Names	Lotrimin, Lotensin
Clinical Use Evaluation	
Common Adverse Effects	10%: site stinging and burning
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	None
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	None
Special administration technique or considerations	To minimize risk of contamination, do not allow the tip of the dropper to touch the eye, surrounding bodily structures, fingers, or surfaces. Administer other topical ophthalmic solutions at least 5 minutes apart from each other. Remove contact lenses before administration and reinsert at least 15 minutes after administration.
Prepared by	Hagop Margossian
Source	Xdemvy (lotilaner 0.25% ophthalmic solution) [prescribing information] Irvine, CA: Tarsus Pharmaceuticals, Inc.; July 2023.