Product Name: Active Ingredient (Trade) *or* Product Class	**Potential Signal of a Serious Risk / New Safety Information**	**Additional Information (as of May 1, 2012)**
Bortezomib (Velcade)	Death from intrathecal administration (medication error)	The Dosage and Administration and Contraindications sections of the labeling for Velcade were updated January 2012, to include fatal events with intrathecal administration.
Brentuximab vedotin (Adcetris)	Progressive multifocal leukoencephalopathy (PML)	The Boxed Warning and Warnings and Precautions sections of the labeling for Adcetrus were updated January 2012, to include PML.
Fluoroquinolone products	Peripheral sensorimotor neuropathy	FDA is continuing to evaluate this issue to determine if the current labeling, which contains information about peripheral sensorimotor neuropathy, is adequate.
Gabapentin HCl (Neurontin)	Increase in blood creatine phosphokinase levels and rhabdomyolysis	FDA is continuing to evaluate these issues to determine the need for any regulatory action.
Gadolinium-based contrast agents (GBCA) products	Acute kidney injury	FDA is continuing to evaluate this issue to determine if the current labeling, which contains information about kidney injury, is adequate.
Iloprost inhalation solution (Ventavis)	Hemoptysis	The Adverse Reactions section of the labeling for Ventavis was updated April 2012, to include hemoptysis.
Loperamide HCl-containing products (Imodium)	Pancreatitis	FDA decided that no action is necessary at this time based on available information.
Magnesium sulfate for injection	Fetal skeletal demineralization, hypermagnesemia, and other bone abnormalities with continuous long-term use in pregnant women.	FDA is continuing to evaluate these issues to determine the need for any regulatory action.
Milnacipran HCl (Savella)	Homicidal ideation	FDA decided that no action is necessary at this time based on available information.
Pegloticase (Krystexxa)	Anaphylaxis and infusion reactions	The Warnings and Precautions section of the labeling for Krystexxa was updated April 2012, to include anaphylaxis and infusion reactions.
Phenytoin (Dilantin) and non-depolarizing neuromuscular blocking agents	Drug interactions resulting in decreased effectiveness of the non-depolarizing neuromuscular blocking agent	FDA is continuing to evaluate this issue to determine the need for any regulatory action.

Polyethylene Glycol (PEG) 3350 over-the-counter oral laxative (Miralax)	Neuropsychiatric events	FDA decided that no action is necessary at this time based on available information.
Proton pump inhibitors (PPIs) Over-the-counter (OTC) products	Clostridium difficile-associated diarrhea	FDA is continuing to evaluate this issue to determine the need for any regulatory action.
Rubidium Rb 82 generator (CardioGen-82)	Unintended radiation exposure to strontium isotopes following myocardial imaging scans.	CardioGen-82 was voluntarily recalled by the manufacturer in July 2011; a return to the U.S. market is planned. The Boxed Warning, Dosage and Administration, and Warnings and Precautions sections of the labeling for CardioGen-82 were updated February 2012, to include information about unintended radiation exposure.
Sorafenib tosylate (Nexavar)	Osteonecrosis of the jaw	FDA is continuing to evaluate this issue to determine the need for any regulatory action.
Telaprevir (Incivek)	Serious skin reactions including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) and Stevens-Johnson Syndrome (SJS)	FDA is continuing to evaluate this issue to determine the need for any regulatory action.