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NEWS RELEASE

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Innovation Outpaces Regulation in FDA Probiotics Labeling Guidance

Current Probiotic Supplement Labeling Regulations for Declaring Quantity Per Serving are “obsolete,” Says NPA

WASHINGTON, D.C. – The Natural Products Association (NPA) today in formal comments to the Food and Drug Administration (FDA) said that supplement labeling regulations regarding probiotics, are “obsolete and ineffective” and that the government’s recent guidance “falls short as a remedy to the problem.” NPA’s comments are in response to the FDA’s new draft guidance titled “Policy Regarding Quantitative Labeling of Dietary Supplements Containing Live Microbials; Draft Guidance for Industry.”

“This is an example of innovation outpacing regulation. The current labeling regulations for probiotics need to be updated to reflect the new innovative products consumers are demanding,” said Daniel Fabricant, Ph.D., president and CEO of NPA. “Consumers should have access to products with clear labels that convey useful information about the product to guide their decision making. FDA’s current labeling laws allow for unscrupulous companies to fly under the radar and sell probiotics with no viable microbial ingredients in the product. We look forward to working directly with the FDA towards a solution that communicates meaningful information to consumers.”

NPA specifically took issue with the way the FDA requires live probiotic supplements to be measured in metric units instead of colony formation units, or CFUs. CFUs provide a more accurate serving level for consumers because live activity is taken into account. Using metric units on probiotic supplement labels “does not make regulatory sense for dietary ingredients in which activity is an essential parameter to convey to consumers” said NPA.

NPA noted that the “reasonable consumer” has an expectation that microbial ingredients in probiotics are alive and that CFUs are widely accepted in the scientific community and are consistent with international accepted definitions of probiotics as live microorganisms.

NPA’s full comments can be viewed [here](#).

Natural Products Association

The **Natural Products Association (NPA)** is *the* trade association representing the entire natural products industry. We advocate for our members who supply, manufacture and sell natural ingredients or products for consumers. The Natural Products Association promotes good manufacturing practices as part of the growth and success of the industry. Founded in 1936, NPA



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represents approximately 1,100 members accounting for more than 10,000 locations of retailers, manufacturers, wholesalers and distributors of natural products, including foods, dietary supplements and health/beauty aids.

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