OTC Industry Supports FDA Advisory Committee Recommendations on New Dosing Instructions

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WASHINGTON, May 18, 2011 /PRNewswire-USNewswire/ -- The Consumer Healthcare Products Association (CHPA), representing makers of over-the-counter (OTC) single-ingredient acetaminophen medicines for children, applauds the U.S. Food and Drug Administration (FDA) efforts to help parents and caregivers give their children the right amount of medicine. Today, the FDA's Nonprescription Drugs Advisory Committee and Pediatric Advisory Committee recommended enhancing the labels of all OTC single-ingredient pediatric acetaminophen products. If FDA acts on these recommendations, the revised labels would include:

- Dosing instructions for children between ages 6 months to 2 years of age, based on weight and age; and
- Dosing instructions by weight (as well as age) on the Drug Facts label for all children's single-ingredient acetaminophen medicines.

"The manufacturers of pediatric acetaminophen products support the FDA advisory committee's recommendations to give parents and caregivers more accurate and detailed dosing information where it is needed – directly on the Drug Facts label," said Scott M. Melville, president & CEO of the Consumer Healthcare Products Association. "The advisory committee unanimously recognized that providing parents and caregivers information on how to dose by weight and how to dose for children 6 months to 2 years of age will help reduce dosing confusion. These recommendations are consistent with our members' longstanding commitment to provide parents and caregivers with devices and information needed to help ensure children receive accurate dosing of these safe and effective medicines."

In a formal vote, the joint committees unanimously voted in support of the addition of weight-based dosing for children ages 2 to 12. The joint committees unanimously voted that the pharmacokinetic (PK), safety, and efficacy data support the addition of new label directions
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