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# FDA Letter: Sugar Free Claims

*Guidance document representing FDA's current thinking on sugar free claims.*

Dear Manufacturer:

The Food and Drug Administration (FDA) is concerned about the number of products we have seen that contain claims regarding the absence of sugar, such as *sugar free* but that fail to bear the required disclaimer statement when these foods are not *low* or *reduced in calories* or fail to bear the required disclaimer statement in the location or with the conspicuousness required by regulation. As part of our continuing effort to reduce the incidence of obesity in the United States, FDA wants to ensure that consumers are provided with the label information they need to make informed choices for maintaining a healthy diet. We are highlighting accurate claims about the absence of sugar as a regulatory priority. The agency intends to take appropriate action against products that we encounter that bear a claim about the absence of sugar (e.g., *sugar free*) but that fail to meet each of the requirements of the regulation that defines *sugar free*. We intend to pay particular attention to those foods that are required to bear a disclaimer statement under the regulation that defines *sugar free*, but that fail to do so or otherwise fail to comply with the regulation, 21 CFR 101.60(c). Therefore, we are taking this opportunity to remind food manufacturers and distributors of conventional food products that the definition of “sugar free” includes several requirements.

Under the authority of the Nutrition Labeling and Education Act of 1990, FDA issued regulations for the nutrient content claim *sugar free* 58 Federal Register (FR) 2302 at 2415. *Sugar free* is defined in Title 21 of the Code of Federal Regulations 101.60(c) (21 CFR 101.60(c)) as a claim that may be used on a food that contains less than 0.5 g of sugars, as defined in § 101.9(c)(6)(ii), per reference amount customarily consumed and per labeled serving (21 CFR 101.60(c)). For a food that meets the definition of a *meal* in 21 CFR 101.13(l) or *main dish* in 21 CFR 101.13(m), the food must contain less than 0.5 g of sugars per labeled serving. In addition, such foods may not contain any ingredient that is a sugar or that is generally understood by consumers to contain sugars, unless the listing of the ingredient in the ingredient statement is fol-

lowed by an asterisk that refers to the statement that appears below the list of ingredients, and that provides: *adds a trivial amount of sugar, adds a negligible amount of sugar, or adds a dietarily insignificant amount of sugar.*

FDA has historically taken the position that consumers may associate claims regarding the absence of sugar with weight control and with foods that are low calorie or that have been altered to reduce calories significantly. Therefore, the definition for *sugar free* includes the requirement that any food that is not low or reduced in calorie disclose that fact. Without such information some consumers might think the food was offered for weight control. See 56 FR 60421 at 60435. Consequently, the definition for *sugar free* includes the requirement that the food be labeled with the claim *low calorie* or *reduced calorie* or bear a relative claim of special dietary usefulness labeled in compliance with 21 CFR 101.60(b)(2), (b)(3), (b)(4), or (b)(5) or such claim is immediately accompanied, each time it is used, by one of the following disclaimer statements: *not a reduced calorie food, not a low calorie food, or not for weight control* (see 21 CFR 101.60(c)(1)(iii)). The disclaimer statement, when required, must accompany the claim each time it is used. In addition, the disclaimer statement is subject to the requirements of 21 CFR 101.2(c) and must appear prominently and conspicuously but in no case may the letters be less than one-sixteenth inch in height.

FDA encourages food manufacturers and distributors to review their labels and ensure that any food that bears a claim regarding the absence of sugar meet each of the requirements for that claim including the placement and conspicuousness of the disclaimer statement in 21 CFR 101.60(c)(1)(iii) when required. FDA will take appropriate action, consistent with our priorities and resources, when we find problems with the use of nutrient content claims regarding the absence of sugar in foods.

Sincerely,  
Barbara O. Schneeman, PhD  
Director, Office of Nutritional Products, Labeling, and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration