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March 19, 2013

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

Re: Docket No. FDA-2013-N-0032, Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling Notification Procedures for Statements on Dietary Supplements; 78 Fed. Reg. 4153-4 (January 18, 2013)

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA) welcomes the opportunity to comment on the above captioned request published in the January 18, 2013 Federal Register. CHPA is the 132-year old trade association representing manufacturers and distributors of nonprescription or over-the-counter (OTC) medicines. CHPA is also one of a number of national trade associations representing manufacturers and distributors of dietary supplements in the United States. As such, CHPA has an interest in the subject matter of the request for comments.

The Food and Drug Administration (FDA) has requested comment on the information collection provisions of Section 403(r)(6) of the Food, Drug, and Cosmetic Act (the FD&C Act). Section 403(r)(6) permits manufacturers of dietary supplements to make nutritional deficiency, structure/function, or general well-being claims in the labeling of dietary supplements, provided those claims are truthful and not misleading. The dietary supplement manufacturer must have substantiation that the statement is truthful and not misleading, and must include in the statement the following disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

No later than 30 days after the marketing of the dietary supplement containing such a statement, the manufacturer must notify FDA that such a statement is being made. The information currently required includes: (1) name and address of the manufacturer, packer or distributor of the dietary supplement; (2) the text of the statement being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement; and (5) the signature of a responsible individual certifying the accuracy of the information and that the available substantiation for the statement is truthful and not misleading. Regulations implementing these requirements are codified at Sec. 101.93 (21 CFR 101.93).

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The agency has requested comments on the following topics: whether the proposed collection of information is necessary and will have practical utility; the accuracy of the estimate of the burden of the proposed collection of information; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden (*i.e.*, through the use of automated collection techniques).

CHPA and its member companies marketing dietary supplement products believe that the annual reporting burden provided by the agency reflects a reasonable estimate of the time necessary to submit the required information and that the existing requirements codified at Sec. 101.93 (21 CFR 101.93) provide the FDA with the necessary information on the introduction of dietary supplements. However, if automated techniques (*i.e.*, electronic submission) were available to submit the required information, this could potentially decrease the reporting burden.

CHPA member companies thank the Agency for the opportunity to provide comments about the notification procedures for statements on dietary supplements.

On behalf of the CHPA Dietary Supplements Committee,

Jay E. Sirois
Director, Regulatory & Scientific Affairs