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May 10, 2013

**VIA ELECTRONIC SUBMISSION**

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

**Re: Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues**

**Docket No. FDA-2011-D-0376 --- 76 Fed. Reg. 39111 (July 5, 2011)**

The Consumer Healthcare Products Association (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. We take this opportunity to voice our support of comments submitted by the American Herbal Products Association (AHPA) on April 27, 2013 regarding proposed revisions to Section VI.A. of the agency's July 2011 Draft Guidance on New Dietary Ingredient (NDI) Notification. The comments submitted by AHPA highlight the need for guidance on this issue given the "absence of a specific regulatory requirement to submit information on the identity of an NDI" as well as that a common reason for agency objection to recent NDI notifications has been that they were "unable to establish the identity of the dietary ingredient" from the information supplied by the notifier. In their recent submission to the docket, AHPA provides an overview of the identity information necessary for characterization of a new dietary ingredient.

Previous comments to this docket by the dietary supplement trade associations, including a joint submission by CHPA and the Council for Responsible for Nutrition (December 2, 2011) addressed a number of concerns associated with the July 2011 Draft Guidance. While the trade associations

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continue to meet with the agency to discuss these important topics, we urge the agency to provide a separate stand-alone guidance on ingredient identification to provide clarity to manufacturers submitting NDI notifications for their ingredients. Prioritizing the release of draft guidance concerning the information required in an NDI notification will allow this area of need to be addressed in an expeditious fashion and will benefit both dietary supplement manufacturers and the agency.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read "Jay E. Sirois". The signature is fluid and cursive, with the first name "Jay" and last name "Sirois" clearly legible.

Jay E. Sirois  
Director, Regulatory & Scientific Affairs  
Consumer Healthcare Products Association