

**BEFORE THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

**In the Matter of Obesity Working Group;
Public Workshop: Exploring the Link Between
Weight Management and Food Labels and Packaging
Docket No. 2003N-0338**

**Comments of the Staff of
the Bureau of Consumer Protection,
the Bureau of Economics,
and the Office of Policy Planning**

I. Introduction

Obesity is a growing public health problem, with steady and substantial increases in

¹ Food and Drug Administration Obesity Working Group; Public Meeting, 68 Fed. Reg. 58,117 (Oct. 8, 2003).

review of its food labeling regulations, policies, and practices, it consider:

- Reviewing certain serving sizes to make sure that they are accurate and evaluating whether serving size information is clear and prominent on the label.
- Allowing companies greater flexibility in making reduced calorie claims for foods.
- Permitting comparative claims between different types and portion sizes of food.
- Allowing health claims that relate reduced calorie consumption to a reduction in risk of obesity-related diseases.

The FTC staff encourages the FDA to consider revising its regulations to adopt these changes because they likely would aid consumers in identifying healthier, lower calorie foods and encourage food companies to develop and market such products. We also encourage the FDA to create, solicit, and analyze consumer research as part of its evaluation of the costs and benefits of any changes to the current food label that it may undertake.

II. FTC Experience

The FTC enforces the Federal Trade Commission Act,² which broadly prohibits unfair

² 15 U.S.C. § 45 *et seq.*

³ *Id.* The FTC and the FDA have shared jurisdiction to regulate the labeling, and promotion of foods, over-the-counter drugs, cosmetics, and medical devices. Under a long-standing liaison agreement between the agencies, the FDA exercises primary responsibility for regulating the labeling of these products, while the FTC has primary responsibility for ensuring that their advertising is truthful and not misleading. Working Agreement Between FTC and Food and Drug Administration, 4 Trade Reg. Rep. (CCH) ¶ 9,850.01 (1971).

health-related advertising claims to be one of its highest priorities and has acted in numerous cases involving deceptive health-related claims about foods.⁷ Through implementing its law enforcement mandate, the FTC has developed expertise in understanding the role of food advertising and labeling in providing information to consumers.⁸

The Commission's staff also has substantial experience in policy issues related to food advertising and labeling. The FTC staff, for example, has examined the effect of government regulation on market performance, including the performance in markets for foods. We

food labeling and have

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⁷ In 1994, the FTC issued an Enforcement Policy Statement on Food Advertising (May 1994), available at <<http://www.ftc.gov/bcp/policystmt/ad-food.htm#11>>.

⁸ See *Comments of the Staffs of the Bureau of Economics and Consumer Protection of the Federal Trade Commission in the Matters of Nutrition Labeling: Nutrient Content Claims: Health Claims; Ingredient Labeling Proposed Rules Before the Department of Health and Human Services Food and Drug Administration*, Docket Nos. 91N-0384, 84N-0153, 85N-0061, 91N-0098, 91N-0099, 91N-0094, 91N-0096, 91N-0095, 91N-0219 (1992).

⁹ See P. Ippolito & J. Pappalardo, *Advertising Nutrition & Health: Evidence from Food Advertising 1977-1997* (2002); P. Ippolito & A. Mathios, *Information and Advertising Policy: A Study of Fat and Cholesterol Consumption in the United States, 1977-1990* (1996); P. Ippolito & A. Mathios, *Health Claims in Advertising and Labeling: A Study of the Cereal Market* (1989); J. Calfee & J. Pappalardo, *How Should Health Claims for Foods Be Regulated? An Economic Perspective* (1989).

¹⁰ See *Comments of the Staff of the Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the Federal Trade Commission in the matter of Food Labeling: Trans Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements*, Docket No. 03N-0076 (Oct. 9, 2003), available at <<http://www.ftc.gov/os/2003/10/fdafattyacidscomment.pdf>>; *Comments of the Staff of the Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the Federal Trade Commission in the matter of Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims and Health Claims*, Docket No. 94P-0036 (Dec. 16, 2002), available at <<http://www.ftc.gov/be/v030003.htm>>; *Comments of the Staff of the Bureau of*

In addition to our work on food issues, the FTC staff has sought to assist overweight Americans through an aggressive program to prevent deceptive claims in advertising for weight loss products. Since 1990, the Commission has brought over one hundred law enforcement actions against those making deceptive claims in their advertising for weight loss products. Most of these cases involved dietary supplements. On December 9, 2003, the Commission staff issued a report recommending publication of guidance on scientifically infeasible claims for nonprescription weight-loss products.¹¹

III. Value of Health and Caloric Information to Consumers and Competition

As in other markets, truthful, non-misleading health information about foods can benefit consumers and competition. Such information empowers consumers to make better-informed choices about the health consequences of the foods they include in their diets. As health consequences become a more important consideration for consumers, food marketers have a powerful economic incentive to develop and market foods based on their nutritional attributes. These efforts, in turn, can provide consumers with even healthier products and more information about the health consequences of the foods they eat. An example of this beneficial cycle involved the dissemination of advertising and labeling in the 1980s

Economics and Consumer Protection of the Federal Trade Commission in the matter of Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims and Health Claims; Proposed Rule Before the Food and Drug Administration, Docket No. 94P-0036 (Apr. 17, 2000), available at <<http://www.ftc.gov/be/v000003.htm>>

¹¹ *Deception in Weight Loss Advertising Workshop: Seizing Opportunities and Building Partnerships to Stop Weight-Loss Fraud*, FTC Bureau of Consumer Protection Staff Report (2003), available at www.ftc.gov/os/2003/12/031209weightlossrpt.pdf. The report identifies seven specific weight loss claims that a panel of experts opined are scientifically infeasible. The report encourages industry, including the media, not to disseminate ads with these specific claims.

concerning the link between fiber in cereals and cancer risk. This information increased consumer awareness of the link between fiber and cancer risk, which increased demand for high fiber cereals, which, in turn, caused manufacturers to expand the range of high fiber cereals available to consumers in the market.¹²

Government education efforts are an important part of raising consumer awareness of the health consequences of foods. The FTC staff thus supports the FDA Obesity Working Group's consideration of expanding and improving consumer education as a means of highlighting the link between calories and obesity and its related diseases.

In addition, private efforts to disseminate health information on food labels and in food ads are an essential complement to government education efforts. Food ads may raise consumer awareness about the attributes and significance of the nutrients in particular foods and prompt consumers to examine the food label for more nutrition information.¹³ Food labels provide important information about the nature and effect of nutrients. Labeling information is critically important because consumers receive it close to their actual purchase decision concerning a particular product.¹⁴

¹² P. Ippolito & A. Mathios, *Health Claims in Advertising and Labeling: A Study of the Cereal Market*, FTC Bureau of Economics Staff Report (1989).

¹³ Consumer research suggests that consumers who know about diet-disease relationships or believe that diet is important for reducing disease risks are more likely to use nutrition labels. See, e.g., Marian L. Neuhouser *et al.*, *Use of Food Nutrition Labels Is Associated with Lower Fat Intake*, 99 J. Am. Diet. Assoc. 45 (Jan. 1999); Lisa R. Szykman *et al.*, *A Proposed Model of the Use of Package Claims and Nutrition Labels*, 16 J. Pub. Pol'y & Mktg. 228 (Fall 1997); Christine Moorman, *The Effects of Stimulus and Consumer Characteristics on the Utilization of Nutrition Information*, 17 J. Consum. Res. 362 (Dec. 1990).

¹⁴ According to a 1996 survey of 4,200 food shoppers, 70% of brand purchase decisions are made in the store, the point at which consumers are being directly exposed to label information. Point of Purchasing Advertising Institute, *1996 POPAI Consumer Buying Habits*

Government regulatory policies can affect the nature and extent of health information that consumers receive about food products. In 1990, Congress passed the Nutrition Labeling and Education Act (“NLEA”).¹⁵ The NLEA-based rules established standards that food

Study 8 (1996).

¹⁵ 21 U.S.C. § 343 *et seq.*

¹⁶ P. Ippolito & J. Pappalardo, *Advertising Nutrition & Health: Evidence from Food Advertising 1977-1997* (2002).

¹⁷ *Id.* at 52-53.

¹⁸ See 21 U.S.C. § 343(q)(1).

¹⁹ See 21 U.S.C. § 343(q)(1)(A)(i); see also 21 C.F.R. §101.9(b)(1) (“The term serving or serving size means an amount of food customarily consumed per eating occasion by persons 4 years of age or older which is expressed in a common household measure that is appropriate to the food.”). Unlike the serving sizes in the USDA’s Food Guide Pyramid, a serving size for purposes of FDA food labeling regulations does not represent an amount recommended for consumption. See *Food Labeling; Serving Sizes*, 58 Fed. Reg. 2229, 2232 (Jan. 6, 1993).

²⁰ See 21 C.F.R. §§ 101.9(b)(2); 101.12.

²¹ 21 C.F.R. § 101.12(h) permits FDA, on its own initiative, to propose amending reference amounts.

²² See generally Committee on the Nutrition Components of Food Labeling, Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, *Nutrition Labeling*:

Moreover, the FDA may want to consider whether the presentation of serving size information on the Nutrition Facts Panel is sufficiently clear and prominent. Serving size information on packages often is segregated from and in smaller type than the nutrient information, including calories per serving, on the Nutrition Facts Panel. This presentation of serving size information may not make clear to consumers that the calories and other nutrients listed are per serving and are based on a specified serving size. Revising the Nutrition Facts Panel to clarify and emphasize the link between serving sizes and nutrients might assist consumers in making better-informed dietary choices.

The FTC staff thus suggests that the FDA re-evaluate²⁹ the existing reference amounts to determine whether they continue to represent amounts that Americans customarily consume.³⁰ Staff also recommends that the FDA consider whether the presentation of serving size information on the Nutrition Facts Panel is sufficiently clear and prominent to inform

²⁹ At the public workshop on November 20, 2003, FDA officials expressed concern that a review of serving sizes for all foods would involve a substantial commitment of resources. Presentation of Christine Taylor, FDA, “Current FDA Food Labeling Policies” (Nov. 20, 2003). A less resource-intensive approach would be to solicit public comment about foods consumers are typically eating in portions greater than the current serving size. The FDA could use such comments to identify the foods whose serving sizes the agency should reexamine.

³⁰ Individually packaged foods are often consumed in one sitting but they are not considered to be a single serving. Labels for these foods may state the calories based on a single serving rather than calories in the entire package. For instance, a 20 oz. soft drink is often consumed in one sitting, yet its label might state that it has 2.5 servings and 100 calories per serving. Some consumers may not read the label carefully and mistakenly conclude that the number of calories in a serving (100) is the number of calories in the bottle (250) because most consumers drink the contents of the entire bottle at a sitting. Changing serving sizes to reflect more accurately the portion sizes that consumers actually eat may substantially reduce the prospect of such consumer confusion. If serving sizes are not changed, the FDA may want to consider requiring the labels of these foods to state both calories per serving and the total calories in the package.

consumers that the nutritional information provided is based on the specified serving size.

B. Comparative Claims

The FTC staff believes that consumers and competition would benefit if the FDA reconsidered some of its regulations, policies, and practices that may make it difficult for food marketers to make comparative claims relating to calories. Comparative claims confer substantial benefits on consumers. The Commission, after conducting an extensive economic analysis, has concluded that:

[c]omparative advertising, when truthful and non-deceptive, is a source of important information to consumers and assists them in making rational purchasing decisions. Comparative advertising encourages product improvement and innovation, and can lead to lower prices in the marketplace.³¹

The FTC staff believes that these conclusions also apply to the use on food labels of truthful, non-misleading comparative claims related to calories. Because of the importance of comparative claims related to caloric content, the FTC staff makes four specific recommendations concerning how the FDA could alter its food labeling regulations, policies, and practices to facilitate such claims.

1. Reduced/Fewer Calorie Comparisons

Current food labeling regulations limit “reduced calorie” and “fewer calories” claims to foods that meet a minimum calorie reduction of 25 percent compared to an appropriate reference food.³² In addition, such claims are prohibited for any food that is already low

³¹ FTC Policy Statement in Regard to Comparative Advertising, 16 C.F.R. § 14.15(b).

³² 21 C.F.R. § 101.60(b)(4).

³³ *Id.*

³⁴ See Food Labeling: Nutrient Content Claims, General Principles, 58 Fed. Reg. 2302, 2347-49 (Jan. 6, 1993). The preamble discussion of this issue also states a secondary goal of providing an incentive for manufacturers to produce meaningful changes in their foods' nutrient profiles. *Id.* at 2349. Finally, the preamble states that, because of product variability, it would be difficult to measure reliably reductions of 10% or less in calories or specific nutrients. *Id.*

³⁵ The cumulative benefits of small incremental changes in caloric intake may be

³⁶ In addition, the current regulation imposes different approaches to calorie reductions of equal nutritional significance. Claims involving an identical absolute reduction in calories may be prohibited or permitted based on small differences in the total caloric content of the reference food. Thus, a reduced calorie claim is permitted for a food that has 50 fewer calories as long as the reference food has no more than 200 calories, whereas a reduced calorie claim would be prohibited for the same 50-calorie reduction if the reference food contained 210

would allow more calorie comparisons in the marketplace and benefit consumers.³⁸

2. Comparison to Food of Different Portion Size

Obesity researchers suggest that one good approach to achieving a reduction in calories is by reducing portion sizes.³⁹ For example, one of the American Diabetes Association's primary recommendations for weight loss is to reduce portion sizes.⁴⁰ Comparative claims between foods with different portion sizes could help consumers reduce calories moderately. For example, a maker of frozen meals could say, "Instead of our competitor's 15 oz. chicken and rice casserole, try our 10 oz. chicken and rice casserole with 33 percent fewer calories."

The FDA nevertheless only allows comparative claims between foods based on a standard serving size or an ounce for ounce basis for main dishes and meals.⁴¹ If comparative claims were allowed across portion sizes of foods, it likely would encourage some firms to compete by offering healthier portion sizes. Accordingly, the FDA should consider allowing food marketers to make truthful, non-misleading label claims comparing foods of different portion sizes.

³⁸ Eliminating the 25% threshold would also give manufacturers more latitude to make useful comparisons of the overall nutrient profile of food products. For example, the current regulations would not allow the claim, "Our product now has 25% more fiber, 50% less fat and cholesterol, and 20% fewer calories." The FTC staff believes that allowing the advertiser to highlight the 20% calorie reduction in addition to the changes in other nutrients is beneficial. It informs consumers of all of the ways in which the improved product is better, rather than implying that it is better only on the specific nutrient differences that meet the 25 % threshold.

³⁹ See, e.g., J.O. Hill, H.R. Wyatt, G.W. Reed and J.C. Peters, "Obesity and the Environment: Where Do We Go from Here?," *Science*, Volume 299 (Feb. 7, 2003).

⁴⁰ www.diabetes.org/health/weightloss

⁴¹ 21 C.F.R. § 101.60(b).

⁴² 21 C.F.R. § 101.13, (j)(1)(i)(a).

⁴³ According to USDA nutrition data, a piece of cherry pie (one-eighth of a nine-inch pie) has 325 calories and 14 grams of fat while an 8 oz. carton of branded low-fat fruit

labeled and reference foods. Although the disclosures regarding the reference food, the percent change, and the absolute amounts of the nutrient in both foods may provide useful information to consumers, they may also be burdensome. Experience under these requirements appears to indicate that they may inhibit comparative claims and, in turn, deter development of healthier products.

For example, a baked potato chip may be lower in both calories and fat than a regular potato chip, but label claims explaining the benefits would be awkward to place (and read) on the front panel. Under current FDA rules, the claim would read as follows (italicized phrases may be placed on the back nutrition label):⁴⁴

Reduced fat and fewer calories than our Classic Potato Chips. Fat reduced by 85 percent, *from 10 grams per ounce to 1.5 grams per ounce*. Calories reduced by 27 percent, *from 150 calories per ounce to 110 calories per ounce*.

The primary advantage of the current disclosure rule is that nutrient levels are included on the front panel of the package so the consumer does not have to turn to the back panel for that information. The disadvantage is that the length of the disclosure may add to label clutter, which may make all the label information on the front panel less comprehensible to consumers, thereby decreasing the incentive of some firms to make these comparative claims. The FTC staff, therefore, recommends that the FDA consider whether all the information currently required is necessary to avoid consumers being misled by comparative claims or whether a shorter disclosure would be sufficient. The FTC staff also recommends that the FDA consider whether the costs of these disclosures under its current labeling regulations

⁴⁴ If sodium were also reduced by more than 25 %, the claim would be even more unwieldy; in this case sodium was only reduced by 17 %.

may unduly deter food marketers from making truthful, non-misleading comparative claims, including comparative calorie claims, on food labels.

C. Health Claims Linking Reduced Calorie Consumption to Reduction in Risk of Obesity-Related Diseases

Finally, the FTC staff believes that the FDA should consider allowing the label claim that reduced calorie intake is a way to reduce the risk of the many diseases associated with obesity, such as heart disease, diabetes, and cancer. The broad dissemination of this health claim would help educate consumers about the negative health consequences of being overweight or obese. Consumers who are more aware of these consequences might be more likely to choose lower calorie foods or to eat smaller portions of foods.

It is well established that reducing calories is an effective way to reduce the risk of diseases associated with being overweight or obese. The Surgeon General's 2001 report, for example, states that being overweight or obese increases the risk of several chronic diseases and other health conditions, including coronary heart disease, type 2 diabetes, endometrial cancer, colon cancer, breast cancer, osteoarthritis, asthma, and sleep apnea.⁴⁵

also cites healthful eating, including moderation in energy or calorie consumption, as an important factor in maintaining a healthy weight and overall health.⁴⁶

⁴⁵ *The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity (2001)* at 8-9. The many serious health risks of overweight and obesity were also reported in a 1998 report by the National Heart, Lung and Blood Institute and the National Institute of Diabetes and Digestive and Kidney Diseases. *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report* (NIH Sept. 1998) at 12. The NHLBI/NIDDK Report recognizes a low calorie diet as one effective method to achieve weight loss. *Id.* at 41-42.

⁴⁶ *Id.* at 1.

consumer awareness of the effects of being overweight or obese on overall health.⁴⁷

Given the strength of the science supporting the link between excess caloric consumption and obesity and its related diseases, the FTC staff believes that the FDA should consider allowing the use of labeling claims describing this relationship. The dissemination of such a claim would clearly further FDA's objectives of empowering consumers to make better dietary choices, a goal set forth in the agency's Consumer Health Information for BematIortuoritattann8.60

⁴⁷ *Id.* at 17.

⁴⁸ See *The Food and Drug Administration's Strategic Action Plan Protecting and Advancing America's Health: Responding to New Challenges and Opportunities* (FDA Aug. 2003).

⁴⁹ The FDA may want to consider either: (1) encouraging food marketers to convey this message as a dietary guidance statement that does not require agency approval, or (2) approving it as a health claim based on authoritative statements of a scientific body or an assessment of the underlying science.

⁵⁰ We would note that such a claim might mislead consumers if, for example, it was made on the label of a food that was high in calories or otherwise had a nutrient profile that might increase the risk of obesity or obesity-related diseases.

⁵¹ Of course, any such claim would have to be carefully worded to avoid the implication that one may eat unlimited amounts of the food and still reduce the risk of diseases associated with obesity.

policies, and practices to determine whether there are changes that could assist in the government's efforts to decrease the incidence of obesity and its related diseases among American consumers. We encourage the FDA to consider the possible changes discussed above to help consumers identify healthier, lower calorie foods and to encourage food companies to develop and market more of these foods. We also suggest that the FDA create, solicit, and analyze consumer research as part of its evaluation of the costs and benefits of any changes to the current food label.

Respectfully submitted,

J. Howard Beales, III, Director