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July 25, 2011

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

Re: Docket No. FDA-2011-N-0403: Agency Information Collection Activities; Proposed Collection; Comment Request; Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act

The following comments on the U.S. Food and Drug Administration's (FDA) estimated burden on the industry to generate data to substantiate dietary supplement claims made under the Federal Food, Drug, and Cosmetic Act (FDCA), 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 under the FDCA range from 44 -120 hours. CRN members agree that this is an appropriate estimate of the time required to properly substantiate dietary supplement claims. However, the Federal Register Notice also suggests that no capital costs are associated with the collection of the data necessary to substantiate health related claims made for dietary supplements. FDA's "Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403 (r) (6) of the Federal Food, Drug, and Cosmetic Act" recommends that dietary supplement manufacturers carefully draft their labeling claims and carefully review the

support for each claim to ensure the substantiation relates to the specific product and claim, is scientifically sound, and is adequate in the context of the surrounding body of evidence. Furthermore, the consequences of unsubstantiated and/or misleading claims can be significant. Responsible dietary supplement manufacturers do commit capital resources in the development of claims in order to comply with the Agency's recommendation to carefully develop and review claims prior to their use. These capital costs include, but are not limited to, paid subscriptions to scientific journals and libraries to gain access to full-text scientific literature, consultants to develop appropriate wording for claims, and legal review of claims by qualified professionals that are familiar with health-related advertising law. These capital costs are increased for smaller firms that may not have the relevant expertise on staff to properly substantiate claims per FDA and FTC guidelines or provide the appropriate legal review of claims.

CRN believes that the Agency's estimated burden of 44 – 120 hours required to generate data to substantiate dietary supplement claims is consistent with estimates provided by CRN members. However, CRN members want the Agency to be aware that there are capital costs associated with the development of claims, which can be significant for smaller firms.

Respectfully Submitted,

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Council for Responsible Nutrition