

**DOCKET NO. FDA-2016-D-2335**

**BEFORE**

**THE UNITED STATES OF AMERICA**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**FOOD AND DRUG ADMINISTRATION**

**COMMENTS OF THE**

**AMERICAN HERBAL PRODUCTS ASSOCIATION**

**ON**

**FDA's Request for Comments on use of the term "Healthy" in labeling of  
human food products**

**April 26, 2017**

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## **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 manufacturers and marketers of herbs and herbal products, as well as non-herbal products, including conventional foods and dietary supplements. AHPA serves its members by promoting the responsible commerce of herbal and non-herbal products including conventional human foods and dietary supplements.

On September 28, 2016, the U.S. Food and Drug Administration (FDA or the Agency) published a Federal Register notice<sup>1</sup> in which the Agency invited comments on the term “healthy” as a nutrient content claim in the context of food labeling and on certain specific questions contained in the notice (the September 28 Request for Comments).

The current regulation for use of the term “healthy” (and related terms, such “health,” “healthful,” “healthfully,” “healthfulness,” “healthier,” “healthiest,” “healthily,” and “healthiness”) as an implied nutrient content claim on the label or in labeling of a food is codified at 21 CFR § 101.65 (d)(2). This regulation establishes specific criteria for this implied nutrient content claim related to the levels of fat, saturated fat, cholesterol, and other nutrients present in a food subject to such claim, irrespective of the food ingredients from which the nutrients are derived.

In the September 28 Request for Comments FDA also noted that a variety of stakeholders from academia and industry, as well as consumers, have requested FDA update additional nutrition labeling regulations for nutrient content and health claims, including the implied nutrient content claim “healthy”; FDA identified in particular and in some detail a citizen petition dated December 1, 2015 and submitted by KIND LLC.

FDA also issued on September 28, 2016 a separate Federal Register notice<sup>2</sup> (the September 28 Notice of Guidance Availability) in which it announced the availability of a guidance document titled, “Use of the Term ‘Healthy’ in the Labeling of Human

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<sup>1</sup> 81 FR 66562; Docket No. FDA-2006-D-2335.

<sup>2</sup> 81 FR 66527; also identified as Docket No. FDA-2006-D-2335.

Food Products: Guidance for Industry” (the “Healthy” Guidance). In this second Federal Register notice, and also in the “Healthy” Guidance, FDA stated its intention to exercise enforcement discretion, until such time as the Agency amends 21 CFR § 101.65 (d)(2), with respect to some of the existing criteria for the implied nutrient content claim “healthy” if the alternative nutrient criteria described in the “Healthy” Guidance are met.

Many AHPA members manufacture and market conventional foods and dietary supplements that may qualify for use of the term “healthy” as a nutrient content claim. These comments are submitted on behalf of AHPA and its members to address both of the September 28 Federal Register notices identified herein; as noted in footnote 2, both documents are identified as Docket No. FDA–2006–D–2335.

### **AHPA supports FDA’s expressed enforcement discretion**

As already noted, FDA stated in both the September 28 Notice of Guidance Availability and in the “Healthy” Guidance itself its intention to exercise enforcement discretion, until such time as the Agency amends 21 CFR § 101.65 (d)(2), with respect to some of the existing criteria for the implied nutrient content claim “healthy” if the alternative nutrient criteria described in the “Healthy” Guidance are met.

AHPA agrees that FDA should continue to exercise the enforcement discretion described in these documents until such time as 21 CFR § 101.65 (d)(2) is amended.

### **AHPA encourages FDA to amend 21 CFR § 101.65 (d)(2) promptly**

FDA notes in the “Healthy” Guidance as introduced by the September 28 Notice of Guidance Availability that nutrition science has evolved over time, such that, for example, the 2005 edition of *Dietary Guidelines for Americans* recommended diets low in total fat whereas the current (2015) edition of this reference no longer recommends limiting overall fat intake but instead prioritizes increasing intakes of polyunsaturated and monounsaturated fats and decreasing intakes of saturated fat and *trans* fat. Since the 2005 edition was current at the time 21 CFR § 101.65 was codified, the current regulation reflects a dated view of nutrition science, at least in

regard to this specific attention to fat consumption, that is no longer considered to be in the best health interests of Americans.

AHPA therefore recommends FDA prioritize its attention to amending 21 CFR § 101.65 (d)(2). AHPA notes that under federal law the current edition of *Dietary Guidelines for Americans* “shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program.”<sup>3</sup> This statutory requirement is relevant to FDA’s regulation of nutrient content claims; it also supports AHPA’s recommendation to prioritize amending 21 CFR § 101.65 (d)(2) insofar as the current regulation is inconsistent with *Dietary Guidelines for Americans* 2015-2020.

### **Criteria other than nutrient content should be considered for “healthy” claims**

FDA inquires in the September 28 Request for Comments whether the term “healthy” is most appropriately categorized as a claim based only on nutrient content, and if not, what other criteria (*e.g.*, inclusion of foods from specific food categories) would be appropriate to consider in defining the term “healthy” for use in food labeling.

AHPA believes that the criteria on which allowance for a “healthy” claim on food labeling are based should not be limited only to a food’s nutrient content. AHPA notes that the *Dietary Guidelines for Americans* 2015-2020 identifies as a “key recommendation” a “healthy eating pattern” as including:

- A variety of vegetables from all of the subgroups—dark green, red and orange, legumes (beans and peas), starchy, and other
- Fruits, especially whole fruits
- Grains, at least half of which are whole grains
- Fat-free or low-fat dairy, including milk, yogurt, cheese, and/or fortified soy beverages
- A variety of protein foods, including seafood, lean meats and poultry, eggs, legumes (beans and peas), and nuts, seeds, and soy products
- Oils

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<sup>3</sup> 7 U.S.C. § 5341 (a)(1).

It would thus be reasonable, and also consistent with this key recommendation in the *Dietary Guidelines for Americans 2015-2020*, for FDA to craft a regulation that would allow, and in fact encourage, labeling of foods that are recommended to be included in a “healthy eating pattern” as “healthy” in food labeling,” with such additional criteria as are needed to ensure that a “healthy” claim for any specific food consisting of or containing the foods identified in this key recommendation is truthful and nonmisleading.

Such an approach is supported by the findings of the *Scientific Report of the Dietary Guidelines Advisory Committee* issued in February 2015 (the 2015 DGAC Report or the Report). The Report “encourages the consumption of healthy dietary patterns that are low in saturated fat, added sugars, and sodium” and goes on to say that rather than focusing purely on reduction, “emphasis should also be placed on replacement and shifts in food intake and eating patterns.”

One example of such replacement is presented in the Report for sodium, where it suggests that “emphasis should be placed on expanding industry efforts to reduce the sodium content of foods and helping consumers understand how to flavor unsalted foods with spices and herbs.” Such healthy options to reduce sodium intake could allow herb and spice blends or prepared foods that substitute herbs and spices for salt to bear a claim such as “a healthy alternative to salt.” The ability to make such claims might provide encouragement for food producers to reduce the sodium content in their products and would assist companies that market herbs and spices to help consumers learn more about these as salt substitutes.

Similarly, the 2015 DGAC Report suggests that “added sugars should be reduced in the diet and not replaced with low-calorie sweeteners, but rather with healthy options, such as water in place of sugar-sweetened beverages.” AHPA suggests that another legitimate option to sugar-sweetened beverages would be unsweetened teas, including black and green teas and herbal teas, and believes again that companies that market teas would be motivated to provide healthier options if regulations allowed a “healthy” claim, such as “unsweetened tea is part of a healthy diet.”

## Closing

AHPA greatly appreciates the opportunity to present comments on this matter. 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.

Respectfully submitted,



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