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

Re: Docket No. FDA-2011-N-0410: Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification for a New Dietary Ingredient

The following comments on the U.S. Food and Drug Administration's (FDA) estimated burden on the industry to generate data to meet the requirements of the premarket notification for a new dietary ingredient (NDI), published in the Federal Register on June 3, 2011, are submitted on behalf of the Council for Responsible Nutrition (CRN). CRN is a Washington, D.C. - based trade association representing the dietary supplement industry. Our members include some of the largest and most well-known ingredient suppliers, manufacturers, direct sellers and retailers of dietary supplements and dietary ingredients.

The Federal Register Notice suggests that the average time necessary to generate data to meet the requirements of an NDI notification is 20 hours. CRN members with experience filing NDI notifications have verified that this estimate is significantly too low and reported estimates of 100 – 350 hours. Furthermore, FDA's estimates are based on NDI notifications filed prior to the release of the New Dietary Ingredient Notification Draft Guidance that is intended to provide additional clarity on the types of information that should be included in an NDI notification.

Prior to the availability of an FDA Draft Guidance, the dietary supplement industry has been operating without guidance on the type and scope of chemistry information, processing

information, production information, or safety information to include in an NDI notification. The estimated burden on industry of 20 hours proposed by FDA will have little relevance to the burden of filing NDI notifications now that the Draft Guidance is available. The NDI Draft Guidance has only been recently released and the dietary supplement industry has not fully evaluated its implications; therefore, time is needed before both industry and FDA can be fully operational under this new framework and provide sound estimates of the burden of filing NDI notifications.

In developing time estimates related to the preparation of NDI notifications, FDA should use data from "successful" notifications only; the number of hours spent on notifications to which FDA does not object more accurately reflect the burden on industry. The Agency has objected to the majority of NDI notifications that have been reviewed to date. In many cases, the "unsuccessful" NDI notification may result from insufficient allocation of time and other resources by the notifying firm. Thus, including the hours used by firms to submit inadequate NDI notifications results in an average that does not represent the true burden on the dietary supplement industry whose goal is to satisfactorily submit NDI notifications to FDA. In addition, the evaluation of the number of hours spent filing a successful NDI notification should be based on successful NDI notifications completed after the release of a final FDA NDI Notification Guidance.

It is noteworthy that the June 3, 2011 Federal Register Notice suggests that there are no capital costs associated with the collection of information required to submit NDI notifications. However, CRN members do invest significant capital resources in hiring consultants to extract and summarize information for NDI notifications, paying for full-text scientific journal articles, and obtaining legal review of NDI notifications. The high rate of failed NDI notifications and the lack of an FDA NDI Guidance for the past 17 years make it necessary for firms to contract consultants (scientific, regulatory, and legal) with specific experience and knowledge regarding NDIs to navigate the 75-day pre-market notification process. Furthermore, the recently released NDI Draft Guidance appears to prescribe a high standard with regard to the type and scope of information required for NDI notifications. The dietary supplement industry anticipates that

adhering to the FDA NDI Guidance will significantly increase the resource burden on industry to file successful notifications.

In conclusion, CRN believes that FDA has grossly underestimated the burden of the NDI notification process on the dietary supplement industry in terms of time resource and capital cost.

Respectfully Submitted,

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Council for Responsible Nutrition