

Case #3499 (10/1/98)

PROCTER & GAMBLE

Olean Fat Substitute

Grey Advertising, Inc/New York, NY

Basis of Inquiry: An advertising campaign by The Procter & Gamble Company ("P&G") for olestra (also known as "Olean"), a fat substitute, including television commercials, magazine advertisements and brochures for medical professionals, was challenged by The Center for Science in the Public Interest ("CSPI"), a nonprofit organization concerned about the impact of foods and food additives on the public health.

Television: Three :30 broadcast commercials were challenged. Each is set on a farm and features farmers or farm workers; the commercials contain visuals of fields containing what the audio refers to as soybeans or a close-up of an individual soybean.

In one commercial, entitled *My Momma Always Said*, a woman holding a calf states that the first time she heard of snacks cooked in Olean she wondered what it was. She continues:

"Starting from crops that grow here. Like soybeans. Though I don't like too much snacking, I do think that chips fried up in Olean are a better choice than the regular kind. It tastes real good, has a lot less fat and fewer calories."

While she speaks, visuals of oil being poured into a pan of frying chips and a bag of Lays WOW potato chips are shown.

In another commercial, entitled *Farmer Reminisces*, an older, male farmer relates that a farm coop worker had told him that soybeans, like the farmer, are now being used for a new kind of cooking oil. The farmer states:

"It seems the folks who make Crisco had come up with Olean, the cooking oil that fries up snacks without adding any fat or even a single calorie.. And without all the fat, a little healthier to eat than regular chips...now I see what I'm part of and it makes me feel good."

Similarly, in the third commercial, entitled *News About Soybeans*, a farmer states:

"It seems that Crisco came up with a way to fry snack chips without adding any fat or calories. They figured without all the fat of regular chips, this Olean could help a whole lot of folks eat a little healthier."

Visuals of oil being poured into a pan of frying chips and a bag of WOW potato chips are also displayed in these two commercials.

Magazine: Five magazine advertisements, appearing in national publications, were part of the challenged campaign. One features a picture of the farmer in the *Farmer Reminisces* broadcast commercial looking out at his fields, and contains the following copy:

"Doing good in your own backyard. Of course, mine is 250 acres of soybeans. I remember the day I first heard about it. How soybeans like mine were going to be used to make a new kind of cooking oil."

"Seems the folks who make Crisco had come up with Olean, an oil that would fry up fat-free snack chips without adding any calories. Make them taste especially good. Yet still be a little healthier to eat than regular snacks. It only goes to show, good things can start from anywhere. Even your own backyard."

The second magazine advertisement features a farmer standing in a field of soybeans, and starts with the headline, "Out here, you come to count on yourself... use your own judgment" and then continues:

".. the Crisco people came up with a way to use soybeans like we grow here as part of a new kind of oil. One that fries up snack chips and such with a lot less fat. And fewer calories. Figured it would make them a little healthier to eat than the regular kind."

"Now, knowing something like this starts with soybeans like mine.., it makes me feel good."

The third advertisement features a picture of a woman holding a lamb (as in the *My Momma Always Said* television commercial) and contains the following language:

"...starting from good things like our soybeans...chips fried up with Olean are a better choice than the regular kind. They cut down on fat and calories, while tasting great. Sounds like a pretty fair deal to me."

The fourth advertisement features a family in a more urban-looking setting and contains the following language:

"...the Crisco people came up with a way to use farm-grown crops like soybeans to make a different kind of oil."

"...Olean is the fat-free cooking oil that's frying up great-tasting snack chips."

The fifth advertisement, appearing in medical journals, such as *the New England Journal of Medicine*, states:

"Will Olean compromise my patients' nutrition? No.. Olean simply cannot affect the vitamins and carotenoids that have already been absorbed by the body."

"Olean.. ..cooking oil made starting from common ingredients processed in a new way..."

"Now that snacks made with Olean are available in your area, your patients have great-tasting alternatives for cutting back on fat and calories."

Brochures for Health Professionals: The brochures contain similar language to the Journal advertisement.

In addition, the advertiser provided NAD with a brochure for Fat -Free Pringles, which states: "Olean is a cooking oil made starting from farm-grown ingredients like soybeans processed in an improved way..."

Challenger's Position: CSPI asserted that the advertisements are misleading because they contain express and implied claims that are not substantiated and they fail to disclose material facts regarding the effects of consuming olestra-containing foods under ordinary conditions of use, particularly in light of representations made about olestras health benefits. The challenger requested that NAD recommend that any unsubstantiated claims be discontinued and require appropriate disclosures.

The challenger maintained that the following claims are not substantiated:

"A Little Healthier to Eat" and "A Better Choice." CSPI contended that these express claims are inaccurate because Olean inhibits the absorption of carotenoids and therefore, despite the fact that Olean snacks have fewer calories and less absorbable fat than conventional snacks, they cause negative health consequences, and are therefore not "a little healthier to eat" or a better choice" than regular chips. The challenger stated that although the FDA did not require a labeling disclosure referring to carotenoids, other federal agencies consider carotenoids important: for example, the Department of Health and Human Services ("HHS") and the Department of Agriculture consider carotenoids of sufficient importance to encourage consumers to eat foods containing these nutrients,² and the National Cancer Institute, a branch of HHS, state; that numerous studies have found evidence that "carotenoids reduce the risks of some cancers." CSPI averred that in one P&G study, eating as little as one-third of an ounce of Olestra chips per day with meals caused up to a 38% depletion of blood levels of various carotenoids. The

challenger maintained that P&G should disclose to consumers the facts about Olestra effect on carotenoid absorption because of their effect on health and asserted that Harvard School of Public Health experts on diet and disease estimate that even a 10% average reduction in blood levels of carotenoids in American snacking consumers due to Olestra snacks would lead to hundreds of extra cases of blindness, thousands of extra deaths from prostate and lung cancer, and tens of thousands of extra deaths from coronary heart disease each year³.

No Adverse Side Effects: Further, the challenger asserted that the "little healthier" and "better choice" claims imply that Olestra does not cause any adverse side effects, when in fact it does. CSPI contended that the FDA stated that olestra may be used safely only in accordance with certain conditions, including a mandatory labeling disclosure stating:

"This Product Contains Olestra. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added."

and maintained that these gastrointestinal ("GI") effects are sometimes severe.⁴ The challenger argued that although the FDA does not require the inclusion of diarrhea on the label statement, it has acknowledged that olestra causes diarrhea (61 FR 3155) and noted that after a review of a P&G study, the FDA determined that a significant number of test subjects who consumed Olestra reported severe diarrhea, a condition that CSPI maintained could present risks to young children and the elderly. The challenger asserted that while many consumers who reported suffering from diarrhea after consuming chips made with olestra may not have suffered "medical" diarrhea (including loss of fluids and electrolytes), the conditions of what FDA designated as loose stools (but classified by the people suffering from them as diarrhea), is relevant in that it effected their comfort and interfered with their normal routines.

In addition, CSPI maintained that some of P&G's small clinical trials demonstrate that olestra causes severe GI effects. See section on pre-approval eight week studies, below. The challenger contended that in light of the adverse GI reactions caused by consumption of olestra, P&G's claims that foods containing olestra are "a little healthier" and a "better choice" are inaccurate and misleading. The challenger also noted that the FDA, although it had approved the use of olestra, required a further FDA review, within 30 months of the approval date, of new studies that P&G said it would conduct:

"Only with data from the broader marketing of olestra can the agency be in the position to evaluate in the future whether there continues to be reasonable certainty of no harm from the use of olestra in savory snacks,"

and asserted that it knew of no other instance where the FDA pledged to review the safety of a food additive after approval. CSPI also reasoned that because the 30 month review had not yet been completed, the unsettled nature of the olestra debate is another reason to ensure that consumers receive all relevant information about olestra-containing products in order to be able to evaluate the risks.

Pre-Approval Studies: The challenger asserted that the preapproval studies relied on by the FDA for its approval (including the required labeling) of olestra, are more relevant to this challenge than the post-approval studies and maintained that their results are not diminished by the newer studies. The challenger listed pertinent pre-approval studies as follows:

a) Eight-Week Studies. The challenger alleged that the two pre-approval eight-week clinical trials, which involved giving four groups of subjects (17 to 24 per group) 0, 8, 20 or 32 grams of olestra per day, show a statistically significant dose-related increase for the symptoms of diarrhea combined with loose stools, and for fecal urgency for the 20 and 32 gram groups. CSPI asserted that FDA's analysis of these studies found that the number of subjects reporting one or more severe GI symptoms was significantly increased in the groups eating 20 and 32 grams per day of olestra as compared to subjects eating no olestra.

b) **Oil Loss Study** This study was conducted to determine if increasing olestra stiffness would eliminate passive oil loss. Over five days, six groups consumed 34 grams of olestra per day in chips at various degrees of stiffness while the placebo group ate regular chips. According to the challenger, the FDA found a significant increase in adverse GI effects in subjects eating olestra consistent with the eight-week clinical trials.

c) **1989 Clinical Rechallenge Study.** This study tested consumers who had previously complained about adverse GI effects after eating olestra. In this four-week cross-over study, 18 (out of 52 original) screened subjects consumed olestra at 0, 10, or 20 grams per day for a period of seven days each. The challenger maintained that the FDA concluded that the number of these subjects reporting diarrhea increased with increasing olestra doses.

Post-Approval Studies: CSPI discounted the three p051:-approval studies submitted by P&G to the FDA as irrelevant to the challenged advertisements: First, the studies were not considered as part of the approval process; second, the two studies for which documentation was supplied are not sufficiently sensitive to draw valid conclusions; and, there is insufficient documentation to permit any evaluation of the third study CSPI asserted that the two studies for which documentation was supplied, the movie theater and the re-challenge studies, are inadequate to assess safety because they involve only one (movie theater study) or two (re-challenge study) isolated exposures to Olean⁷ -The challenger maintained that the contrasting results of the more sensitive pre-approval studies, which involved exposure over periods of five to 56 days and demonstrated significant increases in severe GI effects, are much more accurate and relevant.

Olean is an Oil. The challenger maintained that by referring to Olean as a "new kind of cooking oil" and depicting Olean being poured from a container, the advertisements falsely imply that Olean is an oil, notwithstanding the fact that Olean is not a liquid at room temperature, but more like a semi-solid shortening. CSPI asserted that while fats and oils share the same general structure and chemical properties,⁸ the primary difference between them is their form: at room temperature, fats are solid and oils are liquid.⁹ According to the challenger, unlike liquids, Olean, at room temperature, cannot be poured from one container to another and does not conform to the shape of the container into which it is poured: it is therefore a fat, and should not be referred to as an oil. In addition, CSPI challenged the accuracy of P&G's depiction of Olean, apparently clear of bubbles and at room temperature, being poured into a pan of frying chips.

Olean Does Not Compromise Nutrition. The challenger maintained that the advertiser's representation (in medical journal advertisements) that Olean will not compromise patients' nutrition because it "cannot affect the vitamins and carotenoids that have already been absorbed by the body" is misleading because it fails to disclose that olestra interferes with the absorption of carotenoids that have been eaten recently, resulting in a lowering of carotenoid levels.

Olean Can Help Patients Cur Back on Fat and Calories. CSPI contended that P&G's claim (in medical journal advertisements) that Olean snacks are "great-tasting alternatives for cutting back on fat and calories" is not substantiated because it knows of no long-term studies on the effect of olestra on calorie consumption, and that two short-term studies sponsored by P&G indicate that the body maintains constant calorie intake, regardless of whether fat substitutes are consumed,¹¹ and noted that unless used as part of a controlled diet, reduced-fat foods may not result in weight reduction.¹² Further, CSPI noted that a review article on the impact of fat substitutes on fat intake stated that people tend to eat more of a food when they know it is reduced in fat.¹²

Olean is a Natural Product. The challenger asserted that the advertisements, by depicting soybean fields and having a farmer describe how soybeans are being used for a new kind of cooking oil, imply that Olean is a natural product, when, in fact, Olean is a synthetic chemical. While acknowledging that neither the FDA nor the FTC has established a definition of natural, the challenger cited the definition of the Food Safety and Inspection Service (FSIS)¹³ of the US Department of Agriculture as a reasonable guide. According to the challenger, FSIS allows the term "natural" on product labels if the product (1) does not contain any artificial flavoring, coloring ingredient, or chemical preservatives, or any other artificial or synthetic ingredient; and (2) the product and its ingredients are not

more than minimally processed.⁴ The challenger stated that Olean, a manmade, artificial substance that is created through more than minimal processing, would not qualify under this definition as "natural."⁵ The challenger argued that consumers wish to purchase foods advertised as "natural" because they assume- rightly or wrongly- that natural foods are more healthful; thus, the implied natural claim is material and should be prohibited.

Need for Disclosure Statement: CSPI contended that P&G's failure to disclose in advertising for Olean that the product, under ordinary conditions of use, can cause adverse GI effects and depletion of nutrients, renders the advertisements false and misleading.⁶ The challenger asserted that although the FDA determined that olestra did not pose any "adverse health consequences," side effects such as loose stools, cramps, bloating and diarrhea-like symptoms are at the very least physically uncomfortable, and argued that since consumers do not expect snacks to cause GI symptoms or deplete nutrients, advertisements for olestra should contain the same information required on product labels.⁷ Further, CSPI maintained that the advertisements are misleading because they fail to reveal material facts (contained in the label statement) in light of the representations (i.e., "a little healthier to eat than regular chips," "far free" and "fries up snacks without adding any fat or even a single calorie") that imply that Olean is healthful and does not present any deleterious health effects.

The challenger cited FTC's Enforcement Statement on Food Advertising⁸ as requiring such disclosures in advertising, and noted that while packages of olean-containing foods bear the mandated disclosure, it is inconspicuously placed on the back of the package, and therefore, many consumers do not see it. The challenger asserted that because consumers do not expect snack foods to cause side effects, they typically do not scrutinize package labels for possible "cautionary statements," and hence the need for warnings in advertisements. The challenger dismissed the advertiser's assertion that Olean should be treated the same as other food additives (such as bran and sorbitol) that require label disclosures, but not advertising disclosures. CSPI argued that the comparison to bran was inopposite and the stated that the FDA rejected P&G's contention that the effects of olestra (seen in P&G's trials) were comparable to those caused by high-fiber diets.

Advertiser's Position: The advertiser maintained that its claims for Olean are fully substantiated and supported by the most comprehensive clinical study program for any food additive in the world,⁹ including 150 studies (involving 20,000 men, women and children) conducted over a period of 20 years, which were reviewed by the FDA prior to approval. The advertiser stated that Olean adds neither fat nor calories to foods cooked with it and therefore results in a substantial savings of calories and fat. For example, P&G noted that potato chips cooked in Olean contain half the calories of chips cooked in vegetable (triglyceride) oils :150 versus 75 calories) and provide no grams of fat as opposed to the 10 grams of fat found in chips fried in vegetable oil.

The advertiser explained that Olean is a synthetic product formed from two well-known food products, edible (triglyceride) oil, e.g. soybean or cottonseed, and table sugar: First, the three fatty acid chains contained in triglyceride oils are separated from the glycerol backbone by reacting the oil with methanol, a naturally occurring molecule; then, sugar is added and the fatty acid chains attach to the sugar molecule. The newly-formed Olean molecule has eight fatty acid chains (instead of the three found in triglycerides) attached to a glucose backbone (instead of the original glycerol backbone). The result, according to the advertiser, is Olean, a molecule whose right configuration prevents breakdown by digestive enzymes, and causes the molecule to pass through the body unabsorbed.

'A Little Healthier to Eat' and 'A Better Choice.' The advertiser maintained that the terms "healthier" and "better choice" are used to describe only the less fat and/or fewer calorie benefits of Olean snacks. P&G also contended that CSPI failed to provide any consumer perception data to support its broader interpretation of these claims.

With regard to effects on carotenoids, the advertiser asserted that while Olean is lipophilic, i.e., it can absorb fat-soluble substances, such as vitamins A, D, E, K and carotenoids, and prevent the body from obtaining their benefits when foods with such substances are eaten around the same time²¹ as Olean (and are therefore together with Olean in the digestive tract), there is no effect on fat-soluble substances that have already been absorbed by the body. The advertiser asserted that to compensate for this interaction, the FDA requires that vitamins A, D, E and K be added

to Olean snacks. However, according to the advertiser, the FDA concluded that there was no need to add carotenoids because the absorption of carotenoids was "insignificant from a public health standpoint" because "the available data do not establish any identifiable nutritional or prophylactic benefits for the carotenoids" and "the actual magnitude of Olean's effect on carotenoid absorption is likely to be within the range of the normal variation due to diet and bioavailability." (61 FR 3149) The advertiser stated that the FDA found that Olean snacks are no different from other foods in terms of carotenoid effects.

No Adverse Side Effects. The advertiser contended that the challenger's assertion that olestra can cause significant adverse health effects under normal conditions of use was wrong. The FDA, the agency charged by law to make findings on issues of food safety, has already determined that olestra has no negative effects on human health and is safe to use in savory snacks. The advertiser dismissed the challenger's assertion that the package label required by the FDA was related to safety concerns, and cited FDA's declaration that the "FDA is not requiring the labeling of olestra-containing foods in order to ensure the safe use of olestra." (61 FR 3163, n.83) P&G emphasized that CSPI failed to mention numerous studies, of which the challenger is aware, regarding Olean's safety profile, including the post-approval studies (Acute Study and Re-challenge Study), and instead focused on an early memorandum by an FDA employee to back its contention that Olean "may be particularly risky to young children and the elderly" and that Olean may cause "severe diarrhea." According to the advertiser, CSPI took this memo out of context and did not disclose that the author noted the limitations of his conclusions ("recognizing that this study was small and was based on a total of 6 individuals who experienced diarrhea during the stool-collection, period.") In addition, P&G contended that the challenger ignored the conclusions drawn by FDA after it reviewed all of the evidence: "there is no evidence that [GI] effects represent adverse health consequences" and "there are no safety concerns with regard to the effect of olestra or. the GI tract." (61 FR 3160, 3161)

Pre-Approval Studies: The advertiser maintained that approximately 100 pre-clinical and more than 40 controlled clinical studies were submitted to the FDA and the experts on the FDA's Food Advisory Committee (FAC) prior to approval. The advertiser asserted that because these studies focused on safety²¹ they were conducted at exaggerated levels of consumption in order to ensure Olean's safety under normal circumstances. The advertiser cited two pivotal studies (the eight-week studies), relied on by the FDA for its approval of Olean. The participants were split into three test groups, consuming either 8, 20, or 32 grams of Olean every day for 56 days, and a full-fat control group. The advertiser explained that eight grams is approximately equal to a one ounce serving of chips and that the average snacker eats a little more than one ounce of chips three times every two weeks, and thus, the eight and especially the 20 and 32 gram per day test groups consumed significantly more chips than an average snacker would. According to the advertiser, there were no statistically significant differences in any of the digestive effects reported between the eight gram per day and control group. While there were statistically significant differences in loose stools, fecal urgency and cramping between the 20 and 32 gram per day groups on the one hand and the control group on the other, there was no statistical difference in the severity of the effects reported in any of the test groups versus placebo. The advertiser asserted that these studies show that Olean does not cause diarrhea. P&G further stated that Olean's effect on the GI system is so benign that even in a study of patients with a severe GI disorder, patients' consumption of 20 grams a day of Olean for 30 days would not affect the patients' disease activity. (61 FR 3155).

The advertiser emphasized that the FDA had found that Olean is safe for use in savory snacks: the GI effects noted were necessarily benign, or the FDA could not have approved the product. P&G argued that, in fact, the GI effects in these studies were a result of the unrealistically high quantities of Olean eaten over an extended period of time, and would not have resulted from normal consumption. In addition, P&G noted that the FDA stated that "it is not requiring the labeling of olestra-containing foods in order to insure the safe use of olestra," (61 FR 3160, n 83) and that the label is an information statement, not a warning.

Post-Approval Studies:

The advertiser asserted that, in addition to the clinical studies it performed on olestra in the 20 years prior to FDA approval, it executed three post-approval studies involving 4,200 participants. P&G asserted that these three studies are rigorous, well-controlled studies conducted in a manner to be predictive of consumers experience under realistic snacking conditions, and provide a contrast to the exaggerated conditions of the pre-approval tests. The advertiser maintained that these studies demonstrate that when consumed under normal conditions, Olean causes no adverse GI effects.

Olean is an Oil. The advertiser asserted that Olean is a cooking oil that "looks, cooks and tastes like ordinary fat." P&G maintained that at the temperatures used to fry chips, Olean is a liquid, and even at room temperature, it is primarily a liquid. The advertiser dismissed the challenger's assertion that the difference in form (i.e., liquid vs. solid) is of any significance to consumers, the industry or to the FDA. According to the advertiser, *Webster's Dictionary* defines oil as "any of numerous unctuous combustible substances that are liquid or at least easily liquifiable on warming." The advertiser also cited the definition of fats and oils given by The Institute of Shortening and Edible Oils, which notes that the only distinction between fats and oils is that: "When solid appearing they are referred to as 'fats' and when liquid they are called 'oils." Further, P&G noted that the FDA, the agency that regulated food, refers to Olean as an oil in the preamble to its olestra regulation (61 FR 3118,3123). The advertiser contended that the definitions do not hinge on the artificial distinction of liquidity at room temperature, but emphasize traditional characteristics of oil, such as viscosity, solubility and use.

With regard to the challenger's contention that the oil depicted in the television commercial should have contained bubbles, the advertiser asserted that the oil was not at frying temperature, and therefore had a smooth non-bubbly appearance.

Olean Does Not Compromise Nutrition. In response to the challenger's assertion that the representation that Glean will not compromise patients' nutrition is inaccurate (because it fails to disclose that olestra interferes with the absorption of carotenoids that have been eaten recently, resulting in a lowering of carotenoid levels), the advertiser maintained that Olean does not affect the vitamins and carotenoids that have already been absorbed by the body, and its representation is thus accurate.

Olean Can Help Patients Cut Back on Fat and Calories. In response to the challenger's contention that there is no substantiation for the claim that Olean snacks are "great tasting alternatives for cutting back on fat and calories," the advertiser asserted that this claim was fully substantiated. The advertiser asserted that numerous studies support the fact that Olean helps lower calorie intake. For example, one study by Hill et al. found that when people unknowingly ate a diet in which fat was replaced with Olean for 14 days, their total calorie intake was reduced by 8% and their fat intake was reduced by 11% compared to when they ate regular meals. The advertiser maintained that similar results were obtained in studies in which participants both knew and did not know they were eating Glean chips: both groups reduced their fat and calorie intake when eating Glean chips versus regular, full-fat chips.²³ P&G asserted that Glean can help people manage their fat and calorie intake and provides a-i extra foot] choice with respect to fat .modified foods. In addition, P&G noted that Glean is not marketed as a "magic bullet" for achieving weight loss or fat reduction. Instead, the advertiser maintained that the claim in the advertisement is limited in scope, i.e., "help" patients 'cut back' on fat and calories.

Olean is a Natural Product. The advertiser maintained that consumers would reasonably understand the advertisements to mean that Olean is a synthetic product because the advertisements never state that Olean is natural: instead, the advertisements state that Glean "start [s] from crops that grow here" and then refers to the "process" of taking the ingredients in Olean to the final product by the use of language such as "come up with" and "come up with a way." The advertiser contended the advertisements do not imply that Olean is natural, but are only intended to "reassure consumers about Olean's origins," that "the components of Glean—fatty acids and sugar—are indeed as natural as vegetable oil," and that the message conveyed to consumers is that Olean "starts with recognizable ingredients, such as soybeans, cottonseed anti sugar, that are processed in a different way to make Olean a fat-free, calorie-free oil." P&G argued that consumers are capable of distinguishing a product that starts with natural

ingredients from one that grows out of the ground, and noted that the challenger failed to provide consumer perception data on this issue.

Need for Disclosure Statement: The advertiser strenuously objected to the challenger's contention that, because of the claims that Glean chips are "a little healthier" or "a better choice," P&G should disclose, in its advertising, statements regarding both Olean's effect on carotenoid levels and the FDA mandated label statement on possible gastrointestinal effects. The advertiser maintained that these claims are specifically linked to Oleans characteristic of adding neither fat nor calories to foods cooked with it, and are not generalized health claims. P&G pointed out that the "healthier" and "better choice" claims appear in close proximity to language discussing fat and calories.

The advertiser contended that it is long-established law and policy at the FTC that advertising need not contain information that appears (or is required) on product labels, even if the information is material. According to P&G, even after the passage of the Nutrition Labeling and Education Act ("NLEA"), the FTC reaffirmed this policy ("a seller's silence in circumstances that do not give a particular meaning to the silence is not deceptive"²⁴) and reaffirmed that "it would not be feasible to induce [in advertising] all nutritional information that may be of interest to consumers." The advertiser argued that only when an advertisement is likely to be deceptive without a disclosure is it necessary to make one, citing as examples requiring disclosure advertisements where silence implies the opposite of what is true, or that conceal a serious health or safety risk. P&G asserted that neither of these examples apply to Olean, which has been found safe and without adverse health consequences by the FDA. The advertiser cited sorbitol and bran as examples of food additives that require label statements, but not advertising warnings.

DECISION

Background: As a prelude to its decision, NAD notes the importance of the issues raised in this challenge to both parties. The advertiser is deeply committed to Olean, a synthetic fat. It has devoted over 20 years of research to this product, which tastes and feels like other oils used for frying, but, because it is not absorbed by the body, adds neither the fat nor the calories of those oils. The challenger is just as committed to its mission of protecting consumers from foods and food additives that it perceives as harmful or potentially harmful to consumers; it believes that Olean may have a deleterious effect on human health because of its inhibition of the absorption of carotenoids and its GI effects.

In 1987, in response to a petition from P&G asking that olestra be approved for use in savory snacks, FDA began a review of the product. Over eight years later, in January of 1996, after an extensive review of over 150 studies (which collectively included more than 20,000 men, women and children as well as many animals) and materials and comments submitted by the challenger and others, the FDA granted the petition. - The FDA found that olestra was safe" to use (i.e., there is a "reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use"⁵¹) in savory snacks such as potato chips and corn chips. After this comprehensive review and analysis, FDA determined that olestra presents no safety concerns or health consequences to the GI tract. FDA concluded that when fat soluble vitamins (A, D, E, and K) are consumed at approximately the same time as olestra (and are together at the same time in the digestive tract), they mix with and pass out of the body with it: FDA therefore required the advertiser to add those vitamins in amounts that would replace those lost by eating olestra-containing foods. Because FDA concluded that there is no established scientific proof that carotenoids themselves (other than pro-vitamin A), provide any benefits to those ingesting them, it stated that P&G need not add carotenoids, despite the fact that they are fat soluble, and like fat-soluble vitamins, will bind with olestra and not be absorbed by the body.

As part of its approval process, FDA required that packages of olestra-containing foods bear a label statement notifying consumers that the product contains olestra, which may cause loose stools and abdominal cramping. The label must also state that olestra inhibits the absorption of some vitamins and other nutrients, and that vitamins A, D, E and K have been added.

In the Spring of 1998, CSPI filed this challenge with NAD regarding certain advertising claims for Olean.

Rationale for Decision: The instant challenge presents NAD with several issues, some previously decided by the FDA (e.g., the safety of olestras effects on the GI system, the benefits of carotenoids), and some not considered by the FDA (e.g., the need for advertising disclosures, whether the advertisements imply that olestra is natural). With respect to those issues decided by the FDA, after it conducted an exhaustive review, NAD will not substitute its judgment for that of the federal agency mandated by Congress to determine the safety of food additives. With respect to the other issues contained in the challenge, NAD finds as follows:

'A Little Healthier to Eat "and "A Better Choice" Claims

NAD determined that the advertiser's representations that Olean is "a little healthier" or "a better choice" are adequately substantiated. In reaching this conclusion, NAD noted that the challenged claims are closely linked and limited to claims that Olean chips have less fat and fewer calories than regular chips; they are not generalized superiority claims. Further, the words of the comparative health claim are self-limiting, stating only that chips fried with Olean are only a "little" healthier than chips fried in full-fat oil.

For example, the television commercials state:

"... chips fried up in Olean are a better choice than the regular kind. It tastes real good, has a lot less fat and fewer calories." (*My Momma Said*). 'And without all the fat, a little healthier to eat than regular chips (*Farmer Reminisces*). "They figured without all the fat of regular chips, this Olean could help a whole lot of folks eat a little healthier." (*News About Soybeans*). Emphases added.

Similarly magazine advertising links "a little healthier" and a "better choice" to less fat and fewer calories claims:

"Olean, an oil that would fry up fat-free snack chips without adding any calories. Make them taste especially good. Yet still be a little healthier to eat than regular snacks."

.a new kind of oil. One that fries up snack chips and such with a lot less fat. And fewer calories. Figured it would make them a little healthier to eat than the regular kind."

chips fried up with Olean are a better choice than the regular kind. They cut down on fat and calories, while tasting great.

NAD was not persuaded by the challenger's contention that Olean snacks cause negative health consequences because Glean inhibits the absorption of carotenoids, and therefore are not "a little healthier to eat" or a better choice" than regular chips. The FDA concluded that there was no need to add carotenoids to olestra-containing snacks because the FDA concluded that the absorption of carotenoids was "insignificant from a public health standpoint" because the available data do not establish any identifiable nutritional or prophylactic benefits for the carotenoids" and "the actual magnitude of Olean's effect on carotenoid absorption is likely to be within the range of the normal variation due to diet and bioavailability" (61 FR 3149)

Because neither party presented communication data with respect to whether the challenged advertisements imply that olestra produces no adverse (GI) side effects, NAD used its experienced judgment to determine the reasonable interpretations of the "little healthier" and "better choice" claims. It is well established that an advertiser is responsible for all reasonable interpretations of its claims. Given that the advertisements state that chips fried in Glean are a "little healthier" than regular chips, NAD determined that one reasonable interpretation of the advertisements is that olestra has no adverse side effects that are detrimental to health when compared to regular potato chips, the object of comparison. NAD concluded however, that there is evidence to substantiate this interpretation. NAD noted that the FDA, the agency charged by law to make findings on issues of food safety, has

determined that olestra is safe to use in savory snacks. The challenger's assertion that the FDA stated that olestra may be used safely only in accordance with certain conditions, including a mandatory labeling disclosure is not accurate. The FDA stated that it "is not requiring the labeling of olestra-containing foods in order to insure the safe use of olestra."²⁷ Instead, the FDA required the label statement in order to enable consumers to associate olestra with any GI effects it may cause, to preclude "unnecessary concerns about the origin of GI effects, were they to be observed" and "prevent unnecessary or inappropriate medical treatment of those symptoms."²⁸ After reviewing all of the data, the FDA stated: "there is no evidence that [GI] effects represent health consequences" and "there are no safety concerns with respect to the effect of olestra on the GI tract." (61 FR 3160, 3161)

Olean is an Oil

In evaluating the question of whether the advertisements inaccurately represent that Olean is a cooking oil, NAD considered three factors: whether there is a well-established distinction commonly understood by the industry between the terms fat and oil; whether consumers understand the two terms to mean different things; and, if so, whether consumers attribute any significance to the difference. After reviewing the materials submitted by the parties, NAD determined that, in this case, the use of the terms "fats" and "oils" are interchangeable and without significance to the industry, the FDA or to consumers.

The Institute of Shortening and Edible Oils ("the Institute"), in its *Food Fats and Oils* (1994) treats fats and oil as identical. For example, under the heading "IMPORTANCE OF FATS," the Institute states "[f]ats and oils are recognized as essential nutrients. No distinction, functional or chemical, is made. Similarly, in the next section entitled "WHAT IS A FAT," the institute explains "[f]ats and oils are predominantly triesters of fatty acids and glycerol, commonly called triglycerides." The Institute here notes that "when solid appearing, they are referred to as 'fats' and when liquid they are called 'oils.'" Thus, the only distinction made is one of appearance. Significantly, the FDA, in the introductory section of its final rule on olestra, refers to olestra interchangeably as either a fat or an oil without giving any significance to its change in appellation.²⁹ While dictionaries differ in their interpretation of the word "oil," with *Websters Dictionary* requiring that the substance be "easily liquifiable on warming," and *the American Heritage Dictionary* stating that oils are "liquid or liquifiable at room temperature" (emphasis added), NAD finds this disagreement, in the present circumstances, to be inconsequential.

With regard to whether consumers understand the two terms to mean different things, and, if so, attribute any significance to the difference, NAD noted that neither party submitted communications data on how consumers interpreted these claims. Therefore, NAD relied on its experienced judgment to determine what reasonable messages were conveyed by the advertising. Based on its review of the entire record, NAD concluded that the advertiser's use of the term "cooking oil" in these advertisements was neither misleading nor inaccurate. First, NAD noted that many products marketed to consumers as oils, such as coconut oil and palm oil, are solid or semisolid at room temperature. NAD concluded that consumers could reasonably understand a product with the consistency of olestra, described by the challenger as that of a semi-solid shortening, to be an oil. Second, the advertisements do not, nor could they, market Glean for use by consumers as a shortening,³⁰ fat, or oil to be used in preparing meals in their homes because the sale of olestra for this purpose has not been requested or approved.³¹ They focus on the use of Glean by manufacturers for frying chips, not on the sale of Glean to consumers for use at home as either a "shortening" or an "oil." Consumers are therefore even less likely to attach any significance to the terminology or consistency of the olestra used to fry chips.

Depiction of Olestra

NAD agreed with the challenger that the television commercials depicting olestra being poured into a pan, apparently at room temperature, are inaccurate. NAD found that the advertisements, which never identified the pouring oil as having been heated, could reasonably be interpreted by consumers to be room-temperature Olean, despite the fact that at room temperature, Olean is not a clear liquid and cannot be poured. The depiction is therefore not accurate.

Medical Journal Claims

After thoroughly reviewing the entire case record, NAD determined that the advertiser has provided a reasonable basis for the claims that Olean does not compromise nutrition and can help patients cur back on far and calories. CSPI based its challenge to this claim on the ground that Olean inhibits absorption of carotenoids, and thereby compromises nutrition. NAD, however, agreed with the FDAs conclusion that the absorption of carotenoids, as opposed to the total nutrient content of the fruits and vegetables in which they are found, was not significant from a public health standpoint and did not impact on consumer health (see section on the "a little healthier" and "better choice" claims, above). With regard to the claim that Olean can help patients cur back on far and calories, NAD determined that the claim is restricted in its terms, i.e., "help" patients and "cur back." It is neither broad not a guarantee. The studies submitted by P&G are adequate to substantiate this claim.

Olean is a Natural Product

The parties had very different interpretations of the challenged advertisements on the issue of "natural" claims. The challenger asserted that the advertisements, while never using the word "natural," imply that Olean is a natural product; the advertiser maintained that the advertisements communicate that Olean is not a natural product. Since neither parry submitted communications data to support its interpretation of the advertisement with regard to this implied claim, NAD relied on its experienced judgment to determine what reasonable messages were conveyed by the advertising.

Despite the fact that the word "natural" is never used, NAD found that the advertisements imply that Olean is a natural product. While NAD agreed that some consumers may interpret the advertisements to mean that Olean is not a natural product, NAD did not find that this is the only or even the most likely interpretation. It is well established that an advertiser is responsible to substantiate all reasonable interpretations of its claims. Having carefully reviewed all of the advertising submitted, NAD concluded that the advertisements could reasonably be interpreted by consumers to mean that Olean is a natural product. In arriving at this conclusion, NAD noted that a large majority of the advertisements feature farms, farmers and soybeans and state that soybeans are being used to make a new fat-free cooking oil, Olean. NAD also observed that none of the advertisements for Olean even mention the word "processed,"³² indicate that Olean is not just soybean oil that has somehow been rendered fat-free, or suggest that Olean is a chemically manufactured molecule, which is not found in nature.

NAD was not persuaded by the advertiser's argument that because the advertisements state that Olean "starts from crops that grow here" and use language such as "come up with" and "came up with a way," that consumers will understand that Olean is not a natural product. NAD observed that advertisers of food products often state that their products "start with" certain ingredients, such as tomatoes or "nutritious grain" when the food being marketed, e.g., pasta sauce or breakfast bars, is not unnatural. In addition, NAD found that the words "come up with" and "came up with a way," as used in the advertisements, while perhaps implying that Olean is processed, does not necessarily indicate a process that results in the creation of a new molecule. Indeed, NAD found that the advertisements with the cited language, e.g., "I remember the day I first heard about it. How soybeans like mine were going to be used to make a new kind of cooking oil...Seen' the folks who make Crisco had come up with Olean, an oil that would fry up fat-free snack chips without adding any calories... are likely to be reasonably interpreted by consumers to mean that Olean, because its main ingredient is soybeans, is a natural product.

NAD was also not persuaded by the advertiser's argument that consumers will understand that Olean is not a natural product because the message conveyed is that Olean "starts with recognizable ingredients, such as soybeans, cottonseed and sugar, that are processed in a different way to make Olean a fat-free, calorie-free oil." NAD noted that neither cottonseed not sugar (or any ingredient other than soybeans) are referred to in any of the advertisements and that the advertisements do not reveal that soybean oil in its natural molecular structure is not present in Olean. While Olean may start off with soybean oil (or any other edible oil) and sugar, the oil molecules and the sugar molecules are chemically broken apart and then recombined (one part of an oil molecule is combined with one part of

a sugar molecule) to form a new molecule not found in nature. Even if the advertiser's argument [that consumers will reasonably understand the advertisements to communicate that Olean is soybean oil that is processed in a different way] is correct, the advertising does not necessarily connote that Olean is not a natural substance. In fact, except for fresh fruits and vegetables, most foods are processed, but are not therefore necessarily unnatural.³ Moreover, NAD found that the advertiser's argument that it only intended to "reassure consumers about Olean's origins" and that "the components of Olean—fatty acids and sugar—are indeed as natural as vegetable oil," contradict its contention that consumers will understand from the advertisements that Olean is not a natural product.

In reaching its decision on this issue, NAD also reviewed its prior decisions relating to "natural" claims and found the reasoning in its decision regarding advertising for NutraSweet³¹ instructive. In that case, as in the instant case, the advertising never explicitly represented that NutraSweet was natural.

Despite the fact that the components of NutraSweet exist separately in nature and in many common foods, NAD noted that the particular combination of ingredients in NutraSweet does not occur in nature. NAD concluded that, in overall impression, the advertisements might lead a consumer to believe that the combination exists in nature, despite the fact that the advertisements never explicitly made that claim.

As noted above, the instant case involves a series of advertisements that, although never using the words "nature" or "natural," convey an overall impression (through visuals and language) that Olean comes from the farm. NAD concluded that the challenged advertisements could reasonably be interpreted by consumers to mean that Olean is a natural product when, as the advertiser concedes, that is not the case.

Need for Disclosure in Olean Advertising

The FTC's Enforcement Policy Statement on Food Advertising makes it clear that simply because the NLEA requires certain nutrition information on a food label, does not mean that the identical information must appear in all advertising for that food. Moreover, the FTC does not require all information about diet-related diseases that may be relevant to consumption of a particular food to be included in its advertising, but only information necessary to prevent consumers from being misled about the significance of dietary effects on health. The FTC explained its policy as follows:

"When the context of an advertisement as a whole conveys to consumers the net impression that the food makes only positive contributions to a diet, or does not contain any ingredients at levels that raise the risk of diet-related diseases, the failure to disclose the presence of risk-increasing nutrients is likely to be deceptive."

In the case of olestra, however, there is no risk of "diet related diseases" of which consumers need to be informed. FDA did not require package labeling to address safety concerns, and specifically stated that it "is not requiring the labeling of olestra-containing foods in order to insure the safe use of olestra."³⁷ Instead, the FDA required the label statement in order to enable consumers to associate olestra with any GI effects it may cause, preclude "unnecessary concerns about the origin of GI effects, were they to be observed" and "prevent unnecessary or inappropriate medical treatment of those symptoms."³⁸ After reviewing all of the data, the FDA stated: "there is no evidence that [GI] effects represent health consequences" and "there are no safety concerns with respect to the effect of olestra on the GI tract." (61 FR 3160, 3161) Similarly, the FDA concluded that there is a reasonable certainty of no harm from olestra's effects on carotenoid absorption:

While NAD agrees with the challenger that disclosure of safety risks in advertising is required when generalized safety claims are made and silence regarding actual diet-related diseases would mislead consumers to reasonably believe that no risk is present, NAD determined that in the instant challenge, no disclosure is required. In reaching this conclusion, NAD noted that the advertiser's representations that Glean is "a little healthier" or "a better choice" are closely linked to claims regarding less fat and fewer calories, and are not generalized health claims. (See discussion of "A Little Healthier" claims, above.) Further, given the FDA's findings that there are no safety concerns

with respect to the effects of olestra that would require disclosures on olestra labeling,⁴ NAD determined that there is no reasonable basis to require a safety disclosure in the challenged advertising.

CONCLUSION

NAD determined that the advertiser has supplied a reasonable basis for its claims that Olean is "a little healthier" or "a better choice" than regular chips in the context of advertising that limits these claims to representations that Olean chips contain less fat and fewer calories than regular chips.

NAD also concluded that the term "cooking oil" as used in the challenged advertisements was neither misleading nor inaccurate, and that the advertiser provided a reasonable basis for claims in the medical journal advertisements that Glean does not compromise nutrition and can help patients cur back on fat and calories. NAD determined, however, that the depiction of Olean as a liquid at room temperature was inaccurate and recommends that such depictions be discontinued.

With respect to the implied "natural" claims, NAD concluded that the advertisements could reasonably be interpreted by consumers to mean that Glean is a natural product. Because Glean is undeniably not natural, NAD recommends that the advertng be modified to avoid this potential for consumer confusion.

Finally, NAD determined that the information statement required by the FDA on labeling of foods containing olestra does not have to be disclosed in the challenged advertising.

Advertiser's Statement: We are very pleased that NAD has rejected the fundamental arguments that CSPI has made, and continues to make in a variety of forums — specifically, that products made with Olean have negative health consequences that must be disclosed in advertising. We are also pleased that NAD agreed that our claims concerning the benefits of Olean snacks were fully substantiated. With respect to the "natural" issue, it has and will continue to be our intent, to truthfully communicate Oleans origins, and was never our intent, however, to imply that Olean itself is found in nature. Nonetheless, even though the present advertising has run its course, we will take NAD's concerns into account for any future Olean advertising. Finally, we appreciated the opportunity to take part in NAD's self-regulatory process. (#3499 PBS, closed 10/14/98)

1 Carotenoids are nutrients found in such foods as fruits and vegetables and, according to CSPI, may be valuable in reducing the risks of macular degeneration, cancer, cardiovascular disease and other health problems.

2 The challenger cited *The Dietary Guidelines for American*, published by HHS and the Department of Agriculture as stating that carotenoids are among the nutrients that have a "potentially beneficial role in reducing the risk for cancer and certain other chronic diseases.

3 CSPI further argues that P&Gv statement "Olean cannot affect the carotenoids that have already been absorbed by the body," which appears in its journal advertisement, is misleading because olestra interferes with the absorption of carotenoids that have been eaten recently.

4 CSPI noted that the FDA concluded that "GI symptoms associated with ingestion of olestra-containing foods are material fact information... Disclosing this information on food labels will enable consumers to associate olestra with any GI effects it may cause," and that the FDA required such disclosure to preclude consumers from being misled about consequences which may result from the consumption of such food.

5 The challenger stated that some of P&Gv clinical trials demonstrate that medically significant diarrhea does occur in olestra consumers.

7 The challenger argued that these studies lacked the statistical sensitivity to detect increases in adverse (31 effects below 7 to 10 percent, and asserted that an increase in adverse effects of one to two percent after a moderate exposure to Olean, which would not be detected by these studies, would lead to millions of extra cases of those effects annually after national marketing of olestra snacks.

8 The Institute of Shortening and Edible Oils defines "fats and oils" as: predominantly triesters of fatty acids and glycerol, commonly called 'triglycerides.' They are insoluble in water but soluble in most organic solvents. - When solid appearing they are referred to as 'fats' and when liquid they are called oils." Institute of Shortening and Edible Oils. *Esud Airts and Oils* 1(1994).

9 Sec footnote 8. The challenger also cited Ensminger, Ensminger, Konlande, and Robson, *Food and Nutrition Encyclopedia* 1662 (1st Ed.1983); Harold McGee, *On Food and Cooking the Science and Lore oldie Kitchen* 597 (1984); and, Carol Ann Rinzler, *Nutrition for Dummies* 63 (1997).

10 According to CSPI, one study of two- to five-year-olds showed that use of a far substitute at t0% of energy from dietary far did not significantly reduce 24 hour energy intake: the other study, on 21- to 30-year-old men, concluded that subjects are olestra "without affecting tot.,l daily energy intake."

11 Position of the American Dietetic Association: Fat Replacers. 98 .I. *Merican Dietic Association*. 463, at 467.

12 Miller, GD, Groziak, SM. "Impact of Far Substitutes on Far Intake." *Lipids* (1996) Suppl: S293-6.

13 The FSIS has jurisdiction over meat and poultry labeling.

14 According to the challenger, FSIS explains that minimal processing may include traditional processes used to make food edible or preserve it or make it safe for human consumption (e.g., smoking, roasting, freezing, drying and fermenting) or those physical processes which do not fundamentally alter the raw product (as opposed to solvent extraction, acid hydrolysis, and chemical bleaching).

15 The challenger maintained that Olean would also not qualify as natural under FDAs informal policy addressing the use of the term 'natural' on food labels, which permits use of the term on labels of food products if they are composed of substances that are not ma ri made.

16 The challenger noted that in 1996 ii had petitioned the Federal Trade Commission ("FTC") to require advertisements for olestra and olestra-containing products to include the information required by the FDA on product labels and that the FFC is reviewing the petition.

17 The challenger further maintained that a claim can be misleading if it fails to reveal facts that are material in light of the representations made, and that the claims that olestra is a "better choice" or a "little healthier to ear than regular chips" are misleading because they fail to reveal that olestra interferes with the absorption of nutrients and may cause 01 disturbances.

18 59 Fed. Reg. 28,388 (1994). "(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, the failure to disclose the presence of risk-increasing nutrients is likely to be deceptive.)"

19 The FDA amended its food additive regulations, effective January 30, 1996, to provide for the safe use of sucrose certified with medium and long chain fatty acids (olestra) as a replacement for fats and oils in savory (salty) snacks. 61 FR. 3118.

20 The advertiser conceded that foods eaten as much as two hours prior to the ingestion of Olean can remain in the digestive track and therefore have their fat-soluble components, if any, absorbed by Olean and then passed out of the body

21 In evaluating safety, FDA's standard is a "reasonable certainty that no harm will result from the use of an additive." (61 FR 31 19)

22 See footnote 8.

23 P&G stated that when some participants knew they were eating Olean chips, they ate a few extra chips, but still maintained reductions in their fat and calorie intake.

24 59 Fed. Reg. 28388,28392 (1994) FTC's Enforcement Privacy Statement on Food Advertising.

25 "As part of the approval, FDA required that the petitioner conduct further studies of the effects of human consumption, to be submitted to the agency 30 months after the approval date. The submission of new studies was made by the advertiser in June of 1998.

26 - 7661 FR 3119 An effect is harmful "if it affects health, not if it is simply an undesirable or unexpected effect that has no adverse health consequences." 61 FR. 3120

27 - 61 FR 3160, n.83.

28 Id

29 See, 61 FR at 3119, 3121.

30 Although the challenger maintained that Olean is more like a semisolid shortening at room temperature than an oil, CSPI never defines shortening and NAD assumes that the challenger equates shortening with "fat."

31 The FDA approved olestra for use only in savory snacks, not for use as a cooking oil; olestra therefore cannot be marketed as such to consumers.

32 Although a brochure for Fat-Free Pringles (not for Olean) use, the word "processed,": "Olean is a cooking oil made starting from farm-grown ingredients like soybeans processed in an improved way, NAD found that the phrase "processed in an improved way," in the context of this advertisement, does not necessarily convey to consumers the fact that Olean is a new molecule, not found in nature. Many forms of processing are used, such as freezing, drying or heating, that do not change the basic identity of a natural product. Stating that the soybeans in Olean are "processed in an improved way" may imply to some consumers that Olean, like other cooking oils, is processed, the only difference being that Olean's processing is improved.

33 While one print advertisement implies that something more than soybeans go into Olean (Crisco uses "soybeans like we grow here as part of a new kind of oil"), there is no disclosure of what other substances constitute Olean, or in what manner, e.g., physical mixture or chemical synthesis, these other "ingredients" are combined.

34 Similarly, NAD found the advertisers' arguments that the advertisements do not imply that Olean is natural, but are only intended to reassure consumers that "the components of Olean—fatty acids and sugar—are indeed as natural as vegetable oil" unconvincing. As noted above, consumers are never informed that fatty acids and sugar are the components of Olean, and are instead provided with pictures of farms and language stating that soybeans are being used to make Olean, a new cooking oil.

35 Significantly, all cooking oils, including soybean oil, are processed to some degree.

36 *The NutraSweet Company*, NAG Case Report #2490 (April 20, 1987).

37 - 61 FR 3160, n.83.

38 - 8 Id

39 Id at 3168. The FDA also stated that although there is an association between diets rich in fruits and vegetables (including those that contain carotenoids) and decreased cancer risk, "there is no direct evidence that carotenoids themselves are responsible for or contribute in a significant way to that protective benefit."

40 Thus, even had NAD determined that the "little healthier" and "better choice" were not limited to less fat and fewer calories and were generalized health claims, NAD would not necessarily find that advertising disclosures are required.