Council for Responsible Nutrition
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VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Policy Regarding Quantitative Labeling of Dietary Supplements Containing Live Microbials: Draft Guidance for Industry. 83 Fed. Reg. 45454-45455 (September 7, 2018). Docket No. FDA-2018-D-3464 .

The Council for Responsible Nutrition (CRN)[1], the leading trade association that represents dietary supplement and functional food manufacturers and ingredient suppliers, appreciates the opportunity to provide input on FDA's draft guidance, "Policy Regarding Quantitative Labeling of Dietary Supplements Containing Live Microbials: Guidance for Industry" (Draft Guidance).

CRN commends FDA's announcement of its intent to exercise enforcement discretion when supplement marketers use colony forming units (CFUs) when declaring the quantity of live microbials on a Supplement Facts label. CFU is currently the scientifically accepted unit of measure for live microbials, used by scientific researchers, FDA, and other governmental

[1] The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers, marketers, and ingredient suppliers. CRN companies produce a large portion of the functional food ingredients and dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores, and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 150 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control, and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

organizations, according to the Draft Guidance. Weight is not an appropriate unit of measure for live microbial ingredients because it represents the total cellular mass of an ingredient, including live and dead microorganisms. Within a microbial dietary ingredient, it is not possible to distinguish the weight of live microorganisms from that of dead microorganisms. Consequently, dietary supplement manufacturers cannot measure and label the weight of the live microorganism component of a microbial dietary ingredient. If quantity were to be labeled in weight, both live and dead microorganisms would be included and would not provide consumers with information about the amount of the relevant, beneficial ingredient (i.e., live microorganisms). CRN has advocated for the acceptance of CFUs as the unit of measure for live microbials for labeling purposes for several years. We are encouraged by FDA's willingness to recognize that declaration of live microbial dietary ingredient quantity in CFUs would give consumers the most accurate information about the amount of viable microorganisms present in a product throughout shelf life.

However, the Draft Guidance states that supplements must also list the quantitative amount of live microbial dietary ingredients by metric weight, as is required by current regulation applicable generally to other dietary supplements, in addition to an expression of CFUs; supplements must also list live microbial dietary ingredients in a proprietary blend in descending order of predominance by weight. CRN is concerned that the listing of the quantitative amount in CFUs and by metric weight is not feasible because CFUs are not correlated directly to weight. In fact, FDA states in the Draft Guidance that "(t)he weight of microbial dietary ingredient in a product represents the product's total cellular mass, consisting of both live and dead microorganisms, and therefore does not necessarily correlate with the number of viable microorganisms in that product." To achieve a consistent live microbial quantity in CFUs, the weight of a particular CFU count may vary from batch to batch. As such, it is not practical to label the weight of each batch individually or to list individual live microbial ingredients within a blend in descending order by weight for each batch. Further, listing different weights on product labels that contain the same CFU counts would confuse consumers. Therefore, it is practical to declare live microbial ingredient quantities in either CFU or total cellular mass as weight, but not both. However, it is the CFU, and not weight, that is the scientifically accepted unit of measure for declaring quantitative amounts of live microbial ingredients.

Declaration of dietary ingredients in a Supplement Facts label should provide the most meaningful information to consumers and, to that end, FDA has previously ruled that the claimed amount of certain nutrients should be expressed in units that are most helpful to consumers and that do not necessarily match the weight of the source ingredient. For example, vitamin E claims are based on the equivalent amount of alpha tocopherol and different conversion factors are used to determine the vitamin E weight claim that corresponds to the type of vitamin E used in the product. Similarly, vitamin A claims are based on retinol activity equivalents and therefore the amount of vitamin A claimed from non-retinol ingredients such as beta-carotene is different from the weight of the source ingredient. Likewise, a mineral claim does not reflect the total weight of the mineral salt, but only the active elemental mineral component. In the case of probiotics, live microorganisms are the beneficial and relevant portion of the ingredient. As such, only live microorganism quantity should be declared on a Supplement Facts label.

FDA recognizes in the Draft Guidance that "the labeled weight of the microbial ingredient may not accurately reflect the number of live microorganisms throughout the range of times a product is expected to be consumed because live microorganisms are susceptible to cell death throughout the shelf life of a product." Similarly, vitamins and other dietary ingredients are subject to degradation throughout the product lifecycle (e.g., warehouse, shipping, retail, and consumer shelves). To meet the claimed amount at end of shelf life, the addition of an overage at time of manufacture may be required. Just as the amount of a vitamin declared on a Supplement Facts label does not include an intentional overage, the claimed amount of a live microbial ingredient should not include an overage that is included to compensate for cells that die during the product's shelf life. The labeled quantity should reflect only the amount of live, viable cells at the end of shelf life. This is not possible if quantity is declared by weight.

CRN recommends that FDA revise the Draft Guidance to exercise enforcement discretion when marketers declare quantitative amounts of live microbial ingredients in CFUs in the Supplement Facts label only, without any declaration of the quantitative amount by metric weight.

Thank you for considering our comments.

Sincerely,

Andrea W. Wong, Ph.D.
Vice President, Scientific & Regulatory Affairs