

BY ELECTRONIC MAIL

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 2004N-0463; Food Labeling, Prominence of Calories

Dear Sir or Madam:

We are writing with the following comments responsive to the Agency's Advance Notice of Proposed Rulemaking (ANPRM) referenced above. The Wm. Wrigley Jr. Company appreciates this opportunity to make its views known.

Chewing gum is a unique type of food in several respects. It is chewed for an extended period of time but not swallowed. The amount likely to be enjoyed each day by a typical consumer of sugar-free chewing gum delivers fewer than 10 calories. Consumers chew gum for its flavor, for its chewing enjoyment, and for other benefits it provides. The actual amount of energy (calories) attributable to a single piece of chewing gum may vary depending on the length of time the gum is chewed and the extent to which all carbohydrates are chewed out of the gum.

Sugar-free chewing gum is among the best available snack choices for consumers interested in reducing their caloric intake, which may help reduce or maintain body weight when coupled with daily exercise. This is because chewing gum is a low-calorie alternative to other forms of snacking and can help satisfy an urge to snack for an extended period of time. Sugar-free chewing gum is recognized by the American Dietetic Association and the American Diabetic Association as a "free food" which can be eaten whenever desired in weight management and diabetic diets.¹ Health professionals and wellness/fitness groups often recommend chewing gum to control nibbling while cooking or to avoid tempting situations for snacking on high calorie foods.²

FDA's current labeling regulations, however, inhibit the ability of chewing gum manufacturers to convey this information to consumers. Specifically, sugar-free chewing

¹ Exchange Lists for Weight Management, 2003 edition. Exchange lists for (diabetic) meal planning, 2003 edition.

² Shield, J. Weight Watchers Magazine, Nov/Dec 2004. Lakeshore Athletic Clubs. Weekly email to members, June 2, 2005.

gum is generally not eligible for a “low calorie” claim, and, in fact, sugar-free chewing gum must be labeled either with the disclaimer “not a low-calorie food” or a relative claim of special dietary usefulness, as required in the regulations. As FDA examines calorie declarations generally, the Wm. Wrigley Jr. Company urges the agency to consider changes in the nutrient content claim regulations that would allow for helpful and truthful label statements regarding the calorie content of sugar-free chewing gum.

Sugar-free chewing gum is generally formulated with intense sweeteners such as aspartame, sucralose, and acesulfame-K, and also sugar alcohols, such as sorbitol, xylitol, and isomalt. A single three-gram piece of sugar-free stick chewing gum is the Reference Amount Customarily Consumed (RACC) and contains approximately 5 calories. However, sugar-free chewing gum does not qualify as “low calorie” according to the criteria established in 21 C.F.R. 101.60(b)(2), and hence must either be labeled with the disclaimer “not a low calorie food” or it must bear a relative claim of special dietary usefulness, as set forth in §101.60(c) governing sugar content claims. This creates a strange and confusing situation to the consumer.

We respectfully submit that the consumer is not served by this information and is, in fact, misled by it. Survey data consistently demonstrate that among consumers who chew gum, the overall population mean consumption is less than two sticks per day. In the 13-17 year age group (who are the heaviest consumers of chewing gum), mean consumption is less than three sticks per day. This would contribute approximately 15 calories to an individual’s diet per day, which amounts to less than one percent of a 2000-calorie daily value. This should qualify as “low calorie” by any reasonable definition.

Sugar-free chewing gum cannot be labeled as low-calorie, however, because it contains more than 40 calories per 50 grams. (See criteria for low-calorie claims, 21 C.F.R. 101.60(b)(2)) We recognize the reasoning behind application of the calories-per-50-gram criteria. FDA would like to ensure that calorie-dense foods having small RACCs, such as sugar, butter and salad dressings, not be labeled as “low calorie.” This is sensible as a means of discouraging foreseeable over-consumption of these foods.

In the case of chewing gum, however, the calorie content of 50 grams is not at all relevant to foreseeable consumption patterns. At approximately three grams per stick, a consumer would need to chew 17 sticks of chewing gum in one day, or approximately one stick for every waking hour, to chew 50 grams. As noted previously, the estimated mean consumption among teens, the heaviest users of chewing gum, is less than three sticks a day.

Under these circumstances, it is confusing and misleading to consumers that sugar-free chewing gum must be labeled “not a low calorie food.” It is also contrary to the First Amendment to the United States Constitution that FDA’s labeling regulations (1) prohibit a truthful and non-misleading low-calorie claim on sugar-free chewing gum, and (2) go so far as to compel the use of the “not a low calorie food” disclaimer in some cases.

For these reasons, we ask FDA to consider amending the criteria for a low-calorie claim in §101.60 so that the calories-per-50-grams criterion is not applied to sugar-free chewing gum.

We would also like to take this opportunity to comment on other matters discussed in the ANPRM. Wrigley does not support the inclusion of a mandatory calorie content declaration on the principal display panel of packaged foods. Consumers should be able to refer to the familiar nutrition facts panel for all mandatory nutrition information. The best way to make the calorie declaration more prominent in the nutrition facts panel would be to have it provided in bold type. Wrigley does not support a larger type size for the calorie declaration or any other information in the nutrition facts panel because label space on many products, including chewing gum, is limited.

Along these lines, Wrigley agrees that the calories from fat declaration is not particularly useful to consumers and occupies valuable label space. As emphasized in the 2005 Dietary Guidelines, “when it comes to weight control, calories count – not the proportions of carbohydrate, fat, and protein in the diet.” Wrigley also does not support the inclusion of a percent daily value for calories. As emphasized in the 2005 Dietary Guidelines and in USDA’s new MyPyramid, one size does not fit all. There is not a single daily value for calories. Consumers should be encouraged to consider their own individual energy requirements, and valuable label space should not be devoted to a misleading statement in this regard.

Once again, the Wm. Wrigley Jr. Company appreciates this opportunity to make its views known. We would be pleased to answer any questions or contribute additional information or suggestions at any time.

Respectfully submitted,



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