CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
founded 1881

August 23, 2017

Dear Members of the Global Retailer Manufacturers Alliance Joint Committee on Dietary Supplements:

The Consumer Healthcare Association ("CHPA") is the leading national trade association representing manufacturers and distributors of over-the-counter drugs and dietary supplements. Our association is committed to maintaining the highest standards in the manufacture and regulation of dietary supplements.

On behalf of the CHPA Dietary Supplements Committee, we are writing to express our concern with the recent decision by the Joint Committee to include certain elements of 21 CFR 117 within the consensus based standard for dietary supplements. Specifically, the Joint Committee recently voted to include a requirement for manufacturers to comply with 21 CFR 117 Subparts C (Hazard Analysis and Risk-Based Preventive Controls) and G (Supply Chain Programs).

As you know, dietary supplement manufacturers are exempt from these requirements if they comply with 21 CFR Part 111. This was considered by the Food and Drug Administration in the preamble to the proposed rule on Hazard Analysis and Risk-Based Preventive Controls[1] and ultimately contained in the final version of the Food Safety Modernization Act[2]

Adding these requirements would not enhance the safety of dietary supplements. Indeed, supplier qualification requirements codified in 21 CFR 111 already exceed those contained in 21 CFR 117 Subpart G. As such, including a requirement to meet Subpart G would be redundant. As for Subpart C, most dietary supplement products are shelf-stable and thus represent a low risk.

One of the stated goals of the GRMA was to develop a consensus-based auditing standard that closely aligned with federal requirements in order to avoid unnecessary duplicative audits. Placing unnecessary burdens on manufacturers which will not enhance the safety of marketed dietary supplements will only serve to dilute the effectiveness of the GRMA Standard for dietary supplements.

[1] Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 (11) Fed Reg 3646-3824; January 16, 2013.
[2] 21 U.S.C. 342(g)(2), 379aa–1).

We therefore request that the Joint Committee reconsider their decision to include 21 CFR Subparts C and G in the Dietary Supplement Standard and remove these elements.

Thank you for considering our request. Please feel free to contact me should you have any questions.

Regards,

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