



NUTRITION AND INFORMATION LABELING: FRESH-MARKET APPLES

Updated November 2006

This document summarizes the most important elements of the federal requirements for voluntary nutrition labeling of fresh-market apples for sale to the consumer. In addition, other mandatory information labeling requirements are also discussed. It updates the U.S. Apple Association's (USApple) previous summaries on the topic, dated June 2003, August 1994, May 1996, and November 2003. This document is accompanied by camera-ready artwork for a "Nutrition Facts" box for fresh apples that is compliant with current minimum federal nutrition labeling requirements.

Note that this document is not intended to be an exhaustive explanation of nutrition or information labeling requirements, or food safety requirements, but rather seeks to expose fresh-market apple packers to the most salient points. For example, this document does not cover qualified health claims or structure/function claims, currently a rapidly changing landscape in the labeling arena. For more information, review the complete regulations including *Code of Federal Regulations (CFR), Title 21 - Food and Drugs*, available online at <http://www.gpoaccess.gov/cfr/> and the Food and Drug Administration's (FDA) labeling Web page at <http://www.cfsan.fda.gov/label.html> to determine how they may apply to your company's specific circumstances.

The information contained herein was developed in good faith by USApple. USApple may not be held accountable for any errors or omissions, or use that is not in compliance with federal regulations.

Background

The Nutritional Labeling and Education Act (NLEA) of 1990 amended the Federal Food, Drug, and Cosmetic Act (FFDCA) with regard to nutrition labeling requirements and revised some of the information labeling requirements for food products made available for sale. The NLEA amendments to the FFDCA affect all products labeled on or after May 8, 1994.

In July 1994, USApple (then called the International Apple Institute) requested that FDA update its nutrition information database for fresh apples by adopting the results of a nutritional analysis commissioned by the association. In May 1996 FDA officially accepted the association's data and revised the nutrition labeling values accordingly.

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In March 2002 FDA again began the process of updating the nutrition labeling values for fresh produce. After a series of comment periods and revisions, FDA proposed a new set of nutrition labeling values for fresh apples in 2005. At that time, USApple commissioned Food Research, Inc. to assist in evaluating the proposed changes, conducting additional analyses of apples, and preparing comments to FDA. In its comments, USApple submitted additional dietary fiber data to FDA and sought to update the serving size from “1 medium apple” to “1 large apple.” FDA officially accepted the association’s recommendations in the final rule published in July 2006. As a result, the “Nutrition Facts” for fresh apples were then revised.

In July 2003, FDA implemented a federal rule requiring that applicable foods be labeled to report *trans* fat content by January 1, 2006, and announced availability of an anti-cancer dietary guidance message for fruits and vegetables.

This document explains the federally-approved nutrient content and health claims based on the nutrition data approved by FDA in 2006, while the accompanying artwork for a “Nutrition Facts” panel depicts that data.

Defining Display Panels

The term “Principal Display Panel” (PDP) refers to the front panel of a two-panel bag package. The term “Information Panel” (IP) refers to the back panel of a bag package.

Voluntary Nutrition Labeling of Produce

Nutrition labeling for 20 designated raw fruits, including fresh-market apples, is not required by current regulations as long as no nutrition or health claims are made on the product or its packaging. (Reference: 21 CFR §101.45, and “Food Labeling: Questions and Answers,” FDA, August 1993, page 21, question N105.) Instead, these products are subject to a voluntary program of posting nutrition information at retail point of purchase. As long as government surveys conducted every two years find substantial compliance with posting the information at point of purchase, labeling for these raw products will remain voluntary.

If a nutrient content or health claim is made for fresh apples, point-of-purchase posting of the nutrition information at point of sale becomes mandatory; package labeling is voluntary under these conditions. (Reference: 21 CFR §101.9 (j)(10).)

If a company chooses to voluntarily label fresh apple packages, the “Nutrition Facts” box for fresh apples should appear on the package’s IP. USApple has produced the accompanying camera-ready artwork for a “Nutrition Facts” box for fresh apples that complies with minimum guidelines as defined by the NLEA. Again, the accompanying “Nutrition Facts” box art reflects the approved FDA nutritional database for fresh apples, and is the only data that should be used for nutrition labeling of fresh apples.

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In general terms, the same rules apply to voluntary nutrition labeling of fresh produce as apply to labeling of processed food products. The only difference is that FDA does not require a “servings per container” declaration for fresh produce. (Reference: 21 CFR §101.45 (a)(3)(i).)

Allowed Nutrient or Health Claims for Fresh Apples

In addition to defining a product’s nutrition labeling requirements, NLEA also controls the types and content of health and nutrient claims made on a product’s packaging by specifically defining the types of claims that can be made, under what conditions they can be made, and how they should be stated. The types of claims allowed depend upon the product’s nutritional analysis.

Allowed Nutrient Content Claims for Fresh Apples. Based on the nutritional analysis currently approved for fresh apples, certain claims can be made about apples’ nutrient content. The claims that are currently allowed under FDA’s nutritional database for fresh apples include:

- fat free;
- saturated fat free;
- sodium free;
- cholesterol free; and
- excellent source of fiber

Wording of these claims must reflect that apples are typically free of these items; for example, “apples, a sodium-free food” wording is appropriate. (Reference: 21 CFR §101.13(e)(2).)

Nutrient content claims must be made in a type size no larger than two times that of the statement of product identity (see specifications for product identity, below). (Reference: 21 CFR §101.13(f).)

Allowed Health Claims for Fresh Apples. Certain health claims are also allowed to be made about fresh apples based upon that product’s nutritional analysis. These are identified, and model language for each type of claim is provided, below.

When a health claim is made, all information required to be included in the claim must appear in its entirety in one place, without interruption. In addition, the labeling may bear a reference statement directing the consumer elsewhere on the package for the complete claim. Wording such as “See _____ for information about the relationship between _____ and _____” could be used, where the blanks are filled in with a reference to the panel containing the complete health claim, the name of the substance, and the associated disease or health condition. (Reference: 21CFR §101. 14(d)(2)(iv).)

Health claim statements and the related referral statements should appear in type that is no smaller than 1/16 inch in height.

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Be reminded that if nutrient content or health claim(s) are made, nutrition information must appear at point of purchase (or optionally on the package if labeled voluntarily).

- **Fiber-containing fruits and cancer:** The following model health claim may be used in labeling of fresh apples to characterize the relationship between diets low in fat and high in fiber (Reference: 21 CFR §101.76(e)):

“Low fat diets rich in fiber-containing grain products, fruits and vegetables may reduce the risk of some types of cancer, a disease associated with many factors. Apples are an excellent source of fiber.”

The following model health claim may also be used:

“Development of cancer depends upon many factors. Eating a diet low in fat and high in grain products, fruits and vegetables that contain dietary fiber may reduce your risk of some cancers.”

- **Fruits and cancer:** The following model health claim may be used in labeling of fresh apples to characterize the relationship between substances in diets low in fat and high in fruits and vegetables and cancer (Reference: 21 CFR § 101.78(e)):

“Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A and vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. Apples are an excellent source of fiber.”

The following model health claim may also be used:

“Development of cancer depends on many factors. Eating a diet low in fat and high in fruits and vegetables, foods that are low in fat and may contain vitamin A, vitamin C and dietary fiber, may reduce your risk of some cancers. Apples are naturally fat free, 20% of the Daily Value of fiber, 5 grams per apple.”

- **Fat and cancer:** The following model health claim may be used in labeling of fresh apples to describe the relationship between dietary fat and cancer (Reference: 21 CFR § 101.73(e)):

“Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers. Apples are naturally fat-free.”

The following model health claim may also be used:

“Eating a healthful diet low in fat may help reduce the risk of some types of cancers. Development of cancer is associated with many factors, including what you eat. Apples are naturally fat-free.”

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- **Saturated fat and cholesterol and heart disease:** The following model health claim may be used in labeling of fresh apples to describe the relationship between dietary saturated fat and cholesterol and the risk of heart disease (Reference: 21 CFR § 101.75(e)):

“While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease. Apples are naturally fat-free and cholesterol-free.”

- **Sodium and hypertension:** The following model health claim may be used in labeling of fresh apples to describe the relationship between dietary sodium and high blood pressure. (Reference: 21 CFR §101.74(e).)

“Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors. Apples are naturally sodium-free.”

The following model health claim may also be used:

“Development of hypertension or high blood pressure depends on many factors. Naturally sodium-free apples can be part of a low sodium, low salt diet that might reduce the risk of hypertension or high blood pressure.”

Anti-Cancer Dietary Guidance Message

On July 10, 2003, FDA announced availability of a new dietary guidance message for fruits and vegetables, including apples:

“Diets rich in fruits and vegetables may reduce the risk of some types of cancer and other chronic diseases.”

FDA encourages food manufacturers to use this statement in association with those fruits, vegetables and foods that meet the criteria established by the National Cancer Institute’s 5 A Day For Better Health Program:

- all fresh-market fruits and vegetables, excluding coconuts and nuts - including fresh-market apples;
- fruits and vegetables (except dried herbs, coconut and nuts) processed by drying, freezing, or canning - including those with added ingredients - provided that:
 - no sugars, sugar-containing ingredients, or sugar alcohols (e.g., sucrose, glucose, dextrose, fructose, maltose, lactose, sorbitol, mannitol, honey, corn syrup, corn syrup solids, or molasses) have been added;
 - the fat, saturated fat, cholesterol, and sodium content per FDA reference amount and per labeled serving must meet the FDA qualifying limits for “healthy” foods, as follows:
 - fat: less than 3 grams;
 - saturated fat: less than 1 gram, and less than 15 percent of calories from saturated fat;

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- cholesterol: less than 60 milligrams; and
- sodium: less than 480 milligrams; and
- the food is not processed to the extent that it no longer resembles a fruit or vegetable, such as tofu, soy-based “hamburger” patties, popcorn, or powders.

For more information, visit FDA’s Web page on the message at <http://www.cfsan.fda.gov/~dms/lab-dg.html>.

Use of Term “Healthy”

NLEA established specific criteria that must be met if a food is to be labeled “healthy.” To be labeled “healthy,” a food must:

- meet the definition for “low fat,” i.e. contain less than 5 grams of fat per defined serving size;
- meet the definition for “low saturated fat,” i.e. contain less than 2 grams of saturated fat per serving;
- must contain less than or equal to 480 milligrams of sodium per serving;
- except for raw fruits and vegetables, must contain at least 10 percent of the Daily Value per serving of vitamin A, vitamin C, calcium, iron, protein or fiber; and
- must comply with requirements for any specified nutrient content claim (see allowed nutrient content claims, above).

(Reference: 21 CFR §101.65 (d)(2).)

Use of Term “Fresh”

FDA has also attempted to outline what it defines as appropriate uses of the word “fresh.” The agency will allow use of the term “fresh” to describe produce even when the produce is waxed or coated, or pesticides or chlorine/acidic washes are applied post-harvest.

Therefore, it is permissible and appropriate to label bulk or bagged apples as “fresh apples.”

Information Labeling Requirements

While packaged fresh apples are not required to bear “Nutrition Facts” information, the following pieces of information must be included on the package under federal labeling regulations. The guidelines for content and presentation of each piece of information follow below:

- a statement of product identification (must appear on the PDP);
- a net contents statement (must appear on the PDP);
- the producer’s name and address (must appear on either the PDP or IP); and
- statement of ingredients (must appear on the same panel as the name and address).

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The “Nutrition Facts” box, if included, should appear on the same panel as the producer’s name and address and the statement of ingredients.

Post-harvest chemicals do not need to be identified on apple bags.

If apples are shipped in bulk in a container with no other packaging, then the shipping container must bear:

- the product identity;
- packer’s name and address;
- net weight or volume; and
- a statement identifying any post-harvest chemicals used.

Guidelines for presentation of each piece of required information labeling follow.

Statement of Product Identification. The PDP must bear a statement of product identification, i.e. the name of the product (e.g., “apples” or “fresh apples” or “McIntosh apples”). This statement must be presented:

- in bold type;
- in a size reasonably related to the most prominent printed matter on the panel, but no smaller than 1/16 inch in height; and
- parallel to the base of the package.

(Reference: 21 CFR §101.3.)

Net Contents. A declaration of net contents must appear on the PDP following this format:

- appearing within the bottom 30 percent of the panel, in lines generally parallel to the base of the panel; and
- presented in a type size determined by the surface area being labeled:
 - not less than 3/16 inch in height on packages with a PDP area of more than 25 square inches but not more than 100 square inches; or
 - not less than 1/4 inch in height on packages with a PDP area of more than 100 square inches, but not less than 1/2 inch in height if the PDP area is more than 400 square inches.

(Reference: 21 CFR §101.105.)

FDA advises that food labels show net contents in both metric weights and U.S. Customary System weights. Even though federal rules proposed in 1993 governing metric labeling have not yet been finalized, USApple recommends that packers begin presenting net contents in both U.S. and metric units.

The U.S. and metric net contents can be presented in a number of possible formats:

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- the net contents could be presented first in U.S. Customary units, followed by the metric units in parentheses, on the same line of type;
- the metric net contents could follow the U.S. Customary contents on the next line of type (e.g., in stacked format); or
- the metric contents could be presented first, followed by the U.S. Customary units in parentheses, on the same line of type.

(Reference: Public Law 102-329, Aug. 3, 1992; 21 CFR §101.105; FDA *Food Labeling Guide*, September 1994, Chapter III - Net Quantity of Contents Statement, question 3.)

Packer's Name and Address. This statement must include the name and street address (optional if it appears in the local telephone directory), city, state and zip code and should appear in a ratio of height to width not exceeding 3:1. (Reference: 21 CFR §101.5 and 21 CFR §101.2.) The type is to be no smaller than 1/16 inch in height. (Reference 21 CFR § 101.2 (b) and (c).)

This statement should appear on either the PDP or the IP, but it must be on the same panel with the nutrition information (if printed) and ingredient information unless size constraints prevent this. (Reference 21 CFR §101.2 (b), (d), (e); §101.9 (j).)

Ingredients. Ingredients must be stated, in descending order of predominance, on whichever panel, the PDP or IP, the packer's name and place of business appears. The statement should be displayed prominently, in type no smaller than 1/16 inch in height.

Wax/Resin Information. If waxed apples are packaged in bags for retail sale, then specifically-worded language about wax must be included on the package's ingredients statement (see model language, below). Point-of-purchase materials need not bear the wax information if it is declared on the package.

For fruit sold in bulk, wax/resin information can be provided either on the shipping container or in point-of-purchase materials supplied by the packer/shipper. Note that if this bulk container becomes a retail package used at point of purchase, then the ingredients statement must also appear on the container or on point-of-purchase materials. These pieces of information should be presented in type no smaller than ¼ inch in height.

The ingredient statement reference to wax must be worded as follows, as appropriate for the waxes used:

“Coated with food-grade animal-based wax, to maintain freshness.”

OR

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“Coated with food-grade vegetable-, petroleum-, beeswax-, and/or shellac-based wax or resin, to maintain freshness.”

The terms “food grade” and “to maintain freshness” are optional, and “lac resin” can be substituted for “shellac.” (Reference: 21 CFR § 101.4 (a)(22).)

An example of a correctly worded statement is:

“Coated with a food-grade vegetable- and/or lac resin-based wax, to maintain freshness.”

For More Information

For more information, contact the U.S. Apple Association or a qualified labeling attorney.

FDA’s food labeling web page can be found at <http://www.cfsan.fda.gov/label.html>, including the agency’s September 1994 *Food Labeling Guide* at <http://www.cfsan.fda.gov/~dms/flg-toc.html>. Questions and correspondence can also be directed to FDA district offices; a directory of district offices is available online at <http://vm.cfsan.fda.gov/~dms/district.html>. Alternately, questions and correspondence can be directed to: Food and Drug Administration Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling and Dietary Supplements, Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740-3835, tel. 301-436-2373.

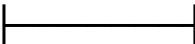
Nutrition Facts Artwork for Fresh-Market Apples

With optional “Calories per gram” footnote

Nutrition Facts			
Serving Size 1 large apple (242 g/8 oz)			
Amount Per Serving			
Calories	130	Calories from Fat	0
% Daily Value *			
Total Fat	0g		0%
Saturated Fat	0g		0%
Trans Fat	0g		
Cholesterol	0mg		0%
Sodium	0mg		0%
Potassium	260mg		7%
Total Carbohydrate	34g		11%
Dietary Fiber	5g		20%
Sugars	25g		
Protein	1g		
Vitamin A 2% • Vitamin C 8%			
Calcium 2% • Iron 2%			
* Percent Daily Values are based on a 2,000 calorie diet. Your calorie needs 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
Potassium		3,500mg	3,500mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g
Calories per gram:			
Fat	9	•	Carbohydrate 4
		•	Protein 4

Without optional “Calories per gram” footnote

Nutrition Facts			
Serving Size 1 large apple (242 g/8 oz)			
Amount Per Serving			
Calories	130	Calories from Fat	0
% Daily Value *			
Total Fat	0g		0%
Saturated Fat	0g		0%
Trans Fat	0g		
Cholesterol	0mg		0%
Sodium	0mg		0%
Potassium	260mg		7%
Total Carbohydrate	34g		11%
Dietary Fiber	5g		20%
Sugars	25g		
Protein	1g		
Vitamin A 2% • Vitamin C 8%			
Calcium 2% • Iron 2%			
* Percent Daily Values are based on a 2,000 calorie diet. Your calorie needs 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
Potassium		3,500mg	3,500mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

1 inch: 

For advice on proper use of this artwork, and other labeling guidance, refer to the U.S. Apple Association’s nutrition and information labeling of fresh apples document.

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