



May 2, 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**Re: Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues  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 Council for Responsible Nutrition (CRN)<sup>1</sup> takes this opportunity to urge FDA to review follow-up comments, submitted on April 27, 2013, by the American Herbal Products Association (AHPA) on the agency's Draft Guidance on New Dietary Ingredient (NDI) Notification (Draft Guidance) issued on July 5, 2011. CRN fully supports the ideas and

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<sup>1</sup> The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 100 companies that manufacture dietary ingredients and/or dietary supplements, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at [www.crnusa.org](http://www.crnusa.org).

viewpoints expressed in AHPA's comments, having had the opportunity to thoroughly review them prior to AHPA's submission.

The AHPA comments specifically address a series of proposed revisions to Section VI.A. of the 2011 Draft Guidance, which detail the information that should be included in a NDI notification to properly characterize a new dietary ingredient. The AHPA comments note that the most common reason FDA objected to previous NDI notifications is that the agency "is unable to establish the identity" of the dietary ingredient that is the subject of the notification from the information supplied by the notifier. The AHPA submission offers a blueprint of what identity information is needed in a NDI notification; one which manufacturers and the agency can agree upon.

As we have pointed out in previous comments to this docket, there are still issues in which CRN and FDA disagree with respect to what constitutes a NDI, how a manufacturer properly demonstrates that its ingredient is not a NDI subject to notification, and the level of science necessary to support the safety of a NDI. We look forward to continuing discussions with FDA to resolve these outstanding issues. However, once a manufacturer determines that a NDI notification is required, what constitutes an adequate description of the ingredient in the NDI notification is an issue where we can agree. The prompt issuance of a new draft guidance limited to the areas detailed in AHPA's April 27, 2013 follow-up comments will address pressing concerns in the NDI matter and provide clarity to manufacturers who submit NDI notifications for their ingredients. Thus, CRN agrees with AHPA that clarifying information needed to identify a NDI that is the subject of a NDI notification should be the first priority for the agency regarding issues related to NDI notifications. We echo AHPA's request that FDA

provide guidance on ingredient identification promptly as a stand-alone guidance, and not wait until the publication of the entire revised Draft Guidance.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Steve Mister". The signature is fluid and cursive, with a large initial "S" and "M".

Steve Mister  
President and CEO  
Council for Responsible Nutrition

A handwritten signature in black ink, appearing to read "D. MacKay". The signature is more angular and less cursive than the one above, with a prominent checkmark-like flourish at the end.

Douglas MacKay  
Vice President, Scientific & Regulatory Affairs  
Council for Responsible Nutrition