

November 6, 2018

VIA ELECTRONIC SUBMISSION

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Policy Regarding Quantitative Labeling of Dietary Supplements Containing Live Microbials: Draft Guidance for Industry, 83 Fed. Reg. 45454-5 (September 7, 2018), Docket No. FDA-2011-D-0376

Herein, the Consumer Healthcare Products Association (CHPA), the 137-year-old trade association representing U.S. manufacturers and distributors of over-the-counter (OTC) medicines and dietary supplements (chpa.org), provides feedback on the Food and Drug Administration's (FDA's) recent draft guidance document addressing the labeling of dietary supplements containing live microbials (also referred to as probiotics).

In the Guidance document, FDA states that they intend to exercise enforcement discretion with respect to the declaration of live microbial quantity in colony forming units (CFUs) provided that companies meet a series of conditions, including that the quantitative amount of the various microorganisms is first listed by weight.

FDA correctly identifies that statement of quantity in CFUs "*is currently the most widely recognized measure of live microbials*" and provides several examples of situations where this term is used to quantify the amount of viable microbial cells. CHPA members are supportive of FDA allowing companies who market probiotic products to provide information concerning the amount of viable microbial cells in CFUs. Unfortunately, requiring companies to list both the quantitative amount as weight (in mg) and as CFUs will present information on product labels in a way that will likely result in consumer confusion.

Currently, a number of dietary supplement trade associations have established voluntary practices regarding the labeling of probiotic products. These guidelines, which provide for the labeling of probiotic products in CFUs, are not intended to replace currently applicable regulations, statutes or guidance. CHPA members support the labeling of probiotic products using CFUs expressed as the number of viable microorganisms at the end of the shelf life of the product. For products containing

multiple strains of bacteria, we support the listing of total CFUs present at the end of shelf life based upon procedures established by the manufacturer.

As an example, the Draft Guidance specifies that “[l]ive microbial dietary ingredients in a proprietary blend are listed in descending order of predominance by weight” (as specified in 101.36(c)(2)). However, order of predominance of individual probiotic strains within a proprietary blend may be different based on CFUs and weight. In addition, stability profiles for various strains differ, such that the order of predominance may change from the time of manufacture compared to the end of shelf life. By adopting a regulation stipulating that the order of predominance for microbial ingredients within a blend be based upon CFUs at the time of shelf life expiry, FDA would ensure a more consistent representation of the active microbial ingredients with a blend and provide more useful information to consumers.

CHPA members encourage the agency to engage in rulemaking to amend 21 CFR 101.36 to allow declaration of the quantitative amount of probiotic ingredients in a dietary supplement to be expressed as CFUs instead of by weight¹ and to stipulate that the order of predominance for microbial ingredients within a blend be based upon CFUs at the time of shelf life expiry. This enhances consumer confidence in the potency of a particular product. We also encourage the agency to propose a pathway for the inclusion of alternative standards for measurement of viable microorganisms, as the field of probiotics science is rapidly advancing.

CHPA and our member companies marketing dietary supplement products appreciate the opportunity to comment on this process. Should you have any questions, please do not hesitate to contact me.

Regards,

A handwritten signature in blue ink that reads "Jay Sirois". The signature is written in a cursive, flowing style.

Jay Sirois, Ph.D.
Senior Director, Regulatory & Scientific Affairs
Consumer Healthcare Products Association

¹ See the November 18, 2016 Citizen Petition from the International Probiotics Association requesting this change