Drug Safety Updates Q2 2017				
Brand Name	**Generic Name**	**Indications**	**Route of Administration**	**Action**
Aranesp	darbepoetin alfa	Anemia due to CKD, Anemia due to Chemotherapy in Patients with Cancer	IV or Sub-Q	The FDA announced that the risk evaluation and mitigation strategy (REMS) requirement for the erythropoiesis-stimulating agents (ESAs), epoetin alfa (Procrit®, Epogen®) and darbepoetin alfa (Aranesp®), regarding their use in patients with anemia due to chemotherapy, is no longer necessary. The ESA REMS is no longer required based on a REMS assessment, data submitted from the manufacturer, and analyses of the impact of regulations and other actions on ESA utilization.
Atripla	efavirenz/emtricitabine/tenofovir disoproxil	HIV	Oral	Drug labels of several human immunodeficiency virus type 1 and hepatitis B medications were updated to remove information related to lactic acidosis/severe hepatomegaly with steatosis from the boxed warnings. These drugs include Atripla®, Descovy®, Emtriva®, Genvoya®, Odefsey®, Stribild®, Vemlidy®, and Viread®. The updated boxed warnings for these medications include the risk for post-treatment acute exacerbation of hepatitis B. Atripla also includes a new warning regarding the risk for QTc prolongation.
N/A	codeine	Moderate to Severe Pain	Oral	New updates will be made to the Contraindications and Warnings sections of all prescription codeine and tramadol drug products regarding their use in children, adolescents and breastfeeding women.
Descovy	emtricitabine/tenofovir alafenamide	HIV	Oral	Drug labels of several human immunodeficiency virus type 1 and hepatitis B medications were updated to remove information related to lactic acidosis/severe hepatomegaly with steatosis from the boxed warnings. These drugs include Atripla®, Descovy®, Emtriva®, Genvoya®, Odefsey®, Stribild®, Vemlidy®, and Viread®. The updated boxed warnings for these medications include the risk for post-treatment acute exacerbation of hepatitis B. Atripla also includes a new warning regarding the risk for QTc prolongation.

Drug Safety Updates Q2 2017				
Brand Name	**Generic Name**	**Indications**	**Route of Administration**	**Action**
Emtriva	emtricitabine	HIV	Oral	Drug labels of several human immunodeficiency virus type 1 and hepatitis B medications were updated to remove information related to lactic acidosis/severe hepatomegaly with steatosis from the boxed warnings. These drugs include Atripla®, Descovy®, Emtriva®, Genvoya®, Odefsey®, Stribild®, Vemlidy®, and Viread®. The updated boxed warnings for these medications include the risk for post-treatment acute exacerbation of hepatitis B. Atripla also includes a new warning regarding the risk for QTc prolongation.
Epogen	epoetin alfa	Anemia due to CKD, Anemia due to use of Zidovudine in HIV, Anemia due to Chemotherapy in Patients with Cancer, Reduction of Alloegeneic Red Blood Cell Transfusions in Patients Undergoing	IV or Sub-Q	The FDA announced that the risk evaluation and mitigation strategy (REMS) requirement for the erythropoiesis-stimulating agents (ESAs), epoetin alfa (Procrit®, Epogen®) and darbepoetin alfa (Aranesp®), regarding their use in patients with anemia due to chemotherapy, is no longer necessary. The ESA REMS is no longer required based on a REMS assessment, data submitted from the manufacturer, and analyses of the impact of regulations and other actions on ESA utilization.
Fareston	toremifene	Metastatic Breast Cancer	Oral	Updates were added to the Warnings and Precautions section of the Fareston drug label, regarding hepatotoxicity and risk of uterine malignancy.
Genvoya	elvitegravir/cobicistat/ emtricitabine/tenofovir alafenamide	HIV	Oral	Drug labels of several human immunodeficiency virus type 1 and hepatitis B medications were updated to remove information related to lactic acidosis/severe hepatomegaly with steatosis from the boxed warnings. These drugs include Atripla®, Descovy®, Emtriva®, Genvoya®, Odefsey®, Stribild®, Vemlidy®, and Viread®. The updated boxed warnings for these medications include the risk for post-treatment acute exacerbation of hepatitis B. Atripla also includes a new warning regarding the risk for QTc prolongation.

Drug Safety Updates Q2 2017				
Brand Name	**Generic Name**	**Indications**	**Route of Administration**	**Action**
Invokana/Invokamet/Invokamet XR	canagliflozin/canagliflozin-metformin	Type 2 Diabetes	Oral	A new Boxed Warning will be added to canagliflozin [Invokana®, Invokamet® (canagliflozin/metformin), Invokamet® XR (canagliflozin/metformin extended-release)] drug labels regarding an increased risk of leg and foot amputations. Similar updates will made to other safety sections of the canagliflozin drug labels.
Keppra/Keppra XR	levetiracetam	Seizure Disorder	Oral	A new Warning was added to the Keppra/Keppra XR drug labels regarding anaphylaxis and angioedema.
Lysodren	mitotane	Inoperable Adrenal Cortical Carcinoma	Oral	A new update was added to the Warnings and Precautions section of the Lysodren drug label, regarding ovarian macrocysts in premenopausal women.
Odefsey	emtricitabine/rilpivirine/tenofovir alafenamide	HIV	Oral	Drug labels of several human immunodeficiency virus type 1 and hepatitis B medications were updated to remove information related to lactic acidosis/severe hepatomegaly with steatosis from the boxed warnings. These drugs include Atripla®, Descovy®, Emtriva®, Genvoya®, Odefsey®, Stribild®, Vemlidy®, and Viread®. The updated boxed warnings for these medications include the risk for post-treatment acute exacerbation of hepatitis B. Atripla also includes a new warning regarding the risk for QTc prolongation.
Opana ER	oxymorphone	Severe Pain	Oral	The FDA requested that Endo remove Opana ER extended-release tablets from the market as the FDA has concluded that the benefits of the drug may no longer outweigh its risks. The FDA's decision is based on a review of all available postmarketing data, which demonstrated a significant shift in the route of abuse of Opana ER from nasal to injection following the product's reformulation. Injection abuse of reformulated Opana ER has been associated with a serious outbreak of human immunodeficiency virus and hepatitis C, as well as cases of thrombotic microangiopathy.
Otezla	apremilast	Psoriatic Arthritis/Plaque Psoriasis	Oral	A new update was added to the Warnings and Precautions section of the Otezla drug label regarding the risk of diarrhea, nausea and vomiting.

Drug Safety Updates Q2 2017				
Brand Name	**Generic Name**	**Indications**	**Route of Administration**	**Action**
Pletal	cilostazol	Intermittent Claudication	Oral	A new update was added to the Warnings and Precautions section of the Pletal drug label regarding left ventricular outflow tract obstruction.
Procrit	epoetin alfa	Anemia due to CKD, Anemia due to use of Zidovudine in HIV, Anemia due to Chemotherapy in Patients with Cancer, Reduction of Alloegeneic Red Blood Cell Transfusions in Patients Undergoing Elective, Noncardiac/Nonvascular Surgery	IV or Sub-Q	The FDA announced that the risk evaluation and mitigation strategy (REMS) requirement for the erythropoiesis-stimulating agents (ESAs), epoetin alfa (Procrit®, Epogen®) and darbepoetin alfa (Aranesp®), regarding their use in patients with anemia due to chemotherapy, is no longer necessary. The ESA REMS is no longer required based on a REMS assessment, data submitted from the manufacturer, and analyses of the impact of regulations and other actions on ESA utilization.
Sensipar	cinacalcet	Hyperparathyroidism, Parathyroid Carcinoma	Oral	New updates were added to the Warnings and Precautions section of the Sensipar drug label, regarding upper gastrointestinal bleeding, hypotension, worsening heart failure and/or arrhythmias.
Stribild	elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil	HIV	Oral	Drug labels of several human immunodeficiency virus type 1 and hepatitis B medications were updated to remove information related to lactic acidosis/severe hepatomegaly with steatosis from the boxed warnings. These drugs include Atripla®, Descovy®, Emtriva®, Genvoya®, Odefsey®, Stribild®, Vemlidy®, and Viread®. The updated boxed warnings for these medications include the risk for post-treatment acute exacerbation of hepatitis B. Atripla also includes a new warning regarding the risk for QTc prolongation.
Ultram	tramadol	Moderate to Severe Pain	Oral	New updates will be made to the Contraindications and Warnings sections of all prescription codeine and tramadol drug products regarding their use in children, adolescents and breastfeeding women.

Drug Safety Updates Q2 2017				
Brand Name	**Generic Name**	**Indications**	**Route of Administration**	**Action**
Vemlidy	tenofovir alafenamide	HBV	Oral	Drug labels of several human immunodeficiency virus type 1 and hepatitis B medications were updated to remove information related to lactic acidosis/severe hepatomegaly with steatosis from the boxed warnings. These drugs include Atripla®, Descovy®, Emtriva®, Genvoya®, Odefsey®, Stribild®, Vemlidy®, and Viread®. The updated boxed warnings for these medications include the risk for post-treatment acute exacerbation of hepatitis B. Atripla also includes a new warning regarding the risk for QTc prolongation.
Viread	tenofovir disoproxil	HIV, HBV	Oral	Drug labels of several human immunodeficiency virus type 1 and hepatitis B medications were updated to remove information related to lactic acidosis/severe hepatomegaly with steatosis from the boxed warnings. These drugs include Atripla®, Descovy®, Emtriva®, Genvoya®, Odefsey®, Stribild®, Vemlidy®, and Viread®. The updated boxed warnings for these medications include the risk for post-treatment acute exacerbation of hepatitis B. Atripla also includes a new warning regarding the risk for QTc prolongation.
Yondelis	trabectedin	Unresectable or Metastatic Liposarcoma or Leiomyosarcoma	IV	A new update was added to the Warnings and Precautions section of the Yondelis drug label, regarding capillary leak syndrome.
Zosyn	piperacillin/tazobactam	Intra-abdominal infections, Skin and Skin Structure infections, Female Pelvic Infections, Community Acquired Pneumonia, Nosocomial Pneumonia	IV	A new update was added to the Warnings and Precautions section of the Zosyn drug label, regarding nephrotoxicity in critically ill patients.