Brand Name	Generic Name	Indications	Route of Administration	Action
Adempas	riociguat	Pulmonary Arterial Hypertension, Chronic Thromboembolic Pulmonary Hypertension	Oral	A new update was added to the Contraindications section of the Adempas drug label pertaining to pulmonary hypertension associated with idiopathic interstitial pneumonias.
Bendeka	bendamustine	Non-Hodgkin Lymphoma, Chronic Lymphocytic Leukemia	IV	New warnings were added to the Warnings and Precautions section of the Bendeka drug label regarding hepatotoxicity and drug reaction with eosinophilia and systemic symptoms.
Direct-Acting Antivirals (Daklinza, Epclusa, Harvoni, Olysio, Sovaldi, Technivie,Viekira Pak/Viekira Pak XR, Zepatier)	daclatasvir, sofosbuvir/ velpatasvir, ledipasvir/ sofosbuvir, simeprivir, ombitasvir/paritaprevir/ritonavir, dasabuvir/ombitasvir/paritaprevir/ ritonavir, elbasvir/grazeprovir	Chronic Hepatitis C Infection	Oral	The FDA announced class labeling revisions for all direct acting antivirals (DAAs) regarding the risk of hepatitis B virus (HBV) reactivation in patients co-infected with hepatitis C virus (HCV) and HBV. As requested by the FDA in October 2016, a boxed warning, regarding the risk of HBV reactivation in patients co-infected with HCV and HBV, was added to the DAA drug labels. A new Warning discusses the risk of HBV reactivation that has been reported in HCV/HBV co-infected patients who were undergoing or had completed treatment with HCV DAAs, and who were not receiving HBV antiviral therapy. In the Dosage and Administration section, information has been added about testing all patients for evidence of current or prior HBV infection by measuring HBsAg and anti-HBc before initiating HCV treatment.
Lamisil	terbinafine	Onychomycosis, Tinea capitis	Oral (tablets and granules)	A new update was added to the Warnings and Precautions section of the Lamisil drug label regarding thrombotic microangiopathy.
Mekinist	trametinib	Metastatic Melanoma	Oral	A new warning was added to the Warnings and Precautions section of the Mekinist drug label regarding colitis and gastrointestinal perforation.

Brand Name	Generic Name	Indications	Route of Administration	Action
Plaquenil	hydroxychloroquine	Rheumatoid Arthritis, Lupus Erythematosis, Malaria	Oral	New updates were added to the Warnings section of the Plaquenil drug label regarding cardiac effects, including cardiomyopathy and QT prolongation, and hypoglycemia. The Plaquenil drug label no longer lists the following as contraindications: presence of retinal or visual field changes attributable to any 4-aminoquinoline compound, or for long-term therapy in children. A new Drug Interactions section was added to the Plaquenil drug label with information regarding use with digoxin, insulin or diabetic drugs, drugs that prolong QT interval and other arrhythmogenic drugs, mefloquine and other drugs known to lower the convulsive threshold, antiepileptics, methotrexate, cyclosporine, praziquantel, antacids and kaolin, cimetidine, and ampicillin.
Prolia, Xgeva	denosumab	*Prolia:* Osteoporosis/Bone Loss *Xgeva:* Hypercalcemia of Malignancy, Bone Metastasis from Solid Tumors, Giant Cell Tumor of Bone	Subcutaneous injection	A new update was added to the Warnings and Precautions section of the Prolia and Xgeva drug labels regarding the risk of multiple vertebral fractures following discontinuation of denosumab treatment.
Pylera	bismuth subcitrate potassium/metronidazole/tetracycline	H. Pylori Infection	Oral	A new boxed warning was added to the Pylera drug label regarding the potential for carcinogenicity. Similar information was added to the Warnings and Precautions section. The Contraindications section was also updated with new information stating that Pylera Is contraindicated during pregnancy. Other new updates to the Warnings and Precautions section include increased plasma concentrations in patients with hepatic impairment, cutaneous reactions, and drug interactions with oral contraceptives, anticoagulants, lithium, and busulfan. Additional new updates were made to the Adverse Reactions section including postmarketing information regarding peripheral neuropathy and skin and subcutaneous disorders. The Pregnancy and Lactation subsection was updated to align with current FDA drug labeling requirements.

Brand Name	Generic Name	Indications	Route of Administration	Action
Tecfidera	dimethyl fumarate	Multiple Sclerosis	Oral	A new update was added to the Warnings and Precautions section of the Tecfidera drug label regarding liver injury. In support of the new warning, the Dosage and Administration section was updated with information stating that serum aminotransferase, alkaline phosphatase, and total bilirubin levels should be obtained prior to treatment with Tecfidera. A new Overdose section was added to the Tecfidera drug label stating that cases of overdose have occurred. The Pharmacokinetics section was updated with new information regarding the use of Tecfidera in conjunction with oral contraceptives.
Trileptal	oxcarbazepine	Seizure Disorder (partial seizures)	Oral	A new update was added to the Contraindications section stating that Trileptal is contraindicated in patients with a known hypersensitivity to Aptiom® (eslicarbazepine). The Warnings and Precautions section was updated with new information regarding risk of seizure aggravation.
Unituxin	dinutuximab	Pediatric High-risk neuroblastoma	IV	New updates were added to the Warnings and Precautions section of the Unituxin drug label. The Warnings and Precautions subsection, Neurotoxicity, has been updated to include the newly identified risks of prolonged urinary retention, transverse myelitis, and reversible posterior leukoencephalopathy syndrome (RPLS). The adverse reactions of pain, peripheral neuropathy, and neurological disorders of the eye, have also been categorized under the new Neurotoxicity subsection. Dosing instructions were revised to include urinary retention, transverse myelitis, and RPLS as adverse reactions requiring permanent discontinuation of Unituxin. In support of the new additions to the Warnings and Precautions section, the boxed warning was revised to include a subheading for neurotoxicity to encompass other serious neurologic adverse reactions in addition to pain and peripheral neuropathy. Similar safety updates were made to the Adverse Reactions and Patient Counseling Information sections and the Postmarketing Experience subsection of the Unituxin drug label.
Various (OTC)	chlorhexidine gluconate	Antiseptic	Topical	Manufacturers of over-the-counter antiseptic products containing chlorhexidine gluconate are required to add a warning about the risk of rare, but serious allergic reactions reported with these products to the Drug Facts labels.
Viberzi	eluxadoline	IBS-diarrhea predominant	Oral	The FDA announced that Viberzi should not be used in patients who do not have a gallbladder. Patients who do not have a gallbladder who are taking Viberzi for irritable bowel syndrome with diarrhea have an increased risk of developing pancreatitis, sphincter of Oddi spasm, and death.