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

Via Email: oira_submission@omb.eop.gov

RE: Docket No. FDA-2018-N-2381: The Food and Drug Administration's Comprehensive, Multi-Year Nutrition Innovation Strategy; Extension of the Comment Period

Dear Food and Drug Administration (FDA) Desk Officer,

The Natural Products Association (NPA) is submitting this letter as general comments to docket FDA-2018-N-2381, regarding FDA's notice titled, "The Food and Drug Administration's Comprehensive, Multi-Year Nutrition Innovation Strategy," for public comment. NPA was founded in 1936 to promote and protect the unique values and shared interests of retailers and suppliers of natural nutritional foods and natural products. NPA is a non-profit 501(c)(6) association whose mission is to advocate for the rights of consumers to have access to products that will maintain and improve their health, the rights of retailers and suppliers to sell these products, and to promote natural products for healthy lifestyles. NPA unites a diverse membership from the smallest health food store to the largest natural products supplier. We are the oldest and largest trade association in the natural products industry, representing over 1,100 members accounting for almost 10,000 retail, manufacturing, wholesale, and distribution locations of natural products, including foods, dietary supplements, and health/beauty aids. We champion consumers' freedom of choice in our marketplace, strengthen and safeguard retailers

and suppliers, and build strong markets to fuel industry growth. We act together with uncompromising integrity, and we encourage all to reach ever higher standards of quality. In short, we are *the* trade association advocating for the dietary supplement industry. NPA appreciates the opportunity to comment, and we are submitting this letter as a formal comment concerning the FDA's comprehensive, multi-year nutrition innovation strategy, originally published in the Federal Register on June 27, 2018 (83 FR 30180). NPA supports the actions of FDA in its plans for the Multi-Year Nutrition Innovation Strategy and its efforts to promote public health and foster the development of healthier food options. NPA also applauds FDA for holding their July 26, 2018 public meeting on the topic.

Background

On March 29, 2018, FDA Commissioner Scott Gottlieb announced FDA's Nutrition Innovation Strategy (NIS) in a speech to the National Food Policy Conference. The strategy promotes public health through efforts to empower consumers to make better and more informed decisions about their diets and health, thereby fostering healthier food options, and expanding the opportunities to use nutrition to reduce morbidity and mortality due to chronic disease. The FDA townhall, held on July 26, 2018, discussed the following topics:

- Considerations for using a standard icon to denote the claim "healthy" on food labels
- Creating a more efficient review strategy for evaluating qualified health claims on food labels
- Discussing new or enhanced labeling statements or claims that could facilitate innovation to produce more healthful foods and more healthful consumer food choices
- Modernizing the standards of identity to provide more flexibility for the development of healthier products, while making sure consumers have accurate information about these food products
- Providing opportunities to make ingredient information more helpful to consumers
- FDA's educational campaign for consumers about the updated Nutrition Facts Label

Creating a more efficient review strategy for evaluating qualified health claims on food labels

In 1990, Congress carved out an exception to the prohibition against foods making a claim to treat or prevent disease by permitting health claims, statements that a product will reduce the risk of acquiring a disease. A health claim usually refers to a long-term, chronic risk reduction. For example, health claims may refer to connections between fiber and the prevention of colon cancer. Qualified health claims are supported by scientific evidence, but do not meet the more rigorous "significant scientific agreement" standard required for an authorized health claim. FDA does not currently "approve" qualified health claim petitions. Petitions with credible scientific evidence, FDA issues a letter of enforcement discretion including specific claim language that reflects the level of supporting scientific evidence; however, the process does not involve rulemaking. As long as any proposed strategy for evaluating qualified health claims involves making it more efficient and simpler for industry, NPA would applaud such changes. The increased demand for natural products means that a streamlined and efficient regulatory structure is critical in order to protect consumers and public health. We are pleased to work with FDA and the Trump Administration to ensure that health conscious American consumers have access to the products they use every day. What NPA does not advocate for is new regulations. NPA urges FDA to enforce and uphold the current laws already on the books and codified in the federal regulations. NPA also urges FDA to consider our list of regulations and issues we have targeted for regulatory reform, as part of President Trump's regulatory reform agenda.

Discussing new or enhanced labeling statements or claims that could facilitate innovation to produce more healthful foods and more healthful consumer food choices

NPA was disappointed that the standards of identity for medical foods, dietary supplements and foods for special dietary use were omitted in their nutrition innovation strategy, especially given the Agency's objected to reduce the burden of chronic disease. Regarding medical foods, the Food and Drug Administration's (FDA) Center for Food Science and Applied

Nutrition regulates medical foods as a distinct category of food under the Orphan Drug Act. Medical foods contain highly purified, food-based therapeutic ingredients specially formulated for dietary management of specific diseases and/or conditions. A "medical food" is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." FDA states that the distinguishing aspect of a medical food from foods for special dietary use is the requirement that a medical food be intended to meet the distinctive nutritional requirements of a disease or condition. FDA explains that "medical foods are not those simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition," but, instead, are a specially formulated food product for patients who require that product as part of a disease or condition's dietary management. Finally, the claims on medical foods must be supported by competent and reliable scientific evidence.

In its finalized guidance on medical foods in May 2016, FDA stated that it "narrowly constrain(s)" this category of products. FDA's medical food definition is so narrow that it only considers the following products as medical foods:

- Nutritionally complete or incomplete formulas
- Formulas for metabolic (genetic) disorders in patients over 12 months of age (ie. Phenylalanine-free formulations for phenylketonuria patients); or
- Oral rehydration products

FDA's guidance also eliminates the potential use of medical foods for the dietary management of conditions like pregnancy and diabetes. FDA believes that while there are nutrient requirements associated with these 2 states, they do not impose distinctive nutritional requirements.

Physicians use probiotics off-label at CFU quantities in the trillions for antibiotic associated diarrhea to prevent *Clostridium difficile* colitis. These are not considered medical

foods, but they are probiotic live microbial ingredients ingested as part of dietary supplements and other foods. Furthermore, these probiotics can't be obtained and ingested by modification of the normal diet because one needs high quantities of a single or combination of probiotics. These probiotics can only be ingested when manufactured and specially formulated to maintain their long-term viability.

NPA is committed to working with FDA, Congress, and the Trump Administration in developing a broader and more transparent definition for medical foods and foods for special dietary use with more examples. NPA believes the main goal should be for FDA to establish a clear path to market for this food commodity while utilizing the current state of nutritional science to benefit the health of all Americans. NPA believes there is considerable science to substantiate the use of many dietary ingredients for disease conditions, and the population would benefit greatly. Claims to reduce disease risk can be made on dietary supplements, foods for special dietary use, or conventional foods, as long as the evidence meets the significant scientific agreement (SSA) through gold standard randomized clinical intervention trials. Probiotics for antibiotic associated diarrhea is just one example where dietary ingredients can be used in a medical food to benefit patients, (or in a dietary supplement with a health claim) as long as the medical food claims or health claim can be substantiated in clinical trials through competent and reliable scientific evidence. This last part necessitates the spending of resources on scientific and clinical research on the part of companies.

Medical Foods

This category was unofficially recognized almost 50 years ago when FDA determined Lofenalac, a powdered formula for infants with phenylketonuria, should be classified as a food for special dietary use rather than as a drug. However, it has never received official FDA sanction or attention. It was not until 1988 that an official definition for 'medical foods' was established, and Congress acknowledged the benefits of medical foods again in 1990 with the passage of the Nutrition Labeling and Education Act (NLEA). Medical foods can be characterized as foods permitted to make a claim for the maintenance of a patient with a specific disease, or, as

Congress put it, a product intended for the "specific dietary management of a disease or a condition for which distinctive nutritional requirements" exist. FDA published an advance notice of proposed rulemaking setting forth many proposed testing and labeling requirements. Unfortunately, the medical foods category has never been treated seriously, especially for products that have been clinically tested for proven safety and efficacy. NPA would like to see the medical foods category revisited as it is a major avenue for reducing morbidity and mortality due to chronic disease. The failure on the part of FDA to broaden medical foods with many more examples outside of oral rehydration and metabolic disorders in children is only a detriment to the consumer. In cases where claims like inflammation are unable to be used on conventional foods or dietary supplement products, it would be beneficial for FDA to acknowledge the instances where these claims can be used on medical foods when the company has invested in the clinical and scientific research to substantiate the claim.

Foods for Special Dietary Use

The full meaning of this category is not clear either for FDA or for industry. Part of the first vitamin and mineral amendment to the Food Drug and Cosmetic Act in 1976, the "foods for special dietary use category has not received any significant regulatory attention by FDA. Such a product is best defined as a conventional food product that makes the claim that it can be consumed by people with certain diseases. For example, frozen food entrees, appetizers, and desserts that are specially formulated without ingredients that aggravate certain conditions can be sold as foods for special dietary use. Diabetes patients may order foods with sugar substitutes that avoid insulin reactions; dysphasia patients may purchase finely processed foods; and phenylketonuria patients may purchase foods for special dietary use with low phenylalanine content. While no disease treatment claims are permitted for these products, the intended uses for this category has not been clearly defined. As a result, many companies with novel approaches to food science are discouraged based upon the lack of clarity in the regulations. This stymies innovation in the industry. NPA believes this category should be clarified and expanded from its present form in the codified federal regulations.

Modernizing the standards of identity to provide more flexibility for the development of healthier products, while making sure consumers have accurate information about these food products

The FDA has issued a request for public comment while it examines its approach to the use of dairy food names like "milk," "cheese," or "yogurt" in the labeling of plant-based foods and beverages. In his statement, FDA Commissioner Dr. Scott Gottlieb said the agency recognized that "some consumers may prefer to use plant-based products instead of dairy products for a variety of reasons, including an allergy or lifestyle choice." Regarding the nutritional equivalency of plant-based milks to cow's milk, Dr. Gottlieb insisted "We must also ensure that the labeling of such products does not mislead consumers, especially if this could compromise their health and well-being." FDA even issued a Request for Information in the Federal Register regarding this very issue of standards of identity and how consumers use plant-based alternatives and how they understand terms like "milk" or "cheese" when used to label products made from soy, peas, or nuts.

Consumers deserve access to accurate and meaningful information about the products they use each and every day. As the FDA considers making changes to the ways many popular products are labeled and branded, we urge FDA to also consider the impact this can have on commercial free speech. Courts handling false advertising cases of plant milks have argued that the federal standard of identity for "milk" limits it to the lacteal secretions from cows. In a December 1, 2015 order, US district judge Vince Chhabria dismissed a class action claim that Trader Joe's misled consumers misbranding products without cow's milk as 'soymilk'.¹ He said no 'reasonable consumer' would confuse soy with dairy milk. He wrote that the fact there is a federal standard of identity for 'milk' [which limits it to lacteal secretions from cows] "does not categorically preclude a company from giving any food product a name that includes the word 'milk'. The standardization of milk simply means that a company cannot pass off a product as 'milk' if it does not meet the regulatory definition of milk. Regarding whether the use of the word

¹ Case number 3:13-cv-01333 (Gitson *et al.* v. Trader Joe's Company).

"soymilk" in Trader Joe's products could violate the federal Food, Drug, and Cosmetic Act, the judge responded with an emphatic "no." NPA supports FDA's enforcement against companies misusing standards of identity, but there is a slippery slope when companies are now prevented from using commercial free speech for soymilk in the name of their products. These comments were echoed by fellow US district judge Samuel Conti, who threw out a similar case (3:13-cv-01953) vs WhiteWave Foods. Similarly, district judge Stephen Wilson of the central district of California argued in the case against Blue Diamond Growers (Almond Breeze) about the nutrition equivalency argument between plant-based and cow's milk. He stated that the word 'milk' did not come with a certain set of nutritional expectations or understanding. He stated "[i]f the consumer is concerned about the nutritious qualities of the product, they can read the nutrition label". However, the reason we are now seeing FDA opine again on the issue of whether plant-based milks must be labeled as 'imitation' comes from the Whitewave ruling. Lawrence O'Neill, the chief district judge in the eastern district of California stated "[t]hough neither party acknowledges it, plaintiff's position—that defendant's [Silk] almondmilk is mislabeled in that it should be labeled as an 'imitation'—is an issue of first impression. The court has conducted extensive research and is unable to locate any authority that suggests the issue has been considered officially by the FDA or the courts." So it appears FDA is going to try to consider the issue officially. He writes "[t]issue of whether defendant's products (or any other plant-based 'milk') should be deemed an 'imitation' under §101.3(e) fits squarely within the FDA's authority, and will require the agency's expertise in determining how to fashion labels so they adequately inform consumer". Now the ball is in FDA's "court" to fully consider the issue in an official capacity through notice and stakeholder comment.

Before any such restrictions are placed on commercial free speech, the government must prove there is a substantial risk to consumers. NPA does not see how labeling plant-based foods as 'milk' in their name will cause substantial risk to consumers. NPA believes this issue regarding standards of identity for plant-based foods to use terms with known standards of identity in their names amounts to a first amendment issue. We are optimistic that FDA's process will lead to an

outcome that both protects consumers and ensures the producers of natural products and plant-based foods are not burdened with unnecessary regulations.

There are also other products on the market which allude to a specific component found in cow's milk or human milk. These could be isolated milk protein or oligosaccharide components that came from milk. Milk component products do, in fact, come from lacteal secretions of cows and humans as they are components found in milk. NPA believes these types of food ingredients and finished products should have the right to call themselves 'milk'. NPA would like to see federal pre-emption of class action lawsuits brought in the states over statement of identity on products. NPA would like to see federal pre-emption of state class action lawsuits involving milk component products. NPA does not want to see a patchwork of 50 different state laws over statement of identity or other issues of product labeling or claims defined federally in the codified federal regulations. Federal pre-emption over the states regarding all aspects of food and supplement labeling is paramount to the industry. NPA hopes FDA will provide clarification on these products in the future and allow them to use terms like 'milk' or other standard of food identity.

Providing Opportunities to Make Ingredient Information More Helpful to Consumers

Regulatory Reform: Revise the Current Labeling of Probiotics with Total Quantitative Amount by Weight (metric units) per Serving with Activity

FDA can make probiotic ingredient information more helpful to consumers on labels where probiotic ingredients are declared in the supplement facts. FDA can revise the way probiotics must be listed for consumers. CFSAN should require probiotics and other dietary ingredients, where conveying 'activity' to consumers is important, to be listed with units of activity in colony forming units or "CFUs" per serving rather than as metric units per serving. The current labeling regulations in 21 CFR 101.36(b)(3)(ii) requires the total quantity by weight per serving for '(b)(3)' dietary ingredients to be listed in metric units, which includes a 'gram' designation. Probiotics should be listed in a way so as to convey their activity to consumers. FDA

should change the listing of serving level quantity from metric units to activity for these types of dietary ingredients. The reasonable consumer has an expectation that when they are purchasing probiotics, these are live microbial ingredients. This would differentiate those companies selling dead microbials from those actually selling live microbial ingredients benefiting the health of the consumer.

While FDA recently released a guidance to address this issue, the Agency's solution does not go far enough. Allowing probiotics to declare metric units rather than forcing them to declare CFUs is an issue over the truthful and not misleading standard for labels and labeling. The new proposed guidance continues to allow any unscrupulous companies to sell dead microbials. FDA instead provides additional hurdles for companies which opt to list CFUs to inform consumers about the living and therefore effective status of their probiotic products. If FDA investigated probiotic products as to whether they met label claim or not, how could they tell the difference in weight between one probiotic strain versus another. CFUs are the only way to convey that information to consumers.

Calculating Protein Content in Dietary Supplements

In accordance with the codified regulations,² protein content is typically calculated on by using the nitrogen content of a food, multiplied by the 'fudge' factor of 6.25. There are many substances with nitrogen-containing amino groups that are not used by the body to create protein and therefore should probably not be counted as protein. Some of these substances are clearly not amino acids, but some are recognized by FDA as amino acids, including ornithine and citrulline.³ According to FDA, "L-[o]rnithine and L-[c]itrulline are amino acids that are not incorporated into protein and that are intermediates in the mammalian metabolism of urea, creatine, and polyamines." While these two 'amino acids' are members of critical components of the urea cycle of the human body, they are not reconstituted into protein as FDA has pointed

² 21 C.F.R. § 101.9(c)(7). Protein content may be calculated on the basis of the factor 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis as given in the 'Official Methods of Analysis of the AOAC International.

³ FDA. (1992). Safety of Amino Acids Used as Dietary Supplements. Life Sciences Research Office Federation of American Societies for Experimental Biology. Bethesda, Maryland. July 1992.

out. However, under the current regulations for counting protein, they could be counted as a nitrogen source for the final protein determination. The current protein calculation should have stricter parameters and guidance on how to calculate protein content. The nitrogen content of any non-amino acids or amino acids not incorporated into protein should not be used in the final calculation of total protein content. FDA should eliminate this practice prescribed in the codified federal regulations by requiring protein to be calculated based upon the linkage of several amino acids linearly to form a peptide. Without labeling reforms on the way protein is currently calculated, the issue of amino acid spiking will always be a concern to consumers.

Conclusion

NPA hopes that the Agency will consider these comments in their roll-out of the Nutrition Innovation Strategy. NPA believes the categories of medical foods and foods for special dietary use are key components toward the use of nutrition to reduce morbidity and mortality due to chronic disease. NPA would also like to continue to see plant-based products be able to use milk or other terms with standards of identity in their name, as long as there is no risk to consumers. Finally, NPA urges FDA to address two regulations that should be modified for the benefit of consumers. Requiring CFUs to be listed on all probiotic supplements and clarification on the calculation of protein are quick fixes and wins for the Agency. NPA appreciates the opportunity to comment on the "Comprehensive, Multi-Year Nutrition Innovation Strategy." We welcome the opportunity to participate in any forum where these issues maybe further discussed in greater detail than what was covered in the FDA townhall.

Sincerely,

A handwritten signature in black ink, appearing to read "Dan Fabricant". The signature is written in a cursive, flowing style.

Daniel Fabricant, Ph.D.
CEO & President
Natural Products Association