Enforcement Policy Statement on Food Advertising

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Introduction

The Federal Trade Commission (FTC) is issuing this statement to provide guidance regarding its enforcement policy with respect to the use of nutrient content and health claims in food advertising. The Commission believes the statement is appropriate in light of the passage of the Nutrition Labeling and Education Act of 1990 (NLEA),[1] and the Food and Drug Administration's (FDA) January 6, 1993, issuance of food labeling regulations implementing the NLEA.[2]

The FTC, FDA, and USDA share jurisdiction over claims made by manufacturers of food products pursuant to a regulatory scheme established by Congress through complementary statutes. Section 5 of the Federal Trade Commission Act (FTC Act) (hereinafter "Section 5") prohibits "unfair or deceptive acts or practices," and, in the case of food products, Sections 12 and 15 of the FTC Act prohibit "any false advertisement" that is "misleading in a material respect."[3] FDA's authority is embodied in part in Section 403(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) which prohibits "labeling

[that] is false or misleading in any particular."[4] Since 1954, the FTC and the FDA have operated under a Memorandum of Understanding,[5] under which the Commission has assumed primary responsibility for regulating food advertising, while FDA has taken primary responsibility for regulating food labeling.[6] The NLEA amended Section 403 of the FDCA and effected broad changes in the regulation of nutrition claims on food labels. In addition to requiring nutrition information on virtually all food products, the NLEA directed FDA to standardize and limit the terms permitted on labels, and allows only FDA-approved nutrient content claims and health claims to appear on food labels.[7] While the NLEA is designed in part to prevent deceptive and misleading claims on labels, Congress also intended that nutrient content and health claims educate consumers in order to assist them in maintaining healthy dietary practices.[8] The NLEA also mandated that FDA undertake a consumer education effort to educate consumers about the new food label and the importance of diet to health.[9] Therefore, in keeping with its recently expanded and unique jurisdictional mandate, the requirements set forth in FDA's regulations have a broader purpose than preventing false and misleading claims in food labeling.

The NLEA applies only to labeling and did not change the FTC's statutory authority to prohibit deceptive acts or practices under Section 5 of the FTC Act. Nevertheless, in light of the comprehensive regulatory scheme established for food labeling claims by the NLEA, the Commission is issuing this statement to clarify how its own authority relates to issues raised by FDA's food labeling regulations.

The Commission recognizes the importance of consistent treatment of nutrient content and health claims in food advertising and labeling and seeks to harmonize its advertising enforcement program with FDA's food labeling regulations to the fullest extent possible under the statutory authority of the FTC Act. The Commission also recognizes the scientific expertise of FDA in this area. The Commission has traditionally accorded great weight to FDA's scientific determinations in matters of nutrition and health and will continue to do so. In addition, as a general matter, it is unlikely that the Commission will take action under Sections 5 and 12 of the FTC Act regarding nutrient content and health claims if they comply with FDA's regulations.[10]

The principal elements of the Commission's authority to regulate nutrient content and health claims in food advertising are set forth below in the discussion of the Commission's legal framework in Part II of this statement. Part III of the statement addresses the Commission's approach to harmonization with the NLEA and FDA's regulations in the area of nutrient content claims in food advertising. Part IV of the statement addresses the Commission's approach to health claims in food advertising. Claims made in food advertising may raise issues addressed in more than one section of this statement. Advertisers, therefore, should comply with all relevant provisions of the statement and not simply the provision that seems most directly applicable.

In issuing this statement, the Commission recognizes that the FDA intends its regulatory approach to be dynamic, designed to respond to changes in science and consumer understanding of nutrition and diet-disease issues. Therefore, while the Commission's purpose in issuing this statement is to provide guidance on how it will enforce Sections 5 and 12 in the food advertising area, the statement is not intended to provide a comprehensive analysis of how each of FDA's regulations relates to the Commission's enforcement policy. Instead, this statement focuses on the general issues that are likely to

remain relevant to the Commission's regulation of food advertising over time, as specific provisions in the FDA regulations are amended.

Legal Framework for Commission Action

As noted above, the FTC regulates food advertising under its statutory authority to prohibit deceptive acts or practices under Section 5 of the FTC Act. The Commission has set forth its interpretations of this authority in its Deception Policy Statement[11] and its Statement on Advertising Substantiation.[12] FTC food cases, applying the principles articulated in these statements, have also established a growing body of precedent against which food advertisers can assess the lawfulness of their claims.[13]

As set out in the Deception Statement, the Commission will find an advertisement deceptive under Section 5 and, therefore, unlawful, if it contains a representation or omission of fact that is likely to mislead consumers acting reasonably under the circumstances, and that representation or omission is material.[14]

The first step in a deception analysis is to identify representations made by an advertisement. A representation may be made by express or implied claims. An express claim directly makes a representation. The identification of an implied claim requires an examination of both the representation and the overall context of the ad,[15] including the juxtaposition of phrases, images, and the nature of the claim and the transaction.[16] In other words, in ascertaining the meaning of an advertisement, the Commission will focus on the ad's overall net impression.[17]

In addition to deception arising from affirmative representations in an advertisement, the omission of material information may also be deceptive in certain circumstances. First, deception can occur through omission of information that is necessary to prevent an affirmative representation from being misleading.[18] Second, "it can also be deceptive for a seller to simply remain silent, if he does so under circumstances that constitute an implied but false representation."[19] However, "[n]ot all omissions are deceptive, even if providing the information would benefit consumers."[20] As with advertisements that contain affirmative representations, the test for whether an omission is deceptive is whether the overall impression created by the ad is deceptive.[21]

The next step in identifying deception in an ad requires the Commission to consider the representation from the perspective of a consumer acting reasonably under the circumstances.[22] Finally, a representation must be material, *i.e.*, likely to affect a consumer's choice or use of a product or service.[23] Express claims and claims involving health or safety are presumptively material.[24]

In addition, objective claims carry with them the implication that they are supported by valid evidence. It is deceptive, therefore, to make an express or implied nutrition or health benefit claim for a food unless, at the time the claim is made, the advertiser possesses and relies upon a reasonable basis substantiating the claim.[25] A reasonable basis consists of competent and reliable evidence. In the context of nutrient content or health claims, substantiation will usually require competent and reliable scientific evidence sufficient to support the claim that is made.[26] Commission orders generally

require that scientific evidence consist of tests, analyses, research, studies or other evidence conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the relevant profession to yield accurate and reliable results.[27] The substantiation must also be examined in the context of the entire body of relevant evidence, particularly if it produces results that are contrary to that body of evidence.

Nutrient Content Claims

A. Claims Describing the Absolute and Comparative Nutrient Content of Foods

As mandated by the NLEA, FDA's regulations define certain absolute and comparative terms that can be used to characterize the level of a nutrient in a food. "Absolute" terms (*e.g.*, "low," "high," "lean") describe the amount of nutrient in one serving of a food. "Relative" or comparative terms (*e.g.*, "less," "reduced," "more") compare the amount of a nutrient in one food with the amount of the same nutrient in another food. With very few exceptions, only these specific terms, and certain approved synonyms, may be used on food labels to characterize the level of a nutrient, although interested parties may petition FDA to authorize new nutrient content terms and synonyms.[28]

1. Absolute Nutrient Content Claims

Prior to the finalization of FDA's regulations, there was no comprehensive set of standardized definitions for absolute terms such as "low" and "high" to describe the level of a nutrient in a food. Now that FDA has established a standard metric to describe the nutrient content of foods, the Commission will apply FDA's definitions for absolute nutrient content terms when those terms are used in the same context in advertising. In general, the Commission will use FDA's serving size or reference amounts customarily consumed, as set forth in FDA's regulations, in its analysis of a claim. If, however, an advertiser chooses to depict a non-standard serving size in an advertisement, the Commission will require the advertiser to meet the FDA's standard both for the reference amount customarily consumed and for the serving size depicted.[29]

The Commission has previously indicated that where a claim is subject to the joint jurisdiction of the FTC and the FDA, it will accord significant deference to the FDA's standards.[30] Consumer understanding will be improved if the agencies responsible for regulating the use of express or implied absolute nutrient content descriptors have consistent requirements for use of these terms. Multiple governmental definitions for the same terms would have the potential to mislead consumers.[31]

Similarly, the use in advertising of FDA-defined terms in a manner inconsistent with FDA's definitions is likely to mislead consumers. The uniform and detailed nutrient content information required on food labels, as well as the NLEA-mandated educational effort, are likely to familiarize consumers with both the FDA-defined terms and their definitions, further reinforcing consumer expectation that nutrient content terms are consistently applied.

Furthermore, the principle that certain claims may be deceptive unless they are based on

a common standard of measurement or testing is well founded under Section 5.[32] At the same time, statements that a food is "high" or "low" in a particular nutrient are objective product claims that imply support by a reasonable basis.[33] The Commission generally determines what level of substantiation constitutes a reasonable basis by weighing the six factors set forth in *Pfizer, Inc.* and subsequent cases.[34] Applying those factors here leads the Commission to conclude that to avoid deception, advertisers should meet FDA's definitions for absolute nutrient content claims.

Where FDA has not established any standard metric, such as "low" or "high," for a specific nutrient, the Commission will closely review claims in food advertising that characterize the level of that nutrient.[35] The Commission has traditionally deferred to FDA's scientific and public health determinations, and will consult with FDA and other government and public health authorities regarding the significance of the nutrient for which such a claim is made.

2. Comparative Nutrient Content Claims

FDA's regulations also establish definitions for comparative terms that characterize the nutrient content of a labeled food relative to that of a comparison or "reference" food. These definitions require that a food bearing a comparative term meet specified minimum percentage differences in the relevant nutrient. For example, the regulations permit use of the terms "less" and "reduced" only where there is a minimum 25 percent difference in the relevant nutrient. In addition, comparative claims must disclose the reference food, the percentage difference in the nutrient between the labeled and reference food (*e.g.*, "50 percent less fat than our regular cheese"), and quantitative information regarding the absolute amount of the nutrient in the labeled and reference foods (*e.g.*, "fat reduced from 6 g. to 3 g. per serving").

Comparative nutrient content claims that comply with FDA's regulations will generally comply with Section 5.[36] The Commission will scrutinize carefully comparative nutrient content claims that characterize nutrient differences in ways that do not comply with FDA's regulations. However, a comparative advertising claim that is accurately qualified to identify the nature of a nutrient difference and to eliminate misleading implications[37] may comply with Section 5, even if the nutrient difference does not meet FDA's prescribed differences for purposes of labeling.[38]

In examining comparative claims, several principles are likely to be applied by the Commission. First, comparative claims should make clear the basis for the comparison.[39] Claims should identify the reference food to which the product is being compared to so that the appropriate comparison is clear to consumers. Second, consistent with the position it has taken on the use of descriptors, the Commission believes that advertisers using unqualified comparative terms must meet FDA's minimum percentage difference requirements for those claims. For example, if an ad represents that a food has "less fat than Brand X," without indicating the percentage or absolute difference in fat, the Commission will rely on FDA's 25% minimum difference requirement in determining whether the claim is deceptive.

Third, comparative claims should not overstate the significance of a nutrient difference.[40] For this reason, some comparative claims may need to be qualified in a manner sufficient to ensure that consumers are not misled regarding the significance of the nutrient

difference. For example, a simple statement of percentage difference for a food that contains only a small amount of a nutrient, such as "our crackers have one-third less fat than Brand X," may suggest that the nutrient difference is greater in an absolute sense than it actually is. This type of claim may need further qualification to prevent the claim from creating a misleading impression (*e.g.*, "one third less fat than Brand X -- theirs has 3 g., ours has 2 g.").

Even where nutrient differences are substantial in an absolute sense, careful qualification may be necessary for products that despite such absolute reductions, still contain appreciable amounts of a nutrient, to ensure that consumers are not misled regarding the absolute level of the nutrient. Thus, a claim such as "20% less fat in our frozen entree compared to Brand X," regarding a product that nevertheless contains a significant amount of fat, may need to identify the quantitative amount of fat in the advertised food and the reference food (*e.g.*, "20% less fat than Brand X -- Brand X has 25 g. fat, ours has 20 g. fat"), particularly in situations where consumers are not likely to be aware that the item is generally high in fat.

In summary, the Commission ordinarily will not challenge comparative nutrient content claims that comply with FDA's regulations, and will carefully scrutinize comparative nutrient content claims that characterize nutrient differences in ways that do not comply with FDA's regulations.[41]

3. Synonyms for Nutrient Content Claims

In addition to authorizing the use of only a limited set of defined nutrient content terms on food labels, FDA's regulations authorize the use of only certain synonyms for these defined terms.[42] The impetus behind Congress's requirement that FDA limit defined terms and synonyms may be found in the educational and public health goals of the NLEA -- to promote consumer understanding of the meaning of the terms through a limited lexicon that will allow consumers to make informed dietary choices.[43]

The Commission will examine advertising to ensure that claims that characterize the level of a nutrient, including those using synonyms that are not provided for in FDA's regulations, are consistent with FDA definitions. Commission precedent establishes that an advertisement that can reasonably be interpreted in a misleading way is deceptive, even though other, nonmisleading interpretations may be equally possible.[44] Thus, when express or implied claims suggest that a food product meets the standard for use of an FDA-defined term, advertisers should ensure that the food actually meets the relevant FDA standard. For example, depending on the context of an ad, use of the phrases "packed with" or "lots of" to describe the level of fiber in a food could convey to some reasonable consumers that the food is "high" in fiber. Because FDA's regulations define the terms "good source" and "high" with respect to fiber,[45] consumers are likely to be misled if a "high fiber" claim is implied by an ad for a food that is only a "good source" of fiber.

4. Implied Nutrient Content Claims

As defined in FDA's regulations, an implied nutrient content claim is a claim that:

i. Describes the food or an ingredient therein in a manner that suggests that a nutrient

is absent or present in a certain amount (*e.g.*, "high in oat bran"); or

ii. Suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (*e.g.*, "healthy, contains 3 grams (g) of fat").[46]

Under this definition, statements about ingredients may or may not be nutrient content claims.[47] FDA has generally adopted a case-by-case approach to statements about ingredients that depends on the overall context of the label. The regulations also provide, however, that certain ingredient statements will be treated as nutrient content claims whenever they appear on labels.[48]

The Commission's approach to implied claims also relies on an analysis of the overall context in which a claim appears. As explained above, the Commission evaluates the overall impression created by an ad, including the ad itself, the arrangement of phrases and images in the ad, and the nature of the claim being made, in order to determine whether a representation is likely to mislead reasonable consumers.[49] If the net impression produced by an ad is likely to mislead reasonable consumers, the ad is deceptive and violates Section 5.

FTC food cases and consent agreements also demonstrate the principle that statements regarding ingredients may have nutrient content implications. For example, advertising may implicitly characterize the amount of a nutrient in a product through representations regarding the ingredients with which the product is made.[50] An ad may imply that a food is free of a particular nutrient by suggesting that the product is free of ingredients that are essentially the same from the consumer's perspective.[51]

Consistent with its statutory authority and its commitment to harmonization, the Commission will look closely at advertisements that may implicitly characterize the level of a nutrient. The Commission will give great weight to any FDA determinations concerning ingredient statements in analyzing the net impression conveyed by an ad.

B. Nutrient Content Claim Disclosures

As mandated by the NLEA, FDA's nutrient content labeling regulations require a number of disclosures. These mandated disclosures include, but are not limited to: (1) a referral statement to the nutrition panel, required whenever a nutrient content claim is made;[52] (2) disclosure of nutrients (fat, saturated fat, cholesterol, and sodium) present in a food at a level that FDA has concluded increases the risk of diet-related disease, required whenever a nutrient content claim is made;[53] and (3) "triggered" disclosures of the amount of certain related nutrients when claims concerning fiber, saturated fat, and cholesterol appear.[54]

As set forth in Part II above, disclosure of material information that is necessary to prevent deception may be required under Section 5 of the FTC Act.[55] For example, it is misleading to fail to disclose qualifying information necessary to prevent an affirmative statement from creating a misleading impression.[56] However, a seller's silence in circumstances that do not give a particular meaning to the silence is not deceptive.[57] The failure to provide nutrition information that consumers may find useful in improving their diet, while subject to challenge under the NLEA with respect to labels, therefore, is not necessarily subject to challenge as deceptive under Section 5.[58] In the context of

advertising that makes affirmative nutrient content claims, the Commission's analysis of deception by omission will be based on a consideration of whether a nutrient content claim gives rise to a misleading impression absent disclosure of other nutrition information.

Some of FDA's disclosures appear designed to fulfill the educational goals of the NLEA, which are beyond the scope of the Commission's law enforcement mandate. For example, all nutrient content claims on a label must be accompanied by a statement referring the consumer to the nutrition panel, where complete nutrition information regarding the product is found.[59] While a complete nutrition portrait of a food may be useful to consumers, it is unlikely that the absence of this referral statement from an advertisement would render the ad deceptive to consumers.

In contrast, other disclosures mandated for food labels may also appropriately be required under certain circumstances to prevent deception in advertising under Section 5. In determining whether such disclosures are necessary to prevent deception, the Commission will consider several factors. First, the Commission will carefully evaluate nutrient content claims for foods that contain a nutrient at a level considered by FDA to increase the risk of a diet-related disease.[60] When the context of an ad as a whole conveys to consumers the net impression that the food makes only positive contributions to a diet, or does not contain any nutrients at levels that raise the risk of diet-related disease, the failure to disclose the presence of risk-increasing nutrients is likely to be deceptive.[61]

Second, the Commission will also scrutinize nutrient content claims for cholesterol, saturated fat, and fiber. Congress enacted "special rules"[62] requiring that claims for these nutrients trigger disclosure of other nutrients.[63] Consumers often may infer that certain nutrient claims imply a characterization of the amount of another nutrient. Similarly, where different nutrients are linked to the same health issue (for example, cholesterol and saturated fat, or dietary fiber and total fat), a claim regarding one of these nutrients is likely to give rise to a misleading impression regarding the benefit of the food absent disclosure of the presence of the other nutrient. Under these circumstances, the failure to correct these misimpressions through adequate disclosures is likely to be deceptive.

IV. Health Claims[64]

FDA's regulations for health claims in food labeling establish general standards for the use of claims that characterize the relationship of a substance in a food to a disease or health-related condition.[65] These general standards include, among other things: (1) limiting authorization of health claims only to those categories for which there is "significant scientific agreement" that the relevant diet-disease relationship is supported by the scientific evidence;[66] (2) establishing disqualifying levels for total fat, saturated fat, cholesterol, and sodium, above which foods are disqualified from bearing any health claims;[67] (3) for the specific substance that is the subject of a health claim, setting a threshold level for the amount of such substance in the food, that is either sufficiently low or sufficiently high to support the health claim;[68] (4) requiring that foods bearing health claims have some minimal nutritional value;[69] and (5) requiring that health claims identify those factors, other than dietary intake of the substance, that affect the diet-disease relationship.[70] In addition, as required by the NLEA, FDA's regulations provide a

petition process for interested persons to seek FDA authorization of additional health claims.[71]

The Commission shares the concerns underlying the NLEA, and embodied in FDA's regulations, that health claims be adequately substantiated and presented in a manner that is truthful and not misleading. These same principles form the foundation of the Commission's well-established deception and advertising substantiation doctrines, described in Part II above. The Commission's approach to the regulation of health claims in food advertising and FDA's approach to such claims in labeling therefore share many basic elements.

A. Standard for Substantiation of Health Claims

The NLEA directed FDA to promulgate regulations authorizing claims about diet-disease relationships only if FDA determined,

> based on the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.[72]

The NLEA directed FDA to apply this "significant scientific agreement" standard in determining whether there was adequate substantiation to permit health claims for ten specific diet-disease relationships.[73] After reviewing the scientific literature, FDA issued regulations authorizing a number of specific categories of health claims.

The Commission's standard for substantiation of health claims in food advertising shares many elements with FDA's approach to such claims in labeling. Like FDA, the Commission imposes a rigorous substantiation standard for claims relating to the health or safety of a product, including health claims for food products.[74] The Commission's standard that such claims be supported by "competent and reliable scientific evidence" has been more specifically defined in Commission orders addressing health claims for food products to mean:

> tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.[75]

Thus, both the Commission and FDA look to well-designed studies, including clinical research and other forms of reliable and probative scientific evidence, in evaluating health claims for foods.

In addition, the Commission, like FDA, evaluates substantiation for health claims in the context of the surrounding body of evidence, and does not look to isolated studies, especially if those studies are unrepresentative of the larger body of evidence. However, the Commission does not require food advertisers to establish that there is scientific consensus in support of their claims. Similarly, FDA has clearly indicated that its

"significant scientific agreement" standard does not require that such agreement represent a "full consensus among scientists."[76]

In evaluating health claims, the Commission looks to a number of factors to determine the specific level of scientific support necessary to substantiate the claim.[77] Central to this analysis is an assessment of the amount of substantiation that experts in the field would consider to be adequate. The Commission regards the "significant scientific agreement" standard, as set forth in the NLEA and FDA's regulations, to be the principal guide to what experts in the field of diet-disease relationships would consider reasonable substantiation for an unqualified[78] health claim.[79] Thus, it is likely that the Commission will reach the same conclusion as FDA as to whether an unqualified claim about the relationship between a nutrient or substance in a food and a disease or health-related condition is adequately supported by the scientific evidence.

The Commission also recognizes the importance of the petition process, established under the NLEA and FDA's regulations, as a mechanism for authorizing health claims in food labeling. The Commission will look with particular care at any health claims not specifically considered by the FDA in this process. The absence of an FDA determination that a health claim is scientifically valid will be a significant factor in the Commission's assessment of the adequacy of substantiation for the claim.[80]

While the Commission's approach to evaluation of unqualified health claims will generally parallel FDA's assessment of whether there is significant scientific agreement supporting the relevant diet-disease relationship, the Commission recognizes that there may be certain limited instances in which carefully qualified health claims may be permitted under Section 5 although not yet authorized by the FDA, if the claims are expressly qualified to convey clearly and fully the extent of the scientific support. At the same time, however, the Commission believes that qualified claims based on evidence that is inconsistent with the larger body of evidence have the potential to mislead consumers, and, therefore, are likely to violate Section 5.

The Commission recognizes the need to scrutinize closely qualified claims to maintain the credibility of health claims in food advertising and labeling. The Commission will therefore be especially vigilant in examining whether qualified claims are presented in a manner that ensures that consumers understand both the extent of the support for the claim and the existence of any significant contrary view within the scientific community.[81] In the absence of adequate qualification, the Commission will find such claims deceptive.[82]

B. Health Claims for Foods That Contain a Nutrient at a Level That Increases the Risk of a Disease

FDA's health claim regulations identify four nutrients -- total fat, saturated fat, cholesterol, and sodium -- the consumption of which has been associated with increased risk of certain diseases or health-related conditions, particularly cancer, cardiovascular disease, and hypertension. For each of these nutrients, the regulations establish levels above which foods containing the nutrient are disqualified from bearing health claims.[83] The disqualifying levels set by FDA were based on an analysis of what level of these nutrients in a food would increase, "to persons in the general population, the risk of a diet-related disease, taking into account the significance of the food in the total daily

diet."[84]

The Commission will rely heavily on FDA's scientific determination as to what levels of total fat, saturated fat, cholesterol, and sodium may increase the risk of a diet-related disease or other health condition[85] and, while not necessarily prohibiting all health claims in advertising for such foods that contain such levels, will carefully scrutinize health claims for such foods to ensure that the claims are truthful and adequately qualified.[86] Situations involving risk-increasing levels established by FDA should not be interpreted as an exhaustive list of instances in which a broad, unqualified health claim for a food may be found deceptive by the Commission.

Unqualified health claims in advertising for such foods are likely to be deceptive when the risk-increasing nutrient is closely related to the subject health claim. Often the presence and significance of such a nutrient will have to be disclosed.Without such disclosures, consumers could infer from the health message that the food does not present any related health risks.[87] The failure to disclose the presence and significance of risk-increasing nutrients that are closely related to the health claim for such foods is likely to constitute an omission of a material fact and render the health claim deceptive.[88]

For example, a claim that a food will reduce the risk of one specified disease is likely to convey to reasonable consumers that the food will not increase the risk of some other health condition closely related to that disease. Thus, an unqualified claim that a food is low in saturated fat and cholesterol, and therefore compatible with a diet designed to reduce the risk of cardiovascular disease, would be deceptive if the food contained so much sodium that it might increase the risk of hypertension and thus, cardiovascular disease.[89] To prevent deception, a health claim for such a food is likely to need a disclosure that clearly conveys both the presence and significance of the risk-increasing nutrient.[90]

Even when the risk-increasing nutrient does not bear directly on the health condition that is the subject of the health claim, it may be necessary to disclose the presence of a risk-increasing nutrient. Depending on context, a specific health claim may convey to consumers a broader message that the food is healthful in all respects. For example, a health claim describing the benefits of calcium in reducing the risk of osteoporosis, when made in advertising for a dairy product that is high in saturated fat, may create the deceptive impression among reasonable consumers that consuming the dairy product will reduce the risk of osteoporosis without increasing the risk of any other health-related condition or disease, for example, heart disease. To prevent deception, a health claim for such a food may need to include a disclosure that conveys the presence and significance of the risk-increasing nutrient.[91]

In those instances, as outlined above, where disclosure of a risk-increasing nutrient level is necessary to prevent deception, the Commission will carefully scrutinize the disclosure to ensure that it is adequate to convey clearly the limited nature of the health claim being asserted.

C. Nutrient/Substance Levels Sufficient to Ensure Meaningful Health Benefits

In addition to establishing levels of total fat, saturated fat, cholesterol, and sodium, above which foods are disqualified from bearing health claims, FDA's regulations also establish

threshold levels for the specific nutrients that are the subject of particular health claims made in food labeling. If a health claim is about the effects of consuming a substance at decreased dietary levels (*e.g.*, lowering saturated fat and cholesterol intake to reduce the risk of coronary heart disease), FDA sets the threshold at a level that it determines is "sufficiently low to justify the claim."[92] If a claim relates to the effects of consuming the substance at other than decreased dietary levels (*e.g.*, increasing calcium intake to reduce the risk of osteoporosis), FDA sets the threshold at a level that it determines is "sufficiently high to justify the claim."[93] In establishing these "high" and "low" thresholds, FDA specifically considered both whether these levels were sufficient to advance the public health policy of assisting consumers in maintaining healthy dietary practices,[94] and whether health claims for foods not meeting such thresholds would be "misleading because the nutrient levels [were] not low enough, or not high enough, to really contribute to the claimed effect."[95]

The Commission shares FDA's view that health claims should not be asserted for foods that do not significantly contribute to the claimed benefit. A claim about the benefit of a product carries with it the implication that the benefit is significant.[96] Thus, consistent with its position on the use of absolute nutrient content descriptors and unqualified comparative nutrient content claims, the Commission will ordinarily apply FDA's thresholds for specific nutrient levels in examining unqualified health claims for the specific nutrient levels that are the subject of the particular health claim.

The Commission recognizes, however, that there may be certain limited instances in which it is possible to craft a qualified, truthful, and nonmisleading claim comparing the relative health benefits of a food product to other products for which the food can be substituted, even if the nutrient level does not meet FDA's prescribed threshold for the food. Such comparative claims, encouraging consumers to substitute a food that is significantly lower or higher in the relevant nutrient than other foods in the same category, will be unlikely to mislead consumers if the claimed benefit from the substitution will contribute significantly to the claimed health effect.

In addition, such comparative claims must be sufficiently qualified to make clear to consumers that the benefit derives only from the substitution of the advertised food for a significantly less healthful alternative and that the subject product does not otherwise offer an overall health benefit. It may be necessary to disclose the actual level of the nutrient that is the basis for the claim and its significance to prevent deception.[97]

D. Minimum Nutritional Value for Foods Bearing Health Claims

Under FDA's regulations, any food bearing a health claim must not only meet the threshold level for the specific substance or nutrient that is the subject of the health claim, as discussed in Part IV, Section C., *supra*, but also must contain a sufficient amount of at least one of six nutrients and substances specified by FDA.[98] For example, a food that is sufficiently low in total fat to meet FDA's threshold level for a health claim about dietary fat and cancer would also need to contain one or more of the six specific nutrients or substances at a sufficient quantity to ensure that the food contributed significantly to a healthful diet. Like FDA's threshold levels, this rule ensures that health claims are reserved for foods that contribute significantly to a healthy diet.[99]

The Commission shares FDA's view that health claims may be misleading to the extent

that they encourage consumers to choose foods that provide calories but have little or no nutritional value, under the mistaken belief that their choices will contribute to a healthy diet. The Commission believes that, like claims for foods that fail to meet FDA's threshold levels, health claims for foods with little or no positive nutritional value have the potential to be deceptive since they imply that the health benefit being asserted is significant.[100] Therefore, the Commission will generally give great deference to FDA's standards for minimum nutritional value for foods bearing unqualified health claims.

The Commission recognizes, however, that there may be some instances in which it is possible to craft a qualified, truthful, and nonmisleading claim comparing the relative health benefits of a food product to other products for which the food can be substituted, even if the food does not meet FDA's minimum nutritional value standards. While the food bearing such a qualified comparative health claim may not contribute in any absolute sense to a healthful diet, the substitution of such food for a less healthful food in the same category could result in a meaningful contribution toward the claimed health effect without detracting from the healthfulness of the overall diet.[101]

As noted in Part IV, Section C., *supra*, such comparative claims must be sufficiently qualified to convey clearly that the claimed health benefit derives only from the substitution of the advertised food for a significantly less healthful alternative.

E. Relevance of Dietary Factors to Claimed Health Benefit

For each category of health claims approved by FDA, the regulations present model health claim language that places the health benefits to be derived from consuming a nutrient in the context of other factors that bear on the relevant disease or health-related condition.[102] For example, in authorizing claims about calcium/osteoporosis, FDA developed model language explaining how other factors like gender, age, ethnicity, and exercise bear on the relationship between calcium consumption and osteoporosis.[103] FDA's model health claims are intended to ensure that health claims are complete, truthful and not misleading. The model statements therefore include reference to the fact that factors other than consumption of the food also bear on the claimed health effect.[104]

The Commission shares FDA's concern that health claims for food products may mislead consumers if they oversimplify the diet-disease relationship or otherwise overstate the relative significance of dietary factors in achieving certain health effects. Health claims in food advertising should therefore be sufficiently qualified to avoid implying to reasonable consumers that consumers can achieve the claimed effect simply by consuming the food and without regard to other factors, such as overall diet, exercise, age, or family history, that may either contribute or detract from the claimed effect.

However, while the Commission recognizes the desirability of educating consumers about the role of other factors that bear on the risk of disease and how such factors interact with diet, the Commission must evaluate whether the failure to disclose such qualifying information in a claim about the health effects of a food would mislead consumers. As explained above, not all omissions of information are deceptive in violation of Section 5. In assessing whether an omission is deceptive, the Commission examines whether the omitted information would be necessary to prevent an affirmative claim from creating a misleading impression.[105]

The Commission will not require food advertisers to include in advertising containing health claims all potentially relevant information about the specific diet-related disease, or affirmatively to disclose that the risk of the disease depends on many factors, unless such disclosure is necessary to prevent consumers from being misled about the significance of diet as one of those factors. Indeed, in many forms of advertising it would not be feasible to include all nutritional information that may be of interest to consumers. While the additional dietary and nondietary factors associated with a health condition may be of interest to consumers, in most cases Section 5 would not require full disclosure of such information to prevent consumers from being misled by statements about the contribution of a particular food to a health effect.

Footnotes

1 Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified in part at 21 U.S.C. § 343(i), (q) and (r)).

2 Simultaneously, the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) issued its own nutrition labeling regulations relating to meat and poultry products. While FSIS's regulations were not mandated by the NLEA, these regulations were intended to implement the NLEA's goals for products regulated by USDA. Although the principles in this statement relate to FDA's regulations, the Commission intends to apply similar principles to consideration of claims for products regulated by USDA.

3 15 U.S.C. §§ 45, 52, 55 (1980).

4 21 U.S.C. § 343(a). USDA's authority is derived from the Federal Meat Inspection Act, 21 U.S.C. § 601 (n)(1) (prohibiting labeling of meat or meat products that is "false or misleading in any particular"), and the Poultry Products Inspection Act, 21 U.S.C. § 453(h)(1) (prohibiting labeling of poultry products that is "false or misleading in any particular").

5 Working Agreement Between FTC and Food and Drug Administration, 4 Trade Reg. Rep. (CCH) ¶ 9,850.01 (1971) (hereinafter "Memorandum of Understanding").

6 The Memorandum of Understanding also reaffirms the agencies' shared commitment to prevent deception of the public, to coordinate their work to eliminate duplication of effort, and to promote consistency in handling matters of mutual concern.

7 The NLEA defines a "nutrient content claim" as any claim that expressly or by implication "characterizes the level of any nutrient." 21 U.S.C. § 343(r)(1)(A) (Supp. 1990). A "health claim" is defined as any claim that characterizes the relationship of any nutrient to a "disease or health related condition." 21 U.S.C. § 343 (r)(1)(B) (Supp. 1990).

8 "Health claims supported by a [sic] significant scientific agreement can reinforce the Surgeon General recommendations and help Americans to maintain a balanced and healthful diet. Similarly, statements regarding the level of these nutrients in foods will assist Americans in following the Surgeon General's guidelines." House Committee on Energy and Commerce, Nutrition Labeling and Education Act of 1990, H.R. Doc. No. 538, 101st Cong., 2d Sess. 9-10 (1990).

9 NLEA, § 2(c).

10 The Commission notes that the manner in which such information is conveyed in advertising may differ from the way it would be presented in labeling. The Commission cautions advertisers to consider carefully

the importance of the context in which they make claims. Some claims that would technically comply with FDA's labeling regulations might be deceptive in advertising if the context of the ad renders the express message of the claim misleading.

11 *See Cliffdale Associates, Inc.*, 103 F.T.C. 110, 176 (1984), reprinting as appendix letter dated Oct. 14, 1983, from the Commission to The Honorable John D. Dingell, Chairman, Committee on Energy and Commerce, U.S. House of Representatives ("Deception Statement").

12 FTC Policy Statement on Advertising Substantiation, 48 Fed. Reg. 10,471 (1984), *reprinted in Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987) ("Substantiation Statement").

13 *See, e.g.*, cases cited *infra* notes 26, 29, 32, 36, 50, 51, 74, 75, 81, 87, 96.

14 Deception Statement, 103 F.T.C. at 183.

15 *Kraft, Inc.*, FTC Dkt. No. 9208, slip op. at 7 (Jan. 30, 1991), *aff'd*, 970 F.2d 311 (7th Cir. 1992), *cert. denied*, 113 S. Ct. 1254 (1993) (citing *Thompson Medical Co.*, 104 F.T.C. at 789, 799; *Cliffdale Associates*, 103 F.T.C. at 164; Deception Statement, 103 F.T.C. at 176).

16 Deception Statement, 103 F.T.C. at 176. The Commission may rely on its own expertise in finding claims that are reasonably clear from the face of an advertisement. *Kraft*, 970 F.2d at 319, and cases cited therein. If the Commission is unable to conclude that an implied claim is conveyed based on a review of the ad itself, the Commission may rely on extrinsic evidence demonstrating that the ad implies a claim. *Kraft*, slip op. at 7; *Thompson Medical*, 104 F.T.C. at 789.

17 *Kraft*, slip op. at 7-8; *Removatron Int'l Corp.*, 111 F.T.C. 206, 292 (1988), *aff'd*, 884 F.2d 1849 (1st Cir. 1989); *Thompson Medical*, 104 F.T.C. at 790.

18 Deception Statement, 103 F.T.C. at 175 n.4; *see also International Harvester Co.*, 104 F.T.C. 949, 1057 (1984); *Campbell Soup Co.*, FTC Dkt. No. 9223 (Aug. 18, 1992) (consent order).

19 *International Harvester*, 104 F.T.C. at 1058.

20 Deception Statement, 103 F.T.C. at 175 n.4; *International Harvester*, 104 F.T.C. at 1059.

21 Deception Statement, 103 F.T.C. at 175 n.4.

22 Deception Statement, 103 F.T.C. at 177.

23 *Id.* at 182.

24 *Kraft*, slip op. at 22-23, *Thompson Medical*, 104 F.T.C. at 816-17; Deception Statement, 103 F.T.C. at 182-83.

25 Substantiation Statement, 104 F.T.C. at 839.

26 *See, e.g., Kraft*, slip op. at 2 (scientific evidence required to substantiate calcium content claims and comparative calcium content claims); *Bertolli, Inc.*, FTC Dkt. No. C-3396 (Aug. 17, 1992) (consent order) (scientific evidence required to substantiate claims regarding edible oil's impact on any physiologic function or risk factor for disease or other health benefit); *Pacific Rice Prods.*, FTC Dkt. No. C-3395 (Aug. 17, 1992) (consent order) (scientific evidence required to substantiate claims regarding health benefits derived from consumption of products); *see also Thompson Medical*, 104 F.T.C. at 822.

27 *See Bertolli; Pacific Rice.*

28 21 C.F.R. § 101.69(b) (1993).

29 *See, e.g., Nestle Food Co.*, FTC Dkt. No. C-2265 (Jan. 21, 1992) (consent order) *and Presto Food Prods., Inc.*, FTC Dkt. No. C-3480 (Feb. 23, 1994) (consent order) (resolving allegations that low fat claims based on the small serving of nondairy creamers that might be used in coffee were deceptive when made with respect to a larger serving that might be used over cereal or fruit or in cooking).

30 *See Thompson Medical*, 104 F.T.C. at 826.

31 In the past, courts have upheld the Commission's position that inconsistent meanings for the same terms have the potential to mislead consumers. In *FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35 (D.C. Cir. 1985), the court held that Brown & Williamson had deceptively advertised its Barclay cigarettes as "1 mg. tar." The 1 mg. tar rating was a result of the cigarettes' different design, which caused the amount of tar that Barclay cigarettes delivered to smokers to be disproportionately greater than that delivered by cigarettes that were similarly rated under the FTC rating system. Considering the claim against the background of the Commission's tar and nicotine rating system, the court affirmed the Commission's position that the claim misled consumers who had come to rely on the FTC rating system to make comparative assessments regarding cigarettes.

32 *E.g., Presto Food Prods., Inc.*, FTC Dkt. No. C-3480 (Feb. 23, 1994) (consent order); *Clorox Co.*, FTC Dkt. No. C-3427 (May 17, 1993) (consent order); *Isaly Klondike Co.*, FTC Dkt. No. C-3412 (Jan. 28, 1993) (consent order); *Nestle Food Co.*, FTC Dkt. No. C-2265 (Jan. 21, 1992) (consent order).

33 Substantiation Statement, 104 F.T.C. at 839.

34 81 F.T.C. 23, 64 (1972); *Thompson Medical*, 104 F.T.C. at 813, 821; *Bristol-Myers*, 102 F.T.C. at 321. These are: (1) the type of product advertised, (2) the type of claim, (3) the benefits of a truthful claim, (4) the ease of developing substantiation for the claim, (5) the consequences of a false claim, and (6) the amount of substantiation that experts in the field believe is reasonable.

35 Under FDA's regulations, a label claim characterizing the level of a nutrient (*i.e.*, a nutrient content claim) is prohibited unless made in accordance with the regulations. 21 C.F.R. § 101.13(b) (1993). However, the label of a product may contain a statement of the amount of a nutrient, such as "1 g. of omega-3 fatty acids" if it does not explicitly or implicitly characterize the level of the nutrient. 21 C.F.R. § 101.13(i)(3) (1993). Thus, statements that merely note the amount of a nutrient without characterizing the level are permitted even for nutrients not approved to appear on the nutrition panel.

36 This principle is already apparent from recent Commission consent orders, which provide safe harbors for those claims specifically permitted in labeling. *See, e.g., Nestle Food Co.*, FTC Dkt. No. C-2265 (Jan. 21, 1992) (consent order) (providing that nothing in the relevant portions of the order shall prohibit certain representations regarding total fat, saturated fat or cholesterol if such representations are specifically permitted in labeling, for the serving size advertised or promoted, by FDA regulation); *Isaly Klondike Co.*, FTC Dkt. No. C-3412 (Jan. 28, 1993) (consent order) (providing that nothing in the Order shall prevent respondent from making representations specifically permitted in labeling for food by the NLEA regulations).

37 As it has in the past, the Commission emphasizes that truthful comparisons may need to be sufficiently qualified to remove deceptive implications. *See* Policy Statement in Regard to Comparative Advertising, 16 C.F.R. § 14.15 (1979) (comparative advertising regarding objective measurable attributes must have sufficient clarity or disclosures to ensure that such comparisons are not deceptive).

38 For example, a small nutrient difference that appears as part of a claim touting the multidimensional nutritional differences offered by a product is less likely to overstate the significance of that difference than would such a claim standing alone. Thus, an advertiser may seek to signal to consumers that, while it has reduced total fat and saturated fat in its product by 25%, it has also achieved a small reduction in sodium compared with other products in the category. In these circumstances, a truthful claim that makes clear that the sodium reduction is less than the 25% reduction in other nutrients and does not overstate the significance of this incidental reduction is unlikely to mislead consumers.

39 *See* Policy Statement in Regard to Comparative Advertising, 16 C.F.R. § 14.15 (1979). The Commission's Guides for the Use of Environmental Marketing Claims also include this requirement. 16 C.F.R. § 260.6(d) (1993).

40 *See P. Lorillard Co. v. FTC*, 186 F.2d 52, 57 (4th Cir. 1950) (advertising claiming that cigarette was lowest in nicotine, tar and resins challenged in part because the difference was, in fact, insignificant); *Sun Co.*, FTC Dkt. No. C-3381 (May 6, 1992) (consent order) (challenging advertising for octane gasoline that represented gas would provide superior power that would be significant to consumers).

41 Although the term "light" is defined in FDA's regulations as a comparative descriptor, the term also has been used to describe the food itself, much like an absolute descriptor such as "low." As reflected in FDA's preamble and regulations, the term also is associated chiefly with substantial reductions in fat or calories. *See* 58 Fed. Reg. 2351-2358. Given the unique characteristics of the term "light" as reflected in FDA's regulations, it is unlikely that the term can be used in advertising without undue confusion unless the food meets FDA's definitions. Accordingly, the Commission will apply FDA's definition for "light" in determining whether advertising using the term is deceptive.

42 21 C.F.R. § 101.13(b) (1993). Interested parties may petition FDA to authorize additional synonyms. 21 C.F.R. § 101.69(b)(2) (1993).

43 58 Fed. Reg. 2319-20 (1993). *See* Nutrition Labeling and Education Act of 1990, § 403(4)(2)(A)(i).

44 *Chrysler Corp. v. FTC*, 561 F.2d 357, 363 (D.C. Cir. 1977); Kraft, slip. op. at 6 n.8. *See also* Deception Statement, 103 F.T.C at 178 n.21 ("A secondary message understood by reasonable consumers is actionable if deceptive even though the primary message is accurate").

45 21 C.F.R. § 101.54(b) and (c) (1993).

46 21 C.F.R. § 101.13(b)(2) (1993).

47 58 Fed. Reg. 2371 (1993).

48 For example, the regulations state that "a claim that a food contains oat bran is a claim that it is a good source of dietary fiber; that a food is made only with vegetable oil is a claim that it is low in saturated fat; and that a food contains no oil is a claim that it is fat free." 21 C.F.R. § 101.65(c)(3) (1993).

49 *Kraft*, slip op. at 7-8; *Removatron*, 111 F.T.C. at 292; *Thompson Medical*, 104 F.T.C. at 790. *See also FTC v. Sterling Drug*, 317 F.2d 669, 674 (2d Cir. 1963) (the Commission examines "the entire mosaic ... rather than each tile separately").

50 *Kraft*, 970 F.2d at 322 (upholding Commission's finding that claims about the amount of milk in processed cheese slices were, in context, implied claims about calcium content).

51 *See Estee Corp.*, 102 F.T.C. 1804 (1983) (consent order) (advertisements that claimed that foods sweetened with high-fructose corn syrup did not contain sugar and were accepted by the American Diabetes Association implied (falsely) that the foods were appropriate for people who needed to avoid sugar).

52 21 C.F.R. § 101.13(g) (1993).

53 21 C.F.R. § 101.13(h) (1993). As discussed in Part IV, *infra*, these same levels of nutrients serve to disqualify foods from bearing health claims. *See* 21 C.F.R. § 101.14(a)(5) (1993).

54 *See* 21 C.F.R. § 101.54(d) (requirements for fiber claims); 21 C.F.R. § 101.62(c) (requirements for saturated fat claims); 21 C.F.R. § 101.62(d) (requirements for cholesterol claims).

55 Deception Statement, 103 F.T.C. at 176.

56 *International Harvester*, 104 F.T.C. at 1057.

57 *Id.* at 1059.

58 *Id.* at 1058 ("[n]ot all omissions are deceptive, even if providing the information would benefit consumers").

59 21 C.F.R. § 101.13(g) (1993).

60 *See North American Philips Corp.*, 111 F.T.C. 139, 177-84 (1988) (Initial Decision) (according great weight to other government agencies' determinations regarding the significance of a chemical added to drinking water by the water filter and thus whether the failure to disclose this fact was material).

61 *Id.* at 175 (Commission's complaint alleged, and the Administrative Law Judge found, that failure to disclose that water filter device introduced a potentially hazardous chemical into drinking water was misleading in light of representations that device would remove organic chemicals and clean the water).

62 House Committee on Energy and Commerce, Nutrition Labeling and Education Act of 1990, H.R. Rep. No. 538, 101st Cong., 2d Sess. 20 (1990).

63 21 U.S.C. § 343(r)(2)(A)(iii)-(v).

64 FDA's definition of a health claim includes two basic elements: (1) a substance or nutrient; and (2) the relationship of that substance or nutrient to a disease or health-related condition. 21 C.F.R. § 101.14(a)(1) (1993). Thus, claims on food labels are not governed by FDA's health claims regulations unless they include either express or implied references to both a substance and a disease. FDA's approach to implied health claims is similar to the Commission's in that this definition includes claims in which the disease element is implied through symbols or by other means, looking at the context of the entire label. *Id.; see also* discussion of FDA's definition of implied health claims, 58 Fed. Reg. 2483 (1993). Like FDA, the Commission examines food claims in the context of the entire advertisement to determine whether an implied health claim is being made. Therefore, the Commission may determine in certain instances, based on its review of the entire context of an advertisement, that a nutrient content claim, even in the absence of any express reference to a disease or health-related condition, conveys an implied health message to consumers.

65 21 C.F.R. § 101.14 *et seq.* (1993).

66 21 C.F.R. § 101.14(c) (1993).

67 21 C.F.R. § 101.14(a)(5) (1993).

68 21 C.F.R. § 101.14(d)(2)(vi)-(vii) (1993).

69 21 C.F.R. § 101.14(e)(6) (1993).

70 21 C.F.R. § 101.14(d)(2)(iii) (1993).

71 21 C.F.R. § 101.70 (1993). This regulation requires that FDA take final action within 190 days of the receipt of a petition, either to deny the petition or to publish a proposal to amend the regulations to allow the use of the requested health claim.

72 21 U.S.C. § 343(r)(3)(B)(i). This standard is also set forth in FDA's regulations at 21 C.F.R. § 101.14(c) (1993).

73 NLEA, § 3(b).

74 *See, e.g., Pacific Rice*, FTC Dkt. No. C-3395 (Aug. 17, 1992) (consent order) (claims about health benefits of consuming rice bran cereal challenged as unsubstantiated); *see also Thompson Medical*, 104 F.T.C. at 822 (claims involving health or safety issues require a "relatively high level of substantiation, typically scientific tests").

75 *Gracewood Fruit Co.*, FTC Dkt. No. C-3470 (Oct. 29, 1993) (consent order); *see also Pompeian, Inc.*, FTC Dkt. No. C-3402 (Oct. 27, 1992) (consent order).

76 58 Fed. Reg. 2505 (1993).

77 *See Pfizer, Inc.*, *supra* note 34. *See also* Substantiation Statement, 104 F.T.C. at 840; *Thompson Medical*, 104 F.T.C. at 821.

78 Unqualified as used in this discussion of substantiation refers to health claims that do not include specific disclosures concerning the extent of supporting scientific evidence.

79 This approach is consistent with the Commission's approach to evaluating the substantiation for claims made for drug products and medical devices regulated by FDA. *See, e.g., Removatron*, 111 F.T.C. at 305 (FDA's determination of efficacy of hair removal device given substantial weight); *Thompson Medical*, 104 F.T.C. at 826 (recognizing importance of applying standard consistent with FDA's in evaluating safety and efficacy of a drug product subject to jurisdiction of both agencies).

80 Food marketers should not expect to circumvent FDA's petition process for health claims simply by limiting the assertion of unapproved or unreviewed claims to advertising.

81 *See, e.g., National Comm'n on Egg Nutrition* (NCEN), 517 F.2d 485 (7th Cir. 1975), *appeal after remand,* 570 F.2d 157 (7th Cir. 1977), *cert. denied*, 483 U.S. 921 (1978). The final Commission order in *NCEN*, as modified by the court, required that the advertiser, if it made any claims regarding the relationship between dietary cholesterol and heart disease, disclose that there was a controversy among experts about the scientific basis for the link between egg consumption and heart disease, and that NCEN was presenting its side of that controversy. Where NCEN characterized the level of scientific evidence, the order further required a disclosure that many medical experts believed that increasing egg consumption might increase the risk of heart disease.

82 In order to be effective, qualifications or disclosures should be sufficiently clear and prominent to prevent deception. *See* Deception Statement, 103 F.T.C. at 180; *Thompson Medical*, 104 F.T.C. at 789 n.9, 842-43; *see also* Guides for the Use of Environmental Marketing Claims, 16 C.F.R. § 260.6(a) (1993). Clarity of language, relative type size and proximity to the claim being qualified, and an absence of contrary claims that could undercut effectiveness, will maximize the likelihood that the qualifications and disclosures are appropriately clear and prominent. *See, e.g., Figgie Int'l, Inc.*, 107 F.T.C. 313, 401 (1986), *aff'd*, 817 F.2d 102 (4th Cir. 1987). For example, the Commission is unlikely to find a video superscript, without accompanying audio, to be an effective method of disclosure in a television ad. *See, e.g., Kraft*, slip. op. at 10. As always, the Commission will also consider any extrinsic evidence of the effectiveness of qualifications and disclosures in its determination of whether a claim is deceptive. In making this determination, the Commission will consider all reasonable interpretations of the advertisement. The Commission will find an advertisement to be deceptive if it can reasonably be interpreted in a misleading way, even though other, nonmisleading interpretations may be equally possible. *See Kraft*, slip. op. at 6 n.8.

83 These specific disqualifying levels are set forth at 21 C.F.R. § 101.14(a)(5) (1993).

84 58 Fed. Reg. 2489 (1993).

85 The Commission has routinely accorded great weight to FDA determinations of the safety and efficacy of food and drug products. *See, e.g., Removatron*, 111 F.T.C. at 305; *Thompson Medical*, 104 F.T.C. at

826; *see also Sterling Drug, Inc.*, 102 F.T.C. 395, 768-69, *aff'd*, 741 F.2d 1146 (9th Cir. 1984), *cert. denied*, 470 U.S. 1084 (1985).

86 For example, USDA has stated its "intention to publish a proposed rule on health claims in line with FDA's proposal." *See* 58 Fed. Reg. 632, 664 (Jan. 6, 1993). If so, the regulation's disqualifying level for cholesterol will preclude health claims on the labels of virtually all meat and poultry products. Notwithstanding the regulations, however, the Commission would not prohibit a truthful advertising claim that explains in a nondeceptive manner the health advantages of substituting meat or poultry items that are relatively low in fat and saturated fat for higher fat alternatives (*e.g.*, a claim suggesting the merit of substituting skinless breast of turkey for hamburger). Such claims would assist consumers who are trying to improve their diets but who are unwilling to forgo all meat and poultry.

87 *See, e.g., Campbell*, FTC Dkt. No. 9223 (Aug. 18, 1992) (consent order required disclosure of sodium content and recommended maximum daily sodium intake in advertisements making claims about heart disease for soups with more than 500 mg. of sodium per 8-oz. serving).

88 The Commission has traditionally required that material information be disclosed if its absence could mislead reasonable consumers. *See* Deception Statement, 103 F.T.C. at 182; *see also International Harvester*, 104 F.T.C. at 1057; *North American Philips*, 111 F.T.C. at 175, 195 (failure to disclose the fact that a water filter could introduce a harmful chemical into the water was misleading).

89 In *Campbell*, the Commission charged that claims that the company's soups contained little fat or cholesterol, and were heart-healthy, were deceptive because the company had failed to disclose that the soups were high in sodium. Specifically, the complaint alleged that the high level of sodium was a material fact given that a diet high in sodium can contribute to hypertension, a risk factor associated with heart disease. FTC Dkt. No. 9223 (Aug. 18, 1992) (consent order).

90 A statement indicating both the amount of the risk-increasing nutrient and the recommended maximum daily intake of that nutrient, as determined by FDA, would be one example of an acceptable disclosure, provided such information adequately conveys the health implications of the risk-increasing nutrient. *See, e.g., Campbell, supra.*

91 Further, the FDA's treatment of health claims in labeling for any food containing a risk-increasing level of a nutrient, as well as the NLEA-mandated educational effort, could well increase consumers' expectations concerning the scope of unqualified health claims, including expectations that the foods do not present any significant health risks.

92 21 C.F.R. § 101.14(d)(2)(vi) (1993).

93 21 C.F.R. § 101.14(d)(2)(vii) (1993).

94 58 Fed. Reg. 2514 (1993).

95 56 Fed. Reg. 60,553 (1992) (discussion of proposed regulations).

96 *See, e.g., Gracewood Fruit Co.*, FTC Dkt. No. C-3470 (Oct. 29, 1993) (consent order). The complaint accompanying the Gracewood consent agreement challenged claims that eating grapefruit could reduce serum cholesterol levels, in part because there was no evidence that the small amount of pectin (the relevant nutrient) in grapefruit was sufficient to cause any meaningful reduction in serum cholesterol. *See also Lorillard*, 186 F.2d at 57 (advertising claiming that cigarettes were lowest in nicotine, tars, and resins challenged in part because the difference was so small as to be insignificant). Similarly, the Commission's Guides for the Use of Environmental Marketing Claims include the general principle that claims should not be presented in a manner that overstates the attribute or benefit of a product, and that "[m]arketers should avoid implications of significant environmental benefits if the benefit is in fact negligible." 16 C.F.R. § 260.6(c) (1993).

97 *See* discussion *supra* at Part III, Section A.2., (comparative nutrient claims).

98 21 C.F.R. § 101.14(e)(6) (1993).

99 58 Fed. Reg. 2522 (1994).

100 *See* discussion *supra* at Part IV, Section C.

101 For example, a qualified comparative health claim suggesting that consumers switch from a high fat to a fat-free salad dressing, and indicating that diets low in total fat may contribute to a reduced risk of some forms of cancer, could encourage a dietary choice resulting in a significant health benefit, even if the fat-free salad dressing did not contain sufficient levels of any of the six nutrients or substances specified by FDA.

102 FDA has stated that model health claim language can be paraphrased as long as all mandatory elements of the model statements are addressed. 58 Fed. Reg. 2510 (1993).

103 21 C.F.R. § 101.72(e) (1993). In authorizing other health claims, FDA provides alternative approaches of either expressly enumerating the relevant factors, or stating more simply that the development of the disease depends on many factors. *See, e.g.*, 21 C.F.R. § 101.73 (1993) (governing claims about dietary fat and cancer).

104 58 Fed. Reg. 2511 (1993); *see also* 21 U.S.C. § 343(r)(3)(B)(iii).

105 Deception Statement, 103 F.T.C. at 176. In *J.B. Williams Co. v. FTC*, for example, the Commission challenged as deceptive advertising claims that a vitamin and iron supplement would reduce tiredness because the advertiser failed to disclose that those symptoms are usually caused by factors other than vitamin and iron deficiency. 381 F.2d 884, 890 (6th Cir. 1967). *See also Keele Hair & Scalp Specialists*, 55 F.T.C. 1840 (1959), *aff'd*, 275 F.2d 18 (5th Cir. 1960) (baldness cure claims challenged for failure to disclose significance of male heredity as cause of baldness, for which cure was ineffective).