November 5, 2018

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


Dear Dockets Management Staff:

On behalf of the American Gastroenterological Association (AGA), which represents more than 16,000 members from around the globe who are involved in all aspects of the science, practice and advancement of gastroenterology, I am pleased to provide comments on the draft guidance “Policy Regarding Quantitative Labeling of Dietary Supplements Containing Live Microbials.” AGA’s Center for Gut Microbiome Research and Education, whose mission is to advance research and education on the gut microbiome with the goal of improving human health, has prioritized probiotics as a focus area due to the need for evidence-based guidance for health care providers and their patients.

AGA commends the FDA’s effort to clarify the expectations of manufacturers who choose to specify the amount of a live microbial component in their product in colony forming units (CFUs) in addition to weight. Further, we support the FDA’s efforts to standardize how CFUs are reported on the Supplement Facts label, when a manufacturer chooses to do so.

Though manufacturers are not currently required to report CFUs, AGA feels strongly that all manufacturers of probiotic supplements should voluntarily report the composition of live microbials in their products as CFUs. However, reporting CFUs alone provides insufficient information to consumers and health care professionals who may recommend probiotic supplements to their patients. Though the draft guidance already specifies a set of conditions that a manufacturer
must meet if reporting CFUs, we recommend that FDA consider additional conditions:

1. The manufacturer should specify the conditions of storage, including storage temperature.
2. The manufacturer should specify an expiration or “use by” date which indicates how long the product will continue to meet the attributes of identity, strength and purity stated on the Supplement Facts label.

We acknowledge that researchers are evaluating other methods and units of measure for not only live microbials but also microbial bioactivity. For example, dead bacteria can still have bioactivity through metabolites or other components that may influence human physiology. However, in the absence of a widely-accepted alternative, which may take several years to develop and adopt, we strongly encourage FDA and manufacturers to take the small step forward of using CFUs now rather than waiting for another solution to emerge.

AGA appreciates the opportunity to comment on the draft guidance “Policy Regarding Quantitative Labeling of Dietary Supplements Containing Live Microbials” [Docket No. FDA-2011-D-0376]. If you have questions or require additional information, please contact Jessica Roth, Director, Regulatory Affairs via electronic mail to jroth@gastro.org or via phone at 240.482.3230.

Sincerely,

Sheila E. Crowe, MD, AGAF
Chair, AGA