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Guidance for Industry

Food Labeling; Nutrient Content Claims; Definition for "High Potency" and Definition for "Antioxidant" for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods

Small Entity Compliance Guide

Additional copies are available from:
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Guidance for Industry[1]

Food Labeling; Nutrient Content Claims: Definition for "High Potency" and Definition of "Antioxidant" for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods Small Entity Compliance Guide

I. Introduction

On September 23, 1997, FDA published in the Federal Register a final rule amended regulations concerning certain nutrient content claims. The amended regulations defined the term "High potency" as a nutrient content claim; defined nutrient content claims using the term "antioxidant" (e.g., "good source of antioxidants," "high in antioxidants," "more antioxidants"); and corrected an omission pertaining to the use of "sugar free" claims on dietary supplements (62 FR 49868). FDA took these actions to provide for the use of additional nutrient content claims on labels or in labeling in accordance with provisions of the Nutrition Labeling and Education Act of 1990. The final rule is effective on March 23, 1999. FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121). This guidance document restates in plain language the legal requirements set forth in 21 CFR 101.54(f) and (g) and 21 CFR 101.60(c)(1)(iii)(A) concerning dietary supplement use of certain nutrient content claims. This regulation is binding and has the full force and effect of law.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's 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 Agency guidances means that something is suggested or recommended, but not required.

[1] This guidance has been prepared by the Division of Dietary Supplement Programs in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

II. Questions and Answers

A. High Potency Claims

1. What is the definition of "high potency?"

   The regulation states that the term "high potency" may be used in a claim on the label or in labeling to describe individual vitamins or minerals that are present at 100 percent or more of the Reference Daily Intakes (RDI) per reference amount customarily consumed (21 CFR 101.54(f)(1)(i)). This means a supplement may be labeled as "high potency" for each nutrient(s) that is present at 100% of the RDI per serving.

2. How should the label or labeling describe the nutrients that are the subject of the high potency claim?

   When the term "high potency" is used to describe individual vitamins or minerals in a product that contains other nutrients, then the label or labeling must clearly identify which specific vitamins or minerals are being described as "high potency." For example, "Botanical X with high potency vitamin E." (21 CFR 101.54(f)(1)(ii))

3. Can I name an entire product "high potency" when not all ingredients are present at 100% or greater?

   The term "high potency" may be used on the label or in labeling of a multi-ingredient product to describe the product (as opposed to describing the level of individual ingredients) if the product contains 100 percent or more of the RDI for at least two-thirds of the vitamins and minerals that are listed in 21 CFR 101.9(c)(8)(iv) and that are present in the product at 2 percent or more of the RDI. For example, "High potency multivitamin, multimineral dietary supplement tablets." (21 CFR 101.54(f)(2))

4. Do any other requirements apply to the use of the term "High potency" in foods?

   Yes. If the nutrient that is the subject of a high potency claims is added to a food that is not a dietary supplement, then that fortification must be in accordance with the policy on food fortification in 21 CFR 104.20 (21 CFR 101.54(f)(3)).

B. Antioxidant nutrient content claims

1. Is an antioxidant claim a nutrient content claim?

   Yes. A claim that describes the level of antioxidant nutrients present in a food is a nutrient content claim and may be used on the label or in the labeling of a food when the conditions of use in the regulation are met (21 CFR 101.54(g)).

2. Can I make an antioxidant nutrient content claim for any ingredient in a food?

   No. An antioxidant nutrient content claim can only be made for nutrients for which there is an RDI established in 21 CFR 101.9 (21 CFR 101.54(g)(1)).

3. Does the claim apply to all nutrients listed in 21 CFR 101.9?

   No. The nutrient that is the subject of the claim must have recognized antioxidant activity. That is, there must be scientific evidence that after it is eaten and absorbed from the gastrointestinal tract, the substance participates in physiological, biochemical, or cellular processes that inactivate free radicals or prevent free radical-initiated chemical reactions (21 CFR 101.54(g)(2)).

4. How much of the nutrient must be present in each serving in order to use the antioxidant nutrient content claim?

   The antioxidant nutrient must meet the requirements for nutrient content claims in 21 CFR 101.54(b), (c), or (e) for "High" claims, "Good source" claims, and "More" claims, respectively. For example, to use a "high" claim, the food would have to contain 20% or more of the Daily Reference Value (DRV) or RDI per serving. For a "good source" claim, the food would have to contain between 10-19% of the DRV or RDI per serving (21 CFR 101.54(g)(3)).

5. What special requirements apply to an antioxidant nutrient content claim for beta-carotene?

   Beta-carotene may be the subject of an antioxidant claim when the level of vitamin A present as beta-carotene in the food using the claim is sufficient to qualify for the claim. For example, if the claim is "good source of antioxidant beta-carotene," then at least 10% of the RDI for vitamin A must be present as beta-carotene per serving (21 CFR 101.54(g)(3)).

6. Does the label claim have to include the name of the nutrient that is an antioxidant, or can the claim simply say "antioxidants?"

   The names of the nutrients that are the antioxidants must appear in the claim. For example, "high in antioxidant vitamins C and E."

Alternatively, when used as part of a nutrient content claim, the term "antioxidant" or "antioxidants" (such as "high in antioxidants"), may be linked by a symbol (such as an asterisk) that refers to the same symbol that appears elsewhere on the same panel of a product label followed by the name or names of the nutrients with the recognized antioxidant activity. If this is done, the list of nutrients must appear in letters of a type size height no smaller than the larger of one half of the type size of the largest nutrient content claim or 1/16 inch (21 CFR 101.54(g)(4)).

C. Sugar-free claims

1. Can dietary supplements include claims on their label such as "sugar free," "free of sugar," "no sugar," "zero sugar," "without sugar," "sugarless," "trivial source of sugar," negligible source of sugar," or "dietarily insignificant source of sugar"?

   Yes. A dietary supplement may include claims in labeling such as "sugar free," "no sugar," or other claims described in 21 CFR 101.60(c) provided it meets all of the eligibility criteria set forth in the regulation (21 CFR 101.60(c)(1)(i)-(iii)). Among other requirements, a food must be labeled as "low calorie" or "reduced calorie" or bear a relative claim of special dietary usefulness. However, a dietary supplement that is prohibited from bearing a "low calorie" or "reduced calorie" claim by 21 CFR 101.13(b)(5) and 101.60(a)(4) can still use a sugar-free claim provided it meets the "low calorie" requirement in 21 CFR 101.60(b)(2) (21 CFR 101.60(c)(1)(iii)).