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# Food Labeling Requirements: Our Health Depends on Them

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Gone are the days when food labels simply contained a logo, a picture of the product, and a slogan. Today, the information on food packaging is so abundant that consumers often spend extra time in the supermarket aisle trying to digest it all. Food packaging now boasts tidbits such as "a good source of calcium," "lowers cholesterol," and "now sugar free" as well as more detailed messages such as, "Diets rich in whole grains and other plant foods and low in cholesterol and saturated fat may help reduce the risk of heart disease."[1]

With the abundance of information on food packaging, it may be easy to assume that consumers can better understand the nutritional information about the products available to them. Unfortunately, that's not necessarily the case. In fact, most consumers don't comprehend the various nutrition and health facts provided by manufacturers. For instance, consumers tend to misunderstand what a whole grain is and how much (or, rather, how little) constitutes a single serving for a particular product.[2]

RDs are uniquely positioned to assist patients and clients with understanding food labels and influencing them to make healthful nutrition choices. This continuing education article will help explain what information is available on food labels, the laws regulating these labels, the oversight process to ensure proper labeling, the limitations of such oversight, and recommendations for improving the labeling system so RDs can assist patients and clients in making positive, healthful food choices in the marketplace.

## Food Labeling Laws

While some foods do not require nutrition labels,[3] most foods are regulated by the labeling laws found in Title 21 of the Code of Federal Regulations. These regulations are numerous (approximately 200 separate parts with additional subparts) and detailed. The following random sampling should give the reader an idea of the varied food products that are regulated and some of the specificities of those regulations:

• Not more than 15% of cherries in a frozen cherry pie can be blemished or discolored.[4]

• Shell eggs are not required to be placed under refrigeration at 45˚F if they have been specifically processed to destroy all viable *Salmonella*.[5]

• Cultured milk may include stabilizers, aroma, citric acid, and color additives so long as those color additives do not impart a color simulating that of milkfat or butterfat.[6]

• Regarding bottled water, an “approved source” is any source of water that comes from a spring, artesian well, drilled well, municipal water supply, or another location that has been inspected and found to be of a sanitary quality according to applicable regulations of the local government agencies.[7]

• Calcium chloride may be added to dry curd cottage cheese so long as harmless lactic acid-producing bacteria are added and it is held until it becomes coagulated.[8]

• Enriched breads and rolls may contain wheat germ or partly defatted wheat germ, but the total quantity thereof shall not exceed 5% of the flour ingredient.[9]

• Grapes may appear in canned fruit cocktail, but only seedless grapes of the species *Vitis vinifera* L or *Vitis labrusca* L and only where the grapes make up more than 6% of the finished cocktail product and less than 20% of the finished product.[10]

• Semolina’s moisture content may not exceed 15%.[11]

• Margarine may include edible fats whose origin is rendered animal carcass fats that may have been subjected to an accepted process of physico-chemical modification.[12]

• Mayonnaise contains 65% or more vegetable oil by weight and may contain frozen egg yolks, dried egg yolks, or liquid egg yolks.[13]

These labeling regulations are clearly more pertinent to a food manufacturer than a consumer. However, the detail in which food manufacturing is regulated illustrates the importance of and need for legal standards in the food industry. Title 21 is not limited to regulations on food manufacturing; it also regulates labeling that directly affects consumers in their perception of a food’s content and a product’s relative health value.

Title 21 specifically identifies certain types of labeling statements that patients often encounter. RDs should have an understanding of the limitations and requirements relating to the types of labeling statements, such as follows:

***Statements Relating to Usefulness in Reducing or Maintaining Body Weight***
This rule stipulates that any food that purports to be for special dietary use shall bear a conspicuous statement of the basis on which the food claims to be useful in that regard. Further, if there are any nonnutritive ingredients in the food, the label will list the nonnutritive ingredient (including nonnutritive sweeteners) and the percentage of that ingredient.[14]

***Nutrition Labeling***
With a few exceptions (relating mainly to small business exemptions and single food products), nutrition information must be provided on all food products. “Serving” or “serving size” refers to an amount of food customarily consumed per eating occasion by anyone 4 years of age or older. Further, the amount must reflect a common household measure (eg, 1/2 cup or 2 TB) that is appropriate for the food.

For food specifically formulated for infants or toddlers, “serving size” refers to an amount of food typically consumed per eating occasion by infants up to 12 months of age or by children aged 1 to 3, respectively.

Generally, nutrition facts labels must include the amount of total calories, calories from fat (except on products that contain less than 0.5 g of fat per serving), fat (total, saturated, and trans), cholesterol, sodium, carbohydrate, dietary fiber, sugar, and protein. Vitamins A and C, as well as and calcium and iron, must be included, and are expressed as a percentage of the recommended daily intake values. Manufacturers may include optional nutrients, such as the B vitamins and trace minerals. Labeling rules also specify how conspicuous the information must be, including rules against letters touching one another and font size.[15]

Some general exemptions from these labeling requirements exist for packaged single-ingredient products that consist of fish or game meat, foods in small packages with a total surface area for a label of less than 12 square inches, shell eggs packaged in a carton with a top lid (in this case, the nutrition information may appear beneath the carton lid), and food products sold in bulk.[15] Small businesses may file a notice with the FDA if production does not exceed 100,000 units sold per year, and need not file if production does not exceed 10,000 units.

The FDA urges but does not require raw fruit, vegetable, and fish producers to voluntarily provide nutrition labeling for their products unless those raw fruits, vegetables, and fish are on the FDA’s most frequently consumed list, which includes the 20 most commonly consumed varieties of fruits, vegetables, and fish, respectively.[16] For those common varieties, the guidelines apply.

***Nutrient Claims***

Statements such as “calorie free,” “zero calories,” and “trivial source of calories” may appear on labels for which the food contains less than 5 kcal per labeled serving. If the food meets this so-called calorie-free condition without the benefit of special processing or alteration to lower the calorie count, it should be labeled to disclose that calories are not usually present in the food (eg, “cider vinegar, a calorie-free food”).[17]

Statements such as “low calorie,” “few calories,” and “low in calories” may be used on a label provided that the food has a customarily consumed reference amount greater than 30 g or 2 TB and does not provide more than 40 kcal per serving. Like the calorie-free claims, if the food is low calorie without the benefit of special processing or alteration, it must be labeled to clearly refer to all foods of its type (eg, “asparagus, a low-calorie food”).[17]

The terms “reduced calorie” or “fewer calories” may be used on a label when the food contains at least 25% fewer calories per reference amount customarily consumed, but such a term may not be used on a food that meets the definition of low calorie.[17]

Claims of a product containing low or no sugar, such as “sugar free,” “zero sugar,” “without sugar,” and “dietarily insignificant source of sugar,” may be used only when a food contains less than 0.5 g of sugar per reference amount customarily consumed and the food contains no

ingredient that is a sugar (or is generally understood by consumers to contain sugars) unless the ingredient listing is followed by an asterisk that refers to a statement below the ingredient list explaining that it “adds a trivial amount of sugar” or similar statement.[17]

The claim “no added sugar” may be used only if no amount of sugar or any ingredient that functionally substitutes for sugar is added during processing or packaging, the product does not contain an ingredient with added sugars (eg, jelly or concentrated fruit juice), and the sugar content has not been increased above the amount present in the ingredients due to the use of enzymes.[17]

A label may contain the terms “light” or “lite” if a food which derives 50% or more of its calories from fat has its fat content reduced by 50% or more per reference amount customarily consumed or if a food which derives less than 50% of its calories from fat has the number of calories reduced by at least one-third per reference amount customarily consumed.[18]

The term “lightly salted” may be used on a product when it contains 50% less sodium than is normally added as long as, if the product is not low in sodium (as defined in a different part), the statement “not a low sodium food” appears adjacent to the nutrition labeling.[18]

### *Health Claims*

A health claim is characterized as the relationship of any food to a health-related condition. A claim may be expressed (“just one cup per day lowers cholesterol”) or implied (a picture of a heart, signifying that the product helps fight heart disease). For a food to be eligible for a permissible health claim, it must be associated with a health-related condition for which a subgroup (eg, senior citizens) or the general US population, as a whole, is at risk. The FDA will authorize the health claim when it determines there is significant scientific agreement from the publicly available scientific evidence that the health claim being made is supported by such evidence.[19]

To obtain authority from the FDA, a company files a petition, which includes a thorough summary of scientific data supporting the proposed health claim. The FDA reviews the petition and either approves or denies it. All information required to be included in the health claim should appear in one place without other intervening or confusing material unless there is a reference to a location where further information subsides (eg, “See back of box for information about fiber and colon health.”).[19,20]

### Enforcement

In the United States, there are 15 federal agencies responsible for food oversight, including food safety, quality control, and labeling. Of those 15, the FDA is authorized under the Nutrition Labeling and Education Act of 1990 to ensure that food products are properly labeled.[21]

The FDA, an agency of the US Department of Health and Human Services, is a federal public health consumer protection agency that regulates most food products (other than meat and poultry), human and animal drugs, medical devices, cosmetics, and animal feed. The agency originated in 1862 from a single USDA chemist and now employs more than 11,000 people, including chemists, pharmacologists, physicians, microbiologists, veterinarians, lawyers, and

pharmacists. The organization consists of the Office of the Commissioner, the Office of Medical Products and Tobacco, the Office of Global Regulatory Operations and Policy, the Office of Operations, and the Office of Foods.

The Office of Foods was created in 2009 to enhance the FDA's ability to address issues related to food safety and nutrition by way of, among other endeavors, the Foods Program. The Foods Program aims to ensure the safety of food, dietary supplements, and animal feed; to set science-based standards for preventing foodborne illness; and to establish "that food labels contain reliable information consumers use to choose healthy diets."[22]

Within the Office of Foods is the Center for Food Safety and Applied Nutrition (CFSAN). The CFSAN is responsible for, among other things, ensuring that the nation's food supply is safe, sanitary, and honestly labeled. It oversees food additives, food ingredients developed through biotechnology, seafood, juice, foodborne contaminants, dietary supplements, infant formulas, medical foods, food labeling, and international food standards.

The FDA's Office of Regulatory Affairs performs inspections and enforcement activities for all FDA centers. In the event that a labeling issue is identified, the FDA may do one of the following: send an informal letter to the offending company recommending that corrective actions be taken, hold a regulatory meeting with the company to resolve a labeling violation, send a formal warning letter notifying the company that enforcement actions may be forthcoming if corrections are not made, and/or ask the company to voluntarily recall the food from the distribution chain. When violations are not corrected, the FDA may obtain a legal order preventing the company from continuing to violate food labeling regulations and/or initiate a seizure of the food product from the marketplace.[23]

If a food is deceptively labeled, the manufacturer may wish to voluntarily recall all the products from the market as an alternative to an FDA-initiated court action. Oftentimes, voluntary recalls initially result from the FDA issuing a request to the manufacturer to recall the product.[24]

A state may bring an action for civil enforcement of an FDA regulation by filing a letter of notification with the FDA.[25] Citizens and citizen groups also may urge the FDA to investigate a potential labeling issue. The FDA will prioritize the complaint in cases where significant injury or illness allegedly resulted from the potential labeling violation.

**Limitations of the Current Oversight System**

The FDA does not seem to have a strong and effective system to ensure that most, if not all, food labels comply with the law. The agency's limitations include infrequent investigations and disciplinary action, failure to properly document consumer complaints, and inaccurate reporting within the agency and to the public.

Between 2001 and 2007, the number of food companies under the FDA's jurisdiction increased from approximately 51,000 to 65,000. The number of label inspections made by the FDA during that time, however, decreased.[26] During a five-year span starting in 2002, the FDA issued only 463 warning letters to companies with serious violations that included labeling violations, and a little over one-half of these warning letters were related to the labeling of

dietary supplements.[26] The time between the day officials identify the violation and the day the FDA issues a warning letter is about four months.[26] This relatively significant time lag is especially concerning when the labeling violation can be causally related to allergic reactions or other adverse physiologic responses.

Further, the FDA does not appear to have a clear and efficient system for tracking and documenting informal letters or regulatory meetings. From 2001 through 2007, the FDA documented approximately 2,600 complaints from consumers about food labeling, such as the omission of certain ingredients or allergens on the label that may harm consumers' health. The data concerning these complaints, however, were not entered into the FDA's system in a way that facilitated analysis. For example, there was no standardized terminology used that would enable organization of the different complaints.[26]

Additionally, the FDA does not provide its managers with routine reports on the status of labeling violations or the trends in labeling violations across the country. Such infrequent communication in this regard potentially disenables the managers from effectively setting priorities and allocating resources. While the FDA's official agency website has listings of informal and warning letters, the list is not always accurate or complete. In its investigation of these letters, the US Government Accountability Office found that the list contained duplicate letters while omitting other letters altogether.[26]

The amount of funding allotted to the FDA to handle food labeling claims has decreased, resulting in a reduced number of inspectors and enforcement employees.[26] Thus, the above limitations, at least in part, are likely due to the lack of resources allotted to the FDA to enforce food labeling laws.

**Recent Enforcement Actions**

Despite the apparent limitations of the FDA's capacity to enforce food labeling infractions, recent enforcement activity has drawn the attention of food manufacturers.

In early 2010, the FDA issued 17 warning letters regarding potential labeling violations to several large food manufacturers including Dreyers Grand Ice Cream, Inc; Gorton's, Inc; Beech-Nut; Nestlé; Nestlé Nutrition; Sunsweet Growers; POM Wonderful; Ken's Foods, Inc; and Diamond Food, Inc. For example, the warning letters sent to Dreyers and Gorton's criticized them for printing statements on their product labels saying their ice cream and fish fillet products, respectively, were free of trans fats but failing to advise the consumer to check the nutrition information for fat and saturated fat content. The FDA noted that clarification statements regarding total and saturated fat are required on foods that make nutrient claims such as "trans fat free" and that contain more than 13 g of total fat or 4 g of saturated fat per labeled serving.

The POM Wonderful labeling issue provides perhaps the most widely-noted recent example of an FDA written warning. On February 23, 2010, the FDA issued a warning letter to POM Wonderful stating that its 100% pomegranate juice was improperly labeled as a food, not a drug, in that its website, as promoted on the juice's label, contains claims of treatment, mitigation, and prevention of disease (eg "[In artherosclerosis] patients who consumed 8

ounces of POM Wonderful 100% Pomegranate Juice daily for a one-year period, [they] experienced a 30% reduction in intima-media thickness of the carotid artery versus a 9% increase for the placebo group").[27] Because the label content implied that the product had druglike features, the product was considered a drug under Title 21 and failed to comply with regulations concerning the labeling of drugs.

POM Wonderful did not heed the FDA's warning, spurring a well-publicized lawsuit involving the Federal Trade Commission (FTC). POM Wonderful claimed that the FTC did not have the authority to require FDA approval before POM makes health-related claims, and the FTC argued that POM Wonderful was engaging in false and misleading advertising.[28] As of March 2012, this case had not been resolved.

While it is unclear whether the FDA will continue to step up enforcement actions, its recent activity may indicate a reaction to the proliferation of food labeling information.

**Impact on Consumers and Recommendations for Improvement**

Although the recent FDA actions may signal a trend of tighter enforcement, the limitations of the current oversight system discussed above increase the likelihood of potential consumer injuries. A consumer may buy a product under the false, but reasonable, impression that it leads to some health benefit. He or she may suffer monetarily (spending money that he or she would not have spent had the labeling been accurate) or physically (becoming ill due to ingesting allergen that was not clearly listed).

In consumer studies, findings suggest that while consumers consider certain labeling terms to be helpful in comparing products, they generally find labeling confusing with regard to the role that nutrients play in their diet. For instance, consumers generally do not understand the relationship between sugar and carbohydrates or the actual definition and nutritional import of a fatty acid.[29]

Some consumer groups have advocated different methods of improving company-to-consumer communication with regard to food labeling, and some interesting developments are taking place, such as the following:

**Front-of-package labeling:** This kind of labeling would employ some systematic rating system, terms, or images to signify a food's health value. While discussions are ongoing regarding a standardized form for this type of simplified labeling system, there is currently no FDA-mandated standard. In October 2011, the Institute of Medicine released its report on front-of-package nutrition rating systems and symbols and recommended the implementation of "a single, standardized front-of-package system that can be easily understood by most consumers and that would appear on every product."[30]

There are several front-of-label systems under development and in different stages of implementation by both food retailers and manufacturers. For instance, Wal-Mart's new Great For You icon purports to simplify healthful food decisions. The Facts Up Front labeling system, developed jointly by the Grocery Manufacturers Association and the Food Marketing Institute, and the independently developed NuVal Nutritional Scoring System are two more

comprehensive front-of-package labeling systems currently seeking acceptance from the food manufacturing community. Reports indicate the FDA may endorse the Facts Up Front Program.[31]

**Clearer whole grains labeling:** Such labeling would enable consumers to have a clearer understanding of the actual amount of whole grains in a food. The need for this marking became clear after studies revealed that consumers cannot accurately identify which foods are primarily whole grains.

In a related note, the Whole Grains Council, a nonprofit consumer group whose mission is to increase whole grain consumption, has created a Whole Grain Stamp. It identifies products with at least a one-half serving of whole grains. A "100%" banner may be placed on the stamp where all of the grain in the product is whole grain.

**Trans fat-free labeling:** The goal of this endeavor is for the FDA to prohibit foods with a substantial amount of saturated fats from being labeled as "trans fat free." The trans fat-free label entices consumers to buy the food item thinking it may be a low-fat food. But the food may be high in saturated fat, which raises LDL cholesterol levels in the blood and increases the risk of heart disease.

**Total nutrition information for items commonly consumed in one sitting:** Consumers are often misled by labels that give calorie, fat, and carbohydrate figures for a partial amount of the food item when such item is commonly consumed all at once. For example, a 20-oz bottle of fruit drink may list the nutritional information for a serving size of one-half of the bottle, listing that the bottle contains two servings. The average consumer, however, typically drinks the entire bottle at once.

**Clarification of "natural":** The FDA has not established an official definition of the word natural, although the term, rampantly used in the marketplace, likely leads consumers to believe that a product is the result of minimal to no processing.

**Gluten-free labeling:** With the rise in celiac disease and gluten intolerance diagnoses, it is notable that the FDA still has not set guidelines for what a product labeled "gluten free" should or should not contain. The FDA did introduce a proposal in 2007 that wheat, barley, and rye products could not contain the label gluten free unless they have less than 20 ppm of gluten.[32] It is speculated that a decision on the proposal may be issued in 2012.[33]

These action items may significantly assist consumers in their evaluation of products, but it is unclear where these items fall on the FDA's list of priorities considering its already-taxed system and funding restrictions.

**Suggestions for RDs**

Patient education is critically important because patients would benefit from understanding the above-mentioned limitations on food labeling when making their own eating and nutrition decisions. Nothing replaces a good one-on-one session between a patient and an RD. To the extent that an RD wants his or her patient to be able to rely on helpful resources outside the

provider-patient relationship, there are numerous resources that may assist in counseling a consumer on how to read a food label.

One of the more comprehensive and user-friendly resources is the Mayo Clinic's Interactive Guide to Food Labels.[34] This guide is a free online tool that any consumer can access via the Internet. A user is shown a Nutrition Label and can simply move the mouse pointer over a nutrient on the label to see what the Nutrition Label means. The Mayo Clinic website also contains links from that page to information about health and lifestyle.

Obesity and chronic illness are widespread problems in America due, in part, to poor diet and lifestyle choices. If government's effective regulation of food labels can assist consumers in making sense of often confusing nutrition messages and understanding nutritional information about the foods they eat, then continued improvements in labeling regulations can only benefit consumers and the RDs who teach and counsel them.

*—Dara Lovitz, Esq is the author of* ***Muzzling a Movement: The Effects of Anti-Terrorism Law, Money, and Politics on Animal Activism*** *who has written numerous articles and book chapters on law and policy.*

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## Examination

**1. Food labeling regulations are codified in:**
A. the nutrition laws of each individual state.
B. the US Constitution.
C. the US Agricultural Act.
D. Title 21 of the Code of Federal Regulations.

**2. A serving size on a food label is a serving typically consumed by someone:**
A. 2 years of age or older.
B. 4 years of age or older.
C. 10 years of age or older.
D. 18 years of age or older.

**3. All foods manufactured and distributed in the United States must meet the FDA's food labeling requirements except for:**
A. food prepared at an organic facility.
B. all raw fruits, vegetables, and fish.
C. some raw fruits, vegetables, and fish.
D. foods that are naturally fat free.

**4. A food can be labeled "calorie free" when it has:**
A. fewer than 5 kcal per serving.
B. fewer than 8 kcal per serving.
C. fewer than 10 kcal per serving.
D. fewer than 12 kcal per serving.

**5. The following food label is not a health claim:**
A. a heart symbol.
B. image of a person running through a race finish line.
C. the words "helps fight the common flu."
D. the statement "proven to reduce joint inflammation in senior citizens."

**6. The FDA is an agency of:**
A. the Federal Trade Commission.
B. the US Department of Health and Human Services.
C. the Center for Food Safety.
D. the Farm Bureau.

**7. The FDA's authority to regulate food labeling is set forth in:**
A. the Nutrition Labeling and Education Act.
B. the Food Labeling and Resource Law.
C. the President's Referendum of Food Safety.
D. the Government Authority Statute.

**8. If the FDA finds a food labeling violation, it may do which of the following:**
A. write a letter to the manufacturer warning it to take measures to correct the error.
B. order a seizure of the food items to remove them from the marketplace.
C. request that the company remove the food item from the marketplace.
D. All of the above

**9. From 2002 to 2007, the FDA issued how many warning letters to food manufacturers for labeling violations?**
A. 2
B. 19
C. 463
D. 3,589

**10. There is currently no official FDA definition of which of the following terms:**
A. “natural”
B. “healthful”
C. “gluten free”
D. All of the above