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(BCHD08-026) Public Health Advisory - FDA Recommends That Over-the-Counter Cough and Cold Products Not Be Used For Children Under 2 Years of Age

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FDA Releases Recommendations Regarding Use of Over-the-Counter Cough and Cold Products

Products should not be used in children under 2 years of age: evaluation continues in older populations

The U.S. Food and Drug Administration today issued a Public Health Advisory for parents and caregivers, recommending that over-the-counter (OTC) cough and cold products should not be used to treat infants and children less than 2 years of age because serious and potentially life-threatening side effects can occur from such use. OTC cough and cold products include decongestants, expectorants, antihistamines, and antitussives (cough suppressants) for the treatment of colds.

There are a wide variety of rare, serious adverse events reported with cough and cold products. They include death, convulsions, rapid heart rates, and decreased levels of consciousness. These medicines, which treat symptoms and not the underlying condition, have not been shown to be safe or effective in children under 2.

The agency plans to issue its recommendations on use of the products in children ages 2 to 11 years to the public as soon as review is complete.

Pending completion of the FDA's ongoing review, parents and caregivers that choose to use OTC cough and cold medicines to children ages 2 to 11 years should:

- . Follow the dosing directions on the label of any OTC medication

- . Understand that these drugs will NOT cure or shorten the duration of the common cold
- . Check the "Drug Facts" label to learn what active ingredients are in the products because many OTC cough and cold products contain multiple active ingredients
- . Only use measuring spoons or cups that come with the medicine or those made specially for measuring drugs.

The FDA recommends that anyone with questions contact a physician, pharmacist or other health care professional to discuss how to treat a child with a cough or cold.

For more information and the full list of the FDA's recommendations, visit: Public Health Advisory: Nonprescription Cough and Cold Medicine Use in Children

http://www.fda.gov/cder/drug/advisory/cough_cold_2008.htm

Questions and Answers for Consumers <http://www.fda.gov/consumer/updates/coughcold011708.html>

No action is required of local health departments at this time. If any action is required in the near future, the Food and Drug Safety Program will contact you.