Drug Safety Updates Q3-2017				
Brand Name	**Generic Name**	**Indications**	**Route of Administration**	**Action**
Aralen	chloroquine	Malaria,Extraintestinal amebiasis	Oral	The FDA approved updates to the *Warnings* section of the Aralen (chloroquine) drug label regarding treatment of exoerythrocytic forms of malaria, cardiac effects, and hypoglycemia.
Epogen/Procrit	epoetin alfa	CKD, Anemia in patients being treated with zidovudine for HIV, Anemia in patients with non-myeloid malignancies, To reduce the need for allogeneic RBC transfusions in patients who are at high risk for preoperative blood loss from non-cardiac, non-vascular surgery	SQ	The FDA approved updates to the *Warnings and Precautions* section of the Epogen/Procrit (epoetin alfa) drug label regarding severe cutaneous reactions and risk of serious adverse reactions due to benzyl alcohol preservative.
Foshan Flying Medical Products	alcohol pads/benzalkonium chloride towelettes	Antiseptic	Topical	The FDA alerted health care professionals and patients not to use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products due to the lack of sterility assurance and other quality issues.
Gleevec	imatinib	CML, ALL, GIST, myelodysplastic/myeloproliferative disases, systemic mastocytosis, hypereosinophilic syndrome, dermatofibrosarcoma protuberans	Oral	The FDA approved an update to the *Warnings and Precautions* section of the Gleevec (imatinib) drug label regarding the risk of renal toxicity.

Drug Safety Updates Q3-2017				
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Immediate-release opioids	various	Pain	Oral, buccal, IM,nasal,sublingual, SQ, transmucosal	The FDA announced that a Risk Evaluation and Mitigation Strategy (REMS) is necessary for immediate-release (IR) opioid analgesics to ensure that the benefits of these drugs continue to outweigh the risks, and the IR opioid analgesics that are intended to be used in the outpatient setting will be subject to the same REMS requirements as the extended-release/long-acting (ER/LA) opioid analgesics.
Januvia,Janumet XR, Jentadueto, Jentadueto XR, Tradjenta, Glyxambi	sitagliptin, sitagliptin/metformin,sitagliptin/metformin XR,linagliptin/metformin, linagliptin/metformin XR, linagliptin, linagliptin/empagliflozin	Type 2 Diabetes mellitus	Oral	The FDA approved updates to the *Warnings and Precautions* sections of the Januvia (sitagliptin), Janumet (sitagliptin/ metformin), Janumet XR (sitagliptin/metformin XR), Jentadueto (linagliptin/metformin), Jentadueto XR (linagliptin/metformin XR), Tradjenta (linagliptin), and Glyxambi (linagliptin/empagliflozin) drug labels regarding heart failure.
Kayexalate	sodium polystyrene sulfonate	Hyperkalemia	Oral	The FDA announced that Kayexalate (sodium polystyrene sulfonate) drug labels will be updated to state that the dose should be separated by at least 3 hours from other orally administered drugs.
Keytruda	pembrolizumab	Melanoma, Non-small cell lung cancer, Head and Neck squamous cell cancer, classical Hodgkin lymphoma, urothelial carcinoma, microsatellite instability-high cancer	IV	The FDA approved updates to the *Warnings and Precautions* section of the Keytruda (pembrolizumab) drug label regarding immune-mediated skin adverse reactions and other immune-mediated adverse reactions to include solid organ transplant rejection.
Ocaliva	obeticholic acid	Primary biliary cholangitis	Oral	The FDA announced that Ocaliva (obeticholic acid) is being incorrectly dosed in some patients with moderate to severe decreases in liver function, resulting in an increased risk of serious liver injury and death.

Drug Safety Updates Q3-2017				
Brand Name	**Generic Name**	**Indications**	**Route of Administration**	**Action**
Privigen	IVIG	Primary humoral immunodeficiency, chronic immune thromocytopenic purpura, CIDP	IV	SL Behring announced the FDA approval of Privigen (immune globulin intravenous [human], 10%) for the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment.
Revlimid	lenalidomide	Multiple myeloma, tranfusion-dependent anemia due to myelodysplastic syndromes, mantle cell lymphoma	Oral	The FDA approved an update to the *Warnings and Precautions* section of the Revlimid (lenalidomide) drug label regarding early mortality in patients with mantle cell lymphoma (MCL).
Tysabri	natalizumab	Multiple Sclerosis, Crohn's disease	IV	The FDA approved a new warning to the Tysabri (natalizumab) drug label regarding acute retinal necrosis (ARN).
Vancomycin	vancomycin	MRSA, Penicillin-allergic patient who cannot receive or failed to respond to other drugs, Vancomycin-susceptible organisms resistant to other antimicrobials,	Intracameral, intravitreal	The FDA approved an update to the *Warnings* section of the vancomycin injection drug label regarding hemorrhagic occlusive retinal vasculitis (HORV).
Victoza	liraglutide	Type 2 Diabetes mellitus	SQ	Novo Nordisk announced the FDA approval of Victoza (liraglutide), to reduce the risk of major adverse cardiovascular (CV) events [CV death, non-fatal myocardial infarction (MI), or non-fatal stroke] in adults with type 2 diabetes mellitus (T2DM) and established CV disease.
Zelboraf	vemurafenib	Metastatic Melanoma	Oral	The FDA approved an update to the *Warnings and Precautions* section of the Zelboraf (vemurafenib) drug label regarding Dupuytren's contracture and plantar fascial fibromatosis.