Federal Trade Commission

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OFFICE OF THE SECRETARY

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FAX Number: 202-326-2496

Facsimile Transmittal Sheet

To:	Food and Drug Administration Fax number: (301) 827-6870	Total number of pages sent (including this cover sheet): 23
From:	Don Clark Telephone: (202) 326-2514	Sending Org Code: 0825 Date: 7/30/2004 Time: 3:45 a.m.
Subject:	Comment of FTC In Dockets Nos. 1994P-0390 and 1995P-0241	
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94P-0390 C66

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

In the Matter of
Request for Comments on Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims; Reopening of the Comment Period

Docket Nos. 1994P-0390 and 1995P-0241

Comments of the Staff of
the Bureau of Consumer Protection,
the Bureau of Economics,
and the Office of Policy Planning
of the Federal Trade Commission

July 27, 2004*

***These comments represent the views of the staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the Federal Trade Commission. They do not necessarily represent the views of the Federal Trade Commission or any individual Commissioner. The Commission has, however, voted to authorize the staff to submit these comments.**

I. Introduction

The Federal Trade Commission and the Food and Drug Administration (FDA) share the goals of helping consumers make informed dietary choices and of promoting competition among manufacturers to develop and market healthier food products. As part of its Consumer Health Information for Better Nutrition Initiative, the FDA recently reopened the comment period for its proposed rule concerning certain nutrient content and health claims in food labeling.[1] Among other things, the FDA is seeking comment on whether: (1) health claims should be permitted for some foods that do not meet the minimum nutrition contribution requirement; (2) health claims should be permitted with a disclosure about disqualifying nutrients rather than banned entirely based on the amount of these nutrients; and (3) nutrient content claims should be allowed with unapproved synonyms in lieu of FDA-defined terms.

Based on its experience in encouraging truthful and non-misleading information, including health claims, to consumers, the staff of the Federal Trade Commission's Bureau of Consumer Protection, Bureau of Economics, and Office of Policy Planning (FTC staff) recommends that the FDA:

- Allow health claims if a food meets a "nutrient density" standard[2] as an alternative to having a specified minimum amount of the nutrient. In addition, permit on a case-by-case basis health claims for foods that meet neither a minimum nutrient contribution requirement nor a nutrient density standard if such claims would inform consumers of healthier substitutes for foods in their diets.

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[1] 69 Fed. Reg. 24,541 (May 4, 2004).

[2] A nutrient density standard generally measures the beneficial nutrients in a food relative to its caloric content.

- If consumer research demonstrates that a health claim on a label for a food with a problematic nutrient leads consumers to take away an implied claim that the food is healthful in all respects, then the FDA should consider mandating the use of disclosures to address any such implied claim consistent with the results of consumer research on ways to provide qualifying information that prevents consumers from being misled.
- Allow the use of truthful, non-misleading synonyms for FDA-defined terms in nutrient content claims.

The FTC staff encourages the FDA to consider revising its regulations to adopt these changes, because they likely would aid consumers in making better-informed purchasing decisions about foods and encourage food companies to develop and market healthier foods. Helping consumers to select foods that make a healthful contribution to overall diets would aid in addressing the national obesity problem. We also encourage the FDA to continue to create, solicit, and analyze consumer research as part of its evaluation of the costs and benefits of changes to its food labeling regulations.

II. FTC Experience

The FTC enforces Section 5 of the Federal Trade Commission Act (FTC Act), which broadly prohibits "unfair or deceptive acts or practices in or affecting commerce."[3] In addition, Section 12 of the FTC Act more specifically prohibits the dissemination of false advertisements for foods, drugs, devices, services, or cosmetics.[4] Essentially, the FTC's mission is to protect

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[3] 15 U.S.C. § 45.

[4] 15 U.S.C. § 52. The FDA and the FTC generally share jurisdiction over prescription drug advertising, although the FDA exercises primary responsibility for such advertising pursuant to a memorandum of understanding between the two agencies. Working Agreement Between FTC and Food and Drug Administration, 4 Trade Reg. Rep. (CCH) ¶ 9,851

consumer sovereignty by addressing practices that impede consumers' ability to exercise informed choice in the marketplace.

One of the FTC's primary responsibilities is to bring law enforcement actions against deceptive practices in national advertising. The FTC considers the prevention of deceptive health-related advertising claims to be a high priority. The Commission has taken action against numerous deceptive health-related claims for foods, drugs, dietary supplements, and medical devices. Through these law enforcement activities and through research conducted in support of its mission, the FTC has developed expertise in analyzing the role of advertising in conveying health-related information to consumers.

In addition to its law enforcement experience, the FTC staff also has examined the effect of government regulation on the health-related information that consumers receive.[5] Food labels can provide valuable 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.[6] We welcome this opportunity to provide views on some of the food labeling issues on which the FDA is seeking public comment.

(1971).

[5] *See, e.g.*, 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); J. Calfee & J. Pappalardo, *How Should Health Claims for Foods Be Regulated? An Economic Perspective* (1989); A. Masson & R. Steiner, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* (1985).

[6] 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 directly exposed to label information. Point of Purchasing Advertising Institute, *1996 POPAI Consumer Buying Habits Study* 8 (1996).

III. Minimum Nutrient Contribution Requirement

A. Background

Under FDA regulations, a health claim is a representation describing the relationship between a substance or nutrient and a disease or health-related condition.[7] For instance, a food marketer could state "diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors" on the label of an appropriate low sodium food.[8] Another example is that a food marketer could state "development of cancer depends on many factors. A diet low in total fat may reduce the risk of certain cancers" on the label of an appropriate low fat food.[9]

The FDA, however, prohibits marketers from making a health claim on a food label unless the food contains a meaningful amount of an important nutrient. Specifically, a marketer can make a health claim for a food only if, prior to fortification,[10] it contains 10 percent or more of the reference daily intake (RDI) or daily value (DV) for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed (RACC).[11] The "minimum nutrient

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[7] 21 C.F.R. § 101.14(a)(1).

[8] 21 C.F.R. § 101.74(e).

[9] 21 C.F.R. § 101.73(e).

[10] If food marketers could meet the minimum nutrient contribution requirement through fortification, it would give them an incentive to fortify foods just to make health claims. Because excessive amounts of some of these nutrients in the diet may create health risks, the FDA did not want to encourage food marketers to over-fortify the United States's food supply. 60 Fed. Reg. 66,206 at 66,212.

[11] 21 C.F.R. § 101.14(e)(6). The DV or DRV for a nutrient is the daily recommended amount of that nutrient a person should eat in a day, calculated based on a 2000-calorie diet. 21 C.F.R. §§ 101.9(c)(7)(iii) and (c)(9) . Similarly, the RDI for a vitamin or mineral is the recommended amount of these substances that a person should eat in a day, calculated

contribution requirement"[12] was an attempt to limit health claims to only so-called "healthy foods," which the original regulations define as foods that contain a significant amount of one of these important nutrients.[13]

FDA found, however, that the minimum nutrient contribution requirement may have had the unintended effect of barring health claims for some foods that could help consumers maintain a balanced and healthful diet.[14] Many fruits and vegetables, as well as certain whole grain products, did not satisfy the standard despite making a healthful contribution to the overall diet. The minimum nutrient contribution requirement, for example, generally precludes the FDA from approving health claims for canned vegetables with no salt added, peaches in light syrup, as well as frozen vegetables in sauce.

Recognizing that its minimum contribution requirement could preclude health claims for some foods that can significantly contribute to a healthy diet, the FDA proposed to exempt certain specific types of foods from the minimum nutrient contribution requirement. In 1995, the agency proposed amending its regulations to exempt: (1) fruit and vegetable products composed solely of fruits and vegetables; (2) whole grain products that conform to a standard of identity; and (3) bread that conforms to a standard of identity[15] for enriched bread, but contains whole

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based on a 2000-calorie diet. 21 C.F.R.. §§ 101.9(c)(8)(i) through (iv). The RACC is an FDA-specified quantity of food customarily consumed that is used to determine serving size. 21 C.F.R. §§ 101.9(b)(2) and 101.12(b) .

[12] 69 Fed. Reg. at 24,543.

[13] *Id.*, *citing* 60 Fed. Reg. 66,206 at 66,213.

[14] *Id.*, *citing* 60 Fed. Reg. 66,206 at 66,212.

[15] A standard of identity defines the criteria that must be met for a food to be described as a particular food, its name, and the ingredients that must be used, or may be used, in

grain products not permitted under that standard.[16] Some of these products, including frozen or canned fruits and vegetables with the same nutritional profile as raw fruits and vegetables, currently may be labeled with certain health claims under subsequent FDA regulations defining those health claims. Even with such an exemption, the minimum nutrient contribution requirement would continue to prevent health claims for some foods that can contribute to a healthy diet. These include fruit and vegetable products with added oils, sodium, sauces, syrups, or other ingredients, as well as breakfast cereals and other foods with high grain content.[17] Accordingly, the FDA requested comment in 1995 as to whether it should modify its regulations to exempt these additional types of products from the minimum nutrient contribution requirement.[18]

B. Proposed Alternative Nutrient Density Approach

The FDA now seeks comment on whether it should use an alternative nutrient density approach that would also allow health claims for more foods that do not meet the minimum nutrient contribution requirement.[19] Specifically, the FDA now proposes the following nutrient density standard: health claims could be approved if the percentage of the DV or RDI of vitamin C, vitamin A, calcium, iron, protein, or fiber per RACC in a food is equal to or greater than its

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the manufacture of the food. *See* 21 U.S.C. § 341; 21 C.F.R. § 130.3; *see also* 21 C.F.R. 136.115 (standard of identity for enriched bread).

[16] 60 Fed. Reg. at 60,214.

[17] 69 Fed. Reg. at 24,543, *citing* 60 Fed. Reg. at 66,214.

[18] *Id.*

[19] The language that the FDA would permit to be used in a particular health claim would be identical regardless of whether the food was eligible for that claim under a minimum nutrient contribution standard or a nutrient density standard.

percent caloric contribution per RACC, based on a 2,000-calorie per day diet.[20] For instance, the FDA could approve a health claim for a food that has 100 calories per serving and 8% of one's daily amount of Vitamin C, because the food accounts for a greater proportion (8%) of the daily requirement of Vitamin C than it does for the total daily amount of calories (5%).

The FTC staff supports a nutrient density standard as an alternative means of satisfying the minimum nutrient contribution requirement. Food marketers would no longer be precluded from providing information on how many processed fruits and vegetables can be used to improve the healthfulness of consumer diets. Frozen vegetables in some sauces or canned fruit in light syrup, for example, can contribute to a healthier diet, and a nutrient density standard would permit health claims for many of these relatively nutrient-rich foods.[21] On the other hand, a nutrient density standard would continue to prohibit health claims for relatively nutrient-poor foods, such as candy or soft drinks.[22]

Moreover, a nutrient density standard would permit some health claims that promote substitution to healthier foods. Many low-fat or fat-free products may be beneficial if consumers substitute them for similar products that are higher in fat and calories. The minimum nutrient contribution requirement, however, would preclude health claims for some of these low-fat or

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[20] 69 Fed. Reg. at 24,543.

[21] For example, a serving of canned peaches in light syrup has 3% of the calories, 6% of the Vitamin A, and 8% of the Vitamin C recommended per day. A health claim for these canned peaches might be "You know reducing saturated fat in your diet is important to heart health. Instead of peach pie for dessert, try Brand X's delicious cling peaches in light syrup. Delicious and heart healthy, too."

[22] A serving of jelly beans, for instance, contributes about 7.5% of the calories in a 2,000 calorie per day diet, but provides none of the six nutrients used to measure nutritional value.

fat-free foods, because they have less than 10% of any important nutrient. By contrast, a nutrient density standard in many cases would allow such health claims.

The FTC staff believes that adopting a nutrient density standard as an alternative in addition to the minimum nutrient contribution requirement would result in consumers' receiving information that can assist them in making better-informed dietary decisions. The Commission staff therefore concludes that adopting such a standard would be useful.

C. Case-by-Case Allowance of Health Claims

The FTC staff believes that the FDA should allow health claims, on a case-by-case basis, for products that would meet neither the minimum contribution requirement nor a nutrient density standard if the FDA determines the information can help consumers construct better diets. The diets of consumers are composed of a variety of different foods, with consumers making numerous decisions as to what foods to include or not include in their diets. Consumers often make choices as to whether to substitute one food for another in their diet. To enable consumers to make such substitutions, it is critical that they receive information as to the relative attributes and health consequences of consuming different foods. Such information empowers consumers to replace some of the foods in their diet with healthier alternatives, including lower calorie options.

The FTC staff thus encourages the FDA to consider allowing health claims for foods that would not be eligible to make such claims if it would provide consumers with information that would assist them in including more healthy foods in their diets. For example, many fat-free,

lower-calorie salad dressings would not be eligible for an obesity-related health claim[23] based on either a minimum contribution requirement or a nutrient density standard. Nonetheless, consumers could be encouraged to substitute a fat-free, lower-calorie salad dressing for a regular salad dressing if the FDA were to allow an obesity-related health claim on the label for the fat-free, lower-calorie salad dressing. Permitting truthful, non-misleading health claims in such circumstances may encourage food marketers to develop and market healthier foods to consumers.

D. Recommendation

In summary, the FTC staff supports the FDA's proposal to use a nutrient density standard as an additional alternative to a minimum nutrient contribution requirement, so that consumers can receive truthful and non-misleading health information about more foods.[24] In addition, the FTC staff recommends that the FDA adopt a rule stating that it will approve health claims for foods that do not meet either the minimum nutrient contribution requirement or a nutrient density standard if the FDA determines these claims would provide consumers with truthful, non-

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[23] In a prior comment, the FTC staff suggested that the FDA consider approving or allowing a health claim linking calories, obesity, and obesity-related diseases. *See* Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the Federal Trade Commission 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*, Dkt. No. 2003N-0338 (Dec. 12, 2003) ("Obesity Comment"). If the FDA approves an obesity-related health claim, it will specify at that time the language that can be used in the claim.

[24] Foods that contain small amounts of vitamins or fiber but are not considered good sources of such nutrients under the minimum nutrient contribution requirement may contribute significant amounts of such vitamins or fibers to an individual's diet if these foods are eaten often. It may be useful in the future for the FDA to evaluate what types of health claims are made under the proposed nutrient density standard and whether such claims are helping consumers to choose healthier diets.

misleading information that would assist them in selecting healthier foods.

IV. Use of Disclosures Rather Than Disqualifying Amounts

A. Current Disqualifying Amounts Standard

As discussed above, the FDA permits health claims for foods that describe the relationship between a substance or nutrient in a food and a particular disease or health condition. If a food contains a nutrient or substance that reduces the risk of a particular disease or health condition, the FDA generally will allow a health claim for that food. The FDA, however, will not permit a health claim for a food that has other problematic nutrients in two circumstances.

First, the FDA will not allow a health claim if the net health effect of a food is not a reduction in the risk of a particular disease. Food marketers, for example, generally can make the claim that foods high in calcium may lower one's risk of osteoporosis. Nevertheless, a health claim for such a food is not permitted if the food contains more phosphorous than calcium on a weight-per-weight basis,[25] because phosphorous may affect the osteoporosis-risk reduction benefits of the calcium.

Second, even if the net health effect of the nutrients in a food is a reduction in the risk of a particular disease or health condition, the FDA will not permit a health claim if the food contains more than the prescribed amount of certain problematic nutrients. Specifically, a food marketer generally cannot make health claims for a food that contains more than 13 g fat, 4 g saturated fat, 60 mg cholesterol, or 480 mg of sodium per serving or reference amount

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[25] 21 C.F.R. § 101.72(c)(2)(ii).

customarily consumed.[26] Even though these problematic nutrients do not necessarily obviate the reduction in the risk of the specific disease or health condition that would be the subject of the health claim, the FDA has used these "disqualifying levels" to preclude health claims because these other nutrients create an increased risk of other diseases in the general population.[27]

Among other things, the FDA requests comment on whether a disclosure of disqualifying nutrients in connection with a health claim would be preferable to prohibiting health claims entirely based on the presence of these nutrients.[28] The FDA also requests comment and seeks scientific and consumer research on the effectiveness of such disclosures (through appropriate referral statements) in assisting consumers to construct healthy diets.[29] FTC staff address these two issues below.

B. Implied Claims About Problematic Nutrients from Health Claim on Label

An initial question for the FDA to address is what, if any, implied claims consumers take away from a health claim on the label of a food that contains a problematic nutrient that exceeds the disqualifying amount of that nutrient. For example, assume that a marketer of a food high in calcium and sodium makes the health claim on the food label that "foods rich in calcium reduce one's risk of osteoporosis." If consumers take away from this health claim an implied claim that

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[26] 21 C.F.R. § 101.14(a)(4).

[27] 58 Fed. Reg. 2,489 (1993) (Statement of Basis and Purpose).

[28] In 1995, the FDA rejected a proposal to allow health claims for foods that exceed the disqualifying levels so long as the presence of problematic nutrient amounts are disclosed. 69 Fed. Reg. at 24,544.

[29] In particular, the FDA seeks comments on a health claim on the principal display panel that is accompanied by a statement referring consumers to the Nutrition Facts Panel for more information about a problematic nutrient.

the food is healthy in all respects (including its sodium content), then a disclosure may be needed to prevent this implied claim from misleading consumers. If consumers do not take away such an implied claim, then no disclosure is needed to prevent consumers from being misled.

The FTC's Policy Statement on Food Advertising recognizes that there may be circumstances in which consumers take away an implied claim about a problematic nutrient from a health claim in an advertisement, and, therefore, the marketers making such a claim must disclose information about the nutrient in the ad to prevent deception.[30] First, if a food marketer makes a health claim and a problematic nutrient is "closely related to the subject health claim," consumers might take away the misleading impression from the ad that the food "does not present any related health risks" unless the food marketer also discloses the "presence and significance" of the problematic nutrient.[31] For instance, a claim in an advertisement that a food low in saturated fat and trans fat will reduce one's risk of heart disease would be deceptive if the food marketer failed to disclose that the food contained so much sodium that it might increase the risk of heart disease.

Second, even if a problematic nutrient "does not bear directly on the health condition that is the subject of the health claim," in some contexts consumers might take away the misleading impression that "the food is healthful in all respects."[32] In such cases, the food marketer "may need to include a disclosure that conveys the presence and significance" of the problematic

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[30] *See* Federal Trade Commission, *Enforcement Policy Statement on Food Advertising* at 21-23 (May 1994) ("Policy Statement on Food Advertising").

[31] Policy Statement on Food Advertising at 22.

[32] *Id.* at 23.

nutrient. For example, a food marketer's claim that a food high in calcium would reduce the risk of osteoporosis might create the impression that the advertised food does not create an increased risk of other diseases or health conditions. If so, and the food increases the risk of cardiovascular disease because it is high in saturated fat, the food marketer would have to disclose the presence and significance of the saturated fat to prevent deception.

The FTC staff has not tested in what contexts, if any, consumers take away an implied claim that a food is healthful in all respects from health claims on *labels* of foods with a problematic nutrient.[33] We therefore recommend that the FDA consider conducting consumer research to determine in what contexts consumers take away such an implied claim. In the absence of such an implied claim, as discussed above, there is no need for the FDA to mandate a disclosure on the label about a problematic nutrient to prevent deception.[34]

C. Preference for Disclosure Over Outright Ban of Health Claims

If consumer research does not demonstrate an implied claim, as discussed above, there is no need for the FDA to mandate a disclosure on the label about a problematic nutrient to prevent deception. If consumer research shows that a health claim on a label for a food with a

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[33] In the context of advertising, an FTC Staff study using experimental techniques did not find significant evidence that the use of health claims in ads raised consumer perceptions of the overall healthiness of the advertised food or inappropriately shaped consumers' assessments of problematic nutrients, compared to their perceptions based on nutrient content claims alone or a control ad with no nutrition-related claim. *See* D. Murphy, *et al.*, *Generic Copy Test of Food Health Claims in Advertising, Joint Staff Report of the Bureaus of Economics and Consumer Protection*, Federal Trade Commission 21-25 (1998).

[34] This comment does not address other reasons that the FDA may decide to require a disclosure, such as to encourage consumers to eat healthier foods or help them construct healthier diets. The comment also does not address whether such disclosures would survive a First Amendment challenge.

problematic nutrient leads consumers to take away the implied claim that the food is healthful in all respects, there are two possible alternatives. One alternative is for the FDA to impose an outright ban on the health claim. The other alternative is to require an appropriate disclosure. FTC staff believes that the FDA should consider mandating the use of disclosures consistent with the results of consumer research on ways to provide information that qualifies any such implied claims to prevent consumers from being misled.

Allowing health claims with an appropriate disclosure of problematic nutrients – instead of an outright prohibition on health claims based on the presence of those nutrients – is consistent with First Amendment jurisprudence. The First Amendment embodies a "preference for disclosure over outright suppression" as the method of advancing the government's substantial interest in preventing false or misleading commercial speech.[35] The government "disregard[s] a far less restrictive means" of advancing its interest "where it chooses a policy of suppression over disclosure -- at least where there is no showing that disclosure would not suffice to cure misleadingness."[36] Thus, the First Amendment likely precludes the FDA from banning health claims for foods that exceed disqualifying amounts of nutrients unless disclosures about these nutrients would not be effective in preventing deception.[37]

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[35] *Pearson v. Shalala*, 164 F.3d 650, 656 (D.C. Cir. 1999); *see also Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002).

[36] *Pearson*, 164 F.3d at 658; *see Thompson v. Western States Medical Center*, 535 U.S. 357, 358 (2002) (government bans on commercial speech are more extensive than necessary if the government "could have achieved its interests in a manner that does not restrict speech or that restricts less speech.")

[37] The First Amendment requires the FDA to demonstrate that an outright ban on health claims for foods with problematic nutrients is not more extensive than necessary in order to prevent deception, if that is the underlying basis for its ban. *See Western States Medical Center* at 358 (government bans on commercial speech are more extensive than necessary if the

Allowing health claims with disclosures related to problematic nutrients to prevent deception also is consistent with the conclusion that the free flow of truthful and non-misleading nutrition and health information is critical to consumers and competition.[38] For instance, a food marketer may want to make a comparative health claim for a cooking oil that is low in saturated fat. The claim might, for example, inform consumers of the heart-health benefits that could be achieved by using the oil instead of butter, margarine, or other cooking oils that are higher in saturated fat. Because the cooking oil would exceed disqualifying levels for total fat, such a heart-health claim currently would be prohibited. If consumers would take away from this heart-health claim on the label the impression that the oil does not contain a problematic amount of fat, a disclosure related to its fat content would be needed to prevent consumers from being misled.[39] FTC staff believes it is preferable to allow food marketers to provide consumers with information about the heart-health benefits of choosing an oil with less saturated fat (with an adequate

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government "could have achieved its interests in a manner that does not restrict speech or that restricts less speech."); *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980); *see, e.g., Pearson*, 164 F. 3d at 660-61 ("While we are skeptical that the government could demonstrate with empirical evidence that disclaimers . . . would bewilder consumers and fail to correct for deceptiveness, we do not rule out that possibility."); *Whitaker*, 248 F. Supp. 2d at 9 ("In this case, the Government has not satisfied its burden - - there is no evidence that the proposed [anti-oxidant] health claim, if accompanied by a disclaimer, would be deceptive or unlawful.").

[38] *See, e.g.*, Obesity Comment at 6-8, *supra* note 23; *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 Request for Comment on First Amendment Issues*, Dkt. No. 02N-0209 (2002).

[39] Of course, as discussed below, it is important to craft such a disclosure with care to ensure that it is effectively communicated.

disclosure to correct any misimpression as needed), rather than simply prohibiting such claims altogether.[40]

D. Effectiveness of Disclosures

Any disclosures about problematic nutrients that the FDA requires on the food label must be sufficiently clear and prominent to convey qualifying information. To be effective, they must be both *noticed* and *understood* by consumers. The FTC has provided guidance on what constitutes a clear and prominent disclosure, focusing on specific elements such as clarity of language, relative type size and proximity to the claim being qualified, and an absence of contrary claims, inconsistent statements, or other distracting elements.[41] Disclosures do not always work. Accurate information in the text may not remedy a false headline; fine print written disclosures may be insufficient to correct a misleading representation; other practices may direct attention away from the qualifying disclosures; and *pro forma* statements or disclaimers may not cure otherwise deceptive messages or practices.[42]

Although the Commission generally favors disclosures over banning claims as a means of curing deception, disclosures must be crafted with care. The FTC staff has examined the efficacy of disclosures in food advertising to qualify nutrient and health claims. A 1998 report on a generic copy test of various food and dietary supplement advertising claims reveals the

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[40] In 1990 more than 40 percent of advertising for fats and oils included a heart-related claim as firms competed to attract consumers to fats with a better fat profile. By 1997, after the NLEA rules were in place with the disqualifying level approach, the health reasons to choose one fat over another had been completely eliminated from advertising. *See* Ippolito and Pappalardo, *supra* n. 5 at 152.

[41] *Deception Policy Statement, appended to Cliffdale Assocs., Inc.*, 103 F.T.C. 110, 176 n.7 (1984)

[42] *Id.*

challenges associated with crafting disclosures that accurately convey the intended message to consumers. The test results suggest that consumers may misconstrue some qualifying disclosures about problematic nutrients to be part of the seller's promotional message, thereby reinforcing rather than limiting the claim. On the other hand, explicit disclosures concerning the presence and significance of a problematic nutrient were less likely to be misinterpreted.[43] The results of this report underscore the importance of consumer research on disclosures to determine whether consumers take an accurate net impression from proposed qualifying language.

The FDA proposes that a health claim on the principal display panel of the food label be accompanied by a statement referring consumers to the Nutrition Facts Panel elsewhere on the food label for more information about a problematic nutrient. The purpose of the Nutrient Facts Panel is to provide consumers with information about the nutrients in foods, so that they can make better informed choices as to which foods to include in their diet.[44] Allowing the use of such a referral statement would be consistent with the FDA's current requirement that nutrient content claims for a food with a problematic ingredient be accompanied by a similar referral

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[43] *See* Murphy *et al.*, *Generic Copy Test of Food Health Claims in Advertising*, *supra* n. 33 at 21-25.

[44] As research has demonstrated, consumers can use the nutrition information on the Nutrition Facts Panel to determine and select healthier foods for their diets. *See, e.g.*, B. Derby and A. S. Levy, *Do Food Labels Work? Gauging the Effectiveness of Food Labels Pre- and Post-NLEA*, in *Handbook of Marketing & Society*, Paul N. Bloom and Gregory T. Gundlach, (eds.) (2000); A.S. Levy, S. Fein & R. Schucker, *Performance Characteristics of Seven Nutrition Label Formats*, 15 J. Pub. Pol'y & Mktg. 1 (1996).

statement.[45] Consumer research would be useful to determine whether referral statements are effective in the health claims context.

The FTC staff has not tested the use and effectiveness of such a referral statement or any other disclosures on the food label in connection with a health claim to correct any misimpression about a problematic nutrient. We specifically have not tested whether consumers actually notice and understand the referral statements, including whether the statements effectively alert consumers to the presence of problematic nutrients and the relevant information on the Nutrition Facts Panel.

FTC staff therefore encourages the FDA, industry, and consumer groups to conduct and consider consumer research on the language and format of various disclosures about problematic nutrients to ensure that they are effective in preventing deception. Such research will assist the FDA in developing a sound empirical basis for its regulatory decisions.

V. Use of Synonyms in Nutrient Content Claims

By regulation implementing the NLEA, the FDA specifically defines express claims about the level or range of a nutrient in food. Such defined terms include, for example, "free," "reduced," and "good source." Synonyms for defined terms also are listed in FDA's regulation

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[45] 21 C.F.R. § 101.13(h). For example, if a food with a high sodium level makes a "Low Saturated Fat" claim on the principal display panel, it must state immediately adjacent to that claim "See Nutrition Information for Sodium Content."

(e.g., "no," "little," and "rich in").[46] These "listed" synonyms may be used in place of the defined term so long as they meet the same requirements for using the relevant defined term.[47]

If a marketer seeks to use an unlisted synonym for a defined term, it first must obtain FDA approval through a petition process. In 1995, the National Food Processors Association proposed that the FDA allow food marketers, without prior approval, to substitute unlisted synonyms for defined terms. The FDA now seeks comment on whether unlisted synonyms would be reasonably understandable to consumers and not false or misleading.

In its Policy Statement on Food Advertising, the FTC addressed the use in food ads of synonyms for defined terms in FDA-approved nutrient content claims.[48] The FTC stated that if consumers took away from the use of a term in a food ad the same meaning as a defined term in an FDA-approved nutrient content claim, then the advertised food must meet the standard for the defined term. For example, if use of the phrase "packed with" fiber conveys to reasonable consumers that the food is "high" in fiber, it should meet the FDA's standard for use of the term "high." The rationale is that because FDA's regulations define "high" with respect to fiber, consumers are likely to be misled if a "high fiber" claim is implied by an ad for a food that does not satisfy that standard.[49]

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46 *See, e.g.*, 21 C.F.R. §§ 101.54 and 101.56.

47 *See generally* 21 C.F.R. § 101.69.

48 *See* Policy Statement on Food Advertising at 6.

49 *Id.*

FTC staff recommends that the FDA likewise consider allowing the use of unlisted synonyms in the labeling context so long as the food satisfies the FDA's standard for the defined term.

VI. Conclusion

The staff of the FTC encourages the FDA to examine ways to facilitate the flow of truthful, non-misleading information in food labeling in a manner that is easy for consumers to understand. We support the FDA's ongoing efforts to develop an empirically based approach to health claims for food products and to assess the costs and benefits of alternatives to the current regulations' reliance on potentially over-exclusive minimum and maximum requirements for making health claims on food labels. Revising its regulations to allow food marketers to provide greater and more accurate health-related information will assist consumers in selecting from a wider range of foods as they attempt to construct healthful diets.

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