Colorado Department of Public Health and Environment

NEWS RELEASE

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FOR IMMEDIATE RELEASE: Jan. 5, 2012

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FDA issues drug safety communication regarding liquid acetaminophen marketed for infants

DENVER – The state's chief medical officer at the Colorado Department of Public Health and Environment today reminds all parents of young children to pay attention to the warning issued by the FDA regarding dosing changes of liquid acetaminophen marketed for infants.

On Dec. 22, 2011, the FDA posted a drug safety communication titled Addition of another concentration of liquid acetaminophen marketed for infants. In the communication, the FDA informs the public that an additional concentration of liquid acetaminophen marketed for "infants" (160 mg/5 mL) now is available at local stores. Until now, liquid acetaminophen marketed for infants only was available in 80 mg/0.8 mL or 80 mg/mL concentrations. This change in the concentration will affect the amount of liquid given to an infant, and should be especially noted if someone is accustomed to using the 80 mg/0.8 mL or 80 mg/mL concentrations of liquid acetaminophen.

In addition to this change in concentration, this product also may be packaged with an oral syringe instead of a dropper.

The FDA recommends, to avoid confusion and potential dosing errors, consumers, parents and caregivers should carefully read the "drug facts" label on the package to identify the concentration of the liquid acetaminophen (in mg/mL), dosage and directions for use. Do not depend on banners stating it is a new product to identify different concentrations of liquid acetaminophen. Many products have similar banners.

It also is important to use the dosing device provided with the product to correctly measure the amount of liquid acetaminophen to be given. Patients and caregivers should contact their healthcare professional if they find the measuring device confusing or are unsure how to measure a dose for a child using the device provided.

Health care professionals should make sure to provide directions to patients that specify the concentration and dose of liquid acetaminophen that should be given to a child.

FDA has prepared a list of questions and answers and has issued a Consumer Update to provide an additional overview of these changes to over-the-counter liquid acetaminophen marketed for infants.

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