Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS) between October - December 2011

The table below lists the names of products and potential signals of serious risks/new safety information that were identified for these products during the period October - December 2011 in the AERS database. The appearance of a drug on this list does not mean that FDA has concluded that the drug has the listed risk. It means that FDA has identified a ***potential safety issue***, but does not mean that FDA has identified a causal relationship between the drug and the listed risk. If after further evaluation the FDA determines that the drug is associated with the risk, it may take a variety of actions including requiring changes to the labeling of the drug, requiring development of a Risk Evaluation and Mitigation Strategy (REMS), or gathering additional data to better characterize the risk.

FDA wants to emphasize that the listing of a drug and a potential safety issue on this Web site does not mean that FDA is suggesting prescribers should not prescribe the drug or that patients taking the drug should stop taking the medication. Patients who have questions about their use of the identified drug should contact their health care provider. FDA will complete its evaluation of each potential signal/new safety information and issue additional public communications as appropriate.

Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS) October - December 2011

Product Name: Active Ingredient (Trade) *or* Product Class	Potential Signal of a Serious Risk / New Safety Information	Additional Information (as of March 1, 2014)
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. **Bortezomib (Velcade) Labeling approved January 23, 2012 (PDF - 2.22MB) (http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021602s027lbl.pdf)**

Brentuximab vedotin (Adcetris)	Progressive multifocal leukoencephalopathy (PML)	**FDA Drug Safety Communication (/Drugs/DrugSafety/ucm287668.htm)** The Boxed Warning and Warnings and Precautions sections of the labeling for Adcetrus were updated January 2012, to include PML. **Brentuximab vedotin (Adcetrus) Labeling approved January 13, 2012 (PDF - 217KB) (http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/125388s0005lbl.pdf)**
Fluoroquinolone products	Peripheral sensorimotor neuropathy	UPDATED The Warnings and Precautions section of the labeling for fluoroquinolone products was updated August 2013, to include information about peripheral sensorimotor neuropathy. **FDA Drug Safety Labeling Changes August 2013 (/Safety/MedWatch/SafetyInformation/ucm365214.htm)**
Gabapentin HCl (Neurontin)	Increase in blood creatine phosphokinase levels and rhabdomyolysis	The Adverse Reactions section of the labeling for Neurontin was updated May 2013, to include increase in blood creatine phosphokinase levels and rhabdomyolysis. **Gabapentin HCl (Neurontin) Labeling approved May 1, 2013 (PDF - 288KB) (http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020235s054s055s056,020882s038s039s040,021129s035s036s037lbl.pdf)**

Gadolinium-based contrast agents (GBCA) products	Acute kidney injury	UPDATED The Warnings and Precautions section of the labeling for gadolinium-based contrast agents was updated October 2013, to include information about acute kidney injury. **FDA Drug Safety Labeling Changes October 2013 (/Safety/MedWatch/SafetyInformation/ucm373523.htm)**
Iloprost inhalation solution (Ventavis)	Hemoptysis	The Adverse Reactions section of the labeling for Ventavis was updated April 2012, to include hemoptysis. **Iliprost inhalation solution (Ventavis) Labeling approved April 26, 2012 (PDF - 377KB) (http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021779s013lbl.pdf)**
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 Drug Safety Communication (/Drugs/DrugSafety/ucm353333.htm)** The Dosage and Administration and Warnings and Precautions sections of the labeling for Magnesium sulfate for injection were updated May 2013, to include information about fetal harm. **Magnesium sulfate for injection Labeling approved May 29, 2013 (PDF - 120KB) (http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/019316s018lbl.pdf)**

Milnacipran HCl (Savella)	Homicidal ideation	The Adverse Reactions section of the labeling for Savella was updated December 2012, to include aggression, anger and homicidal ideation. **Milnacipran HCl (Savella) Labeling approved December 6, 2012 (PDF - 504KB) (http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022256s013lbl.pdf)**
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. **Pegloticase (Krystexxa) Labeling approved April 16, 2012 (PDF - 146KB) (http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/125293s034lbl.pdf)**
Phenytoin (Dilantin) and non-depolarizing neuromuscular blocking agents	Drug interactions resulting in decreased effectiveness of the non-depolarizing neuromuscular blocking agent	UPDATED The Precautions / Drug Interactions section of the labeling for Cerebyx was updated March 2013, to include information about drug interactions resulting in decreased effectiveness. **Fosphenytoin sodium injection (Cerebyx) Labeling approved March 6, 2013 (PDF – 210KB) (http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020450s020lbl.pdf)** FDA is continuing to evaluate this issue to determine the need for any further 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 Drug Safety Communication (/Drugs/DrugSafety/ucm290510.htm)** 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.	**FDA Drug Safety Communication (/Drugs/DrugSafety/ucm291758.htm)** 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. **Rubidium Rb 82 generator (CardioGen-82) Labeling approved February 8, 2012 (PDF - 465KB) (http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/019414s014lbl.pdf)**
Sorafenib tosylate (Nexavar)	Osteonecrosis of the jaw	UPDATED The Adverse Reactions section of the labeling for Nexavar was updated October 2013, to include osteonecrosis of the jaw. **Sorafenib (Nexavar) Labeling approved October 30, 2013 (PDF - 653KB) (http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021923s015lbl.pdf)**

Telaprevir (Incivek)	Serious skin reactions including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) and Stevens-Johnson Syndrome (SJS)	**FDA Drug Safety Communication (/Drugs/DrugSafety/ucm332731.htm)** A Boxed Warning for serious skin reactions including DRESS, SJS and Toxic Epidermal Necrolysis (TEN) was added to the labeling for Incivek December 2012, as well as updates to the Warnings and Precautions and Adverse Reactions sections of the labeling describing these issues. **Telaprevir (Incivek) Labeling approved December 14, 2012 (PDF – 496KB) (http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/201917s007lbl.pdf)**

More in FDA Adverse Events Reporting System (FAERS) (/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm)

FDA Adverse Event Reporting System (FAERS): Latest Quarterly Data Files (/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082193.htm)

FDA Adverse Event Reporting System (FAERS) Statistics (/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070093.htm)

Potential Signals of Serious Risks/New Safety Information Identified from the FDA Adverse Event Reporting System (FAERS) (/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082196.htm)

FDA Adverse Events Reporting System (FAERS) Electronic Submissions (/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm115894.htm)