Council for Responsible Nutrition
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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-0197: Agency Information Collection Activities; Proposed Collection; Comment Request; Criteria Used To Order Administrative Detention of Food For Human or Animal Consumption.

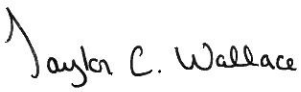
The following comments on the U.S. Food and Drug Administration's (FDA) proposed amendment to its rule pertaining to the criteria needed to order administrative detention of a human or animal food, published in the Federal Register on May 5, 2011, are submitted on behalf of the Council for Responsible 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. We commend the FDA's efforts to develop regulations, rules and guidelines to better protect public health by ensuring the safety and security of the food supply. CRN has supported the recently enacted Food Safety Modernization Act and its emphasis on using a risk-based approach to prevent food safety problems rather than reacting to problems after they occur. CRN wishes to offer the following comments for consideration to better assist in the amendment of the aforementioned rule.

Under the new criteria FDA can order administrative detention if there is "reason to believe" that an article of food is adulterated or misbranded. The "reason to believe" a food is adulterated or misbranded would be made on a case-by-case basis. The amendment to the rule nullifies prior

language dictating that the Agency needed credible evidence or information indicating that a product presented a threat of adverse effects before detaining a shipment. CRN believes that FDA should provide the industry with guidance and clarify what constitutes "reason to believe." For example, FDA currently and commonly places incoming shipments of raw ingredients from China under quarantine until results from FDA lab analyses are complete. This cautious approach is attributed to the economically motivated adulteration of some ingredients/products originating from China. While we support this respectable process to ensure the safety of the food supply, some CRN member companies have reported challenges in being able to maintain finished product inventories because of detention of products for testing purposes. Appropriate guidance and/or a definition of "reason to believe" would help the industry prepare for administrative detention of identified products, help meet supply chain demands and develop appropriate tracking plans for products, while easing the burden on FDA.

The success of the dietary supplement industry is dependent on predictability and certainty surrounding supply chain management. Inconsistent enforcement of administrative detention may lead to problems in the supply chain and an increased regulatory burden on FDA.

Respectfully Submitted,



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