Council for Responsible Nutrition
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VIA ELECTRONIC SUBMISSION

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2016-P-3968; Citizen Petition from International Probiotics Association

The Council for Responsible Nutrition (CRN) respectfully submits these comments to the Food and Drug Administration (FDA) in support of the petition submitted by the International Probiotics Association (IPA) requesting that FDA amend 21 CFR §101.36 to require the quantitative amount of probiotic ingredients in a dietary supplement to be declared in Colony Forming Units (CFUs) instead of by weight on product labels. CRN is the leading trade association for the dietary supplement and functional food industry, representing manufacturers of dietary ingredients and of national brand name and private label dietary supplements[1].

Currently, 21 CFR § 101.36(b)(3)(ii) requires that the quantitative amount of "other dietary ingredients," which include probiotics, be declared by weight per serving. However, probiotics are live microorganisms and declaration of weight does not indicate the viability of the probiotics in the product throughout shelf life. The quantity in CFUs represents the amount of viable microorganisms in the product and is the scientifically accepted unit of measure for probiotics. Providing science-based, accurate labeling information will help consumers and healthcare professionals to make informed choices. Therefore, 21 CFR § 101.36(b)(3)(ii) should be

[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.

amended to require the quantitative amount of probiotic dietary ingredients to be declared in CFUs.

For proprietary blends, 21 CFR § 101.36(c)(2) indicates that "other dietary ingredients" contained in the proprietary blend shall be declared in descending order of predominance by weight. Further, 21 CFR § 101.36(c)(3) requires that the quantitative amount by weight specified for the proprietary blend shall be the total weight of all other dietary ingredients contained in the proprietary blend. FDA should similarly amend these regulations to require the quantity of a probiotic blend of probiotics to be declared in CFUs, and to require the probiotic dietary ingredients in the proprietary blend to be declared in descending order of predominance by CFUs.

Responsible dietary supplement manufacturers and marketers want to provide scientifically accurate and meaningful information on product labels. CRN and IPA, in collaboration with nearly 40 companies, developed science-based, voluntary probiotic guidelines that reflect industry best practices for probiotics. The guidelines include a recommendation that the quantitative amount of probiotic ingredients in a dietary supplement to be declared in CFUs. CRN seeks assurance that FDA recognizes the rationale for declaring quantity of probiotics in dietary supplements in CFUs and that the agency will refrain from taking regulatory or compliance actions against products that declare probiotic quantity in CFUs instead of by weight. Therefore, CRN requests that FDA exercise immediate enforcement discretion on dietary supplements containing probiotics that declare probiotic quantity in CFUs on the product label.

Respectfully submitted,

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