MedWatch: The FDA Safety Information and Adverse Event Reporting Program

What's New

- **Saba Shark Cartilage Complex, 60 Capsule Bottles: Recall - Possible Salmonella Contamination**
  (http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419445.htm)
  Salmonella can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Posted 10/20/2014

- **Lidocaine HCl Injection, USP 10 MG Per ML, 30 ML Single-Dose, Preservative-Free, by Hospira: Recall - Particulate Matter**
  (http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419322.htm)
  Injected particulate material may result in local inflammation, phlebitis, and/or low-level allergic response to the particulate or microembolic effects. Posted 10/17/2014

- **September 2014**
  (http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm417235.htm)
  Safety Labeling Changes includes 55 products with revisions to Prescribing Information. Posted 10/16/2014

- **LifeCare Flexible Intravenous Solutions by Hospira, Inc.: Recall - Potential for Leakage**
  (http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm418887.htm)
  A puncture in the primary container may be difficult to detect and lead to contamination, compromised sterility, and other adverse events. Posted 10/15/2014
• Medi-Trace Cadence and Kendall Multi-function Defibrillation Electrodes by Covidien: Field Safety Alert - Electrodes Will Not Connect with Philips FR3 or FRx AED units (/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm418644.htm) The mismatch of these devices could contribute to a delay in resuscitation and may contribute to subsequent death. Posted 10/12/2014

FDA Approved Safety Information

• DailyMed (National Library of Medicine) (http://dailymed.nlm.nih.gov/dailymed/about.cfm) Current Drug Prescribing Information. (NOTE: Drugs marked "unapproved" on this site have not been reviewed by FDA for safety and efficacy, and their labeling has not been approved.)

• Medication Guides (/Drugs/DrugSafety/ucm085729.htm) Paper handouts that come with many prescription medicines. Medication Guides address issues specific to particular drugs and drug classes. They contain FDA-approved information that can help patients avoid serious adverse events.

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

• Postmarket Drug and Biologic Safety Evaluations (/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/ucm204091.htm) Evaluations performed 18 months after drug approval, or after its use by 10,000 individuals.