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VIA ELECTRONIC SUBMISSION

Mr. Robert Durkin
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United States Food & Drug Administration
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(copy to) 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Re: Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues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)

Dear Mr. Durkin and Mr. Elkin:

I write to call your attention to previous comments filed by the Council for Responsible Nutrition (CRN)[1] and to renew our recommendation that FDA issue a stand-alone Draft Guidance on the New Dietary Ingredient (NDI) notification issue which addresses the most critical issues involving NDIs, namely a guidance providing clear direction for the information necessary to provide an accurate description of an ingredient that is the subject of an NDI notification prescribed by the Dietary Supplement Health and Education Act (DSHEA), 21 USC §350b. Enclosed with this letter is a copy of our previous submission to the docket on this matter dated May 2, 2013 and the referenced submission of the American Herbal Products Association (AHPA) with which we concur.

It has been over three years since the FDA notified the dietary supplement industry on June 19, 2012 that it would refrain from implementing aspects of the agency's initial Draft Guidance on NDIs that had been issued in 2011. FDA announced then that it would re-issue a revised Draft Guidance in the near

[1]The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing 150+ dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Visit www.crnusa.org. Follow us on Twitter @crn_supplements and @wannabewell and on Facebook.

future addressing many of the concerns and issues raised by various commenters in response that that earlier document. Since that time, the agency has been relatively silent with regard to this revised Draft Guidance and when the industry might expect its release. However, at the same time, the number of NDI notifications submitted to FDA, and rejected by the agency for various reasons, has continued to grow. Likewise, FDA has notified companies on several occasions of their failure to file NDI notifications for new dietary ingredients. We believe the reasons for these incomplete, invalid or neglected notifications is, in part, because of continued confusion by industry of the requirements for submitting an NDI notification, and the requisite information to appropriately describe the ingredient in such notifications. Even as the FDA continues to deliberate other related NDI issues, such as when a grandfathered ingredients is "chemically altered" such that it is a new ingredient, and whether the 75-day notification may apply to an ingredient (as opposed to each new product using that ingredient), FDA certainly could, and should, address the confusion with respect to the contents of an NDI notification with a limited guidance on this topic, and provide clarify on those aspects of compliance.

Given the continuing status of the series of "interim" or "acting" directors for the Division of Dietary Supplement Programs (DDSP), as well as the apparent discussions being conducted within CFSAN about the possibility of elevating DDSP to an Office level, we anticipate that it is unlikely a permanent director of dietary supplements will be announced in the near future. Nevertheless, the industry needs clear direction from FDA on the NDI notification matter, at least with regard to the fundamental requirements for what information should be included in an NDI notification. As some aspects of the original NDI Draft Guidance may need to be reserved until a permanent director is in place, we believe a Guidance that addresses the basic components of an NDI notification such as how to adequately describe the new dietary ingredient with specificity could be released immediately without controversy and would satisfy the need for clarity about this aspect of the law.

Accordingly, CRN formally and respectfully requests the agency reconsider this earlier recommendation to examine the AHPA comments and issue a draft guidance limited to the topic of identifying a new dietary ingredient in an NDI notification submitted pursuant to 21 USC §350b. We would be happy to discuss this issue with the agency in more detail.

Sincerely yours,

Steve Mister

Steve Mister
President & CEO

Attached: CRN Submission to Docket No. FDA-2011-D-0376, dated May 2, 2013
AHPA submission to Docket No. FDA-2011-D-0376, dated April 27, 2013