

Docket No. FDA-2023-D-1027

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON

**QUESTIONS AND ANSWERS ABOUT DIETARY GUIDANCE STATEMENTS IN
FOOD LABELING: DRAFT GUIDANCE FOR INDUSTRY; AVAILABILITY;
AGENCY INFORMATION COLLECTION ACTIVITIES; PROPOSED COLLECTION;
COMMENT REQUEST**

September 25, 2023

Prefatory remarks

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA members include domestic and foreign companies doing business as growers, importers, processors, manufacturers, and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs, including conventional human foods, dietary supplements, health and beauty products, animal products, and other products.

On March 27, 2023, the U.S. Food and Drug Administration (FDA or the Agency) issued a notice announcing the availability of a draft guidance regarding the use of dietary guidance statements in food labeling (the draft guidance).¹ Per the draft guidance, dietary guidance statements are defined as “written or graphic material, based on key or principal recommendations from a consensus report, in food labeling that represent or suggest that a food or a food group may contribute to or help maintain a nutritious dietary pattern.”²

AHPA notes that the draft guidance incorporates concepts and contains several matters in common with the February 16, 2023, proposed rule regarding “healthy” claims for food products (the Healthy Proposed Rule);³ AHPA previously submitted timely comments⁴ on this proposed rule.

The draft guidance is explicitly labeled as not binding on FDA or the public.⁵ However, the draft guidance also states that it provides industry with the Agency’s “current thinking on the appropriate use” of these statements.⁶ In these comments, AHPA does not address the question of FDA’s authority to issue guidance on this matter.

¹ 88 Fed. Reg. 18,149 (Mar. 27, 2023).

² Questions and Answers About Dietary Guidance Statements in Food Labeling: Guidance for Industry (Mar. 27, 2023), at 6.

³ 87 Fed. Reg. 59,168 (Sept. 29, 2022).

⁴ Comments of the American Herbal Products Association on FDA’s Notice on Food Labeling: Nutrient Content Claims; Definition of Term “Healthy” (February 16, 2023).

⁵ *Id.* at 3.

⁶ *Id.* at 4.

The Reagan-Udall Foundation Operational Evaluation of the FDA Human Foods Program (the Reagan-Udall Report) emphasized the importance of FDA’s mandate to advance nutrition, and it observed that, at the time of the report, “generally, nutrition is not recognized at the level implied by the national reliance on the FDA for essential public health nutrition policy.”⁷ The Reagan-Udall Report urged that FDA must play a “key role within a broader, whole-of-government approach” on nutrition policy. If implemented as currently drafted, the draft guidance would not meaningfully help FDA fulfill its mission in this area.

Many AHPA members manufacture, process, or sell foods (such as herbal teas) or dietary supplements that offer nutritional benefits. Products sold by AHPA members bear nutrition labeling, and AHPA members may make dietary guidance statements for such products. AHPA’s members therefore have an interest in the draft guidance, and these comments are submitted on their behalf.

I. Dietary statement policies should be informed by a broad range of consensus reports and standards

The current draft guidance states that dietary guidance statements should be based on the recommendations of a “consensus report,” defined as “a report that represents the consensus produced by a group of qualified experts whose bias and conflicts of interest have been minimized and that are convened to study a specific issue.”⁸

Although the draft guidance provides some examples of entities that may be sources of consensus reports, the sole such report consistently referenced throughout the draft guidance is the USDA Dietary Guidelines 2020-2025 (the Dietary Guidelines).⁹ The concept of a “dietary pattern,” included in the definition of “dietary guidance statements,”¹⁰ appears borrowed from the Dietary Guidelines. Similarly, the draft guidance states that “the public health goal of dietary guidance is to improve the health of consumers by providing information through nutrition statements that are based on the best evidence-based scientific research on dietary patterns,” and it communicates

⁷ Reagan-Udall Report at 18.

⁸ Draft guidance at 14.

⁹ U.S. Department of Agriculture and U.S. Department of Health and Human Services, Dietary Guidelines for Americans, 2020-2025, 9th Edition (Dec. 2020) (“Dietary Guidelines”).

¹⁰ Draft guidance at 6.

that sources not based on this concept from the Dietary Guidelines could not serve the public health goals of dietary guidance. Recommendations from the draft guidance make use of food group equivalents and nutrient limits derived from the dietary patterns found at Appendix 3 to the Dietary Guidelines.¹¹ The draft guidance therefore redirects all sources of acceptable dietary guidance statements back into this single “consensus report.”

The circularity of the draft guidance’s references unduly constrains the scope of dietary guidance statements that may benefit public health and dietary practices. Food products may play a role in healthy dietary practices beyond the serving size and food group equivalent volume framework emphasized in the Dietary Guidelines and draft guidance. For example, Americans increasingly consume teas without added caloric sweeteners, and the Dietary Guidelines itself recognizes that a healthy dietary pattern can include drinking unsweetened teas.¹² A wide number of coffee products are similarly sold and consumed without added sugars. For consumers, these unsweetened plant-based drinks serve as a healthy substitute for caloric or sugar-sweetened beverages, playing a potential role in making healthy dietary behaviors sustainable. Similarly, consumers may use herbs and spices (or mixes thereof) to reduce their reliance on sodium as a flavor enhancer.¹³

The use of dietary guidance statements on products such as teas, herbs, and spices would help serve the nutrition goals that form the basis for the Dietary Guidelines, encouraging improved consumer decisionmaking and incentivizing product reformulation that would drive healthy eating behaviors. Though the beneficial dietary potential of these products is mentioned in the Dietary Guidelines, the role of these and other products in healthy dietary patterns are not directly reflected in the “dietary patterns” identified throughout the Dietary Guidelines and collected in Appendix 3, and therefore they are not included in the framework of food group equivalents and nutrient limits presented as recommendations in the draft guidance.

¹¹ Dietary Guidelines at 142.

¹² *Id.* at 35.

¹³ Further discussion of both of these examples is available in the Comments of the American Herbal Products Association on FDA’s Notice on Food Labeling: Nutrient Content Claims; Definition of Term “Healthy” (February 16, 2023) at 10, 11.

AHPA therefore requests that FDA include examples of other consensus reports and material from them that may serve the basis for acceptable dietary guidance statements. AHPA asks that these examples include consensus reports from sources outside the federal government.¹⁴ AHPA also asks that FDA clarify that dietary guidance statements may reflect a broader range of products and practices involved in healthy dietary patterns, beyond those based on the framework established in Appendix 3 to the Dietary Guidelines.

II. Dietary supplements should be permitted to bear truthful dietary guidance statements

The draft guidance states that industry “should not use Dietary Guidance Statements on products labeled as or purporting to be dietary supplements.” The stated justification for this position is that “[c]urrent consensus report recommendations, including the Dietary Guidelines, encourage Americans to meet nutrient requirements through the consumption of whole foods (e.g., whole fruits and vegetables).” This reasoning does not properly reflect the position of the Dietary Guidelines, is inconsistent with the intended purpose of the draft guidance, and will promote consumer confusion that runs contrary to the draft guidance’s intended public health purposes.

Dietary supplement products are specifically “intended to supplement the diet,” including products intended to “increas[e] the total dietary intake” of beneficial substances.¹⁵ The Dietary Guidelines operate from an underlying assumption that Americans should meet their nutrient requirements primarily from consumption of conventional foods. However, the Dietary Guidelines also explicitly state that “dietary supplements may be useful in providing one or more nutrients that otherwise may be consumed in less than recommended amounts.”¹⁶ The Dietary Guidelines also acknowledge that obtaining recommended intakes of certain nutrients, such as vitamin D, is “harder to achieve through natural sources from diet alone” and require either fortification or supplementation.¹⁷ The Healthy Proposed Rule and the Dietary

¹⁴ *E.g.*, the European Food Safety Authority Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies, and published guidelines of the World Health Organization, including the global action plan for the prevention and control of non-communicable diseases.

¹⁵ 21 U.S.C. § 321(ff)(1).

¹⁶ Dietary Guidelines at 36.

¹⁷ *Ibid.*

Guidelines further identify calcium, potassium, dietary fiber, and vitamin D as nutrients of public health concern across the population, and they identify iron as a nutrient of public health concern for certain population groups.¹⁸ Population groups with dietary restrictions, such as those with plant-based diets, and groups with specialized needs, such as pregnant women, have particular needs for nutrients that are less easily accessible from conventional food sources, including iron, vitamin B₁₂, and omega-3 fatty acids, which may require supplementation.¹⁹ In addition, the Scientific Report of the Dietary Guidelines Advisory Committee 2020 indicates that Americans (age 1 and older) under-consume a host of other essential vitamins, minerals, and food components relative to the Estimated Average Requirement or Adequate Intake of these; the “shortfall” nutrients not separately addressed as nutrients of public health concern include vitamins A, C, E, and K as well as magnesium and choline.²⁰ In all of these cases, the draft guidance does not acknowledge a truth stated plainly by the Dietary Guidelines: dietary supplements are a critically necessary element of inclusive nutritional practices that are accessible and equitable in their reach.

As currently proposed, the draft guidance’s opposition to the use of dietary guidance statements on dietary supplement labels and labeling would create consumer confusion regarding the benefits of dietary supplements, which could lead consumers to incorrectly believe that dietary supplements are not useful in building and maintaining healthy dietary practices. As discussed above, the Dietary Guidelines acknowledge that supplementation is often necessary to obtain adequate nutrient intake and in turn to maintain a healthy dietary practice. Further, discouraging the use of such statements for dietary supplements but permitting their use for conventional food products that contain comparable or even lower amounts of vitamins, minerals, and other essential nutrients could lead to the unsupported and inaccurate impression that nutrients gained from dietary supplements are inferior to those found in conventional foods. In both cases, these incorrect assumptions could lead to a reduction in the use of dietary supplements to address nutrient deficits, creating public health harm. Indeed, FDA regulations prohibit labeling that represents, suggests, or implies that a natural vitamin in a food is superior to an added vitamin.²¹

¹⁸ 87 Fed. Reg. at 59,173; Dietary Guidelines at 36.

¹⁹ Dietary Guidelines at 116.

²⁰ Dietary Guidelines Advisory Committee. 2020. Scientific Report of the 2020 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Agriculture and the Secretary of Health and Human Services. U.S. Department of Agriculture, Agricultural Research Service, Washington, DC.

²¹ 21 C.F.R. § 101.9(k)(4).

For the above reasons, AHPA recommends and requests that the draft guidance be revised to clarify that dietary supplements may bear dietary guidance statements, where such statements truthfully reflect the dietary practice benefit of substances in the product.

III. Dietary supplements should be excepted from the food group equivalent recommendations of the draft guidance

The Dietary Guidelines consensus report relies upon the assumption that Americans should meet their nutrient requirements primarily from consumption of conventional foods.²² Imposing the food group equivalent recommendations of the draft guidance on dietary supplements effectively prohibits many dietary supplements from bearing dietary guidance statements. This reflects how most dietary supplements will not meet the food group equivalent recommendations included in the draft guidance. However, as explained above, dietary supplement use contributes to the creation and maintenance of healthy dietary practices, particularly with regard to nutrients that consumers may not obtain in sufficient amounts from their consumption of conventional foods.

The need for dietary supplementation is further supported by longstanding evidence of the declining nutrient value of some fruit and vegetable crops, particularly due to adverse industrial genetic selection favoring yield over nutrient content.²³ Public guidance that does not reflect this growing need for other sources of key nutrients runs contrary to FDA's stated goals to incentivize both consumer consumption and industrial product formulation behaviors.

AHPA therefore requests that the draft guidance be revised to state that dietary supplements may bear truthful and not misleading dietary guidance statements regardless of whether they meet the food group equivalence recommendations for conventional foods and food products.

²² Dietary Guidelines at 25.

²³ E.g., Marles R. J. (2017). Mineral nutrient composition of vegetables, fruits and grains: The context of reports of apparent historical declines. *Journal of Food Composition and Analysis*, 56, 93-103., and Davis, D. R. (2009). Declining Fruit and Vegetable Nutrient Composition: What Is the Evidence?. *HortScience*, 44(1), 15-19.

IV. Dried fruits or vegetables should be considered as the sourced, undehydrated amount of whole fruits or vegetables for the purpose of calculating food group equivalents

The draft guidance bases its current proposed food content recommendations on the assumption that a cup of a raw or cooked fruit or vegetable is nutritionally equivalent to one-half cup of the same dried fruit or vegetable.²⁴ As was the case in the Healthy Proposed Rule, FDA provides no evidentiary basis to justify the view that a product that has been converted into another form to remove moisture (that is, dehydrated) has reduced nutrient content when compared with the source amount of the whole fruit or vegetable. In the Healthy Proposed Rule, the Agency proposed to categorize fruit and vegetable purees and pastes into their respective food groups on the grounds that such products are “essentially whole [fruits/vegetables]”.²⁵ However, the Agency further proposed that fruit and vegetable powders would not be considered fruits or vegetables for the purpose of its calculations.

The Dietary Guidelines state as a key principle that “all forms of foods, including fresh, canned, **dried** [emphasis added], frozen, and 100% juices, in nutrient-dense forms, can be included in healthy dietary patterns.”²⁶ Whole fruits as described in the Dietary Guidelines may be consumed “in various forms, such as cut, sliced, diced, or cubed.”²⁷ Absent any evidence that such size reduction processing or dehydration of a fruit or vegetable causes significant nutrient depletion, the Agency should not create multiple contradictory standards based on the fresh versus dried status of a commodity. AHPA believes it would be contrary to the public health for the Agency to discourage purveyors of such foods from communicating the beneficial role of such products in healthy dietary patterns.

As per its comments on the Healthy Proposed Rule, AHPA requests that, absent evidence that a specific dehydration action will reduce a fruit’s or a vegetable’s nutrient content, manufacturers of fruit or vegetable products in any dried form (including powders) should be able to rely upon the source amount of material as the basis for

²⁴ This assumption is also present in the Dietary Guidelines at 146. No justification for this nutrient content ratio is present in the Dietary Guidelines or the associated Scientific Report of the 2020 Dietary Guidelines Committee.

²⁵ Healthy Proposed Rule at 59,185 and 59,186.

²⁶ Dietary Guidelines at 25.

²⁷ *Id.* at 32.

the determination of food group equivalency. AHPA further requests that the Agency clarify that fruit or vegetable products that have been subject to cutting slicing, dicing, cubing, or other such processing steps should be treated as whole fruits and vegetables for the purpose of determining food group equivalency.

Summary

AHPA greatly appreciates the opportunity to present comments on the draft guidance regarding dietary guidance statement use in food labeling. AHPA staff and counsel will make themselves available at any mutually convenient time to further address any of the topics addressed herein. Please feel free to contact us if clarification or additional discussion is needed on the issues raised in these comments.

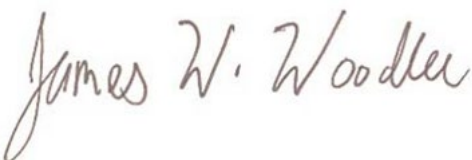
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