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Submitted Electronically via Regulations.gov

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

Re: Docket No. FDA-2016-D- 2335 for “Food Labeling: Nutrient Content Claims; Definition of Term Healthy.”

Dear Sir or Madam:

The International Bottled Water Association (IBWA) appreciates the opportunity to provide written comments to the Food and Drug Administration (FDA) docket regarding the proposed rule on the use of the term “healthy” on food labeling. IBWA is the trade association representing all segments of the bottled water industry, including spring, artesian, mineral, sparkling, well, groundwater, and purified bottled waters. Founded in 1958, IBWA member companies include domestic and international bottlers, distributors, and suppliers.

IBWA applauds the agency’s efforts to update the definition for the implied nutrient content claim “healthy” to be consistent with current nutrition science and the 2020-2025 *Dietary Guidelines for Americans*.

In particular, IBWA strongly supports the provision in the proposed rule revising the definition of “healthy” to include plain water and plain carbonated water without any flavoring or additional ingredients. Water consumption is recommended in the 2020-2025 Dietary Guidelines for Americans and by other organizations and public health agencies. Not only is drinking water strongly encouraged, but the public health community also widely recognizes that water is a preferred source of hydration and positively influences a number of healthy bodily functions and organs. Water is a healthy alternative to sugar-sweetened beverages (SSBs), and its consumption is encouraged to help reduce calorie consumption which may lead to obesity and diabetes.

FDA is also seeking comment on whether allowing bottled water to be labeled “healthy” could potentially lead some consumers to believe that bottled water is healthier than tap water. IBWA thinks that labeling bottled water as “healthy” would not lead consumers to believe that bottled

water is healthier than tap water. Instead, it would educate and remind consumers that drinking “plain water” is “healthy” for them, regardless of whether it is tap, filtered tap or bottled water.

IBWA is offering the comments below to the provisions in the proposed rule related to defining “healthy” for plain water, both still and carbonated.

I. IBWA applauds and supports FDA’s proposal to revise the regulation defining “healthy” nutrient content claims to include plain water, both still and carbonated.

Water – tap, filtered tap, or bottled – is essential for a healthy diet. Water consumption is recognized as being crucial for optimal hydration, necessary for the healthy function of the human body and organs, and to help reduce calorie consumption. Because water has a vital role for the normal, healthy function of the body, it simply would be impossible to have a healthy diet absent adequate water consumption.

Bottled water is a safe, healthy, and convenient food product that is comprehensively regulated by FDA. Bottled water plays an important role to help consumers make smart, healthy dietary choices for maintaining adequate hydration across their lifespans, and as a key component of a more healthful lifestyle. It is an accessible and practical way to support consumers who are striving to limit their added sugar consumption and shift to a healthier lifestyle.

Currently, bottled water products cannot bear a “healthy” nutrient content claim because they do not contain a “good source” level of a beneficial nutrient. The regulation generally requires “healthy” foods to contain at least 10 percent of the reference daily intake (RDI) or daily reference value (DRV) per reference amount customarily consumed (RACC) of one or more of the following: vitamin A, vitamin C, calcium, iron, protein, or fiber.¹

FDA provides a remedy in the proposed rule by acknowledging water does not fall into a food group equivalent under its proposed new definition, but is permitted to use the term “healthy,” explaining, *“there are some foods that we propose to include in the updated criteria for “healthy” including raw, whole fruits and vegetables, and water, that under the proposed updated criteria, will not need to meet requirements for food group equivalents and these foods are included in categories of food that can automatically use the “healthy” claim because of their nutrient content and positive contribution to an overall healthy diet.”* We agree with this approach. Bottled water is similar to fruits and vegetables such as celery and grapes that may not contribute significant amounts of nutrients to encourage but nonetheless are foods that are encouraged under the Dietary Guidelines for Americans. FDA has for decades allowed a healthy claim on these types of fruits and vegetables. Likewise, because plain carbonated or noncarbonated water is so strongly encouraged by dietary guidance as a beverage to consume, it should be eligible regardless of its nutrient or food group content.

In the proposal, FDA supports the importance of water for maintaining health by pointing out that,

¹ 21 CFR § 101.65(d)(2)(i)(F). Additionally, in guidance, FDA has recognized that a product can qualify by virtue of containing at least 10 percent of the RDI for potassium or vitamin D per RAC.

“Organizations, such as the National Academy of Medicine, and public health agencies, such as the Centers for Disease Control and Prevention, widely recognize the benefits of water, that it is a preferred source of hydration, and is necessary for proper functioning of the human body.” We agree. The agency’s proposal would conform the definition of “healthy” to be consistent with federal guidance through incorporating recommendations on water in the Dietary Guidelines for Americans 2020-2025. FDA states, “Water itself is not categorized under a recommended food group in the Dietary Guidelines, 2020-2025. However, water is emphasized in the Dietary Guidelines, 2020-2025 beverage recommendations. The Dietary Guidelines, 2020-2025 recommends that the “primary beverages consumed” should be “beverages that are calorie-free--especially water--or that contribute beneficial nutrients, such as fat-free and low-fat milk and 100 percent fruit juice.”

IBWA’s support for this proposal is consistent with our previous comments to FDA on this issue, which were based on important role of water in maintaining good health and meeting federal dietary recommendations. On August 7, 2017, IBWA sent the attached letter to FDA asking the agency to exercise its enforcement discretion to permit the use of the term “healthy” on the labeling of bottled water. IBWA also submitted the attached written comments on the definition of “healthy” on April 26, 2017, and oral comments at FDA’s public meeting on the definition of “healthy” on March 9, 2017.

II. The proposed rule would not cause consumers to believe that bottled water is healthier than tap water. Instead, it would educate and remind consumers that drinking “plain water” is “healthy” for them, regardless of whether it is tap, filtered tap or bottled water. This positive outcome benefits everyone and is consistent with federal dietary guidance on water generally.

Water consumption plays a vital role in helping Americans achieve adequate hydration. IBWA encourages people to stay hydrated by drinking water, including tap, filtered tap, or bottled water. Importantly, the bottled water industry does not consider tap water to be our competitor in the marketplace. Instead, we compete with carbonated soft drinks, fruit juices and energy drinks. In fact, a significant portion of bottled water’s growth (30 percent since 2012) has come from people switching to bottled water from other less-healthy packaged drinks. Moreover, a Harris Poll conducted for IBWA found that 71 percent of people drink both tap and bottled water.

Tap water should be accessible to people everywhere, and our industry supports a strong, reliable public drinking water system. Tap water systems are regulated by the Environmental Protection Agency (EPA), not by FDA. They are therefore free to inform their customers that water is healthy for them. There are numerous ways this could be done; for example:

- EPA Public Engagement Campaigns: EPA has developed a number of public engagement campaigns to communicate the value of drinking water services, some in conjunction with nonprofit organizations, and has developed a [campaign and community engagement handbook](#) with example campaigns available for use by owners and operators. Example campaigns include social media competitions, brochures with activities for children, and public events like block parties. One example, the *Value of Water Coalition’s Water Works!*

Campaign, already promotes online messaging that “water keeps us safe and healthy.” Similar campaigns could be launched with “healthy” messaging for water. A symbol or icon with this messaging could be used as a short-hand way to communicate the information.

- EPA-Required Consumer Confidence Reports: In accordance with the Safe Drinking Water Act, the EPA requires that all community water systems issue annual [consumer confidence reports](#) (CCRs) on water quality and water system operations. CCRs could include healthy messaging. The EPA has also developed [public service announcement](#) materials (posters and radio ads) that water system owners and operators may use to make the public aware of the existence of these reports. These PSA materials could also include healthy messaging.
- Dietary Guidance/ Consumer Education Initiatives: FDA and USDA could address this issue through federal dietary guidance (e.g., the Dietary Guidelines for Americans, MyPlate guidance), or consumer education as part of updating the healthy criteria, making clear that all plain water, including bottled and tap water, are recommended and healthy beverages.

For these reasons, we do not believe there is any justification to revise the proposal to allow plain or plain carbonated bottled water to include the term “healthy” on the label.

Below we discuss numerous federal dietary recommendations related to plain water that all support the FDA’s proposed allowance under the healthy definition.

National Clinical Care Commission (NCCC)’s recommendations on water

The FDA proposed rule is consistent with several recommendations for promotion and education of consumers from a 2021 federally commissioned report that the National Clinical Care Commission (NCCC) submitted to Congress on "Leveraging Federal Programs to Prevent and Control Diabetes and Its Complications"² encouraging the consumption of water including in place of Sugar Sweetened Beverages (SSB):

Recommendation 4.4: The National Clinical Care Commission recommends that all relevant federal agencies promote the consumption of water and reduce the consumption of sugar-sweetened beverages in the U.S. population, and that they employ all the necessary tools to achieve these goals, including education, communication, accessibility, water infrastructure, and sugar-sweetened beverage taxation.

4.4a. USDA should add a symbol for drinking water to the MyPlate graphic and increase water promotion messaging in all consumer-facing materials issued by its Center for Nutrition Policy Promotion. Water is not currently depicted on the USDA MyPlate.

4.4b. Child nutrition programs should be a conduit for education to promote consumption of water and reduce consumption of sugar-sweetened beverages. USDA should encourage hydrating with

² NCCC, & HHS. *Report to Congress on Leveraging Federal Programs to Prevent and Control Diabetes and Its Complications*.
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water instead of sugar-sweetened beverages and provide safe water education in WIC nutrition education and in childcare settings. Congress should harness the Child Nutrition Reauthorization Act to strengthen existing water provisions for school nutrition programs.

2020-2025 Dietary Guidelines Advisory Committee Report on hydration

The 2020-2025 Dietary Guidelines Advisory committee report³ also acknowledged the importance of hydration, stating that the DGAs should extend beyond specific questions addressed in the DGAC's scientific report on related dietary practices, including maintaining hydration, noting, *The Dietary Guidelines for Americans translation of the Committee's scientific review into the Dietary Guidelines for Americans should extend beyond topics incorporated within the specific questions addressed by the Committee and should include related dietary practices that remain of public health concern including those that have been reviewed by previous Committees. These include, but are not limited to, keeping the intake of trans fats low, reducing sodium intake, building and maintaining bone mass, preventing dental caries, **maintaining hydration**, making healthful snacking choices, and maintaining at least a moderate level of physical activity and appropriate sleep patterns in daily life.[emphasis added]*

National Institutes of Health (NIH) study on benefit of maintaining hydration

The benefit of maintaining adequate hydration was recently highlighted in a January 2023 press release by the National Institutes of Health (NIH) titled, “*Good hydration linked to healthy aging*”⁴ reporting, “*that adults who stay well-hydrated appear to be healthier, develop fewer chronic conditions, such as heart and lung disease, and live longer than those who may not get sufficient fluids, according to a NIH study published in [eBioMedicine\(link is external\)](#).*”

The press release outlined that the study was done, “*Using health data gathered from 11,255 adults over a 30-year period, researchers analyzed links between serum sodium levels – which go up when fluid intake goes down – and various indicators of health. They found that adults with serum sodium levels at the higher end of a normal range were more likely to develop chronic conditions and show signs of advanced biological aging than those with serum sodium levels in the medium ranges. Adults with higher levels were also more likely to die at a younger age.*”

The press release noted that more research is necessary to confirm these findings. However, this data highlights the impact hydration and drinking water, whether tap, filtered tap or bottled, may have on health. This research reinforces that plain water whether tap, filtered tap or bottled is healthy.

³ 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. Part B: Chapter 2: Integrating the Evidence (p. 10-11). Available at: <https://doi.org/10.52570/DGAC2020>

⁴ Dmitrieva, N. I., Gagarin, A., Liu, D., Wu, C. O., & Boehm, M. (2023). Middle-age high normal serum sodium as a risk factor for accelerated biological aging, chronic diseases, and premature mortality. *EBioMedicine*, 87, 104404. <https://doi.org/10.1016/J.EBIOM.2022.104404>

Allowing bottled water to be labelled as “healthy” would not lead consumers to think tap water is not “healthy.” And, as recognized by federal dietary guidance across multiple agencies, water, whether tap, filtered tap or bottled, is an overall “healthy” choice for consumers in maintaining adequate hydration and reducing consumption of sugar-sweetened beverages. We strongly support FDA’s proposal to reinforce this message by allowing a healthy claim on plain water whether noncarbonated or carbonated.

III. IBWA requests that FDA exercise enforcement discretion from the nutrition labeling requirements for bottled water that bears a healthy claim but is otherwise exempt from nutrition labeling because it contains insignificant amounts of the mandatory nutrients.

Currently, most bottled water is exempt from nutrition labeling under FDA regulations at 21 CFR 101.9(j)(4) because it contains insignificant amounts of the mandatory nutrients. However, this exemption to the nutrition labeling rules is contingent upon the product not bearing any nutrient content claims on its label or in labeling. So a bottled water product that bears the term “healthy,” even if otherwise exempt from nutrition labeling, would then be required to bear nutrition labeling despite the fact that the nutrition information would only convey “zero” of the mandatory nutrients. We respectfully request that FDA provide enforcement discretion from nutrition labeling when a bottled water product that otherwise is exempt from nutrition labeling under section 101.9(j)(4) bears a “healthy” statement.

IV. IBWA requests that the proposed “healthy” allowance for plain water and plain carbonated water also be extended to waters with added minerals or electrolytes added for taste, as these are recommended beverages under dietary guidance.

IBWA greatly appreciates the proposed provision on plain water and plain carbonated water with no added ingredients. We believe that the same rationale should apply to water with added minerals or electrolytes for taste. These added minerals/electrolytes include potassium, calcium, magnesium, and others, and are present at low levels—typically no more than 0.5% of the formulation. Their addition does not meaningfully affect the composition of the product, other than to slightly affect the taste of the water, and it does not affect the calorie or sugar content. The DGA recommend consumption of water and beverages without added sugars, and waters with added minerals or electrolytes for taste are one such beverage. Examples include alkaline water with added minerals, and purified water with electrolytes or minerals added for taste. Because they do not contain a food group to encourage, and the nutrients are not present at meaningful levels, we ask FDA to place these beverages in the same category as plain waters, where they would automatically qualify for a healthy claim.

We likewise would be supportive of FDA extending eligibility for a healthy claim to waters (carbonated or noncarbonated) that contain added flavors, as such waters are also encouraged under the DGA and are an enjoyable way for consumers to hydrate while not contributing calories or added sugars. Because these products are outside of the FDA standard of identity for bottled water, and IBWA focuses on standardized bottled water, we do not comment in detail here on this issue.

Conclusion

For all the reasons cited above, IBWA agrees with FDA’s proposal to revise the regulation defining

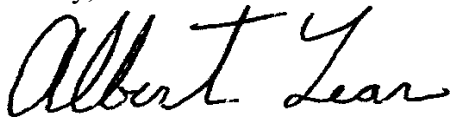
“healthy” nutrient content claims to allow the claim to be used in the labeling of plain water, both still and carbonated.

The proposed rule would not lead consumers to think bottled water is healthier than tap water. Rather, it would help to educate and remind consumers that drinking “plain water” whether it is tap, filtered tap or bottled water is “healthy” for them—a positive outcome that would benefit everyone and emphasize existing dietary guidance.

We also ask FDA to provide enforcement discretion for products that bear a healthy claim on their label or in labeling but otherwise would be exempt from nutrition labeling under 21 CFR 101.9(j)(4); and expand the proposed allowance for plain waters as “healthy” to also include water with added minerals for taste and alkaline water.

IBWA appreciates the opportunity to submit these comments and would be pleased to provide the agency with further information as FDA continues with its work to update the “healthy” definition.

Sincerely,

A handwritten signature in black ink that reads "Albert Lear". The signature is written in a cursive, flowing style.

Albert Lear

IBWA Vice President of Science, Education and Technical Relations

Enclosures:

IBWA Written Request for Enforcement Discretion-Healthy 080717

IBWA Written Comments to FDA Docket on the Use of the Term “Healthy” in the Labeling of Human Food Products; Docket No. FDA-2016-D-2335 (Sept. 28, 2016)

IBWA Oral Comments at FDA Public Meeting on the Use of the Term “Healthy” (Mar. 9, 2017)