



founded 1881

May 25, 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 0901-AF36
Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Required Warnings and Other Labeling, 71 Fed. Reg. 77314-52 (December 26, 2006)

Dear Sir or Madam:

In the December 26, 2006, *Federal Register*, the Food and Drug Administration invited comments on the above-referenced proposed rule, which proposes new warning and other labeling requirements for internal analgesic, antipyretic, and antirheumatic (hereinafter, “internal analgesics”) over-the-counter (OTC) drug products.

The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing manufacturers and distributors of OTC medicines and dietary supplements in the United States, including OTC internal analgesics. CHPA members account for over 90 percent of the domestic retail sales of OTC medicines. As such, we have an interest in the subject matter of the proposed rule.

We are committed to communicating important information about the safe use of OTC medicines through labeling, and while a number of CHPA members have already instituted voluntary label changes to communicate the types of information FDA seeks to address in the proposed rule, we seek a number of clarifications or changes in the proposed rule. These revolve around: (1) proposals which impact the principal display panel; (2) highlighting information within the “Drug Facts” label; (3) efficient use of limited label space; and (4) clarifications.

1. Principal display panel proposals.

(a) The proposal to require ingredient names and “(NSAID)” in a type size one-quarter that of the most prominent matter on the principal display panel is unnecessary, not justified, and should be modified. FDA proposes that the active ingredients acetaminophen, aspirin, and nonsteroidal anti-inflammatories (NSAIDs) in addition to

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