



June 8, 2009

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

Re: Docket No. FDA-2009-N-0138, Joint Meeting of the Drug Safety and Risk Management Advisory Committee, Nonprescription Drugs Advisory Committee, and the Anesthetic and Life Support Drugs Advisory Committee

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments the June 29 and 30, 2009 Joint Meeting of the Drug Safety and Risk Management Advisory Committee, Nonprescription Drugs Advisory Committee, and the Anesthetic and Life Support Drugs Advisory Committee. For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students. Pharmacists in hospitals and health systems are experts in medication use who serve on interdisciplinary patient-care teams. They work with physicians, nurses, and other health-care professionals to ensure that medicines are used safely and effectively.

ASHP commends the FDA's evaluation of strategies to improve the safety of acetaminophen-containing drug products. ASHP has reviewed the recommendations set forth by the working group and appreciates their intent to limit liver toxicity associated with use of these products. While each recommendation offers potential benefits, there are inherent challenges in implementing these changes. In our comments, the Society wishes to focus only on the proposed recommendations to limit tablet strength for nonprescription and prescription products and to limit pediatric liquid formulations to one concentration.

ASHP strongly encourages the FDA to exercise caution prior to recommending reformulation of existing acetaminophen-containing product because such changes can affect patient safety and continuity of care. A thorough examination of the use of each product should be undertaken to ensure appropriate consideration of the benefits and limitations of such decisions and the practice implications. For example, the variety of pediatric formulations has in instances resulted in patient harm when concentrations are

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misread or doses miscalculated. However, a change in the available concentration also has the potential to increase errors and would require significant consumer education to avoid confusion. In addition, determination of the most appropriate single concentration is a difficult task, which must consider variables such as the drug's use in neonatal patients who may not tolerate the volume needed to appropriately dose a less-concentrated solution.

Continuity of care is another significant concern. For example, prescription products used to treat osteoarthritis frequently contain dosages of acetaminophen higher than the limit recommended by the working group. While the intent of the proposed limit is to improve patient safety, an unintended consequence may be a loss of pain management for patients with osteoarthritis and others being treated for chronic pain syndromes.

The Society appreciates this opportunity to present its written comments. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at jcoffey@ashp.org.

Sincerely,

A handwritten signature in cursive script that reads "Justine Coffey".

Justine Coffey, JD, LLM
Director, Federal Regulatory Affairs