WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 6/1/22 – 6/30/22

FDA Drug Safety Communications & Drug Information Updates:

FDA Withdraws Approval of Lymphoma Medicine Ukoniq (umbralisib) Due to Safety Concerns 6/1/22
The FDA has withdrawn approval of umbralisib, previously approved to treat marginal zone lymphoma and follicular lymphoma due to updated findings from the UNITY-CLL trial which show a possible increased risk of death in patients treated with umbralisib. Healthcare providers should stop prescribing umbralisib and switch patients to alternatives. Patients should be informed of the increased risk of death observed during the clinical trial and be advised to stop taking the medication.

Expiration Date for *6 ASCENIV* [Immune Globulin Intravenous, Human-slra, 10% Liquid] Extended 6/13/22
The FDA has approved an extension of the expiration date for ASCENIV from 24 to 36 months (a 12-month extension) when the product is stored 2°C to 8°C (36°F to 46°F). The new expiration date is valid for six ASCENIV lots that were manufactured and distributed in 2019-2020. The affected lot numbers, labeled expiration dates, and new expiration dates can be found at the FDA website. Future lots will be labeled according to the newly approved expiration dating period.

Moderna and Pfizer-BioNTech COVID-19 Vaccines Authorized for Children Down to 6 Months of Age 6/17/22
The FDA amended the emergency use authorization (EUA) for the Moderna COVID-19 vaccine to include use in individuals 6 months through 17 years of age and the EUA for the Pfizer-BioNTech vaccine to include use in individuals 6 months through 4 years of age.

Shelf-Life Extended for REGEN-COV From 24 months to 30 Months 6/27/22
The FDA authorized an extension to the shelf-life from 24 months to 30 months for specific lots of the refrigerated casirivimab and imdevimab monoclonal antibodies, administered together or REGEN-COV. These recommendations apply to all unopened vials of casirivimab, imdevimab, and REGEN-COV that have been held in accordance with storage conditions (refrigerated temperature at 2°C to 8°C [36°F to 46°F]). The affected batch numbers, labeled expiration dates, and new expiration dates can be found at the FDA website.

Shelf-Life Extension of Evusheld under Emergency Use Authorization 6/28/22
The shelf-life for specific lots of the refrigerated antibody therapy, Evusheld (tixagevimab co-packaged with cilgavimab) has been extended from 18 months to 24 months. Unopened vials of Evusheld stored under refrigerated temperature at 2°C to 8°C (36°F to 46°F) in the original carton can be stored for an additional 6 months from the labeled date of expiry. The affected lot numbers, labeled expiration dates, and new expiration dates can be found at the FDA website. Future lots will be labeled according to the newly approved expiration dating.

Revisions to Evusheld Dosing under Emergency Use Authorization 6/28/22
The Fact Sheet for Evusheld (tixagevimab co-packaged with cilgavimab) has been updated with the recommendation to repeat dosing every six months with a dose of tixagevimab 300 mg and cilgavimab 300 mg for patients needing ongoing protection.

Increased Risk of Death and Serious Side Effects with Cancer Drug Copiktra (duvelisib) 6/30/22
The FDA warned that results from a clinical trial show a possible increased risk of death with duvelisib compared to ofatumumab in the treatment of patients with chronic lymphocytic leukemia or small lymphocytic lymphoma. The trial also found duvelisib was associated with a higher risk of serious side effects, including infections, diarrhea, inflammation of the intestines and lungs, skin reactions, and high liver enzyme levels in the blood. The risks and benefits of continuing treatment should be considered in relation to other available treatments.

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

Milk of Magnesia Oral Suspension and Magnesium Hydroxide/Aluminum Hydroxide/Simethicone Oral Suspension by Plastikon Healthcare: Recall – Microbial Contamination 6/8/22

Plastikon Healthcare, LLC recalled one lot of Milk of Magnesia 2400 mg/10 mL Oral Suspension, one lot of Milk of Magnesia 2400 mg/30 mL Oral Suspension, eleven lots of Magnesium Hydroxide 1200 mg/Aluminum Hydroxide 1200 mg/Simethicone 120 mg per 30 mL Oral Suspension, and two lots of Magnesium Hydroxide 2400 mg/Aluminum Hydroxide 2400 mg/Simethicone 240 mg per 30 mL Oral Suspension to the consumer level due to microbial contamination. More information including affected lot numbers, expiration dates, and NDCs can be found at the FDA website.

BD Intraosseous Needle Set Kits, BD Intraosseous Manual Driver Kits, and BD Intraosseous Powered Drivers by BD: Recall – Non-functioning Intraosseous Access 6/22/22

Becton, Dickinson, and Company (BD) recalled multiple lots of these products due to issues related to delays in care from limited or non-functioning intraosseous access and for needlestick injury potential. More information including affected lot numbers, expiration dates, and NDCs can be found at the FDA website.

CVS Magnesium Citrate Saline Laxative Oral Solution Lemon Flavor: Recall – Microbial Contamination 6/23/22

Vi Jon, LLC recalled one lot of CVS Magnesium Citrate Saline Laxative Oral Solution Lemon Flavor, 10 ounce (296 mL) to the consumer level after testing identified microbial contamination with *Gluconacetobacter liquefaciens*. The affected lot includes the batch number 0556808 and expiration date 12/2023.

Morphine Sulfate Extended-Release Tablets, 30 mg and 60 mg by Bryant Ranch Prepack: Recall - Due to Label-Mix Up 6/29/22

Bryant Ranch Prepack recalled one lot of Morphine Sulfate Extended- Release Tablets, 30 mg (NDC 63629-1088-01, lot 179642, expiration 11/30/2023) and one lot of Morphine Sulfate Extended-Release Tablets, 60 mg (NDC 63629-1089-01, lot 179643, expiration 08/31/2023) due to label-mix up. The products have been found to have incorrect labeling where bottles labeled as Morphine Sulfate 60 mg Extended-Release tablets contain Morphine Sulfate 30 mg Extended-Release tablets and bottles labeled as Morphine Sulfate 30 mg Extended-Release tablets may contain Morphine Sulfate 60 mg Extended-Release tablets.

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***
Allergy Bee Gone for Kids Nasal Swab Remedy*	Seasonal allergies	*Bacillus cereus*
Artri King Reforzado Con Ortiga Y Omega 3*	Arthritis	Diclofenac and dexamethasone
Artri Ajo King Joint Supplements*	Joint support	Diclofenac
"Artri" or "Ortiga" products	Joint pain or arthritis	Dexamethasone, diclofenac, and/or methocarbamol
Launch Sequence Aphrodisia Capsules*	Sexual enhancement	Tadalafil
Launch Sequence Capsules*	Sexual enhancement	Tadalafil
Launch Sequence Euphoria Capsules*	Sexual enhancement	Tadalafil
SnoreStop NasoSpray Homeopathic*	Snoring	*Providencia rettgeri*

*recalled

New Product Shortages	***Date Initially Posted***
Diazepam rectal gel	6/15/22
Remifentanil Injection	6/28/22

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Acetaminophen injection (Ofirmev, Mallinckrodt): 1 g/100 mL (10 mg/mL) in 100 mL glass vials (NDC 43825-102-01) and 100 mL bags (43825-102-03); generic alternatives remain available	6/9/22
Gentamicin and prednisolone acetate ophthalmic suspension (Pred G, AbbVie): 0.3% suspension in 5 mL (NDC 0023-0106-05) and 10 mL (NDC 0023-0106-10) bottles; there are no available generic alternatives	6/9/22
Gentamicin sulfate ophthalmic solution (Genoptic, AbbVie): 5 mL of 0.3% solution in 10 mL bottles (NDC 60758-188-05); generic alternatives remain available.	6/9/22
Humalog (Insulin Lispro) Mix 50/50: 10 mL vial (NDC 0002-7512-01) will be available until August 2023. The Humalog Mix 50/50 3 mL prefilled pens (Kwikpen) will remain available.	6/30/22
Lindane shampoo 1% (Wockhardt): 60 mL (NDC 60432-834-60); no other lindane generics available, select alternative treatment	6/22/22
Nebivolol hydrochloride tablets (Bystolic, AbbVie): 30-count bottle of 20 mg tablets (NDC 0456-1420-30); generic alternatives remain available	6/9/22
Olopatadine hydrochloride nasal spray (Patanase, Novartis): 30.5 mL of solution per bottle (665 mcg olopatadine/ metered spray) (NDC 61314 320-01); generic alternatives remain available	6/21/22
Prednisolone acetate and sulfacetamide sodium ophthalmic suspension (Blephamide, AbbVie): 5 mL of 0.2% and 10% suspension in a 10 mL bottle (NDC 11980-022-05); generic prednisolone sodium phosphate and sulfacetamide sodium (0.23% and 10% ophthalmic solutions) is an alternative	6/9/22
Sulfacetamide sodium ophthalmic solution (Bleph-10, AbbVie): 5 mL of 10% solution in 10 mL bottle (NDC 11980-011-05); generic alternatives remain available	6/9/22
Talc intrapleural aerosol (Sclerosol, M & F Distribution/Lymol Medical) 4 g (NDC 63256-100-30); alternative intrapleural talc products remain available	6/14/22
Tegaserod (Zelnorm, Alfasigma): 6 mg tablets; consider alternative such as linaclotide or plecanatide	6/30/22

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Vutrisiran / Amvuttra / Alnylam Pharmaceuticals Inc	Transthyretin-directed small interfering RNA drug for the treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.	6/13/22

New Indications:	***Description***	***Date Approved***
Rituximab-arrx / Riabni / Amgen	In combination with methotrexate for adults with moderate to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor antagonist therapies.	6/3/22
Mycophenolate mofetil / Cellcept / Genentech USA Inc.	For the prophylaxis of organ rejection in pediatric recipients 3 months of age and older of allogeneic heart or liver transplants, in combination with other immunosuppressants.	6/6/22
Dupilumab / Dupixent / Regeneron Pharmaceuticals Inc.	Indication expanded to include the treatment of patients 6 months and older with moderate to severe atopic dermatitis that is not adequately controlled with topical prescription therapies or when those therapies are not appropriate.	6/7/22
Baricitinib / Olumiant / Eli Lilly and Co.	Treatment for adults with severe alopecia areata	6/13/22
Setmelanotide / Imcivree / Rhythm Pharmaceuticals Inc.	For chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to Bardet-Biedl syndrome.	6/16/22
Risankizumab-rzaa / Skyrizi / AbbVie	For the treatment of adults with moderately to severely active Crohn's disease (CD).	6/16/22
Brexanolone / Zulresso / Sage	Indication expanded to include use in postpartum depression in patients 15 years and older	6/16/22

New Indications continued:	***Description***	***Date Approved***
Adalimumab-bwwd / Hadlima / Samsung Bioepis	Indications expanded to include use for polyarticular Juvenile Idiopathic Arthritis in patients 2 years of age and older and Crohn's disease in patients 6 years and older	6/17/22
Pneumococcal 15-valent conjugate vaccine / Vaxneuvance/ Merck & Co	Immunization in children 6 weeks through 17 years	6/22/22
Dabrafenib mesylate / Tafinlar / Novartis	In combination with trametinib for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment or have not satisfactory treatment alternatives	6/22/22
Trametinib / Mekinist / Novartis	In combination with dabrafenib mesylate for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment or have not satisfactory treatment alternatives	6/22/22
Phentermine Hydrochloride – Topiramate/ Qsymia/Vivus	Indication expanded to include chronic weight management in pediatric patients aged 12 years and older with a BMI in the 95th percentile or greater standardized for age and sex	6/24/22
Lisocabtagene maraleucel/ Breyanzi/ Juno Therapeutics	Change in indication to second-line treatment of large B-cell lymphoma for patients who have disease refractory to first line chemoimmunotherapy or relapse within 12 months of first line chemoimmunotherapy	6/24/22
Carfilzomib / Kyprolis/ Onyx Therap	In combination with isatuximab and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy	6/30/22

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Measles, mumps, and rubella virus vaccine, live / Priorix / GSK	A live vaccine for the prevention of measles, mumps, and rubella in individuals 12 months and older	6/3/22
Sodium phenylbutyrate / Pheburane / Medunik USA	Oral pellets: 84 g per bottle; adjunctive therapy for chronic management of urea cycle disorders	6/17/22
Methylphenidate hydrochloride / Relexxii / Osmotica Pharmaceutical Corp.	Extended-release tablets: 18 mg, 27 mg, 36 mg, 45 mg, 54 mg, 63 mg, and 72 mg; for the treatment of attention deficit hyperactivity disorder in adults and pediatric patients 6 years and older	6/23/22
Drospirenone / Drospirenone / Exeltis USA Inc	Chewable tablet: 3.5 mg, packaged as 24 active tablets and 4 inert tablets in a 28-day package as an oral contraceptive	6/29/22
Venlafaxine Besylate / Venbysi XR / Almatica	Extended-Release tablets: 112.5 mg; for the treatment of major depressive disorder and generalized anxiety disorder in adults	6/30/22

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Vutrisiran / Amvuttra / Alnylam Pharmaceuticals Inc	
Generic Name / Brand Name / Company	Vutrisiran / Amvuttra / Alnylam Pharmaceuticals Inc
Date of approval	6/13/22
Drug Class (Mechanism of Action if novel agent)	Transthyretin-directed small interfering RNA; reduces serum TTR protein and TTR protein deposits in tissues
Indication	Polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults
Comparative agent – Therapeutic interchange?	Alternative treatments: patisiran
Dosage forms/strengths.	Injection: 25 mg/ 0.5 ml in a prefilled syringe
Common Dose/sig	Administer 25 mg as a subcutaneous injection once every 3 months
DEA Schedule	None
Date of market availability	July 2022
Similar Medication Names	Aimovig, valsartan
Clinical Use Evaluation	
Common Adverse Effects	Arthralgia (11%), dyspnea (7%), vitamin A decreased (7%), injection site reactions (4%), immunogenicity (2.5%)
Severe Adverse Effects	Atrioventricular (AV) heart block (1.6%)
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 required
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric populations
Renal or Hepatic Dosing	No dose adjustments recommended in mild to moderate renal impairment or mild hepatic impairment; has not been studied in patients with severe renal impairment or moderate to severe hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Supplementation with the recommended daily allowance of vitamin A is recommended and patients should be referred to an ophthalmologist if they develop ocular symptoms suggesting vitamin A deficiency.
Special administration technique or considerations	Administered by healthcare professional as a subcutaneous injection in the abdomen, thigh, or upper arm.
Prepared by	Ashley Rittenhouse
Source	Amvuttra (vutrisiran) [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc,; June 2022.