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Use of the Term “Healthy” in the Labeling of Human Food Products: Guidance for Industry

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Use of the Term “Healthy” in the Labeling of Human Food Products: Guidance for Industry¹

This guidance represents the current thinking of the Food and Drug Administration's (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

The purpose of this guidance is to advise manufacturers who wish to use the implied nutrient content claim “healthy” to label their food products as provided by our regulations. More specifically, this guidance is intended to advise food manufacturers of our intent to exercise enforcement discretion relative to foods that use the implied nutrient content claim “healthy” on their labels which: (1) Are not low in total fat, but have a fat profile makeup of predominantly mono and polyunsaturated fats; or (2) contain at least ten percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of potassium or vitamin D.

This guidance is immediately effective because the agency has determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Background

Under section 403(r)(1)(A) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(r)(1)(A)), a food² is misbranded if it bears claims, either express or implied, that characterize the level of a nutrient which is of a type required to be declared in nutrition

¹ This guidance has been prepared by the Office of Nutrition and Food Labeling, Nutrition Program Staff, in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

² Section 201(f) of the FD&C Act (21 U.S.C. 321(f)) defines the term “food” to mean articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article.

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labeling³ unless the claim is made in accordance with a regulatory definition established by FDA (see section 403(r)(2) of the FD&C Act, 21 U.S.C. 343(r)(2)). 21 CFR 101.65(d) provides such regulatory definition for use of the term “healthy” or related terms (such as “health,” “healthful,” “healthfully,” “healthfulness,” “healthier,” “healthiest,” “healthily,” and “healthiness”) as an implied nutrient content claim on the label or in labeling of a food. The “healthy” nutrient content claim can be used if the food meets certain nutrient conditions; and, when used with an explicit or implicit claim or statement about a nutrient (e.g. “healthy, contains 3 grams of fat”), suggests that a food, because of its nutrient content, may be useful in creating a diet that is consistent with dietary recommendations. The nutrient conditions for bearing a “healthy” nutrient content claim include specific criteria for nutrients to limit in the diet, such as total fat, saturated fat, cholesterol, sodium, as well as requirements for nutrients to encourage in the diet, including vitamin A, vitamin C, calcium, iron, protein, and fiber. The criteria are linked to elements in the Nutrition Facts label and serving size regulations (see 21 CFR §§ 101.9 and 101.12). The nutrient criteria to use the claim can vary for different food categories (e.g., fruits and vegetables, or seafood and game meat) (see 21 CFR 101.65(d)(2)).

In addition, it is also important to note that under section 403(a)(1) of the FD&C Act (21 U.S.C. 343(a)(1)), a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the FD&C Act (21 U.S.C. 321(n)) provides that labeling is misleading if, among other things, it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual.

III. Discussion

In the *Federal Register* of May 27, 2016, we issued final rules updating the Nutrition Facts label and serving size information for packaged foods to reflect new scientific information, including the link between diet and chronic diseases such as obesity and heart disease (see 81 FR 33742, “Food Labeling: Revision of the Nutrition and Supplement Facts Labels”; 81 FR 34000, “Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments”). Updates to the Nutrition Facts label include changes in the individual nutrients that must be declared and also changes to the Daily Value (DV) of other individual nutrients, reflecting changes in recommended intake levels, based on current science. The individual nutrients included in Nutrition Facts and their DVs significantly influence the regulations on nutrient content and health claims. Because the framework for many of FDA’s other nutrition labeling regulations is linked to elements in the Nutrition Facts label and serving size regulations, we plan to update those other regulations, such as those for health claims and nutrient content claims (including the implied nutrient content claim “healthy”), to align with these most recent updates.

³ Section 201(m) of the FD&C Act (21 U.S.C. 321(m)) defines “labeling” as all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such article.

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The science underlying the final rules, referenced above, is also reflected in the 2015-2020 *Dietary Guidelines for Americans* (2015-2020 *Dietary Guidelines*) (Ref. 1). The *Dietary Guidelines* is designed for professionals to help all individuals ages 2 years and older and their families consume a healthy, nutritionally adequate diet. The *Dietary Guidelines* is the foundation of federal nutrition guidance and is fundamental in shaping federal policies and programs related to food, nutrition, and health. The *Dietary Guidelines* provides information and perspectives on healthy eating patterns and consumption of foods from various food groups, as well as the intake of specific macronutrients such as fats, sugars, and micronutrients such as vitamins and minerals. Specific recommendations in the *Dietary Guidelines* have evolved over time, as nutrition science has advanced. For example, scientific understanding and nutrition guidance has shifted from recommending diets low in total fat (2005 *Dietary Guidelines*) (Ref. 2) to no longer recommending limiting overall fat intake, and instead prioritizing increasing intakes of polyunsaturated and monounsaturated fats and decreasing intakes of saturated fat and *trans* fat (2015-2020 *Dietary Guidelines*). The 2015-2020 *Dietary Guidelines*, also emphasizes the importance of dietary patterns as a whole, the combination of foods and drinks that people consume over time. The body of scientific evidence and the recommendations based on that science in the *Dietary Guidelines* will help FDA shape additional updates to regulations on nutrition related claims and information that are permitted on the food label.

We are re-evaluating the regulatory criteria for use of the implied nutrient content claim “healthy” in light of the latest nutrition science and the current dietary recommendations and seek input on possible future rulemaking to update the existing regulations for this claim. Because the rulemaking process can sometimes be lengthy, we intend to exercise enforcement discretion in the interim with respect to some of the existing criteria for the nutrient content claim “healthy” if the alternative nutrient criteria described below are met. We intend to exercise enforcement discretion until we amend 21 CFR 101.65(d)(2).

A. Low Fat

As stated above, since we published the final rule defining “healthy” (58 FR 2302, January 6, 1993), the science related to public health recommendations for intake of dietary fats has evolved. The focus of the most recent dietary fat recommendations has shifted away from limiting total fat intake to encouraging intakes of mono and polyunsaturated fats. Foods that use the term “healthy” on their labels that are not low in total fat should have a fat profile makeup of predominantly mono and polyunsaturated fats (i.e., sum of monounsaturated fats and polyunsaturated fats are greater than the total saturated fat content of food). Consistent with consensus science and public health recommendations for dietary fats which no longer recommend low total fat intake, we intend to exercise enforcement discretion with respect to the current requirement that any food bearing the nutrient content claim “healthy” meet the low fat requirement (§101.65(d)(2)(i)), provided that: (1) The amounts of mono and polyunsaturated fats are declared on the label and (2) the amounts declared constitute the majority of the fat content. These conditions are necessary so that consumers are made aware that the total fat is mostly made up of fats that are encouraged by current dietary recommendations.

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B. Beneficial Nutrients

The definition for “healthy” also includes a nutrient contribution criterion. Healthy dietary patterns not only restrict nutrients that increase risk of chronic disease, but also help assure nutrient adequacy to ensure sufficient intake of nutrients that are important in sustaining body function and reducing the risk of disease. The current definition of “healthy” has focused on foods providing a good or excellent source of nutrients for which there had been public health concern. Historically, these nutrients have been vitamin A, vitamin C, iron, calcium, and dietary fiber. Nutrient intakes have shifted over time, however, and vitamins A and C are no longer nutrients of public health concern. The nutrients of public health concern now include potassium and vitamin D, in addition to iron and calcium (2015-2020 *Dietary Guidelines*). This change in nutrients of public health concern has been reflected in the mandatory nutrients to be labeled in the Nutrition Facts Label (see 81 FR 33742, May 27, 2016). In recognition of this change, we intend to exercise enforcement discretion with respect to the current requirement that any food bearing the nutrient content claim “healthy” contain at least ten percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of vitamin A, vitamin C, calcium, iron, protein, or fiber, if the food instead contains at least ten percent of the DV per RACC of potassium or vitamin D. The regulations updating the Nutrition Facts label have provided for new DVs for potassium and vitamin D and manufacturers have been given some time to come into compliance with these regulations. If a manufacturer has not yet implemented the updated Nutrition Facts label, they may use the old DVs for potassium and vitamin D. If a manufacturer has already implemented the updated Nutrition Facts label, they must use the new, updated DVs for potassium and vitamin D. In either case, if a food is basing its eligibility for bearing a “healthy” claim on potassium or vitamin D, whichever nutrient is being used as the basis for eligibility should be declared in the Nutrition Facts label.

IV. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of June 1, 2016, FDA had verified the Web site address for the references we make available as hyperlinks from the Internet copy of this guidance, but we are not responsible for any subsequent changes to Non-FDA Web site references after June 1, 2016.

1. U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015 – 2020 Dietary Guidelines for Americans. 8th Edition. December 2015. Available at <http://health.gov/dietaryguidelines/2015/guidelines/>.
2. U.S. Department of Health and Human Services and U.S. Department of Agriculture. Dietary Guidelines for Americans, 2005. 6th Edition, Washington, DC: U.S. Government Printing Office, January 2005. Available at <http://health.gov/dietaryguidelines/dga2005/>.