UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

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

In the Matter of Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims and Health Claims; Proposed Rule

Docket No. 94P-0036

Comments of the Staff of the Bureaus of Economics and Consumer Protection of the Federal Trade Commission

April 17, 2000*

* These comments are the views of the staff of the Bureaus of Economics and Consumer Protection of the Federal Trade Commission. They do not necessarily represent the views of the Commission or any individual Commissioner. Inquiries regarding this comment should be directed to Janis Pappalardo (202) 326-3380, Bureau of Economics.

I. INTRODUCTION

The Food and Drug Administration (FDA) has requested comments on its proposed rule to govern trans fatty acid (trans fat) information in food labeling. The impetus for the proposed rule is the FDA's recent conclusion that trans fatty acids increase the risk of Coronary Heart Disease (CHD) by elevating harmful serum cholesterol levels.(1) Proposed changes include, among others: (1) mandatory trans fatty acid labeling on the Nutrition Facts panel of foods and dietary supplements that contain 0.05 or more grams of trans fat per serving; and (2) defining a "Trans Fat Free" descriptor that manufacturers can use in labeling their food.

In light of the Federal Trade Commission's (FTC) jurisdiction over claims made in advertising, the staff of the FTC's Bureaus of Economics and Consumer Protection submit its views on the proposed mandatory provision of trans fat content information on the Nutrition Facts Panel. The comment also discusses how broadening the scope of permissible trans fat information might further enhance the benefits of the proposed changes.

The FTC enforces sections 5 and 12 of the Federal Trade Commission Act, prohibiting deceptive or unfair practices in or affecting commerce. One of the FTC's primary responsibilities is to prevent false and misleading advertising.(2) The FTC considers the prevention of deceptive health-related advertising claims to be one of its highest priorities, and has taken action in numerous cases involving deceptive health-related claims about food products(3) and dietary supplements.(4) In implementing its mandate, the FTC has developed considerable expertise in understanding the role of advertising and labeling within the overall consumer information environment.(5)

II BACKGROUND INFORMATION

In 1993, the FDA issued final regulations on how nutrition labeling is to be provided on the foods that are regulated by the FDA.(6) These rules required the declaration of total fat and saturated fat on the Nutrition Facts Panel with the declaration of monounsaturated fat and polyunsaturated fat required only when claims are made about fatty acids and cholesterol. The FDA, at that time, believed it was premature to require the presence of trans fatty acid information on the Nutrition Facts Panel because of the lack of consensus on the dietary implications of trans fatty acid intake.

Since that time, the FDA has reviewed additional scientific evidence and has now concluded that recent controlled intervention and observational studies: ". . . consistently indicate that consumption of diets containing trans fatty acids, like diets containing saturated fats, results in increased serum LDL-C [low density lipoprotein cholesterol] compared with consumption of diets containing cis-monounsaturated or cis-polyunsaturated fat sources."(7) Thus, the FDA has proposed new rules governing the Nutrition Facts Panel, as well as subsidiary issues surrounding such information.

III.
TRANS FATTY ACID FACTS LABELING OPTIONS

A. FDA's Tentatively Preferred Facts Panel Option

FDA has considered five options to amend the Nutrition Facts Panel to include trans fatty acid information.(8) Its preferred option is to combine trans fatty acids with saturated fat, naming this combined value "Saturated Fat," and when trans fatty acids are present adding an asterisk to the Nutrition Facts label that refers to a footnote declaring "Contains _____ g trans fat." The basis for the FDA's preference is that saturated and trans fatty acids are similar in their effect upon cardiovascular health and, thus, should be combined into one category. A potential benefit of this approach is that consumers who already understand the potential risks of saturated fats would not necessarily have to be educated about the potential risks of trans fats.

B. Consumers Will Benefit If Trans Fats And Saturated Fats Are Listed Separately on Nutrition Facts Panels

In light of the FDA's conclusion that trans fats increase the risks of CHD, the Nutrition Facts Panel should be amended to include trans fatty acid information. Information is an important ingredient for preventive health,(9) and the Nutrition Facts Panel is a unique component of the total consumer nutrition information environment, which includes the media, reference books, doctors, and nutritionists. Without truthful content information, even those consumers most informed about diet and health would be unable to identify products that best meet their dietary goals. Accurate and truthful nutrition labeling also can help foster product improvements by delivering information to consumers on quality variables that they may not otherwise know about. More information can increase the demand for more healthful products, and provide the incentive for additional investments in research for healthful product innovations.(10)

The FDA may wish to list trans fats separately from saturated fats, rather than combined as favored by the FDA. This option is preferable for two reasons. First, as FDA recognizes, trans fats are chemically distinct from saturated fats, so listing them as a component of saturated fats is technically inaccurate and potentially confusing.(11) Separate saturated and trans fat categories would limit the Nutrition Facts Panel to objective, technically accurate information, and would help maintain and promote consumer confidence in its reliability.

Second, a separate listing would accommodate future scientific developments. Nutrition science is complex and scientific understanding of nutrition effects changes over time.(12) Combining saturated and trans fats might be of little practical significance if scientists were sure that both types of fats behave in exactly the same way. However, current evidence indicates that although there are similarities between some types of saturated fatty acids and some types of trans fatty acids, there also may be important distinctions.(13) Distinct fat categories will help to ensure that

any scientific debate arising over the relative effects of trans fats will take place outside of the context of the Facts Panel. Maintaining the descriptive nature of the panel should advance the Nutrition Fact Panel's credibility. In addition, the separate fat category option will likely minimize the need for future label changes.

The FDA has raised two concerns about separate trans and saturated fat listings that the FDA may wish to reconsider. First, the FDA has noted that consumer knowledge about trans fats is low. For example, the FDA's survey data indicates that almost 90% of consumers did not know how to interpret and use trans fatty acid information in 1995.(14) This survey evidence, however, reflects a period during which trans fatty acid labeling was prohibited. Consumer knowledge is likely to improve as trans fat dietary recommendations accumulate and labeling rules are relaxed. For example, the recent concern over trans fatty acids reflected in the Dietary Guidelines for Americans 2000 is likely to extend to other dietary recommendations and throughout the consumer information environment.(15) Consumer education efforts can also improve consumer knowledge about trans fats. In addition, once trans fatty acid information is required in food labeling, consumers are likely to become more aware of their potential health effects.

Second, the FDA has recognized that currently there are no explicit dietary recommendations for trans fatty acids, thus there is no basis for creating a Percent Daily Value (%DV) piece of information if a separate line is added to the Nutrition Facts label for trans fats.(16) This problem reflects the complex nature of nutrition science. As a point of comparison, however, we note that %DVs do not exist for polyunsaturated or monounsaturated fat. Yet, content information on these fatty acids is deemed important enough to merit separate lines on the nutrition panel.(17) Overall, although the FDA raises legitimate concerns about separate trans and saturated fat listings, a separate listing will likely enhance consumer understanding and consumer welfare more than a combined listing.

As a final comment on the Facts Panel, if the FDA wishes to combine ingredients based on their perceived health effects, it may wish to do so explicitly by devising a "Cholesterol Raising Fat Category," which would be relatively easy for consumers to understand. Such a normative categorization, however, would fundamentally change the nature of the nutrition label, and raises many issues beyond the scope of this proceeding.

IV.
CONSUMERS CAN BENEFIT FROM EXPLICIT TRANS FAT HEALTH CLAIMS

The FDA may wish to consider proposing a health claim that would inform consumers of the potential link between trans fatty acids and heart disease risks.(18) Evidence from the economics, marketing, and nutrition education literatures suggests that explicit health claims in labeling could help to improve consumer awareness and knowledge about the potential links between trans fats and heart disease.(19) Such motivating information appears critical if consumers are to adopt more healthful eating habits.(20)

Although explicit health information might be potentially misleading to some consumers, marketing research in experimental settings suggests that Nutrition Facts Panel information minimizes the likelihood of such deception. For example, researchers have found, at least in experimental settings, that consumers do not draw overly broad product inferences based on health claims, and that consumers appear to recognize that health claims do not provide all the information necessary to judge the healthfulness of products.(21) Findings from similar studies have led researchers to conclude that " . . . [i]f such results are shown to extend to more realistic in-store purchase settings, this suggests that a less restrictive approach to front package nutrient [and health] claims may be preferable if the claim can be verified by information in the Nutrition Facts panel and is presented in a truthful nonmisleading manner."(22) Other experimental research raises concerns that front panel claims can (1) deter consumers from reading Nutrition Fact Panels and (2) lead consumers to believe, incorrectly, that one beneficial health characteristic applies to other unrelated health dimensions.(23) Market data suggest, however, that periods of greater health claim usage are associated with more healthful fat consumption patterns.(24)

V.
CONSUMERS CAN BENEFIT FROM TRANS FAT DESCRIPTORS

The FDA proposes a new "Trans Fat Free" claim (and several synonyms) in the labeling of foods that contain less than 0.5 grams of trans fat and less than 0.5 grams of saturated fat per serving. The development of such a descriptor is likely to be valuable, because it can help consumers identify relatively healthful products more easily, and therefore enhance the benefits of providing Facts Panel information. The FDA also is proposing to allow for the synonymous use of the terms "trans fat" or "trans fatty acids."

The agency also may wish to reconsider authorizing a definition for "Reduced Trans Fat." Marketing flexibility is an important engine for more healthful product improvements and for competition among products on various product attributes. Thus, the FDA may wish to balance this objective with its reasoning that the use of the claim could detract from educational messages that emphasize saturated fatty acids.(25)

VI.
CONCLUSION

The FDA's initiative to conduct a thorough review of trans fat labeling will go a long way toward ensuring that truthful and non-misleading nutrient information can help to improve consumer welfare and market outcomes. Separate saturated and trans fat categories are likely to achieve the FDA's desired goal of non-deceptively informing consumers about trans fatty acids. In addition, consumer understanding and appreciation of trans fat content information is likely to be enhanced even further by defining additional descriptors, such as, "reduced trans fat" and by allowing health information about the likely link between trans fats and heart disease risks in food labeling.

Respectfully submitted,

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Endnotes:

1. 64 Fed. Reg. 62746, 62754 (Nov. 17, 1999) (Notice).

2. 15 U.S.C. §§ 45 et seq. The FTC and FDA have overlapping jurisdiction to regulate the advertising, 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).

3. *E.g., Conopco, Inc.*, C-3706 (Jan. 23, 1997) (consent); *Grey Advertising, Inc.*, C-3691 (Oct. 30, 1996 (consent), *The Dannon Co.*, C-3643 (Mar. 18, 1996) (consent and $150,000 in disgorgement); *Eggland's Best, Inc.*, C-3520

(Aug. 15, 1994)(consent); *Pompeian, Inc.*, C-3402 (Oct. 27, 1992)(consent); *Campbell Soup Co.*, D. 9223 (Aug. 18, 1992)(consent); *Bertolli U.S.A., Inc.*, C-3396 (Aug. 17, 1992)(consent).

4. E.g., Home Shopping Network, Civil Action No. 99-897-CIV-T-25C (April 15, 1999) (Complaint for Civil Penalties, Injunction, and Other Relief and Proposed Consent Decree); Amerfit, Inc., C-3747 (Jun. 16, 1997) (consent and $100,000 in disgorgement); KCD Inc., C-3752 (Jun. 16, 1997) (consent and $150,000 in consumer redress); Schering Corp., 118 F.T.C. 1030 (1994) (consent); U.S. v. General Nutrition, Inc., No. 94-686 (W.D. Pa. April 28, 1994)(stipulated permanent injunction and $2.4 million civil penalty); Miles, Inc., 114 F.T.C. 31 (1991)(consent); General Nutrition, Inc., 111 F.T.C. 387 (1989)(consent and $600,000 for research); FTC v. PharmTech Research, Inc., 576 F. Supp. 294 (D.D.C. 1983)(preliminary injunction), 103 F.T.C. 448 (1984)(consent).

5. Relevant prior comments regarding food labeling issues include: *Comments of the Staffs of the Bureaus 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). Relevant FTC staff research includes: Pauline M. Ippolito and Alan D. Mathios, *Information and Advertising Policy: A Study of Fat and Cholesterol Consumption in the United States*, 1977-1990 (1996); Pauline M. Ippolito and Alan D. Mathios, *Health Claims in Advertising and Labeling: A Study of the Cereal Market* (1989); John E. Calfee and Janis K. Pappalardo, *How Should Health Claims for Foods be Regulated? An Economic Perspective* (1989); and Michael Lynch et al., *Experimental Studies of Markets With Buyers Ignorant of Quality Before Purchase: When do 'Lemons' Drive Out High Quality Products* (1986).

6. 58 Fed. Reg. 2079 (Jan. 6, 1993).

7. Notice, 64 Fed. Reg. at 62753-62754.

8. Notice, 64 Fed. Reg. at 62754-62756. These options include: (1) combining trans fatty acids with saturated fat and identifying the total value as "Saturated Fat;" (2) combining trans fatty acids with saturated fat, naming this combined value "Saturated Fat," and when trans fatty acids are present adding an asterisk that refers to a footnote declaring "Contains _____ g trans fat;" (3) combining trans fatty acids with saturated fat and identifying the total value as "Saturated + Trans Fat;" (4) listing trans fatty acids separately under the saturated fat category; and (5) creating a "Saturated + Trans Fat" category with an explanatory footnote stating the individual amounts of saturated and trans fat.

9. *See, e.g.*, Lorna Aldrich ,*Consumer Use of Information: Implications for Food Policy*, Food and Rural Economics Division, ERS, U. S. D. A., Agricultural Handbook No. 715 (1999); Isobel Contento *et al., The Effectiveness of Nutrition Education and Implications for Nutrition Education Policy*, Programs, and Research: A Review of Research, 27 J. Nutr. Ed. 277 (Nov./Dec. 1995).

10. *See, e.g.*, Pauline M. Ippolito & Alan D. Mathios, *Health Claims in Advertising and Labeling, A Study of the Cereal Market*, Bureau of Economics Staff Report, Federal Trade Commission (1989); Christine Moorman, *Market-Level Effects of Information: Competitive Responses and Consumer Dynamics*, 35 J. Mktg. Res. 82 (Feb. 1998).

11. Notice 64 Fed. Reg. at 62749, 62755.

12. For example, scientific opinion about the health effects of trans fatty acids has shifted considerably during the past decade. During this time, there has been a series of studies suggesting that there is a relationship between trans fat and raised serum cholesterol levels. The FDA's most recent evidence generally indicates that the consumption of trans fatty acids increases serum LDL-C and that there is strong evidence of a relationship between the consumption of higher levels of trans fatty acids and increased risk of CHD. Notice, 64 Fed. Reg. at 62753.

13. For example, some scientists believe that some trans fats are actually more harmful than some saturated fats, a distinction that, if proven correct, may suggest that greater emphasis be placed on trans fatty acids than on saturated fats. *See* Alberto Ascherio *et al., Trans Fatty Acids and Coronary Heart Disease* , 40 New Eng. J. Med.: Sounding Board, 1994 (June 24, 1999).

14. Notice, 64 Fed. Reg. at 62755.

15. Dietary Guidelines for Americans, 32 (Feb. 7, 2000) <www.ars.usda.gov/dgac>. *See, also*, Sally Squires, *Proposed Diet Guidelines Urge Trimming Bad 'Fat'*, Wash. Post (Feb. 4, 2000) at A1.

16. Notice, 64 Fed. Reg. at 62757.

17. Under the FDA's preferred option, a specific %DV for trans fatty acids is not defined because it is combined with the %DV for saturated fats.

18. "Health claims" are statements used in labeling to describe the relationship between individual dietary components and a particular disease that the FDA must approve before they are used in labeling..

19. 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.*, Christine Moorman, *The Effects of Stimulus and Consumer Characteristics on the Utilization of Nutrition Information*, 17 J. Consum. Res. 362 (Dec. 1990); 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).

20. For example, Aldrich concludes: "Providing consumers diet-disease information -- how to reduce the risk of cancer and heart disease -- is likely to be more motivating than offering general information about healthful eating without identifying the benefits." (*See* Lorna Aldrich, *Consumer Use of Information: Implications for Food Policy*, Food and Rural Economics Division, ERS, U. S. D. A., Agricultural Handbook No. 715 at 18 (1999).)

21. Anu Mitra *et al., Can the Educationally Disadvantaged Interpret the FDA-Mandated Nutrition Facts Panel in the Presence of an Implied Health Claim*? 18 J. Pub. Pol'y. & Mktg. 106 (Spring 1999); and Gary T. Ford *et al., Can Consumers Interpret Nutrition Information in the Presence of a Health Claim? A Laboratory Investigation*, 15 J. Pub. Pol'y. & Mktg. 16 (Spring 1996).

22. See e.g., Scott B. Keller *et al., The Effects of Nutrition Package Claims, Nutrition Disclosures, and Motivation to Process Nutrition Information on Consumer Product Evaluations*, 16 J. Pub. Pol'y. & Mktg. 256 at 265 (Fall 1997); and Michael B. Mazis & Mary Anne Raymond, *Consumer Perceptions of Health Claims in Advertisements and on Food Labels*, 31 J. Consum. Aff.. 10 at 23 (Summer 1997).

23. Brian Roe *et al., The Impact of Health Claims on Consumer Search and Product Evaluation Outcomes: Results from FDA Experimental Data*, 18 J. Pub. Pol'y. & Mktg. 89 (Spring 1999).

24. Pauline M. Ippolito and Alan D. Mathios, *Information and Advertising Policy: A Study of Fat and Cholesterol Consumption in the United States*, 1977-1990, Federal Trade Commission (1996).

25. Notice, 64 Fed. Reg. at 62760.