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FDA's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels

Draft Guidance

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For questions regarding this draft document, contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2371.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

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Guidance for Industry[1]

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

This guidance addresses how conventional food and dietary supplement manufacturers should declare small amounts of nutrients and dietary ingredients on nutrition labels. It specifically explains how FDA intends to consider exercising enforcement discretion when a conflict occurs between compliance with § 101.9(c) and compliance with § 101.9(g) of Title 21 of the *Code of Federal Regulations* (21 CFR), such that compliance with both sections is not possible.

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

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

II. Background

FDA's regulations in 21 CFR 101.9 and 21 CFR 101.36 describe requirements for nutrition labeling in conventional foods and dietary supplements, respectively. The requirements for declaring the nutrient value in a serving of conventional food are in 21 CFR 101.9(c)(1)-(8). Certain dietary ingredients in dietary supplements are also required to be declared in accordance with these requirements (see 21 CFR 101.36(b)(2)(ii)). These dietary ingredients are listed in 21 CFR 101.36(b)(2) and are referred to as "(b)(2)-dietary ingredients." Unlike nutrients in conventional food, the (b)(2)-dietary ingredients can only be declared when they are present in dietary supplements in amounts that exceed the amount that can be declared as zero in nutrition labeling according to 21 CFR 101.9(c) (see 21 CFR 101.36(b)(2)(i)).

FDA's regulations under 21 CFR 101.9(g)(4) and (5) describe compliance requirements for declaring nutrients and dietary ingredients[2] in nutrition labeling. A conventional food or dietary supplement declaring the amount of a nutrient or dietary ingredient in its labeling is misbranded under section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(a)(1)] if:

- The nutrient content of the composite of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium is below 80 percent of the value for that nutrient declared on the label (21 CFR 101.9(g)(4)(ii)).[3]
- The nutrient content of the composite of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium is greater than 20 percent in excess for the value of that nutrient declared on the label (21 CFR 101.9(g)(5)).[4]

For the remainder of this document, we refer to 21 CFR 101.9(g)(4)(ii) and 21 CFR 101.9(g)(5) as "the compliance requirements."

III. Discussion

In many cases, the amount of a nutrient or (b)(2)-dietary ingredient declared in nutrition labeling in accordance with 21 CFR 101.9(c)(1)-(8) will not conflict with the compliance requirements. However, certain small amounts of nutrients or (b)(2)-dietary ingredients cannot be declared in accordance with both 21 CFR 101.9(c)(1)-(8) and the compliance requirements. In these cases, the amount declared in accordance with 21 CFR 101.9(c)(1)-(8) is below or above the level provided by the compliance requirements.

Example 1 shows when a conflict occurs between compliance with 21 CFR 101.9(c) and 21 CFR 101.9(g)(4)(ii). Under 21 CFR 101.9(c)(2)(iv), monounsaturated fat content must be expressed

[2] See 21 CFR 101.36(f)(1).
[3] Provided that no regulatory action will be based on a determination of a nutrient value that falls below this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved (21 CFR 101.9(g)(4)(ii)).
[4] Provided that no regulatory action will be based on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved (21 CFR 101.9(g)(5)).

to the nearest 0.5 gram increment below 5 grams. Therefore, if the analyzed value of monounsaturated fat is 0.75 to 1.00 grams, the amount of monounsaturated fat declared in accordance with this requirement is 1.00 gram (or 1g). This declared amount complies with 21 CFR 101.9(g)(4)(ii) if the analyzed value is 0.80 gram or greater. However, this declared amount would not comply with 21 CFR 101.9(g)(4)(ii) if the analyzed value of monounsaturated fat is 0.75 to 0.79 gram because values in this range are not at least equal to 80 percent of 1.00 gram.

Example 1 pertains to the analyzed nutrient values that are below 80 percent of the nutrient value declared on the label for the 21 CFR 101.9(g)(4)(ii) nutrients. Regarding analyzed nutrient values that are greater than the amount declared on the label, the regulations allow for reasonable excesses of nutrients, such as monounsaturated fat, within current good manufacturing practices in accordance with 21 CFR 101.9(g)(6).

Example 1: Monounsaturated fat (amount in grams)

Analyzed value of a nutrient is	Declared amount according to 21 CFR 101.9(c)(2)(iv)	Declared amount is in compliance with 21 CFR 101.9(g)(4)(ii) for analyzed values	Declared amount is not in compliance with 21 CFR 101.9(g)(4)(ii) for analyzed values
0.75–1.00	1.00	≥ 0.80	0.75–0.79

Example 2 shows when a conflict occurs between compliance with §§ 101.9(c) and 101.9(g)(5). Under 21 CFR 101.9(c)(2)(i), saturated fat must be expressed to the nearest 0.5 gram increment below 5 grams, unless the amount is less than 0.5 gram. Therefore, if the analyzed value of saturated fat is 0.50 to 0.74 gram, the amount of saturated fat declared in accordance with this requirement is 0.50 gram (0.5g). This declared amount complies with 21 CFR 101.9(g)(5) if the analyzed value is 0.50 to 0.60 gram. However, this declared amount would not comply with 21 CFR 101.9(g)(5) if the analyzed value of saturated fat is 0.61 to 0.74 gram because values in this range are greater than 20 percent in excess of 0.50 gram.

Furthermore, if the analyzed value of saturated fat is 1.00 to 1.24 grams, the amount of saturated fat declared in accordance with 21 CFR 101.9(c)(2)(i) is 1.00 gram (1g). This declared amount complies with 21 CFR 101.9(g)(5) if the analyzed value is 1.20 grams or less. However, this declared amount would not comply with 21 CFR 101.9(g)(5) if the analyzed value is 1.21 to 1.24 grams because values in this range are greater than 20 percent in excess of 1.00 gram.

Example 2 pertains to the analyzed nutrient values that are above 20 percent of the nutrient value declared on the label for the 21 CFR 101.9(g)(5) nutrients. Regarding analyzed nutrient values that are less than the amount declared on the label, the regulations allow for reasonable deficiencies of nutrients, such as saturated fat, within current good manufacturing practices in accordance with 21 CFR 101.9(g)(6).

Example 2: Saturated fat (amount in grams)

Analyzed value of a nutrient is	Declared amount according to 21 CFR 101.9(c)(2)(i)	Declared amount is in compliance with 21 CFR 101.9(g)(5) for analyzed values	Declared amount is not in compliance with 21 CFR 101.9(g)(5) for analyzed values
0.50–0.74	0.50	≤ 0.60	0.61–0.74
1.00-1.24	1.00	≤ 1.20	1.21–1.24

For certain nutrients, such as total fat and its components (including monounsaturated fat and saturated fat), if the serving contains less than 0.5 gram, the amount must be expressed as zero in nutrition labeling (21 CFR 101.9(c)). Unlike nutrients in conventional food, (b)(2)-dietary ingredients in dietary supplements must not be declared in nutrition labeling when the amount is zero (21 CFR 101.36(b)(2)(i)).

IV. FDA's Policy

As discussed, when the analyzed value of nutrients or (b)(2)-dietary ingredients present in small amounts is declared in nutrition labeling in accordance with 21 CFR 101.9(c)(1)-(8), the declared amount may conflict with the compliance requirements. In such cases, we intend to consider the use of our enforcement discretion with respect to the compliance requirements and recommend that manufacturers declare nutrients and (b)(2)-dietary ingredients in accordance with 21 CFR 101.9(c)(1)-(8).

FDA's nutrition labeling requirements in 21 CFR 101.9(c)(1)-(8) specify the increments and units of measure for declaring nutrient values. However, 21 CFR 101.9(g)(4)(ii) and (5) do not specify the increments and units of measure required for declaring nutrient values. Instead these provisions provide acceptable levels of variance for declared values. FDA considers it more practical and consistent for manufacturers to follow paragraph (c)(1)-(8) when a conflict occurs between 21 CFR 101.9(c)(1)-(8) and FDA's compliance requirements. This policy applies the same requirements to all products in a consistent way.

We will continue to consider the variability generally recognized for the analytical method used in the compliance requirements. We will also continue to consider the reasonable excesses and deficiencies of declared amounts acceptable within current good manufacturing practice (21 CFR 101.9(g)(6)).

We also are considering whether changes to our nutrition labeling regulations are needed to address this issue. If we determine that rulemaking is needed, we will consider whether to revise or withdraw the draft guidance.