FDA New Draft Guidance: CFUs May Be Disclosed on the Supplement Facts Label for Probiotics

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For the last few years, the dietary supplement industry has advocated for the Food and Drug Administration (FDA or Agency) to amend its labeling regulations (21 C.F.R. § 101.36) to allow probiotic ingredients to be labeled by colony forming units (CFUs) rather than by weight. In 2016, the International Probiotics Association (IPA) submitted a Citizen Petition arguing that allowing dietary supplements labels to be labeled by CFUs "would help ensure that consumers have the most useful, relevant information with respect to the amount of probiotic ingredients in dietary supplements." Last week the FDA not only denied IPA's Citizen Petition seeking to amend its labeling regulations, but also announced the issuance of a Draft Guidance advising supplement companies that it intends to exercise enforcement discretion to "allow firms to declare, in the Supplement Facts label, the quantity of live microbials in [CFUs], in addition to the quantitative amount by weight required by regulation."

In denying the Petition and issuing the Draft Guidance, FDA acknowledges that CFU is currently the most widely recognized measure of live microbials; however, the Agency is aware that researches are evaluating other methods and units of measure that have the potential to "more accurately and more efficiently quantify the number of viable cells at a future time." Therefore, FDA has decided to continue to monitor the development of new technologies before deciding whether to engage in a rulemaking to revise the new Supplement Facts Label Final Rule (the compliance date for that rule is January 1, 2020 for manufacturers with $10 million or more in annual food sales (including dietary supplements) and January 1, 2021 for manufacturers with less than $10 million dollars in annual food sales). In the meantime, the agency will exercise enforcement discretion for those firms that choose to declare the quantitative amount of live microbial ingredients in the Supplement Facts label by CFUs in addition to weight, provided the following conditions are met:

- The quantity is first listed in terms of weight;
- The declaration of quantity in CFUs is expressed in a manner that is clearly separate and readily distinguishable from the weight, e.g., as a parenthetical or in a subset line;
- The declaration of quantity in CFUs is formatted in clear terms that can easily be understood by a common reader, e.g., 10 billion or 300* (where the unit that * is intended to represent, such as million or billion, is a typical measure of CFUs and is clearly indicated elsewhere in the Supplement Facts Label);

- The declaration of quantity in CFUs is accurate and not misleading, and does not render misleading other aspects of the Supplement Facts label, or other aspects of the product label;
- The declaration of quantity in CFUs measures only live microbial ingredients and does not include inactive, dead, or nonviable organisms;
- Live microbial dietary ingredients in a proprietary blend are listed in descending order of predominance by weight; and
- The product label otherwise complies with all applicable laws and regulations.

FDA also makes clear that the enforcement discretion policy is limited to dietary supplements containing live microbial ingredients and to the declaration of quantity of these ingredients on the Supplement Facts label in terms of CFUs. The Draft Guidance does not "apply to other foods that contain live or viable microbial ingredients, to dietary supplements that do not contain live microbial ingredient, or to any other FDA-regulated commodities."

Comments to the Draft Guidance should be submitted at www.regulations.gov by November 6, 2018 so that they are considered before FDA issues a final version of the guidance.

Please contact Porzio if you have any questions.