Brand Name/Drug Class	Generic Name	Indications	Route of Administration	Action
Dolutegravir-containing products	Tivicay® (dolutegravir), Juluca® (dolutegravir/rilpivirine), Triumeq® (abacavir/dolutegravir/lamivudine)	HIV	Oral	The FDA announced an update to the ***Warnings and Precautions*** section of dolutegravir-containing products drug labels regarding **embryo-fetal toxicity**. Preliminary data from an observational study showed that dolutegravir, was associated with increased risk of neural tube defects when administered at the time of conception and in early pregnancy. As there is limited understanding of reported types of neural tube defects associated with dolutegravir use and because the date of conception may not be determined with precision, avoid use of dolutegravir-containing products at the time of conception through the first trimester of pregnancy.
Fluoroquinolone Antibiotics	Levaquin® (levofloxacin), Cipro® (ciprofloxacin), ciprofloxacin extended-release tablets, Avelox® (moxifloxacin), and ofloxacin. Factive® (gemifloxacin) and Baxdela™ (delafloxacin)	Serious bacterial infections, including certain pneumonias	Oral, Injection	The FDA announced an update to the Warnings and Precautions section of the fluoroquinolone antibiotics drug labels on risks of **low blood sugar** and **mental health adverse reactions**. Across the fluoroquinolone antibiotic class, mental health side effects are currently noted in the Warning and Precautions section of the drug label. The new class-wide labeling changes require that mental health side effects be more prominent and consistent. The side effects include disturbances in attention, disorientation, agitation, nervousness, memory impairment and delirium. The fluoroquinolone antibiotic class may cause significant decreases in blood sugar. This can result in serious problems including coma, particularly in older people and patients with diabetes who are taking medicines to reduce blood sugar.
Granix®	tbo-filgrastim	Severe Neutropenia	Sub-Q Injection	The FDA announced the **approval** of Teva's Granix (tbo-filgrastim), for the treatment of adult and **pediatric patients 1 month and older** for reduction in the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Previously, Granix was only approved to treat adult patients for this same indication.In addition, updates were made the **Warnings and Precautions** section of the Granix drug label regarding **leukocytosis, simultaneous use with chemotherapy and radiation therapy not recommended, nuclear imaging, and aortitis.**

Brand Name/Drug Class	Generic Name	Indications	Route of Administration	Action
Immediate-release Opioids	Various	Pain	Oral, Injection, Topical	The FDA announced the **approval of the Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)**. The expanded Opioid REMS now applies to **immediate-release (IR) opioid analgesics** intended for use in an outpatient setting application, in addition to extended-release and long-acting (ER/LA) opioid analgesics, which have been subject to a REMS since 2012. Previously, the ER/LA Opioid Analgesic REMS included 62 products. **The modified REMS now requires that 347 opioid analgesics intended for outpatient use be subject to these requirements.**
Kisqali®	ribociclib	Breast Cancer	Oral	The **FDA** announced the **approval** of Novartis' Kisqali (ribociclib), for the treatment of pre/perimenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer as initial endocrine-based therapy; and in combination with Faslodex® (fulvestrant) for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy. **Previously, Kisqali was only approved for use in combination with an AI** for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer as initial endocrine therapy. In addition, a **new warning** has been added to the Kisqali drug label regarding **QT prolongation with concomitant use of tamoxifen.**

Brand Name/Drug Class	Generic Name	Indications	Route of Administration	Action
Lamictal®	Lamtrogine	Epilepsy, Bipolar Disorder	Oral	The FDA approved an update to the *Warnings and Precautions* section of the Lamictal (lamotrigine) drug label regarding the risk of **hemophagocytic lymphohistiocytosis (HLH)**. The immune system reaction HLH has occurred in pediatric and adult patients taking Lamictal for various indications. HLH is a life-threatening syndrome of pathologic immune activation characterized by clinical signs and symptoms of extreme systemic inflammation. It is associated with high mortality rates if not recognized early and treated. **HLH symptoms include fever greater than 101 °F, hepatosplenomegaly, rash, lymphadenopathy, neurologic symptoms, cytopenias, high serum ferritin, and liver function and coagulation abnormalities.** In reported cases of HLH with Lamictal, patients have presented with signs of systemic inflammation and blood dyscrasias. Symptoms have been reported to occur within 8 to 24 days following the initiation of treatment.

Brand Name/Drug Class	Generic Name	Indications	Route of Administration	Action
Sodium-glucose cotransporter-2 (SGLT-2) Inhibitors	Invokana® (canagliflozin), Farxiga® (dapagliflozin), Jardiance® (empagliflozin), and Steglatro™ (ertugliflozin). Combination products containing a SGLT-2 inhibitor include Invokamet® (canagliflozin/metformin), Invokamet® XR (canagliflozin/metformin extended-release), Xigduo® XR (dapagliflozin/metformin extended-release), Qtern® (dapagliflozin/saxagliptin), Glyxambi® (empagliflozin/linagliptin), Synjardy® (empagliflozin/metformin), Synjardy® XR (empagliflozin/metformin extended-release), Segluromet™ (ertugliflozin/metformin), Steglujan™ (ertugliflozin/sitagliptin)	Type 2 Diabetes	Oral	The FDA announced a **new warning** that cases of a rare but serious infection of the genitals and area around the genitals have been reported with the class of SGLT-2 inhibitors. This serious rare infection, called **necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene.**Fournier's gangrene is an extremely rare but life-threatening bacterial infection of the tissue surrounding the perineum. The bacteria usually get into the body through a cut or a break in the skin, where they quickly spread and destroy the tissues they infect. Having diabetes is a risk factor for developing Fournier's gangrene; however this condition is still rare among these patients. Publications report that Fournier's gangrene occurs in 1.6 out of 100,000 males per year in the U.S. **In the five years from March 2013 to May 2018, 12 cases of Fournier's gangrene in patients taking an SGLT-2 inhibitor were reported to the FDA Adverse Event Reporting System (FAERS) or found in the medical literature. These 12 cases included 7 men and 5 women. Fournier's gangrene developed within several months of the patients starting an SGLT-2 inhibitor, and all 12 patients required hospitalization and surgery, resulting in one death.** — In comparison, only six cases of Fournier's gangrene (all in men) were identified in review of other antidiabetic drug classes over a period of more than 30 years.

Brand Name/Drug Class	Generic Name	Indications	Route of Administration	Action
Xtandi®	enzalutamide	Castration-resistant prostate cancer	Oral	Astellas Pharma and Pfizer announced the **FDA approval** of Xtandi (enzalutamide), for the treatment of patients with castration-resistant prostate cancer (CRPC). **This expands the approval of Xtandi to include patients with non-metastatic CRPC.** Previously, Xtandi was only approved for metastatic CRPC. In addition, new updates have been added to the **Warnings and Precautions section o**f the Xtandi drug label regarding **hypersensitivity reactions, ischemic heart disease, falls and fractures, and embryo-fetal toxicity.**
Zithromax®, Zmax®	azithromycin	Mild-to-moderate Infections	Oral	The FDA announced that azithromycin (Zithromax®, Zmax®) **should not be given long-term to prevent bronchiolitis obliterans syndrome in patients with cancers of the blood or lymph nodes who undergo a donor stem cell transplant.** Azithromycin is not approved for preventing bronchiolitis obliterans syndrome. Azithromycin is indicated for the treatment of certain mild to moderate infections caused by susceptible isolates of certain microorganisms. Refer to the drug labels for further indication information. Results of a clinical trial found an **increased rate of relapse in cancers affecting the blood and lymph nodes, including death, in these patients taking long-term azithromycin.**