

INSTITUTE OF SHORTENING AND EDIBLE OILS, INC.

1750 NEW YORK AVENUE, N.W., SUITE 120

WASHINGTON, D.C. 20006

PHONE (202) 783-7960

FAX (202) 393-1367

EMAIL INFO@ISEO.ORG

April 15, 2004

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2003N-0076
Food Labeling: *Trans* Fatty Acids in Nutrition Labeling;
Consumer Research to Consider Nutrient Content and Health
Claims and Possible Footnote or Disclosure Statements

Dear Sir or Madam:

The Institute of Shortening and Edible Oils (ISEO) appreciates the opportunity to comment regarding the Food and Drug Administration's (FDA) Advance Notice of Proposed Rulemaking (ANPR) on *trans* fatty acids in nutrition labeling during the reopening of the comment period. 69 Fed. Reg. 9559 (Mar. 1, 2004).

ISEO is a trade association representing the interests of the refiners of edible fats and oils in the United States. Its 18 members represent about 90-95% of the edible oils and fats processed domestically (20 billion pounds). These fats and oils are used in baking and frying fats (shortening), salad and cooking oils, margarines and spreads, confections and as ingredients in a wide variety of other foods.

ISEO previously submitted comments dated October 9, 2003 on this ANPR (a copy of which is attached), and we reaffirm all of the points made in those comments.

ISEO believes it is premature to establish a Daily Value for *trans* fat, and that a Daily Value should not be set arbitrarily. The quantitative declaration of *trans* fat, already required by FDA, in combination with nutrient content claims about *trans* fat, will achieve FDA's purposes of encouraging industry to reduce or eliminate *trans* fat in food products and encouraging consumers to reduce their *trans* fat intake.

Establishment of a Daily Value (DV) for Trans Fat

1. There is insufficient information at this time to establish a Daily Value for *trans* fat.

ISEO understands the FDA's desire to communicate to consumers the significance of the amount of each nutrient declared in the Nutrition Facts panel in the context of a total daily diet. A Percent Daily Value (%DV) declaration is an effective way to do this, provided FDA has sufficient information to establish a Daily Value for that nutrient. In the case of *trans* fat, we do not believe there is sufficient information to set a Daily Value. Because the Institute of Medicine of the National Academy of Sciences (IOM/NAS) was unable to establish Dietary Reference Intakes (DRIs) for *trans* fat, FDA earlier concluded that it lacked "a scientific basis or recommendation by an authoritative body" needed to set a Daily Value for *trans* fat. 68 Fed. Reg. 41434, 41457 (July 11, 2003). Now, however, FDA is considering establishing a Daily Value for *trans* fat based on "food composition data, menu modeling, and data from dietary surveys to estimate minimum intakes [of *trans* fat] consistent with nutritionally adequate and health-promoting diets for diverse populations." 69 Fed. Reg. at 9559.

ISEO believes that this would be an extremely difficult and highly questionable way to establish a Daily Value. To begin with, the data on which the entire exercise would be based, reliable and up-to-date food composition databases showing the *trans* fat content of the current U.S. food supply, is not available. Most of the *trans* fat in the American diet comes from processed foods, and *trans* fat is present in a wide variety of processed foods. An enormous effort is being made to reformulate processed foods to reduce or eliminate *trans* fat. Due to the rapid pace of food reformulation taking place in the food industry today, food composition databases merely 4 or 5 years old are already out of date. FDA's website, for example, includes a food composition database that is already outdated with respect to *trans* fat. Listed *trans* fat values for household shortening, salad dressing, and margarine and spread products are no longer reflective of the current marketplace and generally overstate the amount of *trans* fat in these products. The other data sources on which the Daily Value would be based are also unreliable. Dietary surveys, such as food frequency and quantity questionnaires, have been shown to be relatively inaccurate due to both under- and over-reporting by participants.

ISEO does not believe there is anything approaching consensus among leading public health and scientific bodies regarding healthy intake levels for *trans* fat. In the past, FDA has based Daily Values for macronutrients (e.g., total fat, saturated fat) on recommendations contained in several reports by authoritative bodies that together reflected a widespread consensus about healthy intake levels for the nutrient in question. For example, in setting the Daily Value for total fat at 65 grams (g), FDA relied on "major available consensus documents" all of which recommended that total fat intake be no more than 30 percent of calories. 58 Fed. Reg. 2206, 2218 (Jan. 6, 1993). These consensus documents were reports such as the *Dietary Guidelines for Americans*, the Recommended Dietary Allowances issued by the IOM/NAS, and reports by the National Institutes of Health. For *trans* fat, there are no such authoritative recommendations, only a suggestion by the IOM/NAS that FDA should set a Daily Value.

In deciding not to set a Daily Value for *trans* fat last year, FDA stated:

The agency agrees with the majority of the comments that the scientific evidence is not sufficient to support the establishment of a DRV for *trans* fat at this time.... FDA emphasizes that existing DRVs are based on quantitative dietary intake recommendations developed from extensive scientific evidence that establishes values that will promote public health.... DRVs have not been based on international recommendations, which may not be germane in the United States, or on average dietary intake levels, which may not represent healthy dietary consumption patterns. 68 Fed. Reg. at 41456.

We question whether there is even real consensus that *trans* fat, at low levels of intake, raises LDL-cholesterol levels. While the IOM/NAS concluded there is a positive linear relationship between *trans* fat intake and LDL cholesterol levels,¹ this conclusion was based on very little data and remains controversial. There have been very few well-controlled studies of the effects of *trans* fat intake at levels typical of the average American diet, 2 to 3 percent of energy.² The IOM/NAS panel's conclusion that there is a "positive linear trend" between *trans* fat intake and serum LDL cholesterol levels appears to have been based on a single chart.³ This chart was originally published in correspondence, not in a peer-reviewed article. The chart plots changes in the ratio of HDL:LDL cholesterol levels as *trans* fat intake increases, using a linear regression model. However, the chart incorporates data points from studies that did not find statistically significant results. If the chart were to be redrawn using only data points of significance, then, rather than showing a positive linear trend, it would be consistent with the conclusion that *trans* fat intake at levels below 4 percent of energy has no significant effect on LDL concentrations.

For all of these reasons, ISEO believes it is premature to establish a DV for *trans* fat at this time.

2. Declaration of the amount of *trans* fat per serving in Nutrition Facts provides adequate information.

While a %DV declaration for *trans* fat may be desirable, we do not believe it is essential. The quantitative declaration of *trans* fat, which will be required for all packaged foods beginning January 1, 2006 and which many food products already provide, is more important than the %DV

¹ IOM/NAS, Letter Report on Dietary Reference Intakes for Trans Fatty Acids (July 10, 2002), p. 6, drawn from Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids.

² FDA estimates that the average *trans* fat intake in the United States is about 2.6 percent of energy, whereas average intake of saturated fat is approximately 4 to 5 times that amount. FDA, Questions and Answers about Trans Fat Nutrition Labeling (updated March 3, 2004).

³ Ascherio et al., *Trans* fatty acids and coronary heart disease, *N. Engl. J. Med.*, 340:1994-1998, 1999 (letter).

and is adequate for FDA's purposes (i.e., encouraging consumers to reduce *trans* fat intake and manufacturers to reduce or eliminate *trans* fat in their products). ISEO believes that, once the requirement to declare the amount of *trans* fat in Nutrition Facts has had sufficient time to have an effect, the entire issue of a %DV declaration may seem moot or at least have lost its urgency. As noted above, food manufacturers, and the fat and oil industry in particular, are working aggressively to develop *trans* fat alternatives that will provide consumers with foods that have the same acceptable functionality and stability as their conventional counterparts. ISEO believes industry should be given a chance to make these changes before a Daily Value for *trans* fat based on inadequate data is hurriedly mandated.

3. Major changes to the food label should be timed to coincide, not adopted piecemeal.

Another reason for not rushing to adopt a Daily Value for *trans* fat is that doing so would present the food industry with the burden of having to re-label the entire U.S. food supply every two years for the foreseeable future.

FDA's final rule mandating declaration of *trans* fat in Nutrition Facts, which will go into effect on January 1, 2006, will affect every packaged food sold in the United States. If FDA were to establish a Daily Value for *trans* fat (either alone or in combination with saturated fat) and to mandate a %DV declaration for *trans* fat (either alone or in combination with saturated fat), this too would require food manufacturers to change the label of every packaged food sold in the U.S.⁴ Other major labeling changes, unrelated to *trans* fat, are also being considered. These include: updating Daily Values and %DV declarations for other nutrients to reflect the new IOM/NAS DRIs, requiring a new declaration of calories per package (in addition to the current declaration of calories per serving), enlarging the declaration of calories to give it greater emphasis, and updating FDA's reference amounts customarily consumed to reflect the most recent consumption data.⁵ Each of these contemplated changes has the potential to require re-labeling of all, or large segments, of the U.S. food supply.

It is imperative that such major food labeling changes not be adopted piecemeal. Such a piecemeal approach to major label changes is extremely costly to food manufacturers and confusing to consumers. If these major label changes are not coordinated but are spread out over several years, the cost burden on industry and the educational burden on consumers would be considerable. Given the large number of major label changes currently under consideration, we urge FDA to first decide which major changes it will mandate and then mandate them at one time rather than taking a piecemeal approach.

⁴ Presumably, a final rule mandating a %DV declaration for *trans* fat would be issued after December 31, 2004 and, therefore, would be subject to FDA's next uniform compliance date of January 1, 2008.

⁵ Changes to reference amounts would change the serving sizes used for many foods, thereby changing the amounts of nutrients declared in Nutrition Facts.

Footnotes and Other Label Statements About Trans Fat

ISEO strongly objects to the use of a footnote or other label statement advising consumers to reduce intake of *trans* fat, either alone or in combination with saturated fat and cholesterol. Footnotes that focus on one or more nutrients in a negative way are likely to be perceived by the consumer as warnings. Consumer research has shown that consumers tend to focus on the subject of the footnote while overlooking other pertinent information on the food label, thus causing consumers to make inappropriate food choices. FDA has in the past rejected suggestions to require warning or disclosure statements about particular nutrients, unless a food makes a nutrient content claim and thereby encourages consumers to emphasize that food in their diet. (See ISEO's comments dated October 9, 2003 for a broader discussion of this point.)

The footnote being contemplated by FDA has many other drawbacks. It would clutter an already crowded Nutrition Facts panel. It would not really help consumers understand the significance of the amount of *trans* fat in the labeled food; it would advise consumers to keep their intake of *trans* fat low but would not explain what "low" means.

The declaration of %DV is the preferred method for informing consumers about the significance of the amount of a nutrient in the context of a total daily diet.

Nutrient Content Claims Involving Trans Fat

ISEO supports the authorization of nutrient content claims about *trans* fat, since they will provide incentives to industry to reduce *trans* fats in the diet through technological advances and subsequent food product reformulation.

In its comments to FDA dated October 9, 2003, ISEO proposed definitions for new nutrient content claims "*trans* fat free" and "reduced *trans* fat" and proposed changes in the definitions of certain existing nutrient content claims. ISEO reiterates those comments.

Summary

ISEO believes the IOM/NAS recommendation that FDA establish a Daily Value for *trans* fat in the future is reasonable. However, ISEO believes it is premature to establish a Daily Value for *trans* fat, individually or in combination with saturated fat, because there is no consensus recommendation on *trans* fat intake from the leading public health and scientific bodies, nor is there adequate data on which to base a Daily Value. There is no need to rush the creation of a Daily Value for *trans* fat.

ISEO strongly opposes a footnote or other label statement advising consumers to limit their intake of *trans* fat, saturated fat, and/or cholesterol. Instead, we support the authorization of the nutrient content claims regarding *trans* fat, which we believe will provide important incentives for industry to create functional alternatives to *trans* fats and reformulate their products to reduce or eliminate *trans* fats.

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ISEO appreciates FDA's consideration of these comments and welcomes any requests for further information.

Respectfully submitted,

Robert M. Reeves, President

INSTITUTE OF SHORTENING AND EDIBLE OILS, INC.

1750 NEW YORK AVENUE, N.W., SUITE 120

WASHINGTON, D.C. 20006

PHONE (202) 783-7960

FAX (202) 393-1367

EMAIL INFO@ISEO.ORG

October 9, 2003

BY HAND DELIVERY

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Docket No. 03N-0076

The Institute of Shortening and Edible Oils (ISEO) is grateful for this opportunity to submit comments to the Food and Drug Administration (FDA) regarding the FDA's advance notice of proposed rulemaking on nutrition labeling of *trans* fatty acids. 68 Fed. Reg. 41,507 (July 11, 2003).

ISEO is the national, not-for-profit trade association representing the refiners of edible fats and oils in the United States. Its 18 members represent approximately 90 to 95 percent of the edible fats and oils processed domestically (18 billion pounds). These edible fats and oils are used in baking and frying fats (*i.e.*, shortening), salad and cooking oils, margarine, confections, toppings, and as ingredients in a wide variety of other foods.

I. BASIC PRINCIPLES

Now that FDA has mandated nutrition labeling of *trans* fat in Nutrition Facts,¹ the agency is turning its attention to *trans* fat in nutrient content claims, health claims, and a possible footnote or disclosure statement. ISEO proposes that FDA keep the following basic principles in mind as it pursues this task:

¹ ISEO supports the definition of "*trans* fat" in FDA's final rule on nutrition labeling of *trans* fat. 68 Fed. Reg. 41,434 (July 11, 2003).

1. The nutrition label should not single out *trans* fat as a nutrient uniquely to be avoided. To stigmatize *trans* fat would be bad public health policy. As FDA has indicated, its goal is to reduce intake of *trans* fat and saturated fat combined, not just one or the other. If *trans* fat is stigmatized, there will be a strong incentive for both manufacturers and consumers to substitute saturated fat for *trans* fat. The end result might be lower consumption of *trans* fat but higher total consumption of *trans* fat and saturated fat combined. This would be especially troubling, given the fact that there is little or no scientific data indicating that *trans* fat at low levels of intake raises serum total or LDL cholesterol.
2. FDA should not require warning or disclosure statements about particular nutrients except where a food makes a nutrient content claim. It has been FDA's longstanding policy that warning or disclosure statements about particular nutrients are not required unless a food makes a claim. This is because "there are no generally recognized levels at which nutrients such as fat, saturated fat, cholesterol, or sodium in an individual food will pose an increased risk of disease."² Only when a food makes a nutrient content claim, and thereby encourages consumers to emphasize that food in their diet, does FDA require disclosure of certain nutrients whose level in the food may increase risk of disease. FDA should not abandon this policy.
3. FDA should not allow nutrition labeling policy to get ahead of scientific understanding. Thus far, FDA deserves praise for its patience and refusal to set policy until there is a basis grounded in adequate scientific data. FDA is correct not to establish a Daily Value (DV) for *trans* fat, given the insufficient data on which to base a DV. ISEO hopes that FDA will continue to set policy only where there is sufficient scientific data to support it.

II. BACKGROUND

The edible fats and oils industry is working aggressively to develop products that are free of *trans* fat or contain reduced levels of *trans* fat. This effort to reduce or eliminate *trans* fat has been going on for several years and will continue. ISEO believes that, in about five to ten years, the food industry will have a wide range of stable, affordable vegetable oil ingredient options that have no *trans* fat or reduced levels of *trans* fat. At that time, the edible fats and oils on the U.S. market will contain far less *trans* fat than they do today.³

² 58 Fed. Reg. 2302, 2307 (Jan. 6, 1993). ISEO believes this is also true for *trans* fat.

³ ISEO notes that *trans* fat also is naturally present in beef and dairy products. The U.S. Department of Agriculture estimates that up to 20 percent of the *trans* fat consumed in the American diet is from these ruminant sources. Hunter, JE and Applewhite, TH, Reassessment of *trans* fatty acid availability in the U.S. diet, *Am J. Clin. Nutr.*, 54: 363-369, 1991.

For the time being, however, for shortening and other products that require specific functional properties, the principal alternatives to partially hydrogenated vegetable oils are vegetable oils high in saturated fat and animal fats high in both saturated fat and cholesterol.⁴ There are alternative products with the same functionality that contain no *trans* fat and reduced levels of saturated fat, but these products are more expensive than competing products. These alternative products require additional processing steps (*e.g.*, interesterification, blending of hydrogenated "hardstock" with unhydrogenated oils) which increases their cost.

In setting labeling policy, ISEO hopes that FDA will take into account the real world formulation options available to food manufacturers today and the risk that harsh labeling requirements designed to quickly eliminate *trans* fat from the food supply are likely to increase use of saturated fat. From a public health viewpoint, this would be unfortunate, especially since the saturated fats that would replace *trans* fat increase serum cholesterol and are already far more prevalent in the U.S. diet than *trans* fat. In the U.S. diet, saturated fat makes up about 12 to 14 percent of energy, whereas *trans* fat constitutes only about 2 to 4 percent of energy.

Thus, the edible fats and oils market is moving aggressively in the direction of *trans* fat free vegetable oils and shortenings, but it is not there yet. FDA's final rule requiring nutrition labeling of *trans* fat will give extra impetus to this movement. More and more, the marketplace is demanding fats and oils that contain no *trans* fat. This process has been set in motion and is well on its way to completion. However, technological change like this takes time, and we do not believe that FDA can speed the process by additional regulatory actions, such as requiring a footnote or warning statement about *trans* fat.

ISEO urges FDA, in considering additional label changes related to *trans* fat, to recognize that the industry is well on its way to achieving drastic reductions in the amount of *trans* fat in vegetable oil products and to take into account the real world formulation options available to the food industry today.

III. COMMENTS

1. ISEO strongly opposes a footnote advising consumers to limit their intake of *trans* fat.

ISEO strongly opposes requiring a footnote advising consumers to limit their intake of *trans* fat or any other nutrient, regardless of the location or wording of such a footnote. We commend FDA for its decision to reconsider the footnote proposed last year. We now urge FDA to withdraw the footnote concept entirely.

⁴ For products/applications that do not require specific functional properties related to solid fat content, it is possible to substitute commodity type oils (*e.g.*, mid-oleic sunflower oil, soybean oil, corn oil, cottonseed oil) for partially hydrogenated oils.

A footnote that singles out one nutrient, or group of nutrients, in a negative way inevitably will be perceived by consumers as a warning. In a recent consumer research study, a footnote about *trans* fat tended to focus consumer attention on *trans* fat to the exclusion of all other nutrients.⁵ However innocuously FDA may try to word the footnote, the consumer take-home message will be to avoid those nutrients. Since the footnote presumably would appear only on the labels of foods that contain the nutrients mentioned in the footnote (*i.e.*, *trans* fat, saturated fat, and/or cholesterol), the message will be that consumers should avoid the labeled food. Even if the footnote is phrased as abstract advice about intake of *trans* fat, consumers will relate the footnote to the labeled food.

Requiring a warning statement about particular nutrients in a food is something that FDA has specifically rejected in the past. In 1993, FDA specifically rejected suggestions that it should require warning statements about particular nutrients, such as fat and saturated fat, when present above specified levels. FDA stated that "there are no generally recognized levels at which nutrients such as fat, saturated fat, cholesterol, or sodium in an individual food will pose an increased risk of disease." 58 Fed. Reg. at 2307. Therefore, it would be inappropriate to require warning or disclosure statements about such nutrients, unless a food makes a nutrient content claim and thereby encourages consumers to emphasize that food in their diet. Using the same reasoning, FDA should not now require a warning statement about *trans* fat in the absence of a claim.

Even if the footnote is viewed as a neutral dietary guidance statement rather than as a warning, it still should not be required. FDA has never mandated any kind of dietary guidance statement on food labels, and ISEO does not believe it should do so now. Mandating a dietary guidance statement about *trans* fat would create a dangerous precedent and would create pressure to mandate dietary guidance statements about other nutrients and foods. If FDA mandates a dietary guidance statement about *trans* fat, saturated fat, and/or cholesterol, why should it not also mandate dietary guidance statements about calories, sugars, sodium, or fruits and vegetables? It has been FDA's longstanding practice to issue dietary advice to the public in the *Dietary Guidelines for Americans* and other educational materials. In addition, dietary advice is communicated to consumers through nutrient content claims, health claims, structure/function claims, and dietary guidance statements on food labels. While such claims are voluntary, food manufacturers generally are eager to make such claims and FDA can exercise considerable control over their use by easing or tightening regulatory restrictions governing their use. Thus, FDA has ample means at its disposal to convey dietary advice to the public without mandating a footnote or other label statement.

⁵ In a study conducted by the International Food Information Council, it was found that the proposed footnote "Intake of *trans* fat should be as low as possible" caused consumers to focus exclusively on *trans* fat rather than the overall nutritional value of the food, resulting in inappropriate food choices. Cogent Research, *Impact of Trans Fat Label Information on Consumer Food Choices* (2003).

FDA has stated that the footnote is needed to help consumers understand the relative significance of the amount of *trans* fat in the context of a total daily diet.⁶ However, the footnote would not do this. If, for example, a food contains 1 gram (g) of *trans* fat per serving, the footnote would advise consumers to keep intake of *trans* fat low but would not explain the significance of 1 g of *trans* fat in a daily diet. The established mechanism for conveying the significance of the amount of a nutrient in the daily diet is the declaration of Percent Daily Value (%DV) in Nutrition Facts.⁷ In the absence of a DV, there is simply no good way to communicate this information to consumers. A footnote cannot take its place. FDA should wait until it has sufficient scientific information to establish a DV for *trans* fat.

ISEO believes there are many other reasons why the footnote is ill-advised, including the following:

- The footnote would result in an overemphasis by consumers on lipids. If FDA were to mandate a dietary guidance statement about a particular nutrient or class of nutrients, many consumers are likely to focus exclusively on those nutrients. In the past decade, the overriding attention paid to fat arguably has led many consumers to pay too little attention to calories, contributing to an epidemic of obesity.
- The footnote would clutter an already crowded Nutrition Facts panel, making it less likely that consumers will read any of it.
- The footnote options being considered by FDA are vague, nuanced, and confusing. ISEO believes they would add little or nothing to consumer understanding of *trans* fat, saturated fat, and cholesterol.
- The footnote would be vulnerable to legal challenges. Under the First Amendment, government regulation of commercial speech, including regulations that compel speech, must be no more extensive than is necessary to advance a substantial government interest. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n. of New York*, 447 U.S. 557 (1980). Because there are far less burdensome ways for FDA to educate the public about *trans* fat, saturated fat, and cholesterol, the footnote would be subject to attack as unconstitutional.

⁶ “In the absence of a %DV for *trans* fat, the footnote statement will provide guidance to consumers when using the quantitative information to help maintain health dietary practices.” 67 Fed. Reg. 69171, 69172 (Nov.15, 2002).

⁷ If the nutrition label uses a %DV to convey this information for some nutrients (*e.g.*, total fat), but a footnote to convey this information for other nutrients (*e.g.*, *trans* fat), the use of two different approaches to convey the same information is likely to confuse consumers.

Instead of mandating a footnote/warning about *trans* fat, FDA can achieve its purpose by means of nutrient content claims, health claims, and dietary guidance statements about *trans* fat, saturated fat, and/or cholesterol. FDA's purpose is to educate consumers about *trans* fat and other cholesterol-raising lipids and to encourage food manufactures to reduce *trans* fat and other cholesterol-raising lipids in their products. All that FDA needs to do is to define new nutrient content claims about *trans* fat and incorporate *trans* fat criteria into existing nutrient content claims and health claims about cholesterol-raising lipids. FDA should also suggest dietary guidance statements regarding *trans* fat, saturated fat, and cholesterol that food manufacturers can use on product labels.⁸ The marketplace will do the rest.

2. FDA should define the nutrient content claims "*trans* fat free" and "reduced *trans* fat."

ISEO supports the creation of two new nutrient content claims about *trans* fat: "*trans* fat free" and "reduced *trans* fat." Authorizing these claims will assist consumers who wish to avoid *trans* fat and will drive the market "in a nutritionally beneficial direction." 68 Fed. Reg. at 41,508. The creation of these nutrient content claims will provide an additional incentive for food manufacturers to develop alternative products with little or no *trans* fat.

a. "*Trans* fat free"

ISEO supports the definition of "*trans* fat free" proposed by FDA in 1999. Under that proposed definition, in order to qualify for a claim of "*trans* fat free," a food must contain less than 0.5 g of *trans* fat and less than 0.5 g of saturated fat per reference amount customarily consumed (RACC) and per serving.

ISEO believes that the definition of "*trans* fat free" should be modeled on the existing definition of the claim "saturated fat free," but with one exception. Under present rules, foods that qualify as "saturated fat free" without the benefit of special processing, alteration, formulation, or reformulation to lower their saturated fat content (*i.e.*, foods that are naturally free of saturated fat) may make a "saturated fat free" claim provided the claim discloses that saturated fat is not normally present in the food (*e.g.*, "broccoli, a saturated fat free food"). Compared to saturated fat, *trans* fat is present in fewer foods, is naturally present in even fewer foods, and usually is present at lower levels. ISEO is concerned that the claim "a *trans* fat free food" might appear on labels of virtually every food in the supermarket. We believe this would be an abuse of the nutrient content claim "*trans* fat free" that would mislead consumers into believing that *trans* fat is far more prevalent in the food supply than is the case. Therefore, we propose that the claim "*trans* fat free" should be

⁸ FDA recently announced its intention to publish an advance notice of proposed rulemaking regarding use of dietary guidance statements in food labeling. FDA, "FDA's Implementation of 'Qualified Health Claims': Questions and Answers" (Aug. 27, 2003), Q8. With regulations governing use of dietary guidance statements, we anticipate that far more food products will use dietary guidance statements in labeling.

limited to foods that have undergone special processing, alteration, formulation, or reformulation to lower their *trans* fat content.

b. "Reduced *trans* fat"

ISEO believes that the claim "reduced *trans* fat" should be defined as a reduction of at least 25 percent in *trans* fat per RACC as compared to an appropriate reference food without increasing saturated fat content by more than 50 percent of the decrease in *trans* fat. This definition would prevent manufacturers from making a "reduced *trans* fat" claim if they have merely substituted saturated fat for *trans* fat. It would, however, recognize that in most foods that require solid fat a significant reduction in *trans* fat content requires addition of saturated fat to maintain the same functional properties. This definition will provide manufacturers with an incentive to reduce *trans* fat levels even where they may not be able to meet the stringent criteria for a "*trans* fat free" claim. We note that both saturated fat and *trans* fat content will be declared in Nutrition Facts. Moreover, if the food making the claim exceeds the disclosure level for saturated fat, the claim would need to be accompanied by a disclosure statement such as "see nutrition information for saturated fat content."

c. "Low *trans* fat"

Because FDA defines "low" claims in relation to the Daily Value of the subject nutrient, and because there is no DV for *trans* fat, ISEO believes it is not possible to define a "low" claim for *trans* fat at this time.

d. Disclosure statements

In the advance notice of proposed rulemaking, FDA indicated that the proposed footnote (e.g., "Intake of saturated fat, *trans* fat, and cholesterol should be kept low while maintaining a nutritionally adequate diet") might be required as "a disclosure statement in conjunction with claims." 68 Fed. Reg. at 41,507. ISEO does not believe that nutrient content claims such as "*trans* fat free" or "reduced *trans* fat" should be required to be accompanied by such a disclosure statement.⁹ Requiring such a disclosure statement is unnecessary, because it is implied in the nutrient content claim. Consumers understand that, if a food claims to have no, low, or reduced levels of a particular nutrient, that nutrient is one that should be kept low. Mandating the disclosure

⁹ ISEO is concerned that the use of the term "disclosure statement" to refer to this statement is likely to be confusing to many in the food industry. Many readers are likely to confuse this with the disclosure required by 21 C.F.R. §§ 101.13(h). The term "disclosure statement" implies that the food has an undesirable attribute that needs to be disclosed. If FDA decides to require this label statement, ISEO would prefer that FDA refer to it using a different term, such as "accompanying information" for certain nutrient content claims.

statement effectively penalizes foods that make the triggering nutrient content claim and may prevent some foods with limited label space from using the nutrient content claim. While FDA might encourage foods making nutrient content claims about *trans* fat, saturated fat, and/or cholesterol to add an accompanying explanatory statement. ISEO believes that such statement should be optional, not mandatory.

3. For existing nutrient content claims, FDA should add a *trans* fat criterion only where doing so is necessary to prevent the claim from misleading consumers.

FDA is considering adding *trans* fat limits to existing nutrient content claims about saturated fat and cholesterol as well as existing claims “lean,” “extra lean,” and “healthy.” Alternatively, FDA is considering requiring that a *trans* fat disclosure statement accompany such claims.

ISEO believes that a *trans* fat limit should be added to existing nutrient content claims about other nutrients only to the extent that doing so is necessary to prevent the claim from being misleading. In considering whether a claim may mislead consumers, FDA should bear in mind that the Nutrition Facts panel will soon include a quantitative declaration for *trans* fat. While FDA has stated that it believes that *trans* fat and saturated fat have similar effects on serum cholesterol, ISEO notes that there continues to be much debate in the scientific community about the impact of *trans* fat and saturated fat on serum cholesterol.

a. “Saturated fat free”

The existing definition of “saturated fat free” already includes a limit on *trans* fat. Under the existing regulation, a food may make a “saturated fat free” claim if it contains less than 0.5 g of saturated fat and less than 0.5 g of *trans* fat per RACC and per serving. 21 C.F.R. § 101.62(c)(1)(i). Therefore, there is no need to amend this nutrient content claim.

b. “Reduced saturated fat”

ISEO believes that the existing definition of “reduced saturated fat” should be amended to require a reduction of at least 25 percent in saturated fat per RACC as compared to an appropriate reference food without increasing *trans* fat content by more than 50 percent of the decrease in saturated fat. This definition will give manufacturers an incentive to reduce saturated fat content even where it may not be possible to meet the strict criteria for a “saturated fat free” claim. This definition would prevent manufacturers from making a “reduced saturated fat” claim if they have merely substituted *trans* fat for saturated fat. It would, however, recognize that in most cases a significant reduction in saturated fat requires a small addition of *trans* fat. We note that both saturated fat and *trans* fat content will be declared in Nutrition Facts. Moreover, if the food making the claim exceeds the disclosure level for saturated fat, the claim would need to be accompanied by a disclosure statement such as “see nutrition information for saturated fat content.”

c. "Low saturated fat"

ISEO believes that the definition of "low saturated fat" should not be changed. FDA has always set the nutrient levels in "low" claims based on the Daily Values for the subject nutrients. Unlike "free" claims (where FDA requires a level at or near the limit of detection) and "reduced" claims (where FDA requires a reduction of at least 25 percent), FDA defines "low" claims exclusively in terms of Daily Values. In the absence of a Daily Value for *trans* fat, ISEO does not see how FDA can set any limit on *trans* fat in a "low" claim.

Instead, ISEO proposes that FDA require a disclosure statement about *trans* fat accompany the claim "low saturated fat" if the labeled food contains more than an insignificant amount of *trans* fat. For example, if the food bearing the claim contains 0.5 g or more of *trans* fat, the claim should be required to be accompanied by the disclosure statement "see nutrition information for *trans* fat content." Such a disclosure would prevent consumers from being misled by a claim of "low saturated fat" on a food that contains *trans* fat.

If FDA nevertheless believes it is essential that there be some limit on *trans* fat in the definition of "low saturated fat," ISEO believes that limit should be 1 g or less of *trans* fat per RACC. We believe that a *trans* fat limit of 1 g or less per RACC is appropriate for this claim. It would be illogical to impose a stricter limit on *trans* fat than is imposed on the nutrient (*i.e.*, saturated fat) that is the subject of the claim.¹⁰ Moreover, setting a lower limit for *trans* fat would mean that the criteria for a "low saturated fat" claim would be almost identical to the criteria for a "saturated fat free" claim. This would have had the effect of eliminating the "low saturated fat" claim, since virtually any food that would qualify as "low saturated fat" could be reformulated to qualify as "saturated fat free." ISEO believes that would defeat the purpose of the "low saturated fat" claim, which is to encourage foods with significant amounts of saturated fat to reduce saturated fat content.

In this connection, we also note that there is virtually no evidence that *trans* fat at low levels of intake increases serum total or LDL cholesterol levels. In addition, *trans* fat is far less prevalent in the food supply than is saturated fat. Americans on average consume 4 to 5 times as much saturated fat as *trans* fat.¹¹

¹⁰ The only "low" claim that includes a limit on a nutrient other than the nutrient named in the claim is "low cholesterol," which includes a limit of 2 g or less saturated fat. 21 C.F.R. § 101.62(d)(2)(i)(B), (ii)(B).

¹¹ "Revealing *Trans* Fat," *FDA Consumer*, Sept.-Oct. 2003, p. 22.

d. "Cholesterol free"

ISEO proposes that the definition of "cholesterol free" be amended to require that a food bearing this claim must contain less than 2 milligrams (mg) of cholesterol, 2 g or less saturated fat, and 2 g or less *trans* fat per RACC.

For the reasons discussed above with regard to the claim "low saturated fat," ISEO believes that a limit of 2 g or less *trans* fat per RACC is appropriate for this claim. Given the far lower prevalence of *trans* fat in the food supply, and the paucity of evidence that low intakes of *trans* fat increase serum cholesterol, a food containing up to 2 g of *trans* fat is consistent with dietary guidelines.

e. "Reduced cholesterol"

ISEO believes that the definition of "reduced cholesterol" should be amended to require that a food bearing this claim must have at least a 25 reduction in cholesterol per RACC as compared to an appropriate reference food, 2 g or less saturated fat per RACC, and 2 g or less *trans* fat per RACC.

For the reasons discussed above with regard to the claim "low saturated fat," ISEO believes that a limit of 2 g or less *trans* fat per RACC is appropriate for this claim. Given the far lower prevalence of *trans* fat in the food supply, and the paucity of evidence that low intakes of *trans* fat increase serum cholesterol, a food containing up to 2 g of *trans* fat is consistent with dietary guidelines.

f. "Low cholesterol"

ISEO believes that the definition of "low cholesterol" should not be changed. FDA has always set the nutrient levels in "low" claims based on the Daily Values for the subject nutrients. Unlike "free" claims (where FDA requires a level at or near the limit of detection) and "reduced" claims (where FDA requires a reduction of at least 25 percent), FDA defines "low" claims exclusively in terms of Daily Values. In the absence of a Daily Value for *trans* fat, ISEO does not see how FDA can set any limit on *trans* fat in a "low" claim.

Instead, ISEO proposes that FDA require a disclosure statement about *trans* fat accompany the claim "low cholesterol" if the labeled food contains more than an insignificant amount of *trans* fat. For example, if the food bearing the claim contains 0.5 g or more of *trans* fat, the claim should be required to be accompanied by the disclosure statement "see nutrition information for *trans* fat content." Such a disclosure would prevent consumers from being misled by a claim of "low cholesterol" for a food that contains *trans* fat.

If FDA nevertheless determines that it is essential to include a limit on *trans* fat in the definition of "low cholesterol," ISEO believes that the limit should be 2 g or less of *trans* fat per

RACC. For the reasons discussed above with regard to the claim “low saturated fat.” ISEO believes that a limit of 2 g or less *trans* fat per RACC is appropriate for this claim. If FDA were to set a lower limit on *trans* fat, many of the foods that currently qualify for this claim likely would no longer qualify. In addition, given the far lower prevalence of *trans* fat in the food supply, and the paucity of evidence that low intakes of *trans* fat increase serum cholesterol, a food containing up to 2 g of *trans* fat is consistent with dietary guidelines.

4. There is no need for FDA to amend existing health claim regulations to add a *trans* fat limit, because all health claims that contain a message about risk of heart disease already require that foods making the claims must be “low in saturated fat” and “low in cholesterol.”

FDA has indicated it is considering whether to add a *trans* fat requirement to existing health claims that contain a message about cholesterol-raising lipids. There is no need for FDA to amend these health claims. That is because all existing health claims that contain a message about risk of heart disease already require that qualifying foods must be “low in saturated fat” and “low in cholesterol.”¹² If FDA adds a *trans* fat limit in the definitions of “low saturated fat” and “low cholesterol,” it would be redundant to add a limit on *trans* fat in the requirements for health claims.

FDA should, however, consider amending the existing health claim for saturated fat and cholesterol and risk of heart disease (21 C.F.R. § 101.75) so that it includes *trans* fat. FDA should not amend the requirements regarding the nature of the food making this claim. Those requirements already specify that the food must qualify as “low saturated fat,” “low cholesterol,” and “low fat” (or “extra lean” in the case of fish and game meat).¹³ 21 C.F.R. § 101.75(c)(2)(ii). However, the regulation should be amended to allow reference to *trans* fat in the claim.

5. Without a Daily Value for *trans* fat, FDA should not set a disclosure/disqualifying level for *trans* fat.

FDA is considering establishing a level of *trans* fat that would trigger disclosure statements for nutrient content claims, under 21 C.F.R. § 101.13(h)(1), and that would disqualify a food from any health claims, under 21 C.F.R. § 101.14(a)(4). FDA’s regulations currently include disclosure/disqualifying levels for total fat, saturated fat, cholesterol, and sodium. For each of these nutrients, the disclosure/disqualifying level is set at 20 percent of the Daily Value for that nutrient.

¹² See 21 C.F.R. §§ 101.75(c)(2)(ii), 101.77(c)(2)(ii)(B), 101.81(c)(2)(iii)(C), 101.82(c)(2)(iii)(B), and 101.83(c)(2)(iii)(B).

¹³ If FDA adds a limit on *trans* fat in the definitions for “low saturated fat” and “low cholesterol,” it would be redundant to add a specific limit on *trans* fat in the criteria for this health claim.

In the absence of a Daily Value for *trans* fat, ISEO does not believe it is appropriate for FDA to set a disclosure/disqualifying level for *trans* fat. Any such disclosure/disqualifying level would necessarily be arbitrary. We believe that any attempt to establish a disclosure/disqualifying level must await a Daily Value for *trans* fat.

6. FDA should clear up public confusion about “hydrogenated oils” and “partially hydrogenated oils.”

Media coverage of *trans* fat, and even some of FDA’s own educational materials, have told consumers that any food containing partially hydrogenated oils contains *trans* fat.¹⁴ This is not true. The fact that a food lists “partially hydrogenated oils” or “hydrogenated oils” in its ingredients declaration does not necessarily mean the food contains *trans* fat. For example, some oil products on the market consist of a blend of unhydrogenated vegetable oils combined with vegetable oils with a relatively high degree of hydrogenation. The resulting blend contains no *trans* fat. Yet, these products will be listed as “partially hydrogenated” or “hydrogenated” oils in the ingredients declaration and perhaps be perceived as containing *trans* fat when in fact they may not.

It is very important that consumers not be steered away from such products because they mistakenly believe they contain *trans* fat. There is potential for a major increase in the use of these *trans* fat free alternative products. However, if consumers are led to believe that all products containing partially hydrogenated oils have *trans* fat, manufacturers will lose their incentive to reformulate their products utilizing these alternative oils.

There is also a media and consumer misperception that all partially hydrogenated oils contain *trans* fat. ISEO urges FDA to revise its educational materials (including the *Dietary Guidelines for Americans*, press releases, and question and answer documents) to reflect a more accurate understanding of partially hydrogenated oils. FDA should advise consumers concerned about *trans* fat to look first for a *trans* fat declaration in Nutrition Facts, since the ingredients declaration is not always the best method of determining *trans* fat presence.

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¹⁴ “*Trans* fats lurk throughout the American diet – in... anything with partially hydrogenated oils as an ingredient.” J. Weinraub, “The Hidden Fat,” *Washington Post*, Sept. 10, 2003, p. F1.

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October 9, 2003

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ISEO appreciates this opportunity to submit comments to the agency, and we look forward to working with FDA on these issues in the future.

Respectfully submitted,

A handwritten signature in cursive script that reads "Robert M. Reeves".

Robert M. Reeves
President