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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

June 27, 2011

Docket No. FDA-2011-N-0002

Dear Sir or Madam,

The Consumer Healthcare Products Association (CHPA) is the 130-year-old-trade association representing U.S. manufacturers and distributors of over-the-counter (OTC) medicines. CHPA was a sponsor at the joint meeting of FDA's Pediatric and Nonprescription Drugs Advisory Committees meeting on May 17-18, 2011. CHPA presented comments at this meeting on behalf of member companies. CHPA strongly supports the unanimous votes by the advisory committees to add weight-based dosing directions to the existing age-based labeled dosing directions for children ages 2-12 and to add new labeled dosing directions corresponding to a 10-15 mg/kg dose for children 6 months to 2 years.

During the meeting, committee members discussed the data supporting analgesic and antipyretic claims for the new labeling for children 6 months to 2 years. The committee voted in favor of labeling antipyretic claims and against labeling analgesic claims for this age range. Data were presented by McNeil Consumer Healthcare supporting both antipyretic and analgesic activity of acetaminophen in this age group. Pharmacokinetic data were also presented supporting extrapolation of acetaminophen efficacy from older children to younger children. During questioning by committee members, FDA staff (Hertz and Kweder) noted that no analgesic labeled for use in children under age 2 had been approved on the basis of clinical efficacy data from that population. Rather, the approvals are based on extrapolated data from older children to support an indication and use in younger children. As expressed during the advisory committees' discussions, the ability of clinical investigators to generate subjective analgesia data in children under age 2, who can neither speak nor rate their pain, is doubtful. Accordingly, CHPA requests that FDA maintain a standard of consistency in determining labeling claims for analgesics in children 6 months to 2 years and permit extrapolation.

**Consumer Healthcare
Products Association**

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OTC acetaminophen has been used safely in children 6 months to under age 2 for more than 30 years. We urge FDA to propose rulemaking for acetaminophen on an expedited timetable, and to include labeling claims for analgesia and antipyresis for children 6 months to under age 2.

Sincerely,

A handwritten signature in cursive script that reads "Barbara A. Kochanowski". The signature is written in black ink and is positioned above the typed name.

Barbara A. Kochanowski, Ph.D.
Vice President, Regulatory Affairs