Council for Responsible Nutrition
1828 L Street, NW, Suite 510 • Washington, DC 20036-5114
(202) 204-7700 • fax (202) 204-7701 • www.crnusa.org

September 19, 2011

Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Re: OMB Control No 0910-0330 [Docket No. FDA-2011-N-0410]: Agency Information Collection Activities; Proposed Collection; Submission for Office of Management and Budget Review; 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), originally 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 responsible 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.

In the June 3, 2011 Federal Register comment request regarding docket number FDA-2011-0410, FDA estimated the average time necessary to generate data to meet the requirements of an NDI notification is 20 hours.

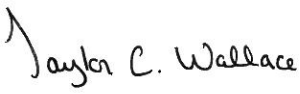
On July 25, 2011 CRN submitted comments on behalf of its 75+ industry members--many of whom have had experience filing NDI notifications--providing estimates for the time to prepare NDI notifications that significantly exceed FDA's estimate. CRN members shared their experiences specific to the paperwork burden resulting from §190.6 and reported committing 100-350 hours to extract and summarize the relevant information from the company's files, and present it in the format that will meet the requirements of section 413 (a) of the FD & C Act and §190.6. CRN would like to make it clear that this estimate does NOT include the time required to generate the data to meet the requirements of an NDI notification, which is information the company should already have developed as the basis for its conclusions that a dietary

supplement containing an NDI will reasonably be expected to be safe. In FDA's response to industry comments published in the August 19, 2011 Federal Register, the Agency appears to have mistaken industry's estimates to include the time necessary to generate the data (e.g. performing required safety and toxicology studies). If this were the case, the time and resource burden would be significantly higher than 100-350 hours. CRN is submitting these comments to the Office of Management and Budget (OMB) to make it clear that our estimates of 100-350 hours only reflect the time necessary to extract and summarize the relevant information from the company's files.

In its August 19, 2011 Federal Register notice, FDA disagreed with comments submitted on behalf of industry stating that, "there is minimal burden on the industry to generate data…because the Agency is requesting only that information that the manufacturer or distributor should already have developed as the basis for its conclusion that a dietary supplement containing an NDI will reasonably be expected to be safe." CRN members with experience submitting NDI notifications have responded with thoughtful comments; however, FDA, with no actual experience extracting and summarizing the necessary information, has decided to disagree without a reasonable basis. FDA continues to use uninformed assumptions to derive the 20 hour estimation for extracting and summarizing relevant information required to prepare an NDI notification in light of the collective data provided by CRN members who are among those companies that submit NDI notifications annually.

CRN feels strongly that FDA has grossly underestimated the NDI notification process' burden on the dietary supplement industry in terms of time resources. Accordingly, CRN seeks consideration of its comments by the OMB in determining the actual burden on industry.

Respectfully Submitted,



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

Taylor C. Wallace, Ph.D.
Senior Director, Scientific & Regulatory Affairs
Council for Responsible Nutrition