FDA Report to PharmPAC
March 1, 2007
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Safety Information

- Did you receive MedWatch's timely information on cardiovascular and psychiatric adverse events associated with ADHD drugs? To receive timely safety information from FDA, please consider joining the MedWatch listserv, by visiting and subscribing to the NIH Listserv

Effectiveness Changes

- Telithromycin (Ketek) is no longer approved for acute bacterial exacerbation of chronic bronchitis due to *Streptococcus pneumoniae*, *Haemophilus, influenzae,* or *Moraxella catarrhalis*; and acute bacterial sinusitis due to Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis, or Staphylococcus aureus; and is now indicated for the treatment of community-acquired pneumonia (of mild to moderate severity) due to Streptococcus pneumoniae, including multi-drug resistant isolates, *Haemophilus influenzae, Moraxella catarrhalis, Chlamydophila pneumoniae,* or *Mycoplasma pneumoniae,* for patients 18 years and older. http://www.fda.gov/cder/drug/infopage/telithromycin/default.htm

News

- FDA commissioner Andrew von Eschenbach proposes to close seven FDA laboratories (Denver, Detroit, Kansas City, Philadelphia, San Francisco, San Juan and Winchester Engineering & Analytical Center) in Fiscal Year 2008.