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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-0238: Agency Information Collection Activities; Proposed Collection; Comment Request; Preventive Controls for Registered Human Food and Animal Food/Feed Facilities.

The following comments on the U.S. Food and Drug Administration's (FDA) docket pertaining to preventive controls for registered human food and animal food/feed facilities, published in the Federal Register on May 23, 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 FDA's efforts to develop guidance 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 in the development of this guidance on preventive controls.

Section 103 of the F SMA amends the Federal Food Drug, and Cosmetic Act (FDCA) and provides that all facilities required to be registered under section 415 take certain actions, including evaluation of the hazards that could affect food manufactured, processed, packed, or held by the facility, and to identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards (new section 418). A written Hazard Analysis and Risk-Based Preventive Controls plan must be prepared to describe the procedures used by the facility to comply.

Dietary supplement facilities that manufacture, process, pack or hold dietary supplements are subject to GMP regulations found at 21 C.F.R Part 111, and thus the requirements under Section 103 of the FSMA do not apply (Section 103(g)). Raw material manufacturers that supply dietary ingredients for use by dietary supplement manufacturers are subject to food GMP regulations found at 21 C.F.R Part 110, and therefore would be subject to the new requirements for compliance under section 418 . However, some of these raw material manufacturers have voluntarily chosen to bring their raw material facilities up to compliance with 21 C.F.R. Part 111. Raw material manufacturers that are voluntarily in compliance with 21 C.F.R. Part 111 have requested additional information from FDA on who affirms that a raw material manufacturer is indeed in compliance with 21 C.F.R. Part 111 (and, therefore, exempt from the new requirement in Section 418)? Can this be achieved through self-proclaimed compliance? Or use of third-party certification?

CRN members have additional comments about facilities solely engaged in the storage of packaged foods that are not exposed to the environment. The FSMA grants FDA the authority to issue regulation that exempts or modifies the requirements for compliance under section 418 (418 (m)) for facilities solely engaged in the storage of packaged foods that are not exposed to the environment. CRN offers the following proposals:

Proposal One:

Exemption for dual purpose facilities engaged in the storage of both foods and dietary supplements (including food and dietary ingredients) that comply with 21 C.F.R. Parts 110 and 111 .

Pursuant to the authority granted under section 418 (m), FDA should consider an exemption or modification of the requirements for compliance for any dual purpose packaged food facility compliant with 21 C.F.R. Part 111 that is engaged in the storage of both packaged foods and dietary supplements (including food and dietary ingredients) that are not exposed to the environment. An example of such facilities is a dual purpose warehouse or depot station storing both protein bars and multivitamins. The exemption for such dual facilities would be predicated on the "holder" adhering to the more stringent 21 C.F.R. Part 111 standard for both the foods and dietary supplements being held.

Proposal Two:

Exemption for facilities engaged in the sole storage of food/dietary ingredients and/or other non-refrigerated shelf stable packaged foods solely compliant with 21 C.F.R. Part 110 (facility does not contain dietary supplements).

Pursuant to the authority granted under section 418 (m), FDA should consider an exemption or modification of the requirements for compliance for any packaged food facility compliant with 21 C.F.R. Part 110 that is solely engaged in the storage of food/dietary ingredients and/or other non-refrigerated shelf stable packaged foods. The exemption is in light of the already stringent regulations surrounding good manufacturing practices. The exercise of FDA's authority under section 418 (m) is appropriate for facilities already complying with 21 C.F.R. Part 110 regulations to ensure that the storage and transportation of finished food/dietary ingredients and packaged foods shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container. For these reasons, these facilities pose an extremely low-risk for food safety concerns.

Conclusion:

CRN members request additional information on the applicability of Section 103(g) (exemption from the new requirement in Section 418 for facilities in compliance with 21 C.F.R. Part 111) for dietary supplement raw material suppliers that have voluntarily chosen to bring their raw material facilities up to compliance with 21 C.F.R. Part 111. In addition, CRN recommends that FDA grant exemption or modify the requirements for compliance under section 418 (m) for: 1) any dual purpose facility engaged in the storage of both packaged foods and dietary supplements that is in compliance with 21 C.F.R. Parts 110 and 111; and 2) any facility engaged in the storage of food/dietary ingredients and/or other non-refrigerated shelf stable packaged foods solely compliant with 21 C.F.R. Part 110 (facility does not contain dietary supplements). This is consistent with the Agency's emphasis to carefully allocate its resources and use risk-based principles to prevent hazards and ensure the safety and security of the U.S. food supply.

Respectfully Submitted,

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