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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-0179: Agency Information Collection Activities; Proposed Collection; Comment Request; Information Required in Prior Notice of Imported Food

The following comments on the U.S. Food and Drug Administration's (FDA) proposed amendment to its regulation pertaining to information required in a prior notice of imported 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 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 (FSMA) 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.

Section 304 of FSMA amends section 801 (m) of the Federal Food, Drug, and Cosmetic Act (FD & C Act) (21 U.S.C. 381 (m)) to require that additional information be provided in a prior notice of imported food. In addition to the information already required, the amendment requires a person submitting a prior notice of imported food to include any country to which the article has

been refused entry. CRN would like to seek clarity around what is meant by the term "the article" and if this phrase is specific to the food contained in the shipment or more broadly refers to food within the same batch or lot numbers (food of the same lot/batch number may be sent to multiple countries). If the article of food is more broadly defined, companies may need to track multiple shipments destined to multiple countries to ensure compliance. This in turn will increase compliance costs and create a greater burden on industry.

Along the same line, CRN also seeks clarity with regard to the treatment of a U.S. manufactured product that is denied entry into a country for a non-safety related reason and then returned to the U.S. Would the returned product be considered an imported product subject to prior notice?

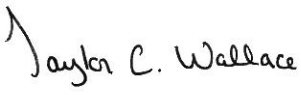
The regulation of dietary supplements varies in different regions of the world and requirements can change frequently. Dietary supplements and their components can be refused entry into a country for a variety of reasons that are not associated with a safety or security risk to consumers. The reason for refusal could be related to regulatory changes or administrative requirements that are independent of safety. For example, CRN members have reported situations where dietary supplements were refused entry into a country because they were:

- Not properly labeled due to new label requirements (not pre-announced) or inconsistent interpretations of existing label requirements.
- Not properly registered due to changes in the classification of a product without prior notice to the dietary supplement industry
- Not having the required documentation due to unannounced changes in requirements or arbitrary requests of a government.

A requirement to report all import refusals regardless of the reason for refusal will generate a significant amount of data. CRN has concerns that data not associated with a safety or security risk submitted to FDA's Prior Notice Center will create background noise that may overwhelm the Center's ability to identify imports that may pose a safety or security risk to U.S. consumers. Resources at the Prior Notice Center are best allocated to follow up on import refusals known to be related to safety or security risks to help identify the products that should be held for examination upon arrival at the port.

CRN recommends that FDA require that persons submitting a prior notice of imported food include any country to which the article has been refused entry only for reasons associated with a safety or security risk. This will reduce the amount of data submitted to the Prior Notice Center and allow personnel of the Center to focus their resources on imports with the highest potential for risk. This is consistent with the Agency's emphasis on prudent allocation of resources and use of risk-based principles to prevent hazards and ensure the safety and security of the U.S. food supply.

Respectfully Submitted,



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