



American Academy of Family Physicians

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May 22, 2007

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

Re: Docket No. 1977N-0094L
(RIN) 0910-AF36

To Whom It May Concern:

The mission of the American Academy of Family Physicians (AAFP) is to improve the health of patients, families and communities by serving the needs of members with professionalism and creativity. In line with this mission, we are committed to our patients' safe use of medicines, including over-the-counter (OTC) analgesics. To that end, we applaud the FDA's recent proposal to clarify OTC analgesic labeling to encourage the safe use of OTC medicines.

We strongly agree with the Agency that clear and complete product labeling for OTC and prescription acetaminophen-containing products complemented by patient and healthcare professional educational efforts are important and necessary to encourage consumers' appropriate use of medicines. As an organization representing over 94,000 family physicians, family medicine residents and medical students, we acknowledge the central role that our members must play in improving the appropriate use of medicines. We are writing to pledge to work to help our members improve this communication.

AAFP recognizes that another opportunity for improvement is related to the clarity of container labeling for prescription acetaminophen-containing products, which often bear the abbreviation "APAP" instead of "acetaminophen". We believe an important step in increasing consumer understanding of the active ingredients in their prescription medications would be to standardize wording of ingredients of prescription labels.

Importantly, AAFP urges that FDA expand OTC labeling of pediatric acetaminophen products to include dosing for children less than 2 years of age. AAFP believes that providing care givers with complete dosing information will decrease the cases of misadministration and potentially, decrease situations of overdose in young children.

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Finally, the health of our patients, families and communities is a shared mission between FDA and the AAFP. Together, we need to share the responsibility to more clearly, thoughtfully and directly encouraging the safe and appropriate use of medicines. We look forward to continuing our work in this area and working collaboratively with FDA.

Sincerely,

Larry S. Fields MD

Larry S. Fields, MD, FAAFP
Chairman, Board of Directors
American Academy of Family Physicians