Declaration of Erich O. Grosz

Exhibit 4

Case No. 1:07-CV-01092 (RJL)

CFSAN Office of Nutritional Products, Labeling and Dietary Supplements
July 9, 2003; Updated March 3, 2004, June 25, 2004, August 1, 2005, September 6, 2005, and January 1, 2006

Questions and Answers about *Trans* Fat Nutrition Labeling

Disclaimer

Section 1 - Fat, Trans Fatty Acid (Trans Fat), and Cholesterol

Section 2 - Foods that Contain Trans Fat, Saturated Fat, and Cholesterol

Section 3 - FDA's Regulation on Trans Fat Labeling

Section 1 - Fat, Trans Fatty Acid (Trans Fat), and Cholesterol

Q: What are fats and fatty acids?

A: Fats are a group of chemical compounds that contain fatty acids. Energy is stored in the body mostly in the form of fat. Fat is also needed in the diet to supply essential fatty acids that are substances essential for growth but not produced by the body itself. The terms fat and fatty acids are frequently used interchangeably.

Q: What are the main types of fatty acids?

A: There are three main types of fatty acids: saturated, monounsaturated and polyunsaturated. All fatty acids are chains of carbon atoms with hydrogen atoms attached to the carbon atoms. A saturated fatty acid has the maximum possible number of hydrogen atoms attached to every carbon atom. It is therefore said to be "saturated" with hydrogen atoms, and all of the carbons are attached to each other with single bonds.

In some fatty acids, a pair of hydrogen atoms in the middle of a chain is missing, creating a gap that leaves two carbon atoms connected by a double bond rather than a single bond. Because the chain has fewer hydrogen atoms, it is said to be "unsaturated." A fatty acid with one double bond is called "monounsaturated" because it has one gap. Fatty acids having more than one gap are called "polyunsaturated."

The fat in foods contains a mixture of saturated, monounsaturated and polyunsaturated fatty acids. In foods of animal origin, a large proportion of fatty acids are saturated. In contrast, in foods of plant origin and some seafood, a large proportion of the fatty acids are monounsaturated and polyunsaturated. The structure of saturated and unsaturated chemical bonds looks like the diagram below.

Saturated Fat
(i.e., saturated fatty acid)

Carbon-Carbon Single Bond

Unsaturated Fat
(i.e., unsaturated fatty acid)

Carbon-Carbon Double Bond

Q: What is *trans* fat?

A: *Trans* fat (also known as *trans* fatty acids) is a specific type of fat formed when liquid oils are made into solid fats like shortening and hard margarine. However, a small amount of *trans* fat is found naturally, primarily in some animal-based foods.

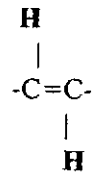
Trans fat behaves like saturated fat by raising low-density lipoprotein (LDL or "bad") cholesterol that increases your risk of coronary heart disease (CHD). *Trans* fat can be found in some of the same foods as saturated fat, such as vegetable shortenings, some margarines, crackers, candies, cookies, snack foods, fried foods, baked goods, and other processed foods made with partially hydrogenated vegetable oils.

Where will I find *trans* fat?

Vegetable shortenings, some margarines, crackers cookies, snack foods, and other foods made with or fried in partially hydrogenated oils.

Trans fat is made when hydrogen is added to vegetable oil -- a process called hydrogenation. Hydrogenation increases the shelf life and flavor stability of foods containing these fats. Usually the hydrogen atoms at a double bond are positioned on the same side of the carbon chain. However, partial hydrogenation reconfigures some double bonds and the hydrogen atoms end up on different sides of the chain. This type of configuration is called "*trans*" (means "across" in Latin). The structure of a *trans* unsaturated chemical bond looks like the diagram below.

***Trans* Fat**
(i.e., *trans* fatty acids)



Hydrogen atoms are on opposite sides of the chain of carbon atoms at the carbon-carbon double bond.

As stated in FDA's labeling regulations, if a fat or oil ingredient is completely hydrogenated, the name in the ingredient list will include the term "hydrogenated." Or, if partially hydrogenated, the name in the ingredient list will include the term "partially hydrogenated." As stated above, oil that is partially hydrogenated is a source of *trans* fat.

Q: What is the role of fat in the diet?

A: Fat is a major source of energy for the body and aids in the absorption of vitamins A, D, E, and K, and carotenoids. Both animal and plant-derived food products contain fat, and when eaten in moderation, fat is important for proper growth, development, and maintenance of good health. As a food ingredient, fat provides taste, consistency, and stability and helps us feel full. In addition, parents should be aware that fats are an especially important source of calories and nutrients for infants and toddlers (up to 2 years of age), who have the highest energy needs per unit of body weight of any age group.

Q: Are all fats the same?

A: Simply put: no. While **un**saturated fats (monounsaturated and polyunsaturated) are beneficial when consumed in moderation, saturated fat and *trans* fat are not. Saturated fat and *trans* fat raise LDL ("bad") cholesterol. Therefore, it is advisable to choose foods low in both saturated and *trans* fats as part of a healthful diet.

Q: What about cholesterol?

A: Cholesterol is a waxy substance that occurs naturally in the tissues of all animals. The human body needs cholesterol to function properly, such as producing vitamin D, bile acids to digest fat, and many hormones. Given the capability of all tissues to synthesize sufficient amounts of cholesterol for their needs, there is no evidence for a biologic requirement for dietary cholesterol. Scientific evidence indicates a positive linear trend between cholesterol intake and LDL-cholesterol levels, and therefore, an increased risk of CHD.

Section 2 - Foods that Contain Trans Fat, Saturated Fat, and Cholesterol

Q: What is the daily *trans* fat intake of Americans?

A: FDA estimates that the average daily intake of *trans* fat in the U.S. population is about 5.8 grams or 2.6% of calories per day for individuals 20 years of age and older. On average, Americans consume approximately 4 to 5 times as much saturated fat as *trans* fat in their diet.

Trans fat can be found in vegetable shortenings, some margarines, crackers, candies, cookies, snack foods, fried foods, baked goods, and other processed foods made with partially hydrogenated vegetable oils. Small amounts of naturally occurring *trans* fat can be found in

some animal products, such as butter, milk products, cheese, beef, and lamb.

Estimates of the average trans fat intake of U.S. adults from food groups (e.g., cakes, cookies, shortening, etc.) are described in the economic analysis for FDA's final trans fatty acid labeling rule, *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims published July 11, 2003 (68 FR 41434 at 41468-41470). FDA based its estimates on USDA's 1994-96 Continuing Survey of Food Intakes by Individuals and on the special 1995 USDA database of *trans* fat content of selected foods.

Q: What foods contain saturated fat, *trans* fat, and cholesterol?

A: Saturated and *trans* fats can be found in some of the same foods, such as vegetable shortenings, some margarines (especially margarines that are harder), crackers, candies, cookies, snack foods, fried foods, baked goods, and other processed foods made with partially hydrogenated vegetable oils. High amounts of saturated fat are found in animal products, such as beef and pork, chicken skin, butter, whole milk, and cheese. Foods high in cholesterol include liver, other organs meats, egg yolks, and dairy fats.

It is important to choose foods with the lower combined amount of saturated fat and *trans* fat and the lower amount of cholesterol.

Q: Should *trans* fat be eliminated from the diet?

A: No. According to experts, eliminating *trans* fat completely from the diet would require such extraordinary dietary changes (e.g., elimination of foods, such as dairy products and meats that contain *trans* fatty acids) that eliminating *trans* fat could cause an inadequate intake of some nutrients and create health risks.

Q: What actions can consumers take to lower their intake of saturated fat, *trans* fat, and cholesterol?

A: Here are some actions you can take every day to keep your consumption of both saturated and *trans* fats and cholesterol low while consuming a nutritionally adequate diet.

- Check the Nutrition Facts panel to compare foods because the serving sizes are generally consistent in similar types of foods. Choose foods lower in saturated fat, *trans* fat, and cholesterol. For saturated fat and cholesterol, use the Quick Guide to %DV: 5%DV or less is low and 20%DV or more is high. (Remember, there is no %DV for *trans* fat.)

- Choose Alternative Fats. Replace saturated and *trans* fats in your diet with mono- and polyunsaturated fats. These fats do not raise LDL (or "bad") cholesterol levels and have health benefits when eaten in moderation. Sources of monounsaturated fats include olive and canola oils. Sources of polyunsaturated fats include soybean, corn, sunflower oils, and foods like nuts.

- Choose vegetable oils (except coconut and palm kernel oils) and soft margarines (liquid, tub, or spray) more often because the combined amount of saturated and *trans* fats is lower than the amount in solid shortenings, hard margarines, and animal fats, including

butter.

- Consider Fish. Most fish are lower in saturated fat than meat. Some fish, such as mackerel, sardines, and salmon, contain omega-3 fatty acids that are being studied to determine if they offer protection against heart disease.
- Limit foods high in cholesterol such as liver and other organ meats, egg yolks, and full-fat dairy products, like whole milk.
- Choose foods low in saturated fat such as fat free or 1% dairy products, lean meats, fish, skinless poultry, whole grain foods, and fruit and vegetables.

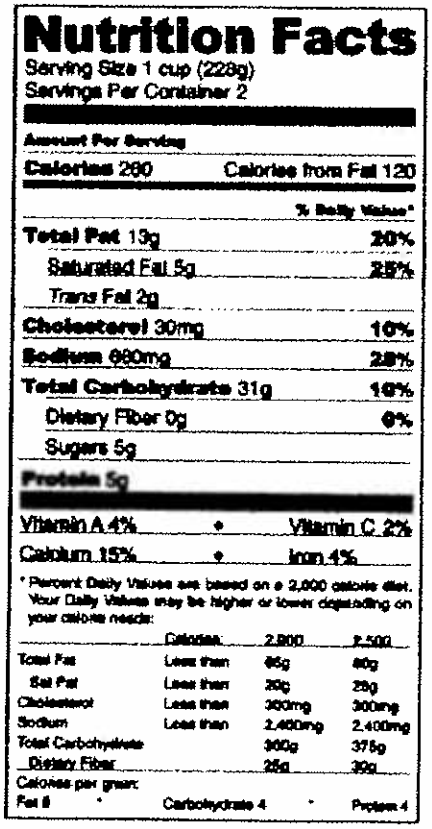
Q: Do dietary supplements contain *trans* fat?

A: Yes, some dietary supplements contain ingredients that also include partially hydrogenated vegetable oil or *trans* fat as well as saturated fat and cholesterol. As a result of FDA's new label requirement, if a dietary supplement contains a reportable amount of *trans* fat, which is 0.5 gram or more, dietary supplement manufacturers must list the amounts on the Supplement Facts panel. Examples of dietary supplements that may contain saturated fat, *trans* fat, and cholesterol include energy and nutrition bars.

Section 3 - FDA's Labeling of Trans Fatty Acids

Q: How will the nutrition label be different?

A: The FDA final rule on *trans* fatty acids (also called "*trans* fat") requires that the amount of *trans* fat in a serving be listed on a separate line under saturated fat on the Nutrition Facts panel (see figure). However, *trans* fat does not have to be listed if the **total** fat in a food is less than 0.5 gram (or 1/2 gram) per serving and no claims are made about fat, fatty acids or cholesterol content. If it is not listed, a footnote will be added stating that the food is "not a significant source of *trans* fat."



Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 260 Calories from Fat 120

	% Daily Value*
Total Fat 13g	20%
Saturated Fat 5g	25%
Trans Fat 2g	
Cholesterol 30mg	10%
Sodium 660mg	28%
Total Carbohydrate 31g	10%
Dietary Fiber 0g	0%
Sugars 5g	
Protein 5g	

Vitamin A 4% • Vitamin C 2%

Calcium 15% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

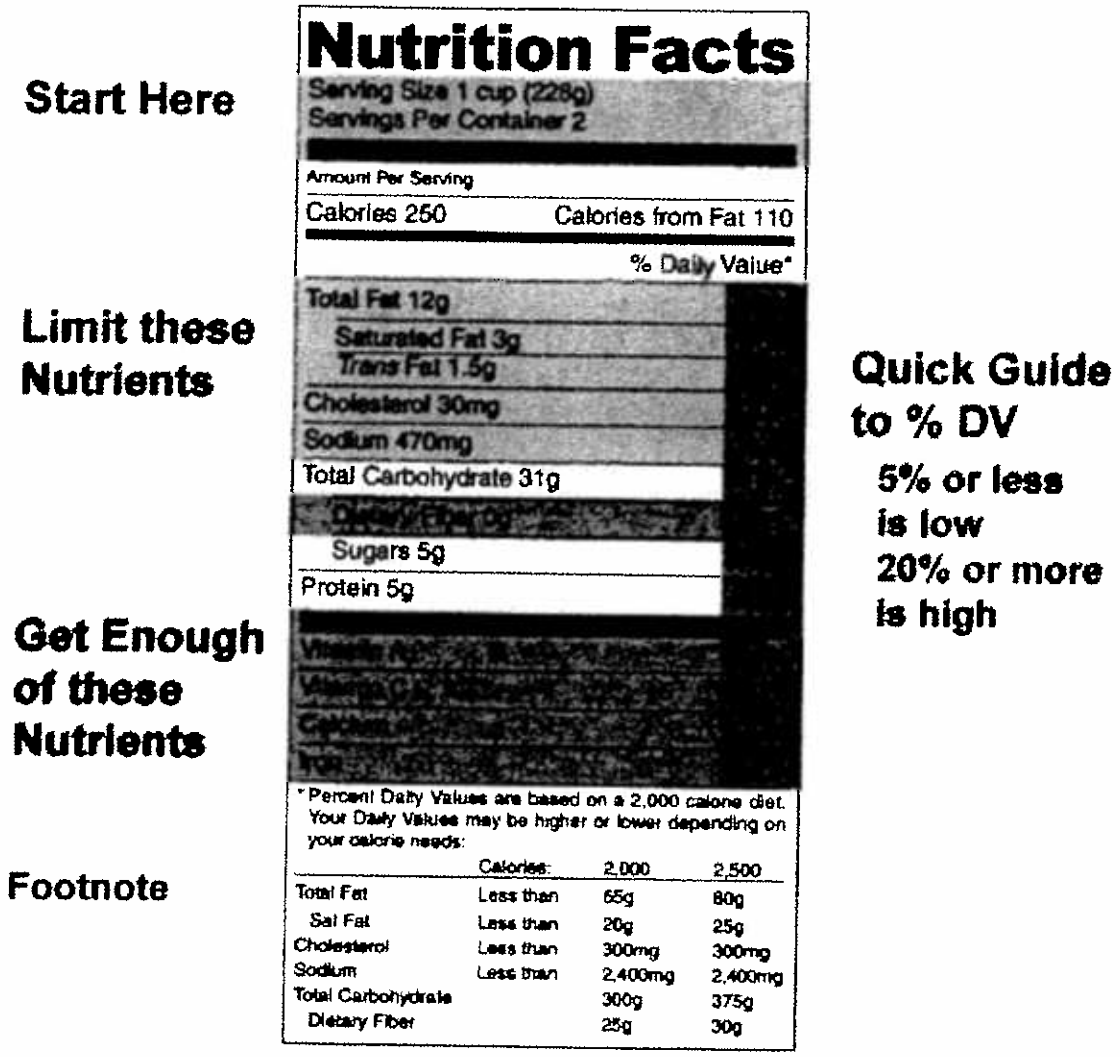
Q: Why is there no %DV for *trans* fat?

A: Although the updated Nutrition Facts panel will now list the amount of *trans* fat in a product, be aware that it does not have a %Daily Value (%DV) for *trans* fat. While scientific reports have confirmed the relationship between *trans* fat and an increased risk of CHD, none has recommended an amount of *trans* fat that FDA could use to establish a Daily Value (DV). Without a DV, a %DV cannot be calculated. As a result, *trans* fat will be listed with only a gram amount.

But saturated fats do have a %DV. To choose foods low in saturated fat and cholesterol, use the Quick Guide to %DV - **5%DV or less is low and 20%DV or more is high.** You can also use the %DV to make dietary trade-offs with other foods throughout the day. You don't have to give up a favorite food to eat a healthy diet. When a food you like is high in any of these cholesterol-raising components, balance it with foods that are low in them at other times of the day.

The following graphic of the Nutrition Facts panel illustrates which nutrients experts recommend you limit and which they recommend you consume in adequate amounts.

Sample Label for
Macaroni and Cheese



Q: Is it possible for a food product to list the amount of *trans* fat as 0 g on the Nutrition Facts panel if the ingredient list indicates that it contains "partially hydrogenated vegetable oil?"

A: Yes. Food manufacturers are allowed to list amounts of *trans* fat with less than 0.5 gram (1/2 g) as 0 (zero) on the Nutrition Facts panel. As a result, consumers may see a few products that list 0 gram *trans* fat on the label, while the ingredient list will have "shortening" or "partially hydrogenated vegetable oil" on it. This means the food contains very small amounts (less than 0.5 g) of *trans* fat per serving.

Q: What about nutrient content claims for *trans* fat?

A: Nutrient content claims are statements that are made on the food label package that indicate that the product contains a range from low to high of the amount of a specific nutrient. Examples: "Low Fat" and "High in Fiber." At this time, FDA has insufficient scientific information to establish nutrient content claims for *trans* fat. Such claims are permitted, however, for saturated fat and cholesterol.

Q: What are the highlights of the *trans* fat rule?

A: This final rule is the first significant change to the Nutrition Facts panel since the Nutritional, Labeling, and Education Act regulations were finalized in 1993. Some significant highlights are:

- This final rule requires manufacturers of conventional foods and some dietary supplements to list *trans* fat on a separate line, immediately under saturated fat on the nutrition label.

- As of January 1, 2006, food manufacturers must list *trans* fat on the nutrition label. The phase-in period, from the date the final rule issued (July 2003) to the effective date (January 2006), minimized the need for multiple labeling changes, allowed small businesses to use current label inventories, and provided economic savings.

- FDA's regulatory chemical definition for *trans* fatty acids is all unsaturated fatty acids that contain one or more isolated (i.e., nonconjugated) double bonds in a *trans* configuration. Under the Agency's definition, conjugated linoleic acid would be excluded from the definition of *trans* fat.

- Dietary supplement manufacturers must also list *trans* fat on the Supplement Facts panel when their products contain reportable amounts (0.5 gram) of *trans* fat. Examples of dietary supplements with *trans* fat are energy and nutrition bars.

Q: It is after January 1, 2006. Why do some products not declare *trans* fat on their labels?

A: There may be two reasons why you are not seeing *trans* fat on a product's label.

First, products entering interstate commerce on or after January 1, 2006 must be labeled with *trans* fat. As this is happening, FDA realizes that it will take some time for food products to move through the distribution chain to a store shelf. Thus, it may take a few months for products that are listing *trans* fat on their label to show up on a store shelf. However, you will see many products with *trans* fat listed since companies have already begun to declare *trans* fat on their products' labels.

Second, FDA has granted enforcement discretion to some firms to use old label stock that do not declare *trans* fat after the effective date of January 1, 2006. In these cases, food firms followed the required process described in FDA's guidance for industry and FDA entitled, "Guidance for Industry and FDA: Requesting an Extension to Use Existing Label Stock after the *Trans* Fat Labeling Effective Date of January 1, 2006 (Revised)". For each request, FDA is considering whether the declared label value for *trans* fat is 0.5 g or less per serving. This information is important because lower amounts of *trans* fat would have less impact on public

health than higher amounts of *trans* fat. Thus, *trans* fat information in the Nutrition Facts panel will be missing on some products (that contain lower amounts of *trans* fat) throughout the next year.

If *trans* fat is not declared on the label and you are curious about the *trans* fat content of a product, contact the manufacturer listed on the label.

Q: I am a food manufacturer. Can I use my old label stock that does not include *trans* fat after the compliance date of January 1, 2006?

FDA understands that some businesses may experience hardship in meeting the compliance date for *trans* fat labeling. Thus, FDA is allowing firms to request enforcement discretion to use existing label stock that does not include *trans* fat after January 1, 2006. See "Guidance for Industry and FDA: Requesting an Extension to Use Existing Label Stock after the Trans Fat Labeling Effective Date of January 1, 2006 (Revised)."

Q: What is the scientific evidence that supports this rule?

A: In finalizing this rule, FDA relied on scientific reports, expert panels, and studies from the Institute of Medicine/National Academies of Science (IOM/NAS), the National Cholesterol Education Program, and DHHS and USDA (Dietary Guidelines for Americans 2000). These reports concluded that consumption of *trans* fatty acids contribute to increased LDL ("bad") cholesterol levels, which increase the risk of coronary heart disease.

The IOM/NAS report on macronutrients recommended that "trans fatty acid consumption be as low as possible while consuming a nutritionally adequate diet."

An expert panel for the National Cholesterol Education Program (NCEP) Report for persons with high risk of CHD in 2001 recommended that intakes of *trans* fatty acids should be kept low and encouraged the use of liquid vegetable oil and soft margarine instead of butter, stick margarine, and shortening.

The Dietary Guidelines for Americans 2000 makes the following statements regarding *trans* fatty acids and food sources of *trans* fat: "Foods high in *trans* fatty acids tend to raise blood cholesterol. These foods include those high in partially hydrogenated vegetable oils, such as many hard margarines and shortenings. Foods with a high amount of these ingredients include some commercially fried foods and some bakery good. Aim for a total fat intake of not more than 30 percent of calories, as recommended in previous Guidelines. If you need to reduce your fat intake to achieve this level, do so primarily by cutting back on saturated and *trans* fats."

Findings from human feeding studies and epidemiological studies show a positive association between the intake of *trans* fatty acids and the incidence of CHD. These studies are described in the *trans* fat final rule. For more detailed information on these studies, see the *trans* fatty acid final rule.

Q: How do I find more detailed information about this rule?

A: The full text of this rule is available online (*Trans* Fatty Acids in Nutrition Labeling,

Nutrient Content Claims, and Health Claims) or on display at the FDA's Dockets Management Branch (Dockets Management Branch, HFA-305, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852).

Q: Is the FDA considering any other regulations about nutrition labeling of *trans* fatty acids?

A: Yes, the Food and Drug Administration (FDA) issued an advance notice of proposed rulemaking (ANPRM) in the Federal Register (Food Labeling: *Trans* Fatty acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements) to solicit information and data that potentially could be used to establish new nutrient content claims about *trans* fat, to establish qualifying criteria for *trans* fat in current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol raising fats, and, in addition, as disclosure and disqualifying criteria to help consumers make heart-healthy food choices. The agency is also requesting comments on whether to consider statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts panel or as a disclosure statement in conjunction with claims to enhance consumers' understanding about such cholesterol-raising lipids and how to use the information to make healthy food choices. Information and data obtained from comments and from consumer studies conducted by FDA may be used to help draft a proposed rule that would establish criteria for certain nutrient content or health claims or require the use of a footnote, or other labeling approach, about one or more cholesterol-raising lipids in the Nutrition Facts panel to assist consumers in maintaining healthy dietary practices.

Section 4 - Diet and Coronary Heart Disease

Q: How do saturated and *trans* fats, unsaturated fats, and dietary cholesterol relate to heart disease?

A: Higher intakes of saturated and *trans* fats, and dietary cholesterol raise low density lipoprotein (LDL or "bad") cholesterol in the blood. An elevated LDL cholesterol increases the risk of developing coronary heart disease (CHD). To decrease LDL cholesterol and the risk of CHD, substitute monunsaturated and polyunsaturated fats for saturated and *trans* fats and decrease the intake of cholesterol.

Q: Do saturated and *trans* fats affect blood cholesterol in different ways?

A: Yes. Like saturated fat, *trans* fat also raises the low density lipoprotein (LDL or "bad") cholesterol in the blood. But, unlike saturated fat, *trans* fat lowers high density lipoprotein (HDL or "good") cholesterol in the blood. An elevated LDL cholesterol increases the risk of developing coronary heart disease.

Q: Is it better to eat butter instead of margarine to avoid *trans* fat?

A: No, because the combined amount of saturated fat and *trans* fat (the cholesterol-raising fats) and cholesterol for butter is usually higher than margarine, even though some margarines contain more *trans* fat than butter.

It is better to eat softer or liquid margarines that contain a lower combined amount of saturated fat and *trans* fat and a lower amount of cholesterol. For a healthful alternative, nonstick cooking spray can be substituted for other fats when "greasing" the pan.

The table compares the amounts and types of fats and amount of cholesterol in butter and some margarines.

FAT TYPE PER SERVING (*)
(Serving Size - 1 tbsp.)

Product	Total Fat g	Saturated Fat g	*Trans* Fat g	Combined Saturated and *Trans* Fats g	Cholesterol mg
Butter*	10.8	7.2	0.3	7.5	31.1
Margarine, stick†	11	2.1	2.8	4.9	0
Margarine, spread†	9.7	1.8	2.7	4.5	0
Margarine, tub†	6.7	1.2	0.6	1.8	0.1
Margarine, bottle‡	0.4	0.1	0	0.1	0.2

(*) Butter values from FDA Table of *trans* Values, dated 1/30/95.
† Values derived from 2002 USDA National Nutrient Database for Standard Reference, Release 15.
‡ Prerelease values derived from 2003 USDA National Nutrient Database for Standard Reference, Release 16.

Answer: Choose the product with the lower combined amount of saturated fat and *trans* fat and the lower amount of cholesterol. In this case, the correct answer is margarine in a bottle.

Q: Is there a shortage of oils that do not contain *trans* fat?

A: Based on informal reports from industry, the requirement to declare *trans* fat on product labeling is already changing consumer demand and prompting product reformulation, which was anticipated by FDA. Representatives from industry have indicated to FDA that the transition from use of oils containing *trans* fats to healthier oils that are both suitable for various processing techniques and continue to meet consumer taste preferences will take time as supplies of healthier oils catch up with demand. High consumer demand for healthier oils, and the accompanying industry response, is a testament to the success of the agency's *trans* fat labeling rule and industry's move to using healthier oils.

Q: When I eat or order out, how do I know if the food contains saturated and *trans* fats?

A: You may not know unless you ask. Restaurants are not required to provide full nutrition

labeling for their food products, unless nutrient claims are made, such as "Low Fat" or "Low Sodium." To know which fats are being used in the preparation of the food you're eating or ordering, a good tip to remember is "**ask before you order**". Also, many fast food or chain restaurants have tables of the nutritional content of their food products that they will provide upon request.

Section 5 - Background about FDA's Trans Fat Regulation

Q: What is the history of the *trans* fatty acid labeling regulation?

A: In 1994, the Center for Science in the Public Interest (CSPI), a consumer advocacy organization, filed a petition (amended in July 1998) with the FDA requesting that the agency take steps to require *trans* fat to be listed on nutrition labels and claims.

In response to the CSPI petition, FDA issued a proposed rule in the Federal Register on November 17, 1999. In that proposed rule, FDA proposed to amend the regulations to require that *trans* fat be listed on nutrition labels.

On December 5, 2000, FDA reopened the comment period for the rule to obtain comments about "reduced claims." FDA reopened another comment period on November 15, 2002, to receive comments about use of footnote with the statement "Intake of *trans* fat should be as low as possible." In total, FDA received over 2,700 comments that addressed the scientific, economic, policy and legal basis for the rule.

In finalizing this rule, FDA relied on scientific reports, expert panels, and studies from the Institute of Medicine/National Academies of Science, 2001 Report of the National Cholesterol Education Program, and the 2000 Dietary Guidelines for Americans.

Q: What legal authority does FDA have to require *trans* fatty acids in nutrition labeling?

A: The Food, Drug and Cosmetic Act (FD&C Act) provides the FDA with statutory authority to require food and nutrition labeling. Specifically, two sections of the FD&C Act provide the legal authority, as follows:

> **Sec. 403(a) of FD&C Act** - requires foods to be adequately labeled and that material facts be disclosed to consumers.
>
> **Sec. 403(q)(2)(A) of FD&C Act** - gives the Secretary authority to require additional nutrients to be included in nutrition labeling if such information will "assist consumers to maintain healthy dietary practices."

Q: Why is FDA addressing *trans* fat?

A: The *trans* fat nutrition labeling rule responds, in part, to a citizen petition from the Center for Science in the Public Interest (CSPI), and is based on recently published human studies and health expert advice on *trans* fat.

Recently the Institute of Medicine, National Academies of Science (IOM/NAS) published a

report that found that *trans* fatty acids increase low density lipoprotein (LDL or "bad") cholesterol, thereby increasing the risk of coronary heart disease. The IOM/NAS report recommended that "*trans* fat consumption be as low as possible while consuming a nutritionally adequate diet." Similar recommendations are made for saturated fat and cholesterol.

This regulation will provide information on food labels about the amount of *trans* fat in foods so that consumers can select foods with lower levels of *trans* fat and thereby lower their intake of *trans* fat as part of a heart-healthy diet. FDA estimates that 3 years after the effective date, *trans* fat labeling would prevent from 600 to 1,200 cases of CHD and 250-500 deaths each year. It takes about 3 years for lower LDL-cholesterol to result in lower CHD risk.

Q: Does this rule mean that FDA is banning *trans* fat from food?

A: No, FDA is not banning food manufacturers from using *trans* fat in packaged foods. FDA is requiring food manufacturers, processors, and distributors to label the amount of *trans* fat in a serving of food on the Nutrition Facts panel. As a result, Americans will have information they need to reduce their intake of *trans* fat, saturated fat, and cholesterol.

Q: What are the public health benefits and costs of the *trans* fat final rule?

A: FDA estimates that 3 years after the effective date, January 2006, *trans* fat labeling would annually prevent from 600 to 1,200 heart attacks and save 250-500 lives. Based on this estimate, this rule will realize a cost savings of $900 million to $1.8 billion per year in medical costs, lost productivity, and pain and suffering.

FDA estimates that industry will incur a one-time cost of approximately $140 to $250 million. These costs include: determining the amount of *trans* fat in the food products, relabeling the Nutrition Facts panel to add *trans* fat, and reformulating products voluntarily to decrease the amount of *trans* fat.

If You Need More Information?

- Federal Register Final Rule: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims (July 11, 2003)
- FDA Acts to Provide Better Information to Consumers on Trans Fats
- Guidance on How to Understand and Use the Nutrition Facts Panel on Food Labels.
- Advanced Notice of Proposed Rule Making: Food Labeling: *Trans* Fatty acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements (July 11, 2003)

Disclaimer: FDA is issuing this document as general information for the public. FDA intends this document to aid the public in understanding how to use the declaration of *trans* fatty acids in the nutrition label of conventional foods and dietary supplements.

This document was issued in July 2003 and updated March 2004, June 2004, August 2005, September 2005, and January 2006
For more information on Food Labeling
See http://www.cfsan.fda.gov/label.html
