Drug Safety Updates Q4 2017				
Brand Name	**Generic Name**	**Indications**	**Route of Administration**	**Action**
Advair Diskus	fluticasone/ salmeterol	Asthma, COPD	Oral inhaler	The FDA announced that the *Boxed Warning* regarding asthma-related death has been removed from the Advair Diskus® (fluticasone/salmeterol), Advair® HFA (fluticasone/salmeterol), Airduo™ Respiclick® (fluticasone/salmeterol), Breo® Ellipta® (fluticasone/vilanterol), Dulera® (mometasone/formoterol), and Symbicort® (budesonide/formoterol) drug labels.
Advair HFA	fluticasone/ salmeterol	Asthma	Oral inhaler	The FDA announced that the *Boxed Warning* regarding asthma-related death has been removed from the Advair Diskus® (fluticasone/salmeterol), Advair® HFA (fluticasone/salmeterol), Airduo™ Respiclick® (fluticasone/salmeterol), Breo® Ellipta® (fluticasone/vilanterol), Dulera® (mometasone/formoterol), and Symbicort® (budesonide/formoterol) drug labels.
Airduo Respiclick	fluticasone/ salmeterol	Asthma	Oral inhaler	The FDA announced that the *Boxed Warning* regarding asthma-related death has been removed from the Advair Diskus® (fluticasone/salmeterol), Advair® HFA (fluticasone/salmeterol), Airduo™ Respiclick® (fluticasone/salmeterol), Breo® Ellipta® (fluticasone/vilanterol), Dulera® (mometasone/formoterol), and Symbicort® (budesonide/formoterol) drug labels.
Alecensa	alectinib	Non-Small Cell Lung Cancer	Oral	Genentech announced the FDA approval of Alecensa (alectinib) for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

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Alimta	pemetrexed	Non-Squamous Non-Small Cell Lung Cancer, Mesothelioma	IV	Information regarding myelosuppression and increased risk of myelosuppression without vitamin supplementation, renal failure, bullous and exfoliative skin toxicity, interstitial pneumonitis, radiation recall, and increased risk of toxicity with ibuprofen in patients with renal impairment were added to the Warnings and Precautions section of the Alimta drug label.
Aranesp	darbepoetin alfa	Anemia due to Chronic Kidney Disease, Anemia due to Chemotherapy in Patients with Cancer	IV or SubQ	The FDA approved an update to the *Warnings and Precautions* section of the Aranesp (darbepoetin alfa) drug label regarding severe cutaneous reactions.
Breo Ellipta	fluticasone/ vilanterol	Asthma, COPD	Oral inhaler	The FDA announced that the *Boxed Warning* regarding asthma-related death has been removed from the Advair Diskus® (fluticasone/salmeterol), Advair® HFA (fluticasone/salmeterol), Airduo™ Respiclick® (fluticasone/salmeterol), Breo® Ellipta® (fluticasone/vilanterol), Dulera® (mometasone/formoterol), and Symbicort® (budesonide/formoterol) drug labels.
Dulera	mometasone/ formoterol	Asthma	Oral inhaler	The FDA announced that the *Boxed Warning* regarding asthma-related death has been removed from the Advair Diskus® (fluticasone/salmeterol), Advair® HFA (fluticasone/salmeterol), Airduo™ Respiclick® (fluticasone/salmeterol), Breo® Ellipta® (fluticasone/vilanterol), Dulera® (mometasone/formoterol), and Symbicort® (budesonide/formoterol) drug labels.

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Gazyva	obinutuzumab	Chronic Lymphocytic Leukemia, Follicular Lymphoma	IV	Genentech announced the FDA approval of Gazyva (obinutuzumab), in combination with chemotherapy followed by Gazyva monotherapy in patients achieving at least a partial remission, for the treatment of adult patients with previously untreated stage II bulky, III or IV follicular lymphoma (FL).
Gilenya	fingolimod	Multiple Sclerosis	Oral	The FDA approved an update to the *Warnings and Precautions* section of the Gilenya (fingolimod) drug label regarding cutaneous malignancies.
Keytruda	pembrolizumab	Melanoma, Non-Small Cell Lung Cancer, Head and Neck Cancer, Classical Hodgkin Lymphoma, Urothelial Carcinoma, Microsatellite Instability-High Cancer, Gastric Cancer	IV	The FDA approved an update to the *Warnings and Precautions* section of the Keytruda (pembrolizumab) drug label regarding increased mortality in patients with multiple myeloma (MM) when Keytruda is added to a thalidomide analogue and dexamethasone.
Lemtrada	alemtuzumab	Multiple Sclerosis	IV	The FDA approved an update to the *Warnings and Precautions* section of the Lemtrada (alemtuzumab) drug label regarding the risk of acute acalculous cholecystitis.
Limbrel (medical food)	flavocoxid/citrated zinc bisglycinate	Osteoarthritis	Oral	The FDA recommended that Primus Pharmaceuticals voluntary recall Limbrel (flavocoxid/citrated zinc bisglycinate) due to serious adverse events, including drug-induced liver injury and hypersensitivity pneumonitis.

Drug Safety Updates Q4 2017				
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Lomotil	atropine/ diphenoxylate	Diarrhea	Oral	The FDA approved updates to the *Indications and Contraindications* sections of the Lomotil (atropine/diphenoxylate) drug label, to limit use to patients ≥ 13 years of age, and to expand the contraindications for pediatric patients from 2 years old to < 6 years old secondary to the risk of respiratory and central nervous system (CNS) depression.
Pomalyst	pomalidomide	Multiple Myeloma	Oral	The FDA approved an update to the *Warnings and Precautions* section of the Pomalyst (pomalidomide), Revlimid (lenalidomide), and Thalomid (thalidomide) drug labels regarding increased mortality in patients with multiple myeloma (MM) when Keytruda® (pembrolizumab) is added to a thalidomide analogue and dexamethasone.
Prevacid, Prevacid SoluTab	lansoprazole	GERD, Gastric/Duodenal Ulcer, Erosive Esophagitis, Zollinger Ellison Syndrome	Oral	The FDA approved updates to the *Warning and Precautions* section of the Prevacid (lansoprazole) and Prevacid SoluTab (lansoprazole) drug labels, regarding interactions with investigations for neuroendocrine tumors and risks in patients with phenylketonuria (PKU).
Promacta	eltrombopag	Thrombocytopenia, Aplastic Anemia	Oral	The FDA approved an update to the *Warnings and Precautions* section of the Promacta (eltrombopag) drug label regarding the increased risk of death and progression of myelodysplastic syndromes (MDS) to acute myeloid leukemia (AML).
Remicade	infliximab	Rheumatoid Arthritis, Crohn's Disease, Ulcerative Colitis, Ankylosing Spondylitis, Plaque Psoriasis	IV	The FDA approved an update to the *Warnings and Precautions* section of the Remicade (infliximab) drug label regarding cardiovascular and cerebrovascular reactions during and after infusion.

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Brand Name	**Generic Name**	**Indications**	**Route of Administration**	**Action**
Revlimid	lenalidomide	Multiple Myeloma, Myelodysplastic Syndromes, Mantle Cell Lymphoma	Oral	The FDA approved an update to the *Warnings and Precautions* section of the Pomalyst (pomalidomide), Revlimid (lenalidomide), and Thalomid (thalidomide) drug labels regarding increased mortality in patients with multiple myeloma (MM) when Keytruda® (pembrolizumab) is added to a thalidomide analogue and dexamethasone.
Reyataz	atazanavir	HIV-1	Oral	The FDA approved an update to the *Warnings and Precautions* section of the Reyataz (atazanavir) drug label regarding chronic kidney disease.
Symbicort	budesonide/ formoterol	Asthma, COPD	Oral inhaler	The FDA announced that the *Boxed Warning* regarding asthma-related death has been removed from the Advair Diskus® (fluticasone/salmeterol), Advair® HFA (fluticasone/salmeterol), Airduo™ Respiclick® (fluticasone/salmeterol), Breo® Ellipta® (fluticasone/vilanterol), Dulera® (mometasone/formoterol), and Symbicort® (budesonide/formoterol) drug labels.
Thalomid	thalidomide	Multiple Myeloma, Erythema Nodosum Leprosum	Oral	The FDA approved an update to the *Warnings and Precautions* section of the Pomalyst (pomalidomide), Revlimid (lenalidomide), and Thalomid (thalidomide) drug labels regarding increased mortality in patients with multiple myeloma (MM) when Keytruda® (pembrolizumab) is added to a thalidomide analogue and dexamethasone.

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Tivicay	dolutegravir	HIV-1	Oral	The FDA approved Tivicay for use in combination with rilpivirine as a complete regimen to replace the current antiretroviral (ART) regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable ART regimen for at least 6 months with no history of treatment failure or known substitutions associated with resistance to either antiretroviral. This update was made for consistency with the new Juluca drug approval.
Triumeq	abacavir/ dolutegravir/ lamivudine	HIV-1	Oral	The FDA announced the approval of ViiV Healthcare's Triumeq (abacavir/dolutegravir/lamivudine) tablets, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in pediatric patients weighing ≥ 40 kg.
Uloric	febuxostat	Gout	Oral	The FDA announced that preliminary results from a post-marketing safety study showed an increased risk of heart-related death and death from all causes with Uloric (febuxostat) compared to allopurinol.