CHPA

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September 4, 2012

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2012-D-0529

Dear Sir or Madam,

Enclosed herein are comments on "Guidance for Industry; Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use – Labeling for Products That Contain Acetaminophen, published as *Draft Guidance*[1]. The Consumer Healthcare Products Association (CHPA) is the national trade association representing the leading manufacturers and distributors of OTC medicines and dietary supplements in the United States. CHPA and its member companies have an interest and expertise in acetaminophen-containing over-the-counter (OTC) drug products and support FDA's efforts to develop guidance for industry on this important topic.

CHPA requests that FDA expand its proposed enforcement discretion regarding the proposed alternative language for the liver warning for acetaminophen. As currently written, FDA provides alternate language to address the potential confusion for OTC acetaminophen-containing products with directions for use that result in a maximum daily dose of less than 4,000 mg of acetaminophen. FDA provides a version of the liver warning that helps ensure appropriate dosing of OTC acetaminophen-containing products while informing consumers that using more than maximum daily dose of 4,000 mg of acetaminophen may result in severe liver damage. FDA say they intend to exercise enforcement discretion if manufacturers use this language on products labeled for adults only.

FDA Proposed Alternate Language (Adults)

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take
- More than 4,000 mg of acetaminophen in 24 hours
- With other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

[1] **Federal Register**, Vol 77, No. 129, July 5, 2012, pp 39710-39711

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The guidance does not describe any circumstances where FDA will exercise enforcement discretion if a product is labeled for adults and children less than 12 years. Currently, some single ingredient, regular strength OTC acetaminophen products are labeled for use by children age 6 and older, as well as by adults. CHPA is requesting that FDA permit the alternate language for these products.

CHPA offers to add to the draft guidance the following proposed alternate language for products labeled for adults and children under 12 years of age for FDA's consideration. This language is simpler than the language in the final rule, follows the logic of the final rule, is in keeping with the intended purpose to eliminate potential confusion and maintains accurate language around the dose at which liver damage may occur.

CHPA Proposed Language (Adults and Children under 12 years of age)

Liver warning: This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

CHPA and its members are willing to discuss our input further and look forward to FDA's response to this proposal.

Respectfully submitted,

Barbara A. Kochanowski

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Vice President, Regulatory & Scientific Affairs

cc: M. Scott Furness, Ph.D., Director, DNRD, FDA (via email)