For nutrients that must appear on labels, content claims expressly or implicitly characterize the level of the nutrient present in the food item, and must be made in accordance with Food and Drug Administration (FDA) regulations.

FDA has never authorized nutrient content claims for total carbohydrates, and has sent warning letters to manufacturers of products bearing “low carb,” “reduced carb,” and “carb lite” labeling claims because they expressly characterize the level of carbohydrates. In addition, some manufacturers omit glycerin (glycerol), polydextrose, and sugar alcohols (polyols) — such as erythritol, isomalt, lactitol, maltitol, mannitol, sorbitol and xylitol — from the total carbohydrate declaration, even though the regulations state that the total carbohydrate content is to be calculated by subtraction of the sum of the crude protein, total fat, moisture and ash from the total weight of a product. FDA has cited manufacturers for violating nutrition labeling requirements by not including glycerin, polydextrose and sugar alcohols in the total carbohydrate declaration.

In response to FDA enforcement actions against products bearing express carbohydrate nutrient content claims, and products that do not count glycerin, polydextrose, and sugar alcohols as carbohydrates, there is a growing trend toward the use of “net carb,” “net effective carb,” “available carb,” “impact carb” and similar claims, directed at consumers monitoring their carbohydrate intake. These terms are not defined by FDA, but generally refer to carbohydrates that have a significant metabolic effect on the body, such as raising blood sugar and insulin levels. The quantity of “net/net effective/available/impact” carbs is obtained by subtracting the grams of fiber, sugar alcohols, glycerin and polydextrose from the total carbohydrates. The claims are based on the theory that controlling blood sugar and insulin levels may be more important for weight loss than controlling calories.

**Regulatory precedent**

There is regulatory precedent for making a distinction between carbohydrate types in connection with health claims. FDA discusses “fermentable” carbohydrates (dietary sugars and starches) in the regulation on making health claims about the relationship...
between sugar alcohols and dental caries. The quantity of fermentable carbohydrates is obtained by subtracting the grams of fiber, sugar alcohols and glycerin from the total carbohydrates.

FDA regulations also provide that a claim is not subject to nutrient content claim requirements if it does not in any way implicitly characterize the level of the nutrient in the food, and is not false or misleading in any respect. Thus, it is permissible to declare “10 grams of carbohydrates” but not “only 10 grams of carbohydrates” because “only” is deemed to characterize the level of carbohydrates in the food. One could argue that a statement of the quantities of different types of carbs in a product, based on metabolic effect, does not characterize the level of carbohydrates in general, and thus is outside the scope of the nutrient content claim requirements.

A counter view is that given the extensive publicity concerning low-carb versus low-fat diets, “net/net effective/available/impact” carb claims may be perceived by consumers as identifying low-carb products and are therefore implied low-carb claims. But even if carb claims are not considered to be nutrient content claims, they still could be challenged by FDA as false or misleading, on grounds including being confusing to consumers.

Even if carb claims are not considered to be nutrient content claims, they still could be challenged by FDA as false or misleading, on grounds including being confusing to consumers.

Although FDA has not yet taken a position on “net/net effective/available/impact” carb claims in general, the issue was discussed in a January 2003 letter from FDA regarding a petition by a manufacturer for approval of its brand name as an implied nutrient content claim for zero sugar or reduced sugar products. (The petition was denied by FDA.) The petitioner’s packaging included a Carbohydrates Facts box with net effective carb information. FDA denied the petition primarily on other grounds that the proposed brand name was misleading, but also noted that a reasonable consumer was likely to be confused by the numbers in the Carbohydrates Facts box — in conjunction with the brand name — and that the information about total carbohydrates listed in the Nutrition Facts box did not remedy the vagueness.

A BETTER BALANCE

At this time, the role of carbohydrates in weight control has not been conclusively established. However, in recent years courts have concluded that the commercial speech doctrine protects truthful and non-misleading claims about FDA-regulated products, and FDA has been striving to achieve a better balance between its obligations to protect public health and to protect First Amendment rights.

It appears that for now, FDA will assess “net/net effective/available/impact” carb claims in the context of the entire label, on a case-by-case basis, to determine whether the claims implicitly characterize the level of carbohydrates in the product, or whether they are false or misleading in any respect. Therefore, claims should be carefully fashioned to avoid raising public health issues that could be used to justify restricting commercial speech.

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