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**EXTERNAL AFFAIRS AND INTERNATIONAL  
TRADE CANADA**

in cooperation with the

**U.S. Food and Drug Administration**

and the

**U.S. Department of Agriculture**

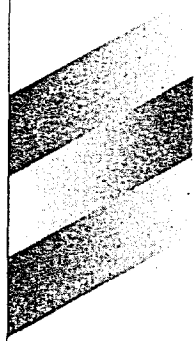
**CROSS-CANADA SEMINAR SERIES**

on the

**NEW U.S. NUTRITION LABELLING REGULATIONS**

**April 1993**

External Affairs and  
International Trade Canada

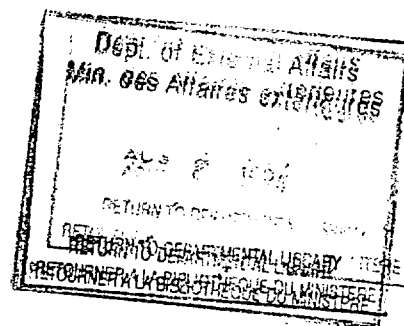


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## The New Food Label

Grocery store aisles are on their way to becoming avenues to greater nutritional knowledge.

The new food label will make it possible. Under new regulations from the Food and Drug Administration of the Department of Health and Human Services and the Food Safety and Inspection Service of the U.S. Department of Agriculture, the food label will soon offer more complete, useful and accurate nutrition information than ever before.

The purpose of food label reform is simple: to clear up confusion that has prevailed on supermarket shelves for years, to help consumers choose more healthful diets, and to offer an incentive to food companies to improve the nutritional qualities of their products.

Among key changes taking place are:

- nutrition labeling for almost all foods. Consumers now will be able to learn about the nutritional qualities of almost all of the products they buy.
- information on the amount per serving of saturated fat, cholesterol, dietary fiber, and other nutrients that are of major health concern to today's consumers
- nutrient reference values, expressed as Percent of Daily Values, that can help consumers see how a food fits into an overall daily diet
- uniform definitions for terms that describe a food's nutrient content—such as "light," "low-fat," and "high-fiber"—to ensure that such terms mean the same for any product on which they appear. These descriptors will be particularly helpful for consumers trying to moderate their intake of calories or fat and other nutrients, or for those trying to increase their intake of certain nutrients, such as fiber.
- claims about the relationship between a nutrient and a disease, such as calcium and osteoporosis, and fat and cancer. These will be helpful for people who are concerned about eating foods that may help keep them healthier longer.
- standardized serving sizes that make nutritional comparisons of similar products easier
- declaration of total percentage of juice in juice drinks. This will enable consumers to know exactly how much juice is in a product.
- voluntary nutrition information for many raw foods.

### NLEA

These and other changes are part of final rules to be published soon in the *Federal Register*. FDA's rules meet the provisions of the Nutrition Labeling and Education Act of 1990 (NLEA), which, among other things, requires nutrition labeling for most foods (except meat and poultry) and authorizes the use of nutrient content claims and appropriate FDA-approved health claims.

Meat and poultry products regulated by USDA are not

covered by NLEA. However, USDA's regulations closely parallel FDA's new rules, summarized here.

### Effective Dates

The new label may start to appear on products soon, although manufacturers have until May 1994 to comply with most of the new labeling requirements. Regulations pertaining to health claims and some parts of the ingredient labeling rule become effective in May 1993.

As provided by Congress under NLEA, FDA extended the implementation date for mandatory nutrition labeling and nutrient content descriptors by one year from the law's target date of May 1993 because of "undue economic hardship" that the earlier effective date would have caused.

### Nutrition Labeling—Applicable Foods

The new regulations will require nutrition labeling on most foods. In addition, nutrition information currently is voluntary for many raw foods: the 20 most frequently eaten fresh fruits and vegetables and raw fish, under FDA's voluntary point-of-purchase nutrition information program. In fact, point-of-purchase information for raw produce and raw fish has been available in some grocery stores since November 1991.

Although voluntary, the programs for raw produce and raw meat, fish and poultry carry strong incentives for retailers to participate. The NLEA states that if voluntary compliance is insufficient, nutrition information for such raw foods will become mandatory.

### Nutrition Labeling—Exemptions

Under NLEA, some foods are exempt from nutrition labeling. These include:

- food produced by small businesses (that is, those with food sales of less than \$50,000 a year or total sales of less than \$500,000)
- restaurant food
- food served for immediate consumption, such as that served in hospital cafeterias and airplanes
- ready-to-eat food prepared primarily on site; for example, bakery, deli, and candy store items
- food sold by food service vendors, such as small cookie counters, sidewalk vendors, and vending machines
- food shipped in bulk, as long as it is not for sale in that form to consumers
- medical foods, such as those used to address the nutritional needs of patients with certain diseases
- plain coffee and tea, some spices, and other foods that contain no significant amounts of any nutrients

Although these foods are exempt, they are free to carry nu-

trition information, when appropriate—as long as it complies with the new regulations.

Also, packages with less than 12 square inches available for labeling do not have to carry nutrition information. However, they must provide an address or telephone number for consumers to obtain the required nutrition information.

Nutrition information about game meats—such as deer, bison, rabbit, quail, wild turkey, and ostrich—may be provided on counter cards, signs, or other point-of-purchase materials rather than on individual labels. Because little nutrient data exists for these foods, FDA believes that allowing this option will enable game meat producers to give first priority to collecting appropriate data and make it easier for them to update the information as it becomes available.

### Nutrition Panel—Content

The new food label will feature a revamped nutrition panel. It will be headed with a new title, "Nutrition Facts," which replaces "Nutrition Information Per Serving." The new name will signal to consumers that the product label meets the new regulations.

There will be a new set of dietary components on the nutrition panel. The mandatory (underlined) and voluntary components and the order in which they must appear are:

- total calories
- calories from fat
- calories from saturated fat
- total fat
- saturated fat
- polyunsaturated fat
- monounsaturated fat
- cholesterol
- sodium
- potassium
- total carbohydrate
- dietary fiber
- soluble fiber
- insoluble fiber
- sugars
- sugar alcohol (for example, the sugar substitutes xylitol, mannitol and sorbitol)
- other carbohydrate (the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol if declared)
- protein
- vitamin A
- vitamin C
- calcium
- iron
- other essential vitamins and minerals

If a claim is made about any of the optional components, or if a food is fortified or enriched with any of them, nutrition information for these components then becomes mandatory.

These mandatory and voluntary components are the only ones allowed on the nutrition panel. The listing of single amino acids, maltodextrin, calories from polyunsaturated fat,

and calories from carbohydrates, for example, may not appear as part of the nutrition facts on the label.

The required nutrients were selected because they address today's health concerns. The order in which they must appear reflects the priority of current dietary recommendations.

Thiamin, riboflavin and niacin will no longer be required in nutrition labeling because deficiencies of each are no longer considered of public health significance. However, they may be listed voluntarily.

### Nutrition Panel—Format

The format for declaring nutrient content per serving also has been revised. Now, all nutrients must be declared as a percent of their Daily Value—the new label reference values. The amount, in grams, of macronutrients (such as fat, cholesterol, sodium, carbohydrates and protein) still must be listed to the immediate right of each of the names of each of these nutrients. But, for the first time, a column headed "% Daily Value" will appear, as will a footnote to help consumers place their individual nutrient needs with respect to the Daily Values used on the label.

Requiring nutrients to be declared as a percent of the Daily Value is intended to prevent misinterpretations that arise with quantitative values. For example, a food with 140 milligrams (mg) of sodium could be mistaken for a high-sodium food because 140 is a relatively large number. In actuality, however, that amount represents less than 6 percent of the Daily Value for sodium, which is 2,400 mg.

On the other hand, a food with 5 grams (g) of saturated fat could be construed as being low in that nutrient. But, in fact, that food would provide one-fourth the total Daily Value because 20 g is the Daily Value for saturated fat based on a 2,000-calorie diet.

### Format Modifications

Variations in the format of the nutrition panel are allowed. Some are mandatory. For example, the labels of foods for children under 2 (except infant formula, which has special labeling rules under the Infant Formula Act of 1980) may not carry information about saturated fat, polyunsaturated fat, monounsaturated fat, cholesterol, calories from fat, or calories from saturated fat.

The reason is to prevent parents from wrongly assuming that infants and toddlers should restrict their fat intake, when, in fact, they should not. Fat is important during these years to ensure adequate growth and development.

Also, the labels of foods for children under 4 may not include the percent of Daily Values per serving or the actual Daily Values for macronutrients. Only the percent of the Daily Values for vitamins and minerals is allowed. The reason: FDA has not established Daily Values for macronutrients for this age group.

Some foods may qualify for a simplified label format. This format is allowed when the food contains insignificant amounts of seven or more of the mandatory nutrients and total calories. "Insignificant" means that a declaration of zero could be made in nutrition labeling, or, for total carbohy-

drate, dietary fiber, and protein, the declaration states "less than 1 g."

For foods for children under 2, the simplified format may be used if the product contains insignificant amounts of six or more of the following: calories, total fat, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamins A and C, calcium, and iron.

If the simplified format is used, information on total calories, total fat, total carbohydrate, protein, and sodium—even if they are present in insignificant amounts—must be listed. Other nutrients, along with calories from fat, must be shown if they are present in more than insignificant amounts. Nutrients added to the food must be listed, too.

Small and medium-size packages will be granted certain exceptions to make the nutrition labeling practical on the smaller space.

### Serving Sizes

Whatever the format, the serving size remains the basis for reporting each food's nutrient content. However, unlike in the past, when the serving size was up to the discretion of the food manufacturer, serving sizes now will be more uniform and will reflect the amounts that people actually eat. They also must be expressed in both common household and metric measures.

NLEA defines serving size as the amount of food customarily eaten at one time. The serving sizes that appear on food labels will be based on FDA-established lists of "Reference Amounts Customarily Consumed Per Eating Occasion."

These reference amounts, which are part of the new regulations, are broken down into 139 FDA-regulated food product categories, including 11 groups of foods specially formulated or processed for infants or children under 4. They list the amounts of food customarily consumed per eating occasion for each category, based primarily on national food consumption surveys. FDA's list also gives the suggested label statement for serving size declaration. For example, the category "breads (excluding sweet quick type), rolls" has a reference amount of 50 grams, and the appropriate label statement for sliced bread or roll is "   piece(s) (   g)" or, for unsliced bread, "2 oz (56 g/   inch slice)."

The serving size of products that come in discrete units, such as cookies, candy bars and sliced products, is the number of whole units that most closely approximates the reference amount. Cookies are an example. Under the "bakery products" category, cookies have a reference amount of 30 g. The household measure closest to that amount is the number of cookies that comes closest to weighing 30 g. Thus, the serving size on the label of a package of cookies in which each cookie weighs 13 g would read "2 cookies (26 g)."

If one unit weighs more than 50 percent but less than 200 percent of the reference amount, the serving size is one unit. For example, the reference amount for bread is 50 g; therefore, the label of a loaf of bread in which each slice weighs more than 25 g would state a serving size of one slice.

Certain rules apply to food products that are packaged and sold individually. If such an individual package is less than

200 percent of the applicable reference amount, the item qualifies as one serving. Thus, a 360-milliliter (12-fluid-ounce) can of soda is one serving, since the reference amount for carbonated beverages is 240 mL (8 ounces).

However, if the product has a reference amount of 100 g or 100 mL or more and the package contains more than 150 percent but less than 200 percent of the reference amount, manufacturers have the option of deciding whether the product can be one or two servings.

An example is a 15-ounce (420 g) can of soup. The serving size reference amount for soup is 245 g. Therefore, the manufacturer has the option to declare the can of soup as one or two servings.

### Daily Value—DRVs

The new label reference value, Daily Value (DV), comprises two new sets of dietary standards: Daily Reference Values (DRVs) and Reference Daily Intakes (RDIs). Only the Daily Value term will appear on the label, though, to make label reading less confusing.

As part of new regulations, DRVs are being introduced for macronutrients that are sources of energy: fat, carbohydrate (including fiber), and protein; and for cholesterol, sodium and potassium, which do not contribute calories.

DRVs for the energy-producing nutrients are based on the number of calories consumed per day. A daily intake of 2,000 calories has been established as the reference. This level was chosen because it has the greatest public health benefit for the nation.

DRVs for the energy-producing nutrients are calculated as follows:

- fat based on 30 percent of calories
- saturated fat based on 10 percent of calories
- carbohydrate based on 60 percent of calories
- protein based on 10 percent of calories. (The DRV for protein applies only to adults and children over 4. RDIs for protein for special groups have been established.)
- fiber based on 11.5 g of fiber per 1,000 calories.

Because of current public health recommendations, DRVs for some nutrients represent the uppermost limit that is considered desirable. The DRVs for fats and sodium are:

- total fat: less than 65 g
- saturated fat: less than 20 g
- cholesterol: less than 300 mg
- sodium: less than 2,400 mg

### Daily Value—RDIs

The RDI replaces the term "U.S. RDA," which was introduced in 1973 as a label reference value for vitamins, minerals and protein in voluntary nutrition labeling. The name change was sought because of confusion that existed over "U.S. RDAs," the values determined by FDA and used on food labels, and "RDAs" (Recommended Dietary Allowances), the values determined by the National Academy of Sciences for various population groups and used by FDA to figure the U.S. RDAs.

However, the values for the new RDIs will remain the

same as the old U.S. RDAs for the time being. Under the provisions of the Dietary Supplement Act of 1992, FDA plans to propose after Dec. 31, 1993, new values for the RDIs.

### Nutrient Content Descriptors

The new regulations also spell out what terms may be used to describe the level of a nutrient in a food and how they can be used. These are the core terms:

- **Free.** This term means that a product contains no amount of, or only trivial or "physiologically inconsequential" amounts of, one or more of these components: fat, saturated fat, cholesterol, sodium, sugars, and calories. For example, "calorie-free" means fewer than 5 calories per serving and "sugar-free" and "fat-free" both mean less than 0.5 g per serving. Synonyms for "free" include "without," "no" and "zero."
- **Low.** This term could be used on foods that could be eaten frequently without exceeding dietary guidelines for one or more of these components: fat, saturated fat, cholesterol, sodium, and calories. Thus, descriptors would be defined as follows:
  - **low fat:** 3 g or less per serving
  - **low saturated fat:** 1 g or less per serving
  - **low sodium:** less than 140 mg per serving
  - **very low sodium:** less than 35 mg per serving
  - **low cholesterol:** less than 20 mg per serving
  - **low calorie:** 40 calories or less per serving.Synonyms for low include "little," "few," and "low source of."
- **Lean and extra lean.** These terms can be used to describe the fat content of meat, poultry, seafood, and game meats.
  - **lean:** less than 10 g fat, less than 4 g saturated fat, and less than 95 mg cholesterol per serving and per 100 g.
  - **extra lean:** less than 5 g fat, less than 2 g saturated fat, and less than 95 mg cholesterol per serving and per 100 g.
- **High.** This term can be used if the food contains 20 percent or more of the Daily Value for a particular nutrient in a serving.
- **Good source.** This term means that one serving of a food contains 10 to 19 percent of the Daily Value for a particular nutrient.
- **Reduced.** This term means that a nutritionally altered product contains 25 percent less of a nutrient or of calories than the regular, or reference, product. However, a reduced claim can't be made on a product if its reference food already meets the requirement for a "low" claim.
- **Less.** This term means that a food, whether altered or not, contains 25 percent less of a nutrient or of calories than the reference food. For example, pretzels that have 25 percent less fat than potato chips could carry a "less" claim. "Fewer" is an acceptable synonym.
- **Light.** This descriptor can mean two things:
  - First, that a nutritionally altered product contains one-third fewer calories or half the fat of the reference food. If the food derives 50 percent or more of its calories from fat, the reduction must be 50 percent of the fat.

Second, that the sodium content of a low-calorie, low-fat food has been reduced by 50 percent. In addition, "light in sodium" may be used on food in which the sodium content has been reduced by at least 50 percent.

The term "light" still can be used to describe such properties as texture and color, as long as the label explains the intent; for example, "light brown sugar" and "light and fluffy."

- **More.** This term means that a serving of food, whether altered or not, contains a nutrient that is at least 10 percent of the Daily Value more than the reference food. The 10 percent of Daily Value also would apply to "fortified," "enriched" and "added" claims, but in those cases, the food must be altered.

### Other Definitions

The regulations also address other claims. Among them:

- **Percent fat free:** A product bearing this claim must be a low-fat or a fat-free product. In addition, the claim must accurately reflect the amount of fat present in 100 g of the food. Thus, if a food contains 2.5 g fat per 50 g, the claim must be "95 percent fat free."
- **Implied:** These types of claims are prohibited when they wrongfully imply that a food contains or does not contain a meaningful level of a nutrient. For example, a product claiming to be made with an ingredient known to be a source of fiber (such as "made with oat bran") is not allowed unless the product contains enough of that ingredient (for example, oat bran) to meet the definition for "good source" of fiber. As another example, a claim that a product contains "no tropical oils" is allowed—but only on foods that are "low" in saturated fat because consumers have come to equate tropical oils with high saturated fat.
- **Meals and main dishes:** Claims that a meal or main dish is "free" of a nutrient, such as sodium or cholesterol, must meet the same requirements as those for individual foods. Other claims can be used under special circumstances. For example, "low-calorie" means the meal or main dish contains 120 calories or less per 100 g. "Low-sodium" means the food has 140 mg or less per 100 g. "Low-cholesterol" means the food contains 20 mg cholesterol or less per 100 g and no more than 2 g saturated fat. "Light" means the meal or main dish is low-fat or low-calorie.
- **Standardized foods:** Any nutrient content claim, such as "reduced fat," "low calorie," and "light," may be used in conjunction with a standardized term if the new product has been specifically formulated to meet FDA's criteria for that claim, if the product is not nutritionally inferior to the traditional standardized food, and the new product complies with certain compositional requirements set by FDA. A new product bearing a claim also must have performance characteristics similar to the referenced traditional standardized food. If the product doesn't, and the differences materially limit the product's use, its label must state the differences (for example, not recommended for baking) to inform consumers.
- **Healthy:** FDA also is issuing a proposal to define the term "healthy." Under that proposal, "healthy" could be used to describe a food that is low in fat and saturated fat and con-

tains no more than 480 mg sodium and no more than 60 mg cholesterol per serving. A final rule is expected in 1993.

### "Fresh"

Although not mandated by NLEA, FDA also issued a regulation for the term "fresh." The agency took this step because of concern over the term's possible misuse on some food labels.

The regulation defines the term "fresh" when it is used to suggest that a food is raw or unprocessed. In this context, "fresh" can be used only on a food that is raw, has never been frozen or heated, and contains no preservatives. (Irradiation at low levels is allowed.) "Fresh frozen," "frozen fresh," and "freshly frozen" can be used for foods that are quickly frozen while still fresh. Blanching (brief scalding before freezing to prevent nutrient breakdown) is allowed.

Other uses of the term "fresh," such as in "fresh milk" or "freshly baked bread," are not affected.

### Baby Foods

FDA is not allowing broad use of nutrient claims on infant and toddler foods. However, the agency may propose later claims specifically for these foods. The terms "unsweetened" and "unsalted" are allowed on these foods, however, because they relate to taste and not nutrient content.

### Health Claims

Claims for seven relationships between a nutrient or a food and the risk of a disease or health-related condition will be allowed for the first time. They can be made in several ways: through third-party references, such as the National Cancer Institute; statements; symbols, such as a heart; and vignettes or descriptions. Whatever the case, the claim must meet the requirements for authorized health claims; for example, they cannot state the degree of risk reduction and can only use "may" or "might" in discussing the nutrient or food-disease relationship. And they must state that other factors play a role in that disease.

They also must be phrased so that the consumer can understand the relationship between the nutrient and the disease and the nutrient's importance in relationship to a daily diet.

An example of an appropriate claim is: "While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease."

The allowed nutrient-disease relationship claims and rules for their use are:

- **Calcium and osteoporosis:** To carry this claim, a food must contain 20 percent or more of the DV for calcium (200 mg) per serving, have a calcium content that equals or exceeds the food's content of phosphorus, and contain a form of calcium that can be readily absorbed and used by the body. The claim must name the target group most in need of adequate calcium intakes (that is, teens and young adult white and Asian women) and state the need for exercise and a healthy diet. A product that contains 40 percent or more of the DV for calcium must state on the label that a total dietary intake greater than 200 percent of the DV for calcium (that

is, 2,000 mg or more) has no further known benefit.

- **Fat and cancer:** To carry this claim, a food must meet the descriptor requirements for "low-fat," or, if fish and game meats, for "extra lean."

- **Saturated fat and cholesterol and coronary heart disease (CHD):** This claim may be used if the food meets the definitions for the descriptors "low saturated fat," "low-cholesterol," and "low-fat," or, if fish and game meats, for "extra lean." It may mention the link between reduced risk of CHD and lower saturated fat and cholesterol intakes to lower blood cholesterol levels.

- **Fiber-containing grain products, fruits and vegetables and cancer:** To carry this claim, a food must be or must contain a grain product, fruit or vegetable and meet the descriptor requirements for "low-fat," and, without fortification, be a "good source" of dietary fiber.

- **Fruits, vegetables and grain products that contain fiber and risk of CHD:** To carry this claim, a food must be or must contain fruits, vegetables and grain products. It also must meet the descriptor requirements for "low saturated fat," "low-cholesterol," and "low-fat" and contain, without fortification, at least 0.6 g soluble fiber per serving.

- **Sodium and hypertension (high blood pressure):** To carry this claim, a food must meet the descriptor requirements for "low-sodium."

- **Fruits and vegetables and cancer:** This claim may be made for fruits and vegetables that meet the descriptor requirements for "low-fat" and that, without fortification, for "good source" of at least one of the following: dietary fiber or vitamins A or C. This claim relates diets low in fat and rich in fruits and vegetables (and thus vitamins A and C and dietary fiber) to reduced cancer risk. FDA authorized this claim in place of an antioxidant vitamin and cancer claim.

### Folic Acid

In its soon-to-be published rules, FDA is denying the use of a health claim for folic acid and neural tube defects. In September 1992, the U.S. Public Health Service recommended that all women of childbearing age consume 0.4 mg of folic acid daily to reduce their risk of having a pregnancy affected with a neural tube defect. PHS identified several issues that remain to be resolved before FDA can take appropriate action to implement the recommendation and to decide whether to authorize a claim. The issues include the appropriate level of folic acid in food, safety concerns regarding increased intakes of folic acid, and specific options for implementation.

In November 1992, FDA convened an advisory committee to consider these issues. FDA is now reviewing that committee's recommendations.

### Ingredient Labeling

As part of the new rules, the list of ingredients will undergo some changes, too. Chief among them is a new regulation that requires full ingredient labeling on "standardized foods," which previously were exempt. Ingredient declaration will now have to be on all foods that have more than one



ingredient.

Also, the ingredient list will include, when appropriate:

- FDA-certified color additives, such as FD&C Blue No. 1, by name
- sources of protein hydrolysates, which are used in many foods as flavors and flavor enhancers
- declaration of caseinate as a milk derivative in the ingredient list of foods that claim to be non-dairy, such as coffee whiteners

The main reason for these new requirements is that some people may be allergic to such additives and will now be better able to avoid them.

As required by NLEA, beverages that claim to contain juice now must declare the total percentage of juice on the information panel. In addition, FDA's regulation establishes criteria for naming juice beverages. For example, when the label of a multi-juice beverage states one or more—but not all—of the juices present, and the predominantly named juice is present in minor amounts, the product's name must state that the beverage is flavored with that juice or declare the amount of the juice in a 5-percent range; for example, "raspberry flavored juice blend" or "juice blend, 2 to 7 percent raspberry juice."

### **Economic Impact**

It is estimated that the new food label will cost FDA-regulated food processors between \$1.4 billion and \$2.3 billion over the next 20 years. The benefits to public health—measured in monetary terms—are estimated to well exceed the costs. Potential benefits include decreased rates of coronary heart disease, cancer, osteoporosis, obesity, high blood pressure, and allergic reactions to food.

### **Public Education**

To help consumers get the most from the new food label,

FDA and USDA have embarked on a multi-year food labeling education campaign. The campaign involves participation from consumer, trade and health groups, as well as other government agencies. Its purpose is to increase consumers' knowledge and effective use of the new food label and assist them in making accurate and sound dietary choices in accordance with the Dietary Guidelines for Americans.

Along with the new food label, education materials are expected to start making their appearance in early 1993.

### **Ordering *Federal Register* Documents**

Reprints of the *Federal Register* document containing the regulations will be available for \$4.50 a set from the U.S. Government Printing Office (GPO). Orders can be made by writing to the Superintendent of Documents, Washington, DC 20401, or calling (202) 783-3238, or faxing to (202) 512-2250. The GPO order number is 069-001-00045-9. Rush service will be available. Check, money order, VISA, and MasterCard are accepted.

Copies also will be available for sale at the main GPO bookstore at 710 North Capitol St., N.W., Washington, DC 20402.

Upon publication, the regulations also will be available on computer diskettes. A package of four diskettes with supplemental printed material will cost \$88.50. Orders can be placed after publication by writing to the Superintendent of Documents or by calling GPO at (202) 512-1530 or faxing to (202) 512-1262. A limited number of diskettes also will be available for sale at the main GPO bookstore in Washington, D.C. To check on availability, call (202) 512-0132. Refer to order number 069-001-00046-7.

The documents also will be available on the Federal Bulletin Board for downloading by those who hold a Superintendent of Documents deposit account. To find out when the documents have been placed on the computer bulletin board, call (202) 512-1387.

# The New Food Label at a Glance

The new food label will carry an up-to-date, easier-to-use nutrition information guide, to be required on almost all packaged foods (compared to about 60 percent of products up till now). The guide will serve as a key to help in planning a healthy diet.\*

Serving sizes are now more consistent across product lines, stated in both household and metric measures, and reflect the amounts people actually eat.

The list of nutrients covers those most important to the health of today's consumers, most of whom need to worry about getting *too much* of certain items (fat, for example), rather than too few vitamins or minerals, as in the past.

The label will now tell the number of calories per gram of fat, carbohydrates, and protein.

## Nutrition Facts

Serving Size 1/2 cup (114g)

Servings Per Container 4

### Amount Per Serving

**Calories 90**      **Calories from Fat 30**

**% Daily Value\***

**Total Fat 3g**      **5%**

Saturated Fat 0g      **0%**

**Cholesterol 0mg**      **0%**

**Sodium 300mg**      **13%**

**Total Carbohydrate 13g**      **4%**

Dietary Fiber 3g      **12%**

Sugars 3g

**Protein 3g**

Vitamin A 80% • Vitamin C 60%

Calcium 4% • 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
Fiber			25g	30g

Calories per gram:

Fat 9 • Carbohydrates 4 • Protein 4

New title signals that the label contains the newly required information.

Calories from fat are now shown on the label to help consumers meet dietary guidelines that recommend people get no more than 30 percent of their calories from fat.

% Daily Value shows how a food fits into the overall daily diet.

Daily values are also something new. Some are maximums, as with fat (65 grams *or less*); others are minimums, as with carbohydrates (300 grams *or more*). The daily values on the label are based on a daily diet of 2,000 and 2,500 calories. Individuals should adjust the values to fit their own calorie intake.

\* This label is only a sample. Exact specifications are in the final rules.  
Source: Food and Drug Administration 1992

# FOOD LABEL FORMATS \*

1. PACKAGE LABELS OF LESS THAN 12 SQ. IN. MUST MEET THE FOLLOWING NUTRITION LABEL REQUIREMENT:

No Nutrition Label. Must display telephone number or address for consumer to call or write for nutrition information.

2. PACKAGE LABELS BETWEEN 12 AND 40 SQ. IN. MUST MEET THE FOLLOWING MINIMUM NUTRITION LABEL REQUIREMENT:

3. PACKAGE LABELS OF 40 OR MORE SQ. IN. MUST MEET THE FOLLOWING MINIMUM NUTRITION LABEL REQUIREMENT:

<b>Nutrition Facts</b>	
Serving Size 1/2 cup (114g)	
Servings Per Container 4	
<b>Amount Per Serving</b>	
<b>Calories 260</b> Calories from Fat 120	
	<b>% Daily Value*</b>
<b>Total Fat 13g</b>	<b>20%</b>
Saturated Fat 5g	<b>25%</b>
<b>Cholesterol 30mg</b>	<b>10%</b>
<b>Sodium 660mg</b>	<b>28%</b>
<b>Total Carbohydrate 31g</b>	<b>11%</b>
Dietary Fiber 0g	<b>0%</b>
Sugars 5g	
<b>Protein 5g</b>	
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.	

<b>Nutrition Facts</b>	
Serving Size 1/2 cup (114g)	
Servings Per Container 4	
<b>Amount Per Serving</b>	
<b>Calories 260</b> Calories from Fat 120	
	<b>% Daily Value*</b>
<b>Total Fat 13g</b>	<b>20%</b>
Saturated Fat 5g	<b>25%</b>
<b>Cholesterol 30mg</b>	<b>10%</b>
<b>Sodium 660mg</b>	<b>28%</b>
<b>Total Carbohydrate 31g</b>	<b>11%</b>
Dietary Fiber 0g	<b>0%</b>
Sugars 5g	
<b>Protein 5g</b>	
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:	
	2,000    2,500
<b>Nutrient</b>	<b>Calories</b> <b>Calories</b>
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
Fiber	25g    30g
1g Fat = 9 calories	
1g Carbohydrate = 4 calories	
1g Protein = 4 calories	

4. PACKAGE LABELS FOR FOODS CONTAINING LIMITED NUTRIENTS MAY USE A SIMPLIFIED FORMAT, E.G., FOR A SOFT DRINK:

<b>Nutrition Facts</b>	
Serving Size 1 can (240 ml)	
<b>Amount Per Serving</b>	
<b>Calories 145</b>	
	<b>% Daily Value*</b>
<b>Total Fat 0g</b>	<b>0%</b>
<b>Sodium 20mg</b>	<b>1%</b>
<b>Total Carbohydrate 36g</b>	<b>12%</b>
Sugars 36g	
<b>Protein 0g</b>	<b>0%</b>
* Percent Daily Value (DV) is based on 2,000 calorie diet. Your Daily Value may be higher or lower, depending on your calorie needs.	

\*These labels are only samples. Exact specifications are in the final rules.

# The New Food Label at a Glance

**Descriptors:** While descriptive terms like "low," "good source," and "free" have long been used on food labels, their meaning — and their usefulness in helping consumers plan a healthy diet — have been murky. Now FDA has set specific definitions for these terms, assuring shoppers that they can believe what they read on the package:

- free           •high
  - light          •low
  - more          •reduced
  - good source •less
- For fish, meat and poultry:
- lean
  - extra lean

**Ingredients** still will be listed in descending order by weight, and now the list will be required on almost all foods, even standardized ones like mayonnaise and bread.

**Health claim** message referred to on the front panel is shown here.



"While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease."

Source: Food and Drug Administration 1992

**Health Claims:** For the first time, food labels will be allowed to carry information about the link between certain nutrients and specific diseases. For such a "health claim" to be made on a package, the Food and Drug Administration must first determine that the diet-disease link is supported by scientific evidence. At this time, FDA is allowing seven specific claims about the relationships between:

- fat and cancer risk
- saturated fat and cholesterol and heart disease risk
- calcium and osteoporosis risk
- sodium and hypertension risk
- fruits, vegetables and grains that contain soluble fiber and heart disease risk
- fiber-containing grain products, fruits and vegetables and cancer risk
- fruits and vegetables and cancer risk.

**THE NEW FOOD LABEL  
SUMMARIES**

**JANUARY 6, 1993**

***FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
WASHINGTON, DC 20204***

## NEW FOOD LABEL SUMMARIES

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January 6, 1993

## **Mandatory Nutrition Labeling -- Final Rule**

### **One of a Series of FDA Regulations Implementing The Nutrition Labeling and Education Act of 1990**

**Brief Summary:** FDA is amending its regulations to require nutrition labeling for most foods offered for sale and regulated by FDA. The nutrition label is required to include information on total calories and calories from fat and on amounts of total fat, saturated fat, cholesterol, sodium, total carbohydrates, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron -- in that order. Manufacturers also may voluntarily declare information on calories from saturated fat and on amounts of polyunsaturated and monounsaturated fat, soluble and insoluble fiber, sugar alcohol, other carbohydrate, potassium, additional vitamins and minerals for which Reference Daily Intakes (RDIs) have been established, and the percent of vitamin A present as beta-carotene. The information presented on the label is to represent the packaged product prior to consumer preparation.

This final rule establishes a standard format for nutrition information on food labels consisting of: (1) the quantitative amount per serving of each nutrient except vitamins and minerals; (2) the amount of each nutrient as a percent of the Daily Value for a 2,000 calorie diet; (3) a footnote with reference values for selected nutrients based on 2,000 calorie and 2,500 calorie diets; and (4) caloric conversion information.

The declaration of percent of Daily Value must be placed in column order. Absolute declarations of the amount per serving of designated nutrients must appear immediately following the nutrient named and not in column order. A simplified format may be used if seven or more of 13 required nutrients are present in only insignificant amounts.

Foods exempt from mandatory nutrition labeling requirements include: (1) food offered for sale by small businesses; (2) food sold in restaurants or other establishments in which food is served for immediate human consumption; (3) foods similar to restaurant foods that are ready to eat but are not for immediate consumption, are primarily prepared on site, and are not offered for sale outside of that location; (4) foods that contain insignificant amounts of all nutrients subject to this rule, e.g., coffee and tea; (5) dietary supplements, except those in conventional food form; (6) infant formula; (7) medical foods; (8) custom-processed fish or game meats; (9) foods shipped in bulk form; and (10) donated foods. Otherwise-exempted foods that make a nutrient content claim or health claim forfeit the exemption.

Special labeling provisions specify that: (1) foods in small packages having less than 12 square inches available for labeling may omit nutrition labeling if an address or telephone number that a consumer may use to obtain required nutrition information is provided on the label; (2) packages of 40 or fewer square inches may present the required information in tabular or linear fashion if the package shape cannot accommodate columns, use specified abbreviations, omit the footnote and caloric conversion information, and present the required nutrition information on any label panel; (3) foods for children less than two years of age must not declare information concerning calories from fat, fatty acids and cholesterol; (4) foods for children less than four years of age must not include Daily Value information; (5) raw fruits, vegetables, and fish should follow voluntary nutrition labeling guidelines; (6) packaged single-ingredient fish or game meat may provide information on an "as prepared" basis; (7) foods sold from bulk containers and game meat products may provide

products may provide nutrition information on labeling; (8) shell eggs may provide the required nutrition information inside the egg carton; (9) under certain conditions, unit containers in multi-unit packages need only provide nutrition information on the outer package; and (10) foods in gift packs may provide information on labeling in accordance with special requirements.

The provisions of this rule become effective on May 8, 1994.

Docket Numbers: 90N-0135 "Food Labeling; Mandatory Nutrition Labeling and Nutrient Content Revision" and 91N-0162 "Food Labeling: Format for Nutrition Label"

Code of Federal Register Citation: 21 CFR 101.9

Contact Persons: Virginia Wilkening, Center for Food Safety and Applied Nutrition (HFF-200), Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-4561; and

Concerning format only: Raymond Schucker, Center for Food Safety and Applied Nutrition (HFF-245), Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-5657.

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### Standard Format

#### The New Food Label

<b>Nutrition Facts</b>	
Serving size 1/2 cup (114 g)	
Servings per container 4	
<b>Amount Per Serving</b>	
<b>Calories 260</b> <b>Calories from fat 120</b>	
%Daily Value*	
<b>Total Fat 13 g</b>	<b>20%</b>
<b>Saturated Fat 5 g</b>	<b>25%</b>
<b>Cholesterol 30 mg</b>	<b>10%</b>
<b>Sodium 660 mg</b>	<b>28%</b>
<b>Total Carbohydrate 31 g</b>	<b>11%</b>
<b>Dietary Fiber 0 g</b>	<b>0%</b>
<b>Sugars 5 g</b>	
<b>Protein 5 g</b>	
<b>Vitamin A 4% • Vitamin C 2%</b>	
<b>Calcium 15% • Iron 4%</b>	
* Percent Daily Values are based on a diet of 2,000 calories a day. Your daily values may be higher or lower depending on your calorie needs:	
	Calories: 2,000    2,500
<b>Total Fat</b>	Less than 65g    80g
<b>Saturated Fat</b>	Less than 20g    25g
<b>Cholesterol</b>	Less than 300mg    300mg
<b>Sodium</b>	Less than 2,400mg    2,400mg
<b>Total Carbohydrate</b>	300g    375g
<b>Dietary Fiber</b>	25g    30g
Calories per gram:	
Fat 9 • Carbohydrate 4 • Protein 4	

#### Simplified format (Soft Drink)

<b>Nutrition Facts</b>	
Serving size: 1 can (240 ml)	
<b>Amount Per Serving</b>	
<b>Calories 145</b>	
%Daily Value*	
<b>Total Fat 0 g</b>	<b>0%</b>
<b>Sodium 20 mg</b>	<b>1%</b>
<b>Total Carbohydrate 33 g</b>	<b>12%</b>
<b>Sugars 33 g</b>	
<b>Protein 0 g</b>	
* Percent Daily Value is based on a 2,500 calorie diet.	





Food and Drug Administration  
Washington DC 20204

January 6, 1993

## Reference Daily Intakes and Daily Reference Values -- Final Rule

### One of a Series of FDA Regulations Implementing The Nutrition Labeling and Education Act of 1990

**Brief Summary:** This regulation establishes reference values for use in nutrition labeling of food. It retains the values established by FDA in 1973 for vitamins and minerals but changes the terms for those values from U.S. Recommended Daily Allowance (U.S.RDA) to Reference Daily Intake (RDI). The regulation also establishes label reference values for eight other nutrients, including fat, cholesterol, and fiber. The values have been established as Daily Reference Values (DRVs). While regulatory requirements make it necessary to distinguish between the two sets of label reference values, to avoid needless confusion, all reference values on food labels will be referred to as Daily Values or DVs.

FDA received more than 1,500 written comments on its proposals published in July 1990 and November 1991 to revise and expand U.S.RDAs to be consistent with the 1989 edition of the Recommended Daily Allowances established by the National Academy of Sciences, and to develop new label reference values for nutrients important to health but for which the Academy had not established RDAs. These comments offered suggestions for changes, but generally supported FDA's efforts to update label reference values for vitamins and minerals and create new values for nutrients of public health importance.

On October 29, 1992, the Dietary Supplement Act of 1992 was signed into law. The act, among other provisions, instructed FDA to not promulgate regulations prior to November 8, 1993 that require the use of, or are based on, RDAs for vitamins and minerals. In effect, the Act required FDA to retain current U.S.RDA values for vitamins and minerals, values that had been developed chiefly by selecting the highest RDA value from among the various sex/age groups listed in RDA tables published in 1968.

Accordingly, this final rule establishes label reference values for 19 vitamins and minerals that are the same as those in existing regulations and that are appropriate for use on foods intended for adults and children four or more years of age. These values, however, will no longer be called U.S.RDAs, but instead will be known as RDIs, a change the Agency agrees is necessary to minimize confusion between RDAs and U.S.RDAs. Since the Dietary Supplement Act did not provide for reference values for infants, children less than four years of age, pregnant women, and lactating women, the preamble to this final rule includes guidance on values that manufacturers may use on labels intended for those groups.

Additionally, the Agency established Daily Reference Values for other nutrients of public health importance which are intended to serve as a point of reference for adults and children four or more years of age. When appropriate, a caloric intake of 2,000 calories per day was used as the basis for these reference values. The nutrients with DRVs are: fat (65 grams), saturated fat (20 grams), cholesterol (300 milligrams), total carbohydrate (300 grams), dietary fiber (25 grams), sodium (2,400 milligrams), potassium (3,500 milligrams), and protein (50 grams).

The provisions of this rule become effective on May 8, 1994.

**Docket Number:** 90N-0134 "Food Labeling: Reference Daily Intakes and Daily Reference Values"

**Code of Federal Regulations Citations:** 21 CFR 101.9(c)(7)(iii), (c)(8)(iv), and (c)(9)

**Contact Person:** Christine Lewis, Center for Food Safety and Applied Nutrition (HFF-265), Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-5588.



January 6, 1993

## Serving Sizes -- Final Rule

### One of a Series of FDA Regulations Implementing The Nutrition Labeling and Education Act of 1990

**Brief Summary:** This regulation establishes criteria for the declaration of serving sizes in nutrition labeling. The final rule on serving sizes:

1. defines serving sizes on the basis of the amount of food customarily consumed per eating occasion;
2. establishes reference amounts customarily consumed for 139 specific food product categories and establishes a petition process for modifying the list;
3. provides rules for using the reference amounts to determine serving sizes for specific food products;
4. requires that both common household and metric measures be used to declare serving size on the label, e.g., 1 cup (240 mL) for milk, 1 slice (28 grams) for a sliced bread;
5. permits optional declaration of serving size in U.S. measures (ounces or fluid ounces) in addition to the household and metric measures, e.g., 1 cup (240 mL/8 fl oz);
6. allows a second column on the nutrition label to express the nutrient content (a) per 100 grams (g) or 100 milliliters (mL) or per 1 ounce (oz) or 1 fluid ounce (fl oz) for all products; (b) per unit for products in discrete units, e.g., sliced products such as bread, muffins, cookies, ice cream bars, etc.; and (c) per cup popped for popcorn;
7. defines a "single-serving container" as any package that contains less than 200 percent of the reference amount for the food product category. For example, 8 fl oz is the reference amount for soft drinks; therefore, a 12-fl oz can of soft drink is a single-serving container, and its nutrient content must be based on the entire contents of the can. For packages that contain more than 150 percent but less than 200 percent of the reference amount when the reference amount is 100 g (or 100 mL) or larger, the manufacturer may determine whether to declare one or two servings. For example, 245 g is the reference amount for soups; therefore, a 15-ounce can of soup may be labeled as 2 servings;
8. defines a unit of products in discrete units (e.g., sliced bread, muffin) in multi-serving containers as a single serving if the unit weighs more than 50 percent but less than 200 percent of the reference amount. For example, the reference amount of bread is 50 g and, therefore, the serving size of sliced bread is 1 slice if a slice weighs more than 25 g;
9. allows claims such as "low sodium" if the product qualifies for the claim on the basis of the reference amount for the product category. If the serving size differs from the reference amount and if the product qualifies for the claim only on the basis of the reference amount, the regulation requires that claims be followed by the criteria for the claim, e.g., "very low sodium, 35 mg or less per 240 mL (8 fl oz)."

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The provisions of the final rule become effective on May 8, 1994.

**Docket Number:** 90N-0165 "Food Labeling; Serving Size"

**Code of Federal Regulations Citation:** 21 CFR 101.9(b) and 101.12

**Contact Person:** Youngmee K. Park, Center for Food Safety and Applied Nutrition (HFF-265), Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-5489.



January 6, 1993

**Definition of Descriptor Terms (Nutrient Content Claims) -- Final Rule  
Definition of "Healthy" -- Proposed Rule**

**One of a Series of FDA Regulations Implementing  
The Nutrition Labeling and Education Act of 1990**

**Brief Summary:** This final rule prescribes definitions and conditions for use of various terms by which the nutritional characteristics and properties of certain foods are described in food labeling. No explicit or implied nutrient content claim can be on a food label unless it uses terms that have been provided for by FDA regulation or, in some instances, in response to a petition.

FDA defines the terms "free," "low," "light" or "lite," "reduced," "less," and "high," as well as selected synonyms, in accordance with provisions of the 1990 amendments. FDA also defines "good source," "very low" (for sodium only), "lean," "extra lean," "fewer," "more," and "added" (or "fortified" or "enriched"). The Agency is also providing for circumstances under which various implied claims may be used and, in a separate document, is proposing a definition for the term "healthy." In addition, the Agency is defining the term "fresh," which is not addressed in the 1990 legislation. FDA has chosen not to define the term "natural" at this time. The Agency also is providing for petitions to request changes in the requirements for nutrient claims including new terms, the use of synonyms for previously defined terms, and the use of implied claims in brand names.

FDA carefully considered more than 2,300 comments submitted in response to its nutrient content claims proposals. These comments came from a wide variety of sources, including industry, consumers, health professionals, and organizations representing these and other interested members of the public.

FDA defines "free" as an amount that is nutritionally insignificant and can be labeled as zero. Frequent consumption of a food that is "free" of a nutrient is not likely to have any physiological effect associated with that nutrient. If a nutritionally insignificant amount of the nutrient is added to the food as part of a food ingredient, a statement such as "adds a trivial amount of fat" is asterisked to the ingredient. The following values to meet the definition of "free" are amounts per reference serving: sodium, less than 5 mg; calories, less than 5 calories; sugars, less than 0.5 g; fat, less than 0.5 g; saturated fat, less than 0.5 g, and trans fatty acids, not exceeding 1 percent of grams of total fat; and cholesterol, less than 2 mg. Foods that are not specially processed to reduce the nutrient -- that is, foods that are inherently free of the nutrient -- must be labeled to indicate that all foods of that type meet the claim, e.g., "leaf lettuce, a sodium-free food."

Cholesterol-free claims and other claims about the amount of cholesterol in a food may be made only on foods that contain 2 g or less of saturated fat per reference serving. Foods having more than 13 g total fat per reference serving, or, if the reference serving is small (i.e., less than 30 g or 2 tablespoons), per 50 g, must also disclose the total fat content per serving immediately adjacent to the cholesterol claim.

FDA defines "low" as an amount that would allow frequent consumption of the product without exceeding recommended dietary guidelines. The following criteria for "low" are based on reference serving sizes or for products having reference amounts of less than 30 g or 2 tablespoons, per 50 g. The values are: sodium, not more than 140 mg; calories, not more than 40 calories; fat, not more

than 3 g; saturated fat, not more than 1 g and not more than 15 percent of calories from saturated fat; and cholesterol, not more than 20 mg. If the food is inherently low in a nutrient, the label must explain that all similar foods have the labeled nutritional characteristic, e.g., "frozen perch, a low-fat food." The Agency defines "very low sodium" as a value of 35 mg or less.

The terms "high" and "good source" are defined in a way to call attention to the beneficial, rather than the harmful, effects of nutrients. They are based on a percentage of the Daily Value (DV) of the specific nutrients in a reference serving. "High" is defined as 20 percent or more of the DV, and "good source" as between 10 and 19 percent of the DV.

Relative terms -- "reduced," "less" (or "fewer"), "light" (or "lite"), "more," and "added" (or "enriched" or "fortified") -- are defined to express the amount of a nutrient in the labeled product compared with an appropriate reference food for the food bearing the claim. For "light," "reduced," and "added" (or "fortified" or "enriched") claims, the reference food must be similar to the product bearing the claim, (e.g., potato chips for potato chips). Also for "light," the nutrient value for the reference food must be representative of a broad base of foods of that type. For "less," "fewer," and "more" claims, the reference food may also be a dissimilar food within a product category that can generally be substituted in the diet for the labeled food, (e.g., pretzels for potato chips). All relative claims must be accompanied by information on the identity of the reference food and the percentage (or fraction) by which the nutrient has been modified. The amount of the nutrient in the labeled product compared to the amount in the reference food must appear on either the information or principal display panel.

To bear a "reduced," "less," or "fewer" claim, the labeled food must contain at least 25 percent less of the nutrient than the reference food. For "more" or "added," the food must contain at least 10 percent more of the nutrient's DV per reference serving than the reference food.

"Light" or "lite" can be used on a food when the reference food derives 50 percent or more of its calories from fat if the labeled food has been reduced in fat by at least 50 percent. If the reference food derives less than 50 percent of calories from fat, the food must be reduced in fat by at least 50 percent, or in calories by at least 1/3, in order to be labeled "light." For foods that are not low in fat or calories, the percentage reduction for both fat and calories must be displayed adjacent to the most prominent claim. A "light" claim, based on a reduction of fat or calories, may not be made if the reference food is both "low fat" and "low calorie." However, such a food may bear a "light" claim if it is reduced in sodium by 50 percent or more. A claim "light in sodium" may be used to describe 50% reductions in sodium compared to an appropriate reference food provided the term "light in sodium" is presented in uniform type size, style, color and prominence. "Light" may also be used to describe a physical or organoleptic characteristic of the food, if that characteristic is adequately described on the label, e.g., "light in color."

The percent or amount of the Daily Value of vitamins and minerals may appear anywhere on the label without further explanation. Other percent and amount characterizations for nutrients may be stated on a food label provided such statements are truthful and not misleading. If a claim lists the percent or amount of a nutrient, and specifies or implies that it meets the defined level of that nutrient for a particular descriptor, the listed nutrient level must be consistent with the defined term or the label must bear a statement indicating that the food does not meet the relevant definition, e.g., "only 4 g fat per serving, not a low-fat food."

The Agency has adopted definitions for "lean" and "extra lean." "Lean" may be used to describe fish or game meat if the food contains less than 10 g of fat, 4 g of saturated fat, and 95 mg of cholesterol per reference serving and per 100 g. To be labeled "extra lean," products must contain less than 5 g of fat, 2 g of saturated fat, and 95 mg of cholesterol per reference serving and per

100 g. These are the same definitions established for meat and poultry products by the U.S. Department of Agriculture.

The rule also provides nutrient definitions for meals and main-dish products. They are similar to the definitions for single-nutrients but, except for "free" definitions, are based on the specified nutrient value per 100 g of food. The following exceptions apply: "High" and "good source" are not defined for meal-type products. Instead, the terms may be used to refer to a single food in the meal that meets the definition for the term. For "low calorie," the value is 120 calories per 100 g. For "light," the product must meet the definition for a "low calorie" meal or a "low fat" meal and must be labeled to show which definition the meal meets, e.g. "Light, a low-fat meal," or must meet the definition for a "low sodium" meal and be labeled "light in sodium."

The Agency has also defined "lightly salted," "no added sugar," and "\_\_\_\_% fat free."

With respect to implied claims, the Agency has specified a number of label statements, such as "100% milk free," "no artificial colors," "made with real butter," "corn oil," (when referring to the name of the product), and "corn oil margarine" that are not deemed to be implied claims, unless the statements are used in a nutritional context.

FDA is proposing a definition for "healthy." The term would be applicable to foods low in fat and saturated fat and not exceeding the disclosure levels for sodium or cholesterol (i.e., 480 mg of sodium or 60 mg of cholesterol) per serving.

Claims similar to those described in the regulations that are made for restaurant foods must meet the applicable definitions. However, those claims can be based on calculations using nutrient data bases for foods or other reliable nutrition information applied to the recipe used to make the product bearing the claim. Restaurants are being given additional time to comply with this requirement. In addition, FDA has advised that menus are not within the coverage of the regulations.

When the term "fresh" is used to imply that the food is unprocessed, the food so labeled must be in its raw state and must not have been frozen or subjected to any form of thermal processing or other means of preservation. Uses of the term "fresh" that do not suggest that the food is unprocessed, e.g., "fresh bread" and "fresh milk," are not affected by this regulation.

The provisions of this final rule become effective on May 8, 1994, except that certain provisions as they apply to restaurant firms consisting of 10 or fewer individual restaurant establishments will become effective on May 8, 1995.

**Docket Numbers:** 91N-0384 "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms" and 84N-0153 "Food Labeling: Definition of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food"

**Code of Federal Regulations Citations:** 21 CFR 101.10, 101.13, 101.54, 101.56, 101.60, 101.61, 101.62, 101.65, 101.69, and 101.95

**Contact Person:** Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFF-312), Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-5229.

Nutrient Content Claims (Final Rule)

Nutrient	Free	Low	Reduced / Less	Comments
	<p>Synonyms for "Free": "Zero", "No", "Without", "Trivial Source of", "Negligible Source of", "Dietarily Insignificant Source of"</p> <p>Definitions for "Free" for meats and main dishes are the stated values per labeled serving</p>	<p>Synonyms for "Low": "Little", "Few" for Calories, "Contains a Small Amount of", "Low Source of"</p>	<p>Synonyms for "Reduced" / "Less": "Lower" ("Fewer" for calories)</p> <p>"Modified" may be used in statement of identity</p> <p>Definitions for meats and main dishes are same as for individual foods on a per 100 g basis</p>	<p>For "Free", "Very Low", or "Low", must indicate if food meets a definition without benefit of special processing, alteration, formulation or reformulation; e.g., "broccoli, a fat-free food" or "cottage, a low calorie food"</p> <p>NOTE: * If ingredient containing a trivial amount of a nutrient is added to food that qualifies for "Free" claim, a statement such as "Adds a trivial amount of [nutrient]" is associated to ingredient</p>
Calories	<p>Less than 5<sup>1</sup> cal per reference serving</p> <p>Not defined for meats or main dishes</p>	<p>40 cal or less per reference serving (and per 50 g if reference serving size is small)</p> <p>Meats and main dishes: 120 cal or less per 100 g</p>	<p>At least 25% fewer calories per reference serving than an appropriate reference food</p> <p>Reference food may not be "Low Calorie"</p> <p>Use term "Fewer" rather than "Less"</p>	<p>"Light" or "Lite": If 50% or more of the calories are from fat, fat must be reduced by at least 50% per reference serving. If less than 50% of calories are from fat, fat must be reduced at least 50% or calories reduced at least 1/3 per reference serving</p> <p>Meat or main dish meats definition for "Low Calorie" or "Low Fat" meat and is labeled to indicate which definition is met</p>
Sodium	<p>Less than 5 mg per reference serving and no ingredient that is sodium chloride or generally understood to contain sodium except as noted above</p>	<p>140 mg or less per reference serving (and per 50 g if reference serving size is small)</p> <p>Meats and main dishes: 140 mg or less per 100 g</p>	<p>At least 25% less sodium per reference serving than an appropriate reference food</p> <p>Reference food may not be "Low Sodium"</p>	<p>"Light" (for sodium reduced products): If food is "Low Calorie" and "Low Fat" and sodium is reduced by at least 50%</p> <p>"Light in Sodium": If food is reduced by at least 50% per reference serving. Entire term "Light in Sodium" must be used in same type, size, color &amp; prominence. "Light in Sodium for meats" = "Low in Sodium"</p> <p>* Very Low Sodium: 35 mg or less per serving (and per 50 g if reference serving size is small). For Meats and main dishes: 35 mg or less per 100 g</p> <p>"Salt Free" must meet criterion for "Sodium Free"</p> <p>"No Salt Added" and "Unsalted" must meet conditions of use and must declare "This is Not A Sodium Free Food" on information panel</p> <p>"Lightly Salted": 50% less sodium than normally added to reference food and if not "Low Sodium", so labeled on information panel</p>
Total Fat	<p>Less than 0.5 g per reference serving and no ingredient that is fat or understood to contain fat except as noted above</p>	<p>3 g or less per reference serving (and per 50 g if reference serving size is small)</p> <p>Meats and main dishes: 3 g or less per 100 g and not more than 30% of calories from fat</p>	<p>At least 25% less fat per reference serving than an appropriate reference food</p> <p>Reference food may not be "Low Fat"</p>	<p>"_ % Fat Free": OK if meets the requirements for "Low Fat"</p> <p>"Light" - see above</p>
Saturated Fat	<p>Less than 0.5 g per reference serving</p> <p>Trans fatty acids are not more than 1% of total fat</p> <p>No ingredient that is understood to contain saturated fat except as noted above</p>	<p>1 g or less per reference serving and 15% or less of calories from saturated fat</p> <p>Meats and main dishes: 1 g or less per 100 g and less than 15% of calories from saturated fat</p>	<p>At least 25% less saturated fat per reference serving than an appropriate reference food</p> <p>Reference food may not be "Low Saturated Fat"</p>	<p>Next to all saturated fat claims, must declare the amount of cholesterol if 2 mg per reference serving or more; and the amount of total fat if more than 3 g per reference serving (or 0.5 g or more of total fat for "Saturated Fat Free")</p>
Cholesterol	<p>Less than 2 mg per reference serving.</p> <p>If less than 2 mg per reference serving by special processing and total fat exceeds 13 g per reference and labeled serving, the amount of cholesterol must be "Substantially Less" (25%) than in a reference food with significant market share (5% of market)</p> <p>No ingredient that contains cholesterol except as noted above</p>	<p>20 mg or less per reference serving (and per 50 g of food if reference serving size is small)</p> <p>If qualifies by special processing and total fat exceeds 13 g per reference and labeled serving, the amount of cholesterol must be "Substantially Less" (25%) than in a reference food with significant market share (5% of market)</p> <p>Meats and main dishes: 20 mg or less per 100 g</p>	<p>At least 25% less fat per reference serving than an appropriate reference food</p> <p>Reference food may not be "Low Cholesterol"</p>	<p>CHOLESTEROL CLAIMS ONLY ALLOWED WHEN FOOD CONTAINS 3 g OR LESS "SATURATED FAT" PER SERVING</p> <p>Must declare the amount of total fat next to cholesterol claim when fat exceeds 13 g per reference and labeled serving (or per 50 g of food if serving size is small)</p>
Sugars	<p>"Sugar Free" Less than 0.5 g per reference serving and no ingredient that is sugar or generally understood to contain sugar except as noted above</p> <p>Dietary intake profile (e.g. "Low Calorie")</p>	<p>Not Defined. No basis for a recommended intake</p>	<p>At least 25% less sugars per reference serving than an appropriate reference food</p>	<p>"No Added Sugars" and "Without Added Sugars" are allowed if no sugar or sugar containing ingredient is added during processing. State if food is not "Low" or "Reduced Calorie"</p> <p>The terms "Unsweetened" and "No Added Sweeteners" remain as factual statements</p> <p>Claims about reducing dental caries are implied health claims</p> <p>Does not include sugar alcohols</p>

"Reference Serving" = reference amount customarily consumed.

"Small Serving" = reference serving 30 g or less or 2 tablespoons or less (for dehydrated foods that are typically consumed when rehydrated with water only, the per 50 g refers to the as prepared form.

\* Statement "See \_\_\_ panel for nutrition information" must accompany all content claims. When levels exceed 13 g Fat, 4 g Saturated Fat, 60 mg Cholesterol, and 480 mg Sodium per reference serving per labeled serving and for foods with small reference servings per 50 g disclosure statement is required as part of claim (e.g. "see side panel for information on fat and other nutrients").

## Relative (or Comparative) Claims

### Accompanying Information

For all relative claims, percent (or fraction) of change and identity of reference food must be declared in immediate proximity to the most prominent claim. Quantitative comparison of the amount of the nutrient in the product per labeled serving with that in the reference food must be declared on information panel.

For Light claims: % reduction for both fat and calories must be stated but % reduction need not be specified if product is low in that nutrient.

### Reference Foods

"Light" / "Lite"	(1) A food representative of the type of food bearing the claim, e.g. average value of top three brands or representative value from valid data base; (2) similar food (e.g. potato chips for potato chips); and (3) not low calorie and low fat (except light sodium foods which must be low calorie and low fat).
"Reduced" and "Added" (or "fortified" and "enriched")	(1) An established regular product or average representative product and (2) similar food.
"More" and "Less" (or "Fewer")	(1) An established regular product or average representative product and (2) a dissimilar food in the same product category which may be generally substituted for labeled food (e.g. potato chips for pretzels) or a similar food.

### Other Nutrient Content Claims

"Lean"	On seafood or game meat that contains < 10 g total fat, < 4 g saturated fat and < 95 mg cholesterol / reference serving and per 100 g. (for meats & main dishes, meats criteria per 100 g and per labeled serving).
"Extra Lean"	On seafood or game meat that contains < 5 g total fat, < 2 g saturated fat and < 95 mg cholesterol per reference serving and per 100 g. (for meats and main dishes, meats criteria per 100 g and per label serving).
"High", "Rich In", or "Excellent Source Of"	Contains 20% or more of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) to describe protein, vitamins, minerals, dietary fiber, or potassium per reference serving. May be used on meals or main dishes to indicate that product contains a food that meets definition.
"Good Source Of", "Contains" or "Provides"	10-19% of the RDI or DRV per reference serving. May be used on meals or main dishes to indicate that product contains a food that meets definition.
"More"	10% or more of the DRV or RDI per reference serving.
"Modified"	May be used in statement of identity that bears a relative claim, e.g. "Modified Fat Cheese Cake, Contains 35% Less Fat Than Our Regular Cheese Cake."
Any Fiber Claim	If food is not low in total fat, must state total fat in conjunction with claim such as "More Fiber".

### Implied Claims

- Claims about a food or ingredient that suggests that the nutrient or ingredient are absent or present in a certain amount or claims about a food that suggests a food may be useful in maintaining healthy dietary practices and which are made with an explicit claim (e.g. "healthy, contains 3 grams of fat") are implied claims and are prohibited unless provided for in a regulation by FDA. In addition, the Agency has devised a petition system whereby specific additional claims may be considered.
- Claims that a food contains or is made with an ingredient that is known to contain a particular nutrient may be made if product is "Low" in or a "Good Source" of the nutrient associated with the claim (e.g. "good source of oat bran").
- Equivalence claims: "contains as much [nutrient] as a [food]" may be made if both reference food and labeled food are "Good Source" of nutrient on a per serving basis.
- The following label statements are generally not considered implied claims unless they are made in a nutrition context: 1) avoidance claims for religious food intolerance or other non-nutrition related reasons (e.g. "100% milk free"); 2) statements about non-nutritive substances (e.g. "no artificial colors"); 3) added value statements (e.g. "made with real butter"); 4) statements of identity (e.g. "corn oil" or "corn oil margarine"); and 5) special dietary statements made in compliance with a specific Part 105 provision.

### Terms Covered That Are Not Nutrient Content Claims

"Fresh"	A raw food that has not been frozen, heat processed, or otherwise preserved.
"Fresh Frozen"	Food was quickly frozen while still fresh.





January 6, 1993

**Nutrition Content Claims for Butter -- Final Rule**

**One of a Series of FDA Regulations Implementing  
The Nutrition Labeling and Education Act of 1990**

**Brief Summary:** Federal legislation dating from 1923 defines butter as a food product commonly known as butter and composed exclusively of milk or cream, or both, with or without salt and coloring, and containing not less than 80 percent milkfat by weight. Concern about limiting the consumption of dietary fats prompts many consumers to look for alternate food products with a fat content lower than that found in the standard product.

The Nutrition Labeling and Education Act authorized FDA to issue regulations permitting the use of nutrient content claims, such as the word "light" to describe butter. Following are the conditions that must be met before a butter product can display a nutrient content claim on its label:

The product must meet FDA's criteria for use of the claim. It must contain cream or milk, or both, which may include milk constituents, such as whey and casein. Salt, safe and suitable colorings, nutrients, and bacterial cultures may be added to the product. The product may contain minor amounts of safe and suitable nondairy ingredients to improve texture, prevent the product from separating into liquid and non-liquid parts (syneresis), add flavor, extend shelf life, improve appearance, and add sweetness. Water may be added to replace milkfat, but the amount of water in the product must be less than the amount of cream, milk, or milk constituents. The product may not be nutritionally inferior to regular butter. If there are any significant differences in performance between a butter product bearing a nutrient claim and regular butter, the difference must be explained on the label. For example, if reduced-fat butter performs differently from regular butter as an ingredient in baked goods, a statement such as "not recommended for baking purposes" must appear on the label of the reduced-fat product.

The goal of this regulation is to make available to nutrition- and health-conscious consumers a selection of accurately and informatively labeled alternatives to regular butter.

The provisions for this final rule become effective May 8, 1994.

**Docket Number:** 91N-0344 "Food Labeling: Use of Nutrient Content Claims for Butter"

**Code of Federal Regulations Citation:** 21 CFR 101.67

**Contact Person:** Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFF-414)  
Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-5112.



January 6, 1993

## **Nutrient Content Claims and Standardized Foods -- Final Rule**

### **One of a Series of FDA Regulations Implementing The Nutrition Labeling and Education Act of 1990**

**Brief Summary:** One of the main purposes of the 1990 legislation was to establish the circumstances in which claims describing the nutrient content of food could be made. Industry and consumers have expressed considerable interest in nutrient content claims that are included in the statement of identity of certain substitutes for standardized foods. Foods that are subject to food standards, or substitute for them, constitute a substantial portion of the nation's food supply. Standardized foods include many types of products such as bread, milk, and cheese.

The Surgeon General's Report on Nutrition and Health emphasized the need for most people to reduce their consumption of fat, saturated fat, and cholesterol and to achieve and maintain a desirable weight. Many consumers now seek to purchase substitute foods, such as light sour cream and reduced fat cheddar cheese, because these foods contain less fat. Therefore, FDA has established general requirements for certain nutritionally equivalent substitutes for standardized foods. The requirements specify conditions under which aspects of traditional standards and nutrient content claims may be used to define new standardized foods.

Under the final rule, nutrient content claims may be made if the product meets FDA's criteria for use of the nutrient content claim and is not nutritionally inferior to the regular food. In addition, the final rule requires that a product bearing a nutrient content claim have performance characteristics similar to those of the standardized food. If it does not, that fact must be displayed prominently in the labeling. The product must contain the ingredients used in the standardized food but may contain certain other safe and suitable ingredients, provided the product is not nutritionally and functionally inferior to the regular standardized food in its performance characteristics. Water and safe and suitable fat substitutes may be used to replace fat and calories.

This final rule supports national nutrition goals and allows modified versions of certain standardized foods to bear descriptive names that are meaningful for consumers.

The provision of this final rule becomes effective May 8, 1994.

**Docket Number:** 91N-0317 et al., "Food Standards: Requirements for Substitute Foods Named by Use of a Nutrient Content Claim and a Standardized Term"

**Code of Federal Regulations Citation:** 21 CFR 130.10

**Contact Person:** Shellee A Davis, Center for Food Safety and Applied Nutrition (HFF-414), Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-5112.



January 6, 1993

## Health Claims for Food: General Requirements -- Final Rule

### One of a Series of FDA Regulations Implementing The Nutrition Labeling and Education Act of 1990

**Brief Summary:** This rule permits food labeling to include health claims that are supported by valid and substantial scientific evidence, but only those claims that FDA has specifically provided for by regulation. The Agency has issued final rules with respect to specific health claims: calcium and osteoporosis (authorized); dietary saturated fat and cholesterol and risk of coronary heart disease (authorized); dietary fat and cancer (authorized); sodium and hypertension (authorized); fiber-containing grain products, fruits and vegetables and cancer (authorized); fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease (authorized); fruits and vegetables and cancer (authorized); folic acid and neural tube defects (not authorized); zinc and immune function in the elderly (not authorized); and omega-3 fatty acids and coronary heart disease (not authorized). The term "health claim" is defined to encompass explicit as well as implied claims, such as symbols (for example, the symbol of a heart), vignettes, and other forms of communication.

The general health claim rule also defines a number of other terms, one of the most important of which is "disqualifying nutrient levels." This term refers to specified levels of total fat, saturated fat, cholesterol, and sodium above which a food will be disqualified from making any health claim because it contains one or more of these nutrients in amounts that would make it difficult for a consumer to construct a daily diet that conforms with widely accepted guidelines for reducing the risk of diet-related diseases. In addition to establishing specific levels for the four disqualifying nutrients for individual foods, the rule also lists a higher set of values for main-dish products and a still higher set for meal products.

Any substance or nutrient for which a health claim is made must be safe. Except for dietary supplements not in conventional food form, a food bearing a health claim must be a good source for at least one of the following nutrients prior to addition of any nutrient to the food: vitamin A, vitamin C, iron, calcium, protein, or fiber. Claims for infant and toddler foods are prohibited unless expressly permitted by a specific health claim regulation.

This final rule identifies the process by which FDA will receive and consider petitions to establish new claims or to modify existing ones. The rule not only specifies in general terms the information a petition is to contain, but also states the administrative procedures the Agency will follow to either authorize or not authorize future health claims.

The provisions of this final rule become effective May 8, 1993.

**Docket Number:** 85N-0061 "Labeling; General Requirements for Health Claims for Food"

**Code of Federal Regulations Citation:** 21 CFR 101.14 and 101.70

**Contact Person:** Victor P. Frattali, Center for Food Safety and Applied Nutrition (HFF-261), Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-4064.



January 6, 1993

## Health Claims: Calcium and Osteoporosis -- Final Rule

### One of a Series of FDA Regulations Implementing The Nutrition Labeling and Education Act of 1990

**Brief Summary:** FDA will allow qualified food or food supplements to bear a health claim on the label that explains the relationship between calcium and osteoporosis. FDA is satisfied that convincing scientific evidence exists demonstrating an association between inadequate calcium intake and osteoporosis.

Factors that make a person most at risk for developing osteoporosis are increased age and being a female of the Caucasian or Asian race. Women at menopause, a stage of life when loss of the hormone estrogen occurs, are particularly vulnerable to the development of osteoporosis. Unlike genetic factors over which people have no control, several lifestyle factors exist through which people can influence their risk of developing osteoporosis later in life. These include consuming an adequate amount of calcium throughout life, eating healthful meals, and exercising regularly.

For those individuals who are at greatest risk of developing osteoporosis later in life, an adequate intake of calcium is thought to help optimize the total amount of bone that is laid down during the teens and early adult life (peak bone mass). Because everyone starts to lose bone after about age 35, those with higher bone mass at skeletal maturity (before age 35) take longer to reach the critically reduced mass at which bone breaks easily. Adequate calcium intake also helps to reduce the increased rate of bone loss that occurs around the time of menopause and later in life in elderly men and women.

To bear a calcium-osteoporosis health claim, a food or supplement must contain 20 percent (200 milligrams) or more of the RDI (Reference Daily Intake) for calcium per reference amount customarily consumed or total daily recommended supplement intake, and should not contain other nutrients at levels that increase the risk of other diet-related diseases or health conditions. In addition, the form of the calcium must be assimilable (bioavailable) and, in the case of calcium supplements, must disintegrate and dissolve in a reasonable amount of time when tested under conditions that mimic those of the human stomach.

To help maintain the ideal calcium-to-phosphorus ratio, no product bearing a health claim shall contain more phosphorus than calcium. If the product contains more than 40 percent (400 milligrams) of the RDI per reference amount customarily consumed or per daily recommended supplement intake, the health claim must state that a total dietary calcium intake greater than 200 percent (2,000 milligrams) of the RDI for calcium offers no added benefit to bone health.

**Model Health Claim Appropriate for Most Conventional Foods:** "Regular exercise and a healthy diet with enough calcium helps teens and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life."

The provisions of this final rule become effective May 8, 1993.

**Docket Number:** 91N-0094 "Food Labeling: Health Claims; Calcium and Osteoporosis"

**Code of Federal Regulations Citation:** 21 CFR 101.72

**Contact Person:** M.S. Calvo, Center for Food Safety and Applied Nutrition (HFF-265), Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-5434.



January 6, 1993

## Health Claims: Sodium and Hypertension -- Final Rule

### One of a Series of FDA Regulations Implementing The Nutrition Labeling and Education Act of 1990

**Brief Summary:** FDA believes that an association between sodium and hypertension (high blood pressure) has been firmly established by scientific investigations. The agency will, therefore, allow health claims pertaining to sodium and high blood pressure in food labeling, in accordance with the general criteria for health claims.

A number of factors influence the development of hypertension in people whose heredity makes them susceptible to the condition. Scientists generally agree that high blood pressure is associated with many factors, including having a family history of the disease, growing older, being overweight, drinking too much alcohol, and eating a diet high in sodium.

The most common source of sodium in the diet is sodium chloride (table salt), which is 40 percent sodium. Sodium occurs naturally in many foods.

Sodium is important for good health, but excess sodium is unnecessary and can be harmful. Ideally, people should consume at least 500 milligrams but not more than 2,400 milligrams of sodium per day. People in the US, however, typically consume 3,000 to 6,000 milligrams daily, far more than that needed for good health.

Blood pressure goes down in many people when they reduce dietary sodium intake. Public health officials recommend that all people use salt and sodium in moderation.

FDA is authorizing claims indicating that diets low in sodium "may" or "might" reduce the risk of high blood pressure. These claims must state that the development of high blood pressure depends on many factors, and they may not include information on the extent of risk reduction associated with reduced dietary sodium intake.

FDA has determined that claims are appropriate only on foods that meet the requirements for "low sodium". In addition, foods must not exceed disqualifying levels for fat, saturated fat and cholesterol, and must naturally contain a significant amount of at least one of six specified nutrients.

**Model Health Claim:** "Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors."

The provisions of this final rule become effective May 8, 1993.

**Docket Number:** 91N-0095 "Food Labeling: Health Claims and Label Statements; Sodium / Hypertension"

**Code of Federal Regulations Citation:** 21 CFR 101.74

**Contact Person:** Ellen M. Anderson, Center for Food Safety and Applied Nutrition (HFF-266), Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-5375.



January 6, 1993

**Health Claims: Dietary Saturated Fat and Cholesterol  
and Risk of Coronary Heart Disease -- Final Rule**

**One of a Series of FDA Regulations Implementing  
The Nutrition Labeling and Education Act of 1990**

**Brief Summary:** FDA will permit foods to bear a health claim relating dietary saturated fat and cholesterol to coronary heart disease (heart disease). FDA's review of available human studies supports the conclusions from Federal government and other authoritative reports that there is strong, convincing and consistent evidence that diets high in saturated fat and cholesterol increase the risk of heart disease; and that diets low in saturated fat and cholesterol decrease the risk of heart disease.

Foods that meet descriptor requirements for "low saturated fat", "low cholesterol", and "low fat" may bear health claims for dietary saturated fat and cholesterol and coronary heart disease; fish and game meats may bear such a health claim if they meet the requirements for "extra lean". The health claim must state that diets low in saturated fat and cholesterol "may" or "might" reduce the risk of heart disease. The claim must use the terms "saturated fat" and "cholesterol", and may include the term "total fat". The claim must indicate that heart disease is caused by many factors.

Of the dietary factors for heart disease, excessive intakes of saturated fat and cholesterol are the major contributors to elevated levels of total-cholesterol and low-density-lipoprotein cholesterol (LDL-cholesterol) and increased risk of coronary heart disease. The effect of dietary changes in saturated fat and cholesterol on blood total- and LDL-cholesterol are variable among individuals. However, most individuals will benefit from diets low in saturated fat and cholesterol.

Public health authorities recommend that Americans consume diets that derive less than 30 percent of calories from total fat, less than 10 percent from saturated fat, and less than 300 milligrams of cholesterol per day. An easy way to reduce the levels of saturated fat and cholesterol in the diet is to reduce total fat consumed. Healthful diets containing a wide variety of foods, such as fruits, vegetables, whole grains, and lean meats, fish, and poultry, can reduce the risk of coronary heart disease for many Americans when combined with healthy lifestyles.

**Example of Model Health Claim:** "While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease."

The provisions of this final rule become effective May 8, 1993.

**Docket Number:** 91N-0096 "Food Labeling: Health Claims and Label Statements; Lipids and Cardiovascular Disease"

**Code of Federal Regulations Citation:** 21 CFR 101.75

**Contact Person:** Paddy Wiesenfeld, Center for Food Safety and Applied Nutrition (HFF-268), Food and Drug Administration, 8301 Muirkirk Rd., Laurel MD 20708. Phone (301) 344-5825.



January 6, 1993

## **Health Claims: Dietary Fat and Cancer -- Final Rule**

### **One of a Series of FDA Regulations Implementing The Nutrition Labeling and Education Act of 1990**

**Brief Summary:** FDA has concluded that an association between dietary fat and some cancers is supported by scientific evidence. Accordingly, the labeling of foods that meet FDA's criteria for low fat are permitted to contain a health claim about dietary fat and cancer.

Diet is only one of many factors believed to be implicated in cancer development. Others include heredity and exposure to environmental factors, such as cigarette smoking. Authoritative scientific reports have established a link between diets high in fat content and some cancers. At present, however, scientific evidence is not sufficient to establish an association between particular types of fatty acids in the diet and cancer. Neither is it possible at this time to say with certainty whether all dietary fats or a particular kind of fat is primarily responsible for the relationship of fat intake to cancer.

Since it is not possible to identify individuals at risk of developing cancer, and since the fat content of the American diet remains well above normal nutritional requirements, public health authorities recommend that all individuals lower their consumption of dietary fats.

To bear the health claim, foods must meet requirements for a "low fat" food; fish and game meats may bear this health claim if they meet requirements for "extra lean."

**An example of a model claim is:** Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.

The provisions of this final rule become effective May 8, 1993.

**Docket Number:** 91N-0097 "Food Labeling: Health Messages; Dietary Lipids and Cancer"

**Code of Federal Regulations Citation:** 21 CFR 101.73

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January 6, 1993

**Health Claims: Fiber-Containing Grain Products,  
Fruits, and Vegetables and Cancer -- Final Rule**

**One of a Series of FDA Regulations Implementing  
The Nutrition Labeling and Education Act of 1990**

**Brief Summary:** FDA is authorizing a food labeling health claim relating to an association between low-fat diets and rich in fiber-containing grain products, fruits, and vegetables, and cancer. The Agency has concluded that there is significant scientific agreement that diets low in fat and rich in fiber-containing grain products, fruits, and vegetables are associated with a reduced risk of certain types of cancer.

The 1990 legislation directed FDA to review scientific information that might justify a health claim concerning dietary fiber and cancer. FDA's review confirmed that evidence exists showing the association of diets rich in fiber-containing grain products, fruits, and vegetables with below normal rates of some cancers. Although the specific role of total dietary fiber, fiber components, and other nutrients and substances contained in these foods are not fully understood, many studies have shown that diets low in fat and rich in fiber-containing grain products, fruits, and vegetables are associated with reduced risk of some types of cancer.

To bear a health claim relating fiber-containing grains, fruits, and vegetables to a reduced risk of cancer, a food must qualify as a low-fat food and meet, without fortification, the nutrient content requirements for a "good source" of dietary fiber. Furthermore, the claim must not attribute any degree of cancer risk reduction to diets low in fat and rich in fiber-containing grain products, fruits, and vegetables, nor may it specify types of dietary fiber that may be related to the risk of cancer.

**An Example of a Model Health Claim** that may be used in food labeling to characterize the relationship between cancer and diets low in fat and rich in fiber-containing grain products, fruits, and vegetables is the following: "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."

The provisions of this final rule become effective May 8, 1993.

**Docket Number:** 91N-0098 "Food Labeling: Health Claims; Dietary Fiber and Cancer"

**Code of Federal Regulations:** 21 CFR 101.76

**Contact Person:** Joyce A. Saltsman, Center for Food Safety and Applied Nutrition (HFF-265), Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-5916.





January 6, 1993

**Health Claims: Fruits, Vegetables, and Grain Products that Contain Fiber,  
Particularly Soluble Fiber, and Risk of Coronary Heart Disease -- Final Rule**

**One of a Series of FDA Regulations Implementing  
The Nutrition Labeling and Education Act of 1990**

**Brief Summary:** FDA is authorizing a health claim on foods relating to an association between diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain dietary fiber, particularly soluble fiber, and risk of coronary heart disease (CHD). The Agency has concluded that there is sufficient scientific evidence and significant scientific agreement that diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of fiber may be useful in reducing the risk of heart disease.

Evidence suggests that lowering the level of cholesterol in the blood of healthy adults can lower the risk of CHD. Federal government and other reviews by recognized scientific bodies have recommended that Americans consume diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products -- rich sources of fiber, particularly soluble fiber -- because these diets are associated with a reduced risk of heart disease.

To bear a health claim relating fruits, vegetables, and grain products that contain fiber to heart disease, a food must meet all the requirements for a claim relating diets low in saturated fat and cholesterol to a reduced risk of heart disease. Because soluble fiber is a useful marker for plant foods whose consumption is associated with reduced heart disease risk, FDA is also requiring that the fruit, vegetable, or grain product contain, without fortification, not less than 0.6 gram of soluble fiber per reference amount customarily consumed. The claim cannot attribute any degree of CHD risk reduction to diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber, but may provide additional information about disease risk factors and the relationship and significance of these diets to reduced heart disease risk.

**An Example of a Model Health Claim that may be used in food labeling is: "Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber may reduce the risk of heart disease, a disease associated with many factors."**

The provisions of this final rule become effective May 8, 1993.

**Docket Number: 91N-0099 "Food Labeling: Health Claims; Dietary Fiber and Cardiovascular Disease"**

**Code of Federal Regulations Citation: 21 CFR 101.77**

**Contact Person: Joyce A. Saltsman, Center for Food Safety and Applied Nutrition (HFF-256), Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-5916.**



January 6, 1993

## **Health Claims: Fruits and Vegetables and Cancer -- Final Rule**

### **One of a Series of FDA Regulations Implementing The Nutrition Labeling and Education Act of 1990**

**Brief Summary:** FDA is authorizing the use on food labels and labeling of health claims that relate diets low in fat and high in fruits and vegetables [foods that are low in fat and are a good source of dietary fiber, vitamin A (in the form of beta carotene), or vitamin C] to a reduced risk of cancer. The Agency is not authorizing health claims that make an association of the antioxidant vitamins themselves to reduced cancer risk. FDA has concluded that, based on the totality of scientific evidence, there is significant scientific agreement that diets low in fat and high in fruits and vegetables reduce the risk of cancer.

The health claim relating to substances in diets low in fat and high in fruits and vegetables must state that such diets "may" or "might" reduce the risk of "some cancers" or "some types of cancer," but may not specify the degree of cancer risk reduction. The food must be or contain a fruit or vegetable that meets the requirements for a "low fat" food and must meet, without fortification, the requirements for a "good source" of vitamin A, vitamin C, or dietary fiber.

**Example of Model Health Claim That May Be Used in Labeling Qualified Foods:** "Low fat diets rich in fruits and vegetables (foods that are low in fat and contain dietary fiber, vitamin A, or vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. Broccoli is high in vitamins A and C, and is a good source of dietary fiber."

The provisions of this final rule become effective May 8, 1993.

**Docket Number:** 91N-0101 "Food Labeling: Health Claims and Label Statements; Antioxidant Vitamins and Cancer"

**Code of Federal Regulations Citation:** 21 CFR 101.78

**Contact Person:** John N. Hathcock, Center for Food Safety and Applied Nutrition (HFF-268), Food and Drug Administration, 8301 Muirkirk Rd., Laurel MD 20708. Phone (301) 344-6006.



January 6, 1993

## **Health Claims: Folic Acid and Neural Tube Defects -- Final Rule**

### **One of a Series of FDA Regulations Implementing The Nutrition Labeling and Education Act of 1990**

**Brief Summary:** FDA has decided not to authorize a health claim associating folic acid and neural tube defects at this time. The U.S. Public Health Service (PHS) recently recommended that:

"All women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 mg of folic acid per day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or other NTDs. Because the effects of high intakes are not well known but include complicating the diagnosis of vitamin B<sub>12</sub> deficiency, care should be taken to keep total folate consumption at < 1 mg per day, except under the supervision of a physician. Women who have had a prior NTD-affected pregnancy are at high risk of having a subsequent affected pregnancy. When these women are planning to become pregnant, they should consult their physicians for advice."

The PHS identified several outstanding issues, including the appropriate level of folic acid in foods and safety concerns regarding increased intakes of folic acid. FDA convened an advisory committee to consider these issues on November 23-24, 1992, and is currently reviewing the advisory committee recommendations.

The provisions of this final rule become effective May 8, 1993.

**Docket Number:** 91N-0100 "Food Labeling: Health Claims and Label Statements; Folic Acid and Neural Tube Defects"

**Code of Federal Regulations Citation:** 21 CFR 101.71(c)

**Contact Person:** Jeanne I. Rader, Center for Food Safety and Applied Nutrition (HFF-268), Food and Drug Administration, 8301 Muirkirk Rd., Laurel, MD 20708. Phone (301) 344-5832.



January 6, 1993

**Health Claims: Zinc and Immune Function in the Elderly  
-- Final Rule**

**One of a Series of FDA Regulations Implementing  
The Nutrition Labeling and Education Act of 1990**

**Brief Summary:** There is no persuasive body of scientific evidence to demonstrate that increasing the amount of zinc in the diet can improve immune function in normal, healthy individuals of any age. FDA, therefore, does not authorize a health claim for zinc and immune functions in the elderly.

Zinc is essential for human health, and zinc deficiency, whether due to disease or diet, interferes with normal immune function. Studies have shown that elderly people in the US consume less than recommended amounts of zinc and that zinc intake declines with advancing age. These factors aroused interest in whether zinc supplements in the diet of elderly persons improved their immune response. Some initial studies appeared to support this hypothesis. Both healthy individuals and those showing depressed immune function appeared to benefit. However, in all of these studies, the improvement was small, as was the number of participants. Several studies had design flaws that further limited their scientific validity.

Well-designed, placebo-controlled studies involving larger numbers of participants have not shown zinc supplementation to improve immune function. In studies in which groups of patients received either supplemental zinc or a placebo, in addition to a multivitamin-mineral preparation, all the groups showed progressive improvement in immune function, but improvement was greatest in the group receiving the placebo. Supplemental zinc appeared to slow down the progressive improvement in immune response up to four months after the zinc was discontinued.

While zinc is one of the least toxic of the essential trace minerals, there are reports of adverse effects from long-term or high-dose zinc supplementation. One of those adverse effects is suppression of immune function.

The provisions of this final rule become effective May 8, 1993.

**Docket Number:** 91N-0102 "Food Labeling: Health Claims; Zinc and Immune Function in the Elderly"

**Code of Federal Regulations Citation:** 21 CFR 101.71(e)

**Contact Person:** James E. Hoadley, Center for Food Safety and Applied Nutrition (HFF-265), Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-5593.



January 6, 1993

## **Health Claims: Omega-3 Fatty Acids and Coronary Heart Disease -- Final Rule**

### **One of a Series of FDA Regulations Implementing The Nutrition Labeling and Education Act of 1990**

**Brief Summary:** FDA has determined that existing, publicly available scientific evidence does not support a claim that omega-3 fatty acids (O3FAs) are associated with reduced risk of coronary heart disease (CHD). FDA does not authorize any such claim in food labeling. The Agency's decision is based on its own search of the scientific literature and its review of comments, including new scientific data, received in response to its proposed rule on O3FAs and CHD.

Surveys, cross-sectional studies, and nonintervention prospective studies do not provide adequate support for a relationship between consumption of O3FAs and CHD. An association between fish intake and CHD has not consistently been found, and in those studies that report such a relationship, that relationship has not been shown to be specific for O3FAs in fish. The only prospective, double-blind, placebo-controlled intervention study to date with CHD morbidity and mortality as endpoints provided evidence that fish consumption reduced the fatality rate after second heart attacks, but did not show that the effect was specific to O3FAs.

Clinical trials have not found that intake of O3FAs reduces total cholesterol or LDL-cholesterol in normal, healthy persons or persons at risk for CHD. O3FAs reduce fasting and postprandial triglycerides, but there is not significant scientific agreement that these blood lipid variables are related to the risk of CHD. Likewise, the evidence that O3FAs raise high density lipoprotein- ("good") cholesterol levels is ambiguous and not persuasive. Numerous other clinical and laboratory studies have examined mechanisms of action by which O3FAs might influence the risk of CHD, but the available information is inadequate to support a health claim in food labeling. Moreover, the agency remains concerned about the possibility that O3FAs may increase LDL-cholesterol among persons with elevated blood lipids, and that O3FAs may worsen control of blood glucose in diabetics.

The provisions of this final rule become effective May 8, 1993.

**Docket Number:** 91N-0103 "Food Labeling: Health Claims and Label Statements: Omega-3 Fatty Acids and Coronary Heart Disease"

**Code of Federal Regulations Citation:** 21 CFR 101.71(f)

**Contact Person:** John Wallingford, Center for Food Safety and Applied Nutrition (HFF-265), Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-5461.



January 6, 1993

## Regulatory Impact Analysis -- Final Rule

### One of a Series of FDA Regulations Implementing The Nutrition Labeling and Education Act of 1990

**Brief Summary:** In an effort to calculate the cost and benefit of major changes in nutrition labeling, FDA contracted with Research Triangle Institute to prepare estimates of the costs to industry (food manufacturers and retailers) and the benefits to consumers of proposed changes in the format and content of nutrition labeling. The agency published estimates of the costs and benefits of nutrition labeling in November 1991. In response to that publication, FDA received approximately 350 comments, on the basis of which FDA estimates that 257,000 labels will have to be changed. Further, the agency calculates, in response to comments received, that 196,000 food products will have to be changed. The agency has included the costs of protein testing and the costs to the Federal government in its final cost estimate.

By allowing restaurants to estimate nutrient values on which claims are based using a "reasonable" basis rather than analytical tests, and deferring any enforcement on small restaurant chains, the cost estimates for restaurants, originally calculated at \$116 million, was reduced by the Agency to \$17 million. FDA estimates the total cost of nutrition labeling to be between \$1.4 billion and \$2.3 billion, the actual amount depending on the frequency of reanalyzing food products. In addition, costs to the Federal government will be \$160 million, and the estimated cost to industry of voluntary labeling of raw fruits, vegetables, and seafood will fall between \$117 million and \$155 million.

Based on its estimates in the Regulatory Impact Analysis, the Agency has determined that compliance with the food labeling regulations would result in undue economic hardship. Therefore, the Agency is extending by 1 year the application of the sections of the 1990 amendments dealing with mandatory nutrition labeling and nutrient content claims.

FDA calculated the monetary value of benefits in terms of the number of life-years and the number of lives saved as a result of decreased rates of cancer, coronary heart disease, osteoporosis, obesity, high blood pressure, and allergic reactions to food. The benefit study focused, however, on cancer and coronary heart disease. If consumers change food selection and consumption practices in response to changes in food labeling, the reduction of the risk of cancer and coronary heart disease would, over a 20-year period, prevent about 39,200 cases of these two illnesses, of which 12,900 would have resulted in death with the loss of 80,900 life-years. FDA increased its earlier benefit estimates to reflect both inflation and increases in personal income from the time the studies were originally conducted to the present. This resulted in benefits ranging between \$4.4 billion and \$26 billion.

The agency believes that both costs and benefits may be underestimated because of the enormous amount of product reformulation expected to take place that was not included in the cost/benefit calculations.

**Docket Number:** 91N-0219 "Regulatory Impact Analysis of the Proposed Rules to Amend the Food Labeling Regulations"

**Contact Person:** Richard A. Williams, Jr., Center for Food Safety and Applied Nutrition (HFF-303), Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-5271.



January 6, 1993

## **State Exemption from Federal Preemption -- Final Rule**

### **One of a Series of FDA Regulations Implementing The Nutrition Labeling and Education Act of 1990**

**Brief Summary:** The 1990 legislation authorizes Federal preemption of certain state and local labeling requirements that are not identical to Federal requirements, such as those pertaining to food standards, nutrition labeling, claims of nutrient content, health claims, and ingredient declaration requirements. It also provides that states may petition FDA for exemption of state requirements from Federal preemption.

Under the final rule, FDA may grant a petition for exemption if a state shows that its requirement would not cause any food to be in violation of any Federal requirement, would not unduly burden interstate commerce, addresses a particular need for information not met by Federal law, and does not pose an increased risk to public health. FDA is providing that, if a petition meets these requirements, FDA will publish a regulation granting an exemption. Such regulations will be subject to the notice and comment rule-making procedure. If an exemption is granted, all information pertaining to the petition will be available for examination by interested parties.

The provisions of this final rule become effective February 5, 1993.

**Docket Number:** 91N-0038 "State Petitions Requesting Exemption from Federal Preemption"

**Code of Federal Regulations Citation:** 21 CFR 100.1

**Contact Person:** Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFF-312), Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-5229.



January 6, 1993

**State Enforcement Under the Nutrition Labeling  
and Education Act -- Final Rule**

**One of a Series of FDA Regulations Implementing  
The Nutrition Labeling and Education Act of 1990**

**Brief Summary:** The 1990 food labeling legislation authorizes states to take action in Federal Courts to enforce a wide range of provisions relating to the processing, composition, packaging, and labeling of foods. This provision enables the states to supplement FDA's enforcement of laws and regulations governing much of the Nation's food supply.

The final regulation spells out criteria that a state must meet in order to exercise these new enforcement powers. Specifically, a state must notify FDA at least 30 days prior to taking any enforcement action under the new law. If FDA begins an enforcement action within that 30-day period, the state must suspend its action an additional 60 days. If FDA is actively prosecuting a firm or has completed an enforcement action against it, a state cannot take action against it.

The provisions of this final rule become effective February 5, 1993.

**Docket Number:** 91N-0343 "State Enforcement Provisions of the Nutrition Labeling and Education Act of 1990"

**Code of Federal Regulations Citation:** 21 CFR 100.2

**Contact Person:** Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFF-302), Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-4561.





January 6, 1993

## Declaration of Ingredients: 2 Final Rules, 1 Proposed Rule

### Three of a Series of FDA Regulations Implementing The Nutrition Labeling and Education Act of 1990

**Brief Summaries:** Two final rules and a related proposed rule address various aspects of ingredient labeling intended to make this aspect of labeling more useful to consumers.

Following are provisions of the two final rules and the proposed rule: A final rule requires that all certified color additives used in foods must be declared by their common or usual name, e.g., "FD&C Blue No. 1." It also requires that all protein hydrolysates used in food must be declared by their usual or common name, which must include the identity of the protein source, e.g., "hydrolyzed soy protein." The proposal would require the common or usual name declaration of protein hydrolysates used for flavor-related purposes to include the parenthetical term "(contains glutamate)."

A final rule requires the declaration of all ingredients in foods subject to a standard of identity. It also requires the declaration of a sulfiting agent in a standardized food when the sulfiting agent has a functional effect in the food or is present at 10 or more parts per million.

A final rule allows for the collective declaration of preservative coatings of fresh fruits and vegetables, e.g., "coated with food-grade, animal-based wax to maintain freshness." Further, A final rule requires the identification of a caseinate as a milk derivative when it appears in the ingredient list of a food claiming to be a non-dairy food. It permits the optional inclusion of the food source in the name of certain sweeteners defined in the food standards, e.g., dextrose anhydrous may be declared as "corn sugar anhydrous." And it provides a uniform format for the voluntary declaration of percentage ingredient information in the ingredient list.

The proposal would also amend the standard of identity for canned tuna to require the term "(includes soybeans)" as part of the name used to declare the ingredient vegetable broth when soybeans are one of the vegetable extractives used to make the vegetable broth, and would also allow the use of "and/or" labeling for the declaration of sweeteners in soft drinks, e.g. "sugar and/or high fructose corn syrup."

The effective date for the provisions for ingredient listing for standardized foods and the declaration of certified color additives is May 8, 1993. The effective date for the other provisions in the final rules and the proposed rule is May 8, 1994.

**Docket Number:** 90N-0361 "Food Labeling: Declaration of Ingredients", 90N-0361D "Food Labeling: Declaration of Ingredients for Dairy Products and Maple Sirup" and 90N-0361M "Food Labeling: Declaration of Ingredients--Common or Usual Name Declaration for Protein Hydrolysates and Vegetable Broth in Canned Tuna; "And/Or" Labeling for Soft Drinks"

**Code of Federal Regulations Citations:** 21 CFR 101.4, 101.22, 101.100, 102.22, 130.3, 130.9, 130.11 and specified food standards

**Contact Person:** Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFF-312), Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-5229.



January 6, 1993

**Percentage Juice Declaration on Beverages -- Final Rule**

**One of a Series of FDA Regulations Implementing  
The Nutrition Labeling and Education Act of 1990**

**Brief Summary:** The ingredient statement included in the labeling of a beverage purporting by means of color, flavor, or labeling to contain fruit or vegetable juice must declare the percentage of total juice contained in the product. This requirement, which becomes effective May 8, 1993, applies to all such beverages whether carbonated or not, concentrated, full strength, diluted, or containing no juice whatever. However, beverages containing small or insignificant amounts of juice for flavor are not required to bear a percent-of-juice declaration, provided they (1) are labeled with a flavor description using a term such as "flavor" or "flavored," (2) do not bear the term "juice" other than in the ingredient statement, and (3) do not otherwise purport to contain juice.

The rule establishes criteria for naming juice beverages. They include the requirement that a beverage with less than 100 percent juice must be called "juice beverage" or "juice drink," etc. -- not "juice." When the label of a multi-juice beverage names one or more, but not all, of the juices present, if the named juice is present in a minor amount, the name of the product must either state that the beverage is flavored with that juice or declare the amount of the juice in a 5-percent range, e.g., "raspberry-flavored juice blend" or "juice blend, 2-7% raspberry juice."

The regulation makes it clear that a term such as "from concentrate" is required in the labeling of a beverage made from concentrated juice, and that when a label states "100% juice," it must declare in the name if non-juice ingredients are present. In addition, the regulation deals with modified juices that have undergone major changes so that they do not have the characteristics and nutrient profile of the original juice. The name of such a modified juice must include a description of the modification, and it cannot be included in calculating the percentage of total juice in the beverage.

The provisions of this final rule become effective May 8, 1993.

**Docket Number:** 80N-0140 "Food Labeling: Declaration of Ingredients; Common or Usual Name for Nonstandardized Foods; Diluted Juice Beverages"

**Code of Federal Regulation Citations:** 21 CFR 101.30 and 102.33

**Contact Person:** Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFF-312), Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-5229.



January 6, 1993

**Sections of the Federal Food, Drug, and Cosmetic Act  
That Are Being Adequately Implemented -- Final Rule, and  
Misleading Containers: Nonfunctional Slack-Fill -- Proposed Rule**

**Two of a Series of FDA Regulations Implementing  
The Nutrition Labeling and Education Act of 1990**

**Brief Summary:** The Nutrition Labeling and Education Act provides for Federal preemption of certain State and local food standards and labeling requirements. States are prohibited from establishing food labeling or packaging requirements that are not identical to requirements in the Federal Food, Drug, and Cosmetic Act.

Certain provisions of the Act dealing with misbranding do not preempt State law until FDA determines that these provisions are adequately dealt with in Federal regulations. FDA has determined that five of the six misbranding provisions are being adequately implemented, i.e., 403(b), 403(f), 403(h), 403(i)(1) and 403(k). Section 403(d), which is concerned with food packaging, declares a food misbranded if its container "is so made, formed, or filled as to be misleading." FDA believes that the terms "made" and "formed" are straightforward. The agency is aware, however, that some States have enacted a variety of laws and regulations concerning fill of containers that go beyond the provisions of 403(d). FDA is proposing to establish a regulation that would define the circumstances in which the empty space, or "slack-fill," within a container is nonfunctional and, therefore, misleading.

FDA tentatively finds that slack-fill is justified to the extent that it performs an appropriate function, such as protecting the contents of the container. Slack-fill in excess of that required to perform a function is nonfunctional and, hence, misleading. The proposal provides for slack-fill caused by normal product settling, as well as that made necessary in the packing of certain convenience foods and gift products.

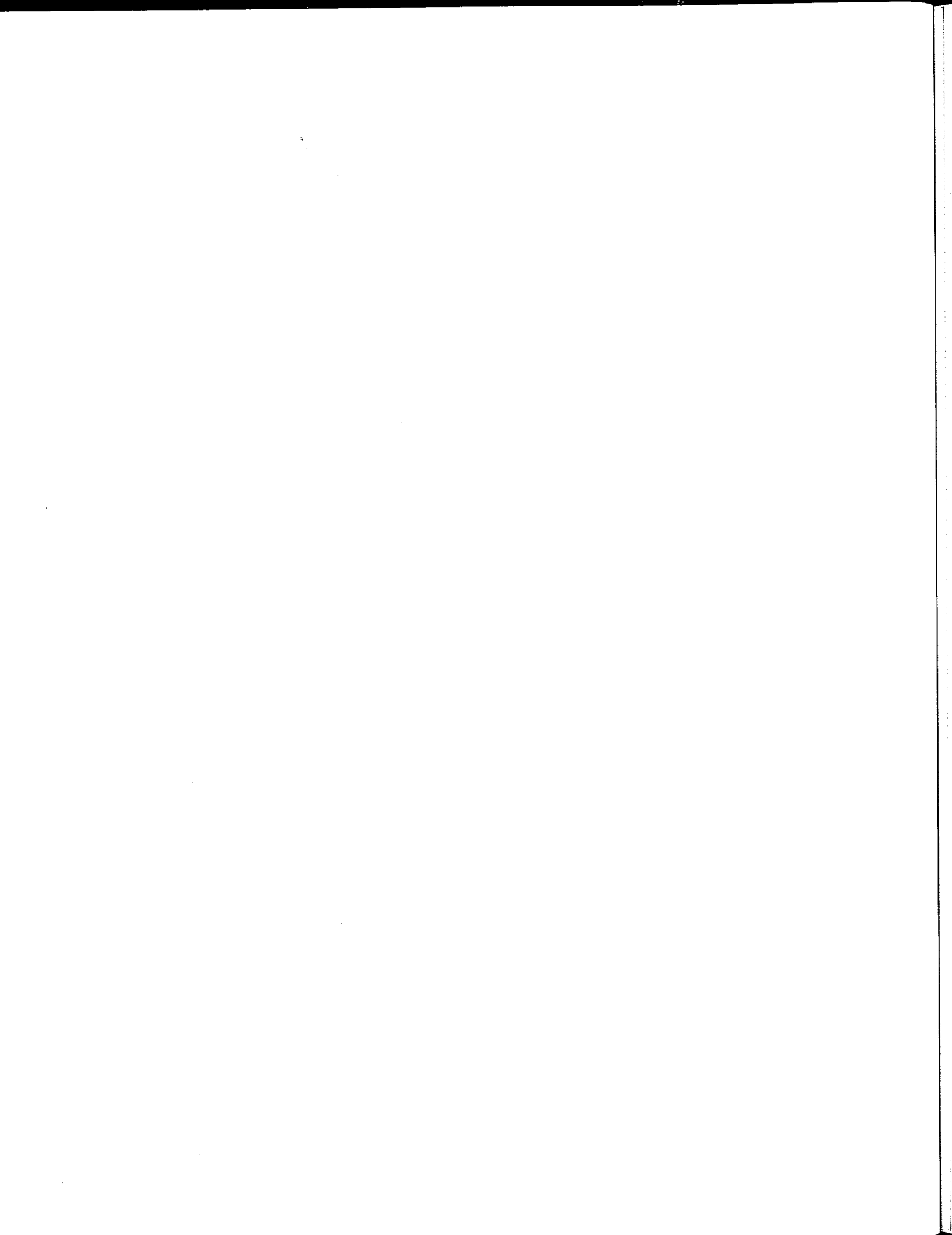
The proposed regulation would ensure adequate implementation of section 403(d) and would provide additional consumer protection against misleading fill of food containers. It would also provide FDA and State agencies with a uniform means of taking action against providers of misleading containers. Manufacturers will be assured that packaging will be treated uniformly throughout the Nation with respect to misleading containers.

The provisions for the final rule become effective February 5, 1993.

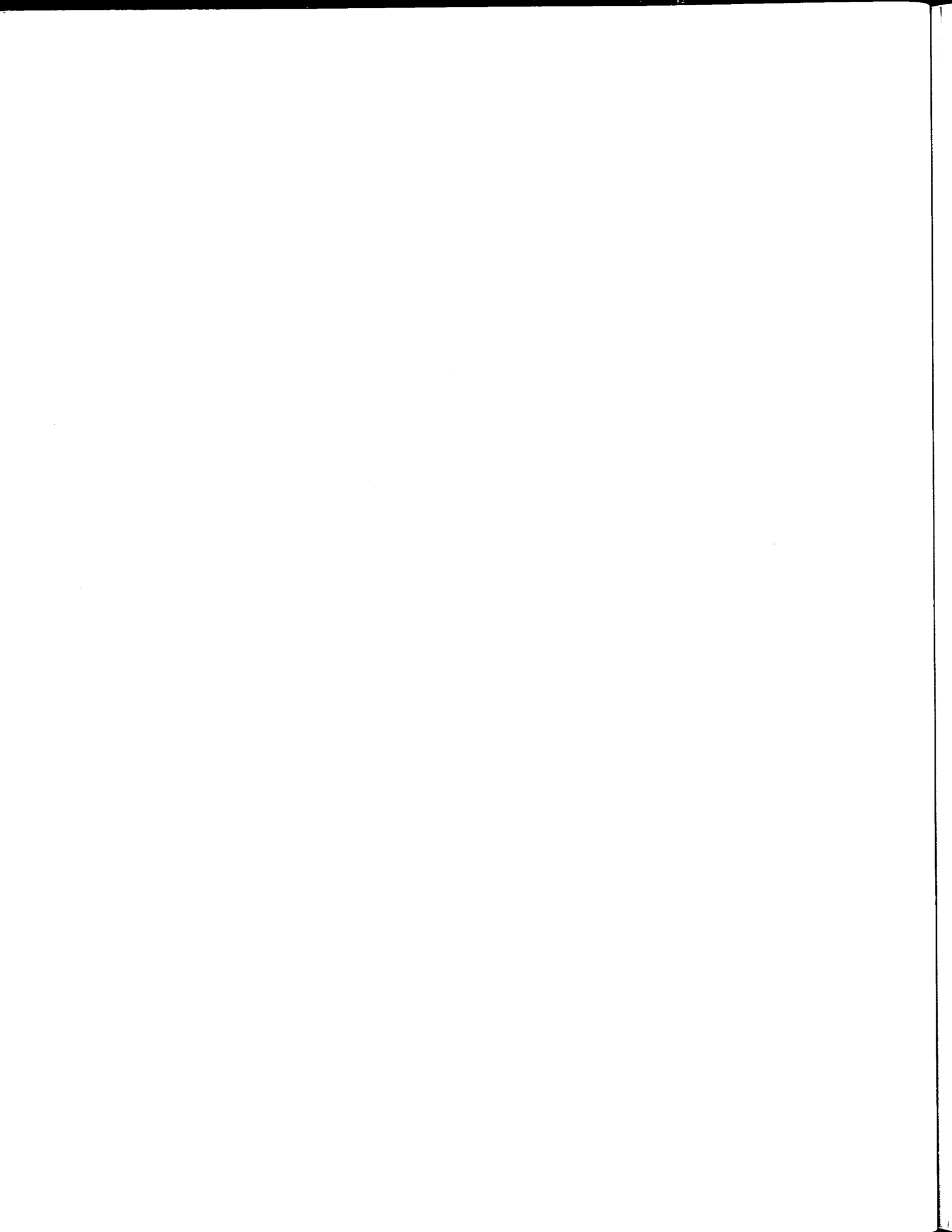
**Docket Numbers:** 91N-0134 "Certain Misbranding Sections of FFDCFA that are, and that are not, Adequately Being Implemented by Regulation; Notice of Final List" and 92N-0383 "Misleading Containers; Nonfunctional Slack-Fill"

**Code of Federal Regulations Citations:** 21 CFR Part 1 and 21 CFR 100.100, respectively

**Contact Person:** Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFF-414), Food and Drug Administration, 200 C St. SW, Washington DC 20204. Phone (202) 205-5106.



## **NUTRIENT CONTENT CLAIMS**



Nutrient Content Claims [Final Rule]

Nutrient	Free	Low	Reduced / Less	Comments
	<ul style="list-style-type: none"> <li>• Synonyms for "Free": "Zero", "No", "Without", "Trivial Source of", "Negligible Source of", "Dietarily Insignificant Source of"</li> <li>• Definitions for "Free" for meals and main dishes are the stated values per labeled serving</li> </ul>	<ul style="list-style-type: none"> <li>• Synonyms for "Low": "Little", ("Few" for Calories), "Contains a Small Amount of", "Low Source of"</li> </ul>	<ul style="list-style-type: none"> <li>• Synonyms for "Reduced" / "Less": "Lower" ("Fewer" for calories)</li> <li>• "Modified" may be used in statement of identity</li> <li>• Definitions for meals and main dishes are same as for individual foods on a per 100 g basis</li> </ul>	<ul style="list-style-type: none"> <li>• For "Free", "Very Low", or "Low", must indicate if food meets a definition without benefit of special processing, alteration, formulation or reformulation; e.g., "broccoli, a fat-free food" or "celery, a low calorie food"</li> <li>• NOTE: * If ingredient containing a trivial amount of a nutrient is added to food that qualifies for "Free" claim, a statement such as "Adds a trivial amount of [nutrient]" is asterisked to ingredient</li> </ul>
Calories	<ul style="list-style-type: none"> <li>• Less than 5 cal per reference amount</li> <li>• Not defined for meals or main dishes</li> </ul>	<ul style="list-style-type: none"> <li>• 40 cal or less per reference amount (and per 50 g if reference amount is small)</li> <li>• Meals and main dishes: 120 cal or less per 100 g</li> </ul>	<ul style="list-style-type: none"> <li>• At least 25% fewer calories per reference amount than an appropriate reference food</li> <li>• Reference food may not be "Low Calorie"</li> <li>• Uses term "Fewer" rather than "Less"</li> </ul>	<ul style="list-style-type: none"> <li>• "Light" or "Lite": if 50% or more of the calories are from fat, fat must be reduced by at least 50% per reference amount. If less than 50% of calories are from fat, fat must be reduced at least 50% or calories reduced at least 1/3 per reference amount</li> <li>• Meal or main dish meets definition for "Low Calorie" or "Low Fat" meal and is labeled to indicate which definition is met</li> </ul>
Total Fat	<ul style="list-style-type: none"> <li>• Less than 0.5 g per reference amount and no ingredient that is fat or understood to contain fat except as noted above*</li> </ul>	<ul style="list-style-type: none"> <li>• 3 g or less per reference amount (and per 50 g if reference amount is small)</li> <li>• Meals and main dishes: 3 g or less per 100 g and not more than 30% of calories from fat</li> </ul>	<ul style="list-style-type: none"> <li>• At least 25% less fat per reference amount than an appropriate reference food</li> <li>• Reference food may not be "Low Fat"</li> </ul>	<ul style="list-style-type: none"> <li>• "___% Fat Free": OK if meets the requirements for "Low Fat"</li> <li>• "Light" - see above</li> </ul>
Saturated Fat	<ul style="list-style-type: none"> <li>• Less than 0.5 g per reference amount</li> <li>• Trans fatty acids are not more than 1% of total fat</li> <li>• No ingredient that is understood to contain saturated fat except as noted above*</li> </ul>	<ul style="list-style-type: none"> <li>• 1 g or less per reference amount and 15% or less of calories from saturated fat</li> <li>• Meals and main dishes: 1 g or less per 100 g and less than 10% of calories from saturated fat</li> </ul>	<ul style="list-style-type: none"> <li>• At least 25% less saturated fat per reference amount than an appropriate reference food</li> <li>• Reference food may not be "Low Saturated Fat"</li> </ul>	<ul style="list-style-type: none"> <li>• Next to all saturated fat claims, must declare the amount of cholesterol if 2 mg or more per reference amount ; and the amount of total fat if more than 3 g per reference amount (or 0.5 g or more of total fat for "Saturated Fat Free")</li> </ul>

Notes: "Reference Amount" = amount customarily consumed.

"Small Serving" = reference amount 30 g or less or 2 tablespoons or less (for dehydrated foods that are typically consumed when rehydrated with water only, the per 50 g refers to the as prepared form).

\* Statement "See \_\_\_ panel for nutrition information" must accompany all content claims. When levels exceed: 13 g Fat, 4 g Saturated Fat, 60 mg Cholesterol, and 480 mg Sodium per reference amount per labeled serving and for foods with small reference amounts per 50 g disclosure statement is required as part of claim (e.g. "see side panel for information on fat and other nutrients").

Nutrient Content Claims [Final Rule]

Nutrient	Free	Low	Reduced / Less	Comments
Cholesterol	<ul style="list-style-type: none"> <li>• Less than 2 mg per reference amount.</li> <li>• If less than 2 mg per reference amount by special processing and total fat exceeds 13 g per reference and labeled serving, the amount of cholesterol must be "Substantially Less" (25%) than in a reference food with significant market share (5% of market)</li> <li>• No ingredient that contains cholesterol except as noted above*</li> </ul>	<ul style="list-style-type: none"> <li>• 20 mg or less per reference amount (and per 50 g of food if reference amount is small)</li> <li>• If qualifies by special processing and total fat exceeds 13 g per reference and labeled serving, the amount of cholesterol must be "Substantially Less" (25%) than in a reference food with significant market share (5% of market)</li> <li>• Meals and main dishes: 20 mg or less per 100 g</li> </ul>	<ul style="list-style-type: none"> <li>• At least 25% less fat per reference amount than an appropriate reference food</li> <li>• Reference food may not be "Low Cholesterol"</li> </ul>	<ul style="list-style-type: none"> <li>• CHOLESTEROL CLAIMS ONLY ALLOWED WHEN FOOD CONTAINS 2 g OR LESS SATURATED FAT PER REFERENCE AMOUNT, OR FOR MEALS AND MAIN DISH PRODUCTS, PER LABELED SERVING SIZE</li> <li>• Must declare the amount of total fat next to cholesterol claim when fat exceeds 13 g per reference amount and labeled serving (or per 50 g of food if reference amount is small)</li> </ul>
Sodium	<ul style="list-style-type: none"> <li>• Less than 5 mg per reference amount and no ingredient that is sodium chloride or generally understood to contain sodium except as noted above*</li> </ul>	<ul style="list-style-type: none"> <li>• 140 mg or less per reference amount (and per 50 g if reference amount is small)</li> <li>• Meals and main dishes: 140 mg or less per 100 g</li> </ul>	<ul style="list-style-type: none"> <li>• At least 25% less sodium per reference amount than an appropriate reference food</li> <li>• Reference food may not be "Low Sodium"</li> </ul>	<ul style="list-style-type: none"> <li>• "Light" (for sodium reduced products): if food is "Low Calorie" and "Low Fat" and sodium is reduced by at least 50%</li> <li>• "Light in Sodium": if food is reduced by at least 50% per reference amount. Entire term "Light in Sodium" must be used in same type, size, color &amp; prominence. Light in Sodium for meals = "Low in Sodium"</li> <li>• "Very Low Sodium": 35 mg or less per serving (and per 50 g if reference amount is small). For meals and main dishes: 35 mg or less per 100 g</li> <li>• "Salt Free" must meet criterion for "Sodium Free"</li> <li>• "No Salt Added" and "Unsalted" must meet conditions of use and must declare "This Is Not A Sodium Free Food" on information panel</li> <li>• "Lightly Salted": 50% less sodium than normally added to reference food and if not "Low Sodium", so labeled on information panel</li> </ul>
Sugars	<ul style="list-style-type: none"> <li>• "Sugar Free": Less than 0.5 g per reference amount and no ingredient that is sugar or generally understood to contain sugar except as noted above*</li> <li>• Disclose calorie profile (e.g. "Low Calorie")</li> </ul>	<ul style="list-style-type: none"> <li>• Not Defined. No basis for a recommended intake</li> </ul>	<ul style="list-style-type: none"> <li>• At least 25% less sugars per reference amount than an appropriate reference food</li> </ul>	<ul style="list-style-type: none"> <li>• "No Added Sugars" and "Without Added Sugars" are allowed if no sugar or sugar containing ingredient is added during processing. State if food is not "Low" or "Reduced Calorie"</li> <li>• The terms "Unsweetened" and "No Added Sweeteners" remain as factual statements</li> <li>• Claims about reducing dental caries are implied health claims</li> <li>• Does not include sugar alcohols</li> </ul>

Notes: "Reference Amount" = amount customarily consumed.

"Small Serving" = reference amount 30 g or less or 2 tablespoons or less (for dehydrated foods that are typically consumed when rehydrated with water only, the per 50 g refers to the as prepared form).

\* Statement "See \_\_\_ panel for nutrition information" must accompany all content claims. When levels exceed: 13 g Fat, 4 g Saturated Fat, 60 mg Cholesterol, and 480 mg Sodium per reference amount per labeled serving and for foods with small reference amounts per 50 g disclosure statement is required as part of claim (e.g. "see side panel for information on fat and other nutrients").



## Relative (or Comparative) Claims

### Accompanying Information

- For all relative claims, percent (or fraction) of change and identity of reference food must be declared in immediate proximity to the most prominent claim. Quantitative comparison of the amount of the nutrient in the product per labeled serving with that in the reference food must be declared on information panel.
- For Light claims: % reduction for both fat and calories must be stated but % reduction need not be specified if product is low in that nutrient.

### Reference Foods

<b>"Light" / "Lite"</b>	(1) A food representative of the type of food bearing the claim, e.g. average value of top three brands or representative value from valid data base; (2) similar food (e.g. potato chips for potato chips); and (3) not low calorie and low fat (except light sodium foods which must be low calorie and low fat).
<b>"Reduced" and "Added" (or "fortified" and "enriched")</b>	(1) An established regular product or average representative product and (2) similar food.
<b>"More" and "Less" (or "Fewer")</b>	(1) An established regular product or average representative product and (2) a dissimilar food in the same product category which may be generally substituted for labeled food (e.g. potato chips for pretzels) or a similar food.

## Other Nutrient Content Claims

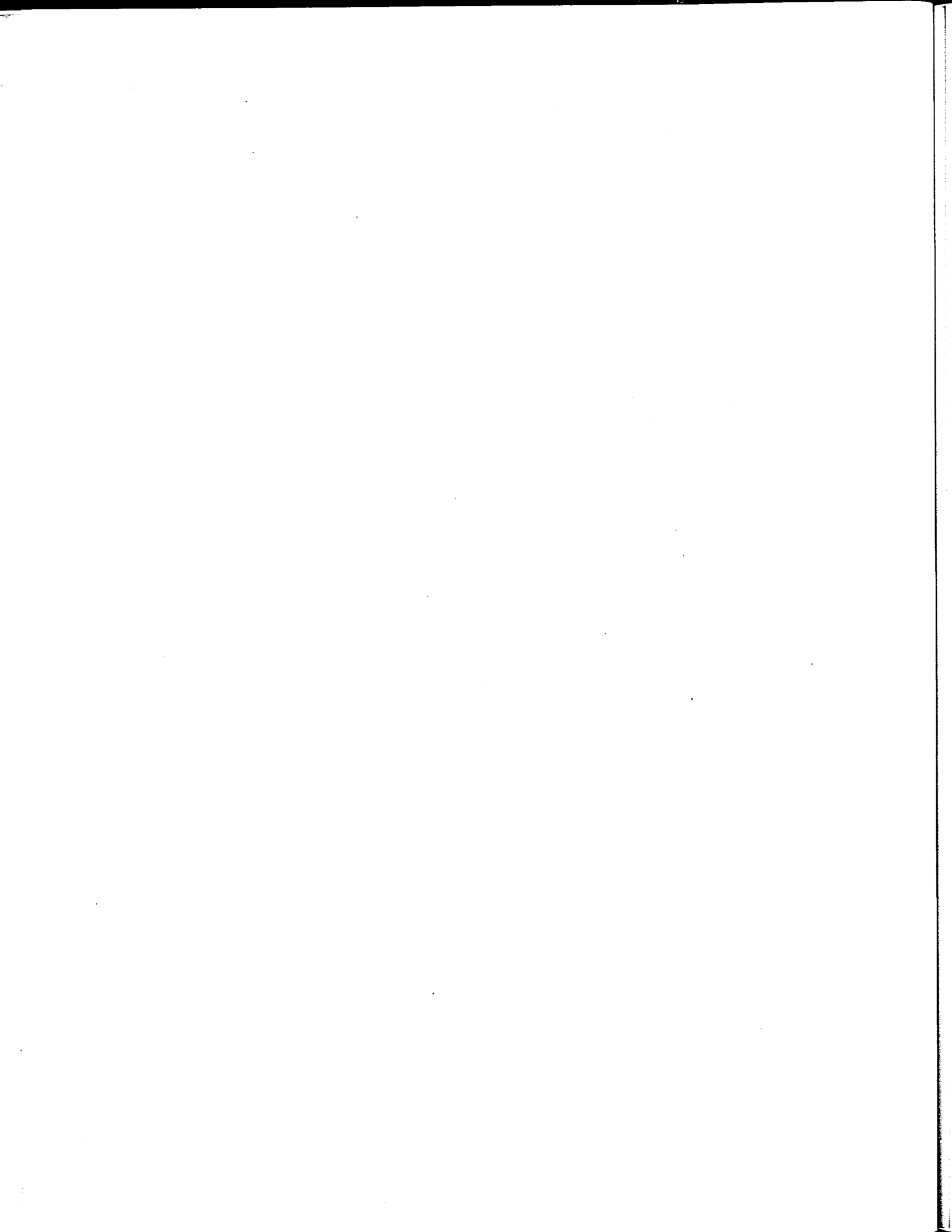
<b>"Lean"</b>	On seafood or game meat that contains < 10 g total fat, < 4 g saturated fat and < 95 mg cholesterol / reference serving and per 100 g.(for meals & main dishes, meets criteria per 100 g and per labeled serving).
<b>"Extra Lean"</b>	On seafood or game meat that contains < 5 g total fat, < 2 g saturated fat and < 95 mg cholesterol per reference serving and per 100 g. (for meals and main dishes, meets criteria per 100 g and per label serving).
<b>"High", "Rich in", or "Excellent Source Of"</b>	Contains 20% or more of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) to describe protein, vitamins, minerals, dietary fiber, or potassium per reference serving. May be used on meals or main dishes to indicate that product contains a food that meets definition.
<b>"Good Source Of", "Contains" or "Provides"</b>	10-19% of the RDI or DRV per reference serving. May be used on meals or main dishes to indicate that product contains a food that meets definition.
<b>"More"</b>	10% or more of the DRV or RDI per reference serving.
<b>"Modified"</b>	May be used in statement of identity that bears a relative claim, e.g. "Modified Fat Cheese Cake, Contains 35% Less Fat Than Our Regular Cheese Cake."
<b>Any Fiber Claim</b>	If food is not low in total fat, must state total fat in conjunction with claim such as "More Fiber".

## Implied Claims

- Claims about a food or ingredient that suggests that the nutrient or ingredient are absent or present in a certain amount or claims about a food that suggests a food may be useful in maintaining healthy dietary practices and which are made with an explicit claim (e.g. "healthy, contains 3 grams of fat") are implied claims and are prohibited unless provided for in a regulation by FDA. In addition, the Agency has devised a petition system whereby specific additional claims may be considered.
- Claims that a food contains or is made with an ingredient that is known to contain a particular nutrient may be made if product is "Low" in or a "Good Source" of the nutrient associated with the claim (e.g. "good source of oat bran").
- Equivalence claims: "contains as much [nutrient] as a [food]" may be made if both reference food and labeled food are "Good Source" of nutrient on a per serving basis.
- The following label statements are generally not considered implied claims unless they are made in a nutrition context:
  - 1) avoidance claims for religious food intolerance or other non-nutrition related reasons (e.g. "100% milk free");
  - 2) statements about non-nutritive substances (e.g. "no artificial colors");
  - 3) added value statements (e.g. "made with real butter");
  - 4) statements of identity (e.g. "corn oil" or "corn oil margarine");
  - and 5) special dietary statements made in compliance with a specific Part 105 provision.

### Terms Covered That Are Not Nutrient Content Claims

"Fresh"	A raw food that has not been frozen, heat processed, or otherwise preserved.
"Fresh Frozen"	Food was quickly frozen while still fresh.



# FSIS BACKGROUND



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

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Media Relations January 1993  
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## Nutrition Labeling of Meat and Poultry Products

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The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) joined in the spring of 1989 with the U.S. Department of Health and Human Services (HHS), Food and Drug Administration (FDA) to reform the food label.

The new labels will help consumers follow the Dietary Guidelines developed by the USDA and HHS. These guidelines emphasize the importance of a well-balanced diet:

- Eat a variety of foods.
- Maintain healthy weight.
- Choose a diet low in fat, saturated fat, and cholesterol.
- Choose a diet with plenty of vegetables, fruits, and grain products.
- Use sugars only in moderation.
- Use salt and sodium only in moderation.
- If you drink alcoholic beverages, do so in moderation.

The new food label marks an enormous collaborative effort:

FSIS is responsible for ensuring accuracy in labeling of meat and poultry products; FDA is responsible for labeling all other foods.

Legislation, named the Nutrition Labeling and Education Act of 1990 (NLEA), required nutrition labeling of foods under FDA jurisdiction. Although the NLEA does not mandate labeling of meat and poultry products, FSIS issued companion regulations for these foods.

FSIS and FDA issued parallel regulations that harmonize as much as possible and that create the most uniform nutrition labels possible for virtually all foods.

## USDA Regulation

On January 6, 1993, USDA issued its final rule on "Nutrition Labeling of Meat and Poultry Products," as did FDA for all other foods. Manufacturers already have begun to redesign their food labels according to the new specifications. The rule becomes effective July 1994, when most processed meat and poultry products must carry the new nutrition label.

### Mandatory Labeling

FSIS requires mandatory nutrition labeling for most meat and poultry products except raw, single-ingredient products. Packages of chili and hot dogs, for instance, must bear nutrition labeling panels.

The label information is based on the product "as packaged." "As packaged" labeling must list information about the nutrients in a serving of food at the time it is purchased, without considering further consumer preparation. The nutrient content of some products, like bacon, may change greatly during preparation. So, a label also may list the information "as consumed," provided that it clearly states preparation and cooking instructions. "As consumed" means the nutritional information is based on the product after it is cooked using common methods, such as oven roasting, that do not add ingredients such as fat, flour, or salt, which could alter the nutrient profile.

FSIS is in the process of reviewing the way it approves labels for meat and poultry products. Until a new system is adopted, the agency will continue to examine and approve every label before the product can enter the marketplace to make sure the nutrient information is accurate.

### Voluntary Labeling

FSIS encourages voluntary nutrition labeling on raw, single-ingredient meat and poultry products, such as beef roasts, raw chicken breasts, and ground beef.

Manufacturers of raw, single-ingredient meat and poultry products who choose to provide nutrition information on the label must adhere to the same requirements of the mandatory program, except that they may declare nutrients based on the product "as consumed" or "as packaged."

FSIS will encourage firms to participate in the voluntary program and will evaluate participation. If 60 percent of evaluated stores are not participating at a significant level in the voluntary program, FSIS plans to initiate proposed rulemaking to determine whether it would be beneficial to require nutrition labeling for raw, single-ingredient products.

*Point-of-purchase materials.* As an alternative to providing nutrition information on the label, manufacturers of meat and poultry products that fall in the voluntary nutrition labeling category also may provide nutrition information through point-of-purchase materials, such as pamphlets, wall posters, and videos.

Nutrition information in point-of-purchase materials is given for meat with external fat or poultry with skin. Optional information may be shown for trimmed meat or poultry without skin.

### Exemptions

FSIS has exempted certain products from the mandatory nutrition labeling provisions. Some of these exemptions are:

- products served in restaurants and other institutions, because consumers won't see the packaging.
- products in small packages weighing less than 1/2 ounce, unless a nutrition claim is made (a modified label is permitted for intermediate-size packages).

- products produced by small businesses, unless a nutrition claim is made. A processed consumer product will be exempt from nutrition labeling if the firm producing it has 500 or fewer employees and produces less than 100,000 pounds of that product a year. This small business exemption will be phased in over a three-year period.
- products produced or packaged at retail, such as sliced bologna.

## The New Nutrition Label at A Glance

### The Front Label

Product claims, such as "low-fat" or "light," on USDA products will be defined by regulation. These definitions ensure that products that carry claims are consistent from manufacturer to manufacturer, and consumers are assured they can believe what they read on the package.

*Nutrient Content Claims* - While descriptive claims like "light" and "low-fat" have long been used on food labels, their meaning—and their usefulness in helping consumers plan a healthful diet—will now be defined in regulations. FSIS has set specific requirements for using the following terms:

- |                  |                |
|------------------|----------------|
| • free           | • light (lite) |
| • less           | • high         |
| • low            | • reduced      |
| • good source of | • lean         |
| • extra lean     | • more         |

For example, if a meat or poultry processor describes an individual food as "low in fat," the food must meet the specific FSIS definition: 3 grams or less of fat per reference amount customarily consumed (RACC). If an individual food is described as "low in calories," it cannot contain more than 40 calories per RACC.

In addition, meat and poultry products can use the terms "lean" or "extra lean" if they meet specific definitions.

*Lean* refers to a serving of meat and poultry with less than 10 grams of fat, less than 4 grams of saturated fat, and less than 95 milligrams of cholesterol per 100 grams.

*Extra lean* refers to meat and poultry with less than 5 grams of fat, less than 2 grams of saturated fat, and less than 95 milligrams of cholesterol per 100 grams.

*Claims in Brand Names* - Often the brand name of a product will use a nutrient content claim—for example, "Lean Cuisine." FSIS permits use of a nutrient content claim in a brand name if the product meets the required definition of the term. A brand name containing a descriptive term that is not defined by the regulation is permitted only if it was in use prior to November 27, 1991 (the date of the proposal). If a firm adopted the brand name after November 27, 1991, it must petition FSIS to use the term.

The word "healthy" and derivatives such as "healthful" or "healthier" often have been used in brand names. FSIS published on January 6, 1993, a proposed rule with request for comments on use of the word "healthy" on the label of a meat or poultry product.

*Health Claims* - FSIS also is studying the use of "health claims," that is, describing a food as low in a nutrient that has been linked to a disease. The description of a food as low in fat, followed by the statement that high fat intake has been linked to a high risk of cancer, would be a health claim. FSIS expects to complete its review of this issue soon, and then will address the issue publicly.

## The Label: Nutrition Guide

Most packaged foods will carry an up-to-date, easy-to-use nutrition information guide that will serve as a key to planning a healthful diet.

### The New Food Label

#### Chili with Beans\*

<b>Nutrition Facts</b>	
Serving Size 1 cup (253 g)	
Servings Per Container 4	
<b>Amount Per Serving</b>	
<b>Calories</b> 260	Calories from Fat 70
<b>% Daily Value*</b>	
<b>Total Fat</b> 8g	<b>13%</b>
Saturated Fat 3g	<b>17%</b>
<b>Cholesterol</b> 130mg	<b>44%</b>
<b>Sodium</b> 1010mg	<b>42%</b>
<b>Total Carbohydrate</b> 22g	<b>7%</b>
Dietary Fiber 9g	<b>36%</b>
Sugars 4g	
<b>Protein</b> 25g	
Vitamin A 35%	• Vitamin C 2%
Calcium 6%	• Iron 30%
* 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	

\* Consult FDA regulation for specific requirements on type size, spacing and other graphic elements.

*Serving Size* - Serving sizes in the new rule are uniform and consistent across product lines, and reflect the average amounts people actually eat. Some serving sizes are listed as ounces—for instance, the serving size for beef steak is three ounces; others are listed in common household measures—for instance, the serving size for chili is one cup.

*List of Nutrients* - The list of nutrients covers those that are currently of public health significance (sodium and fat, for example). Consumers want to know about the levels of these and other nutrients in food products to make dietary choices that benefit their health.

*Calories from Fat* - The number of calories from fat is shown on the label to help consumers meet dietary guidelines that recommend people get only 30 percent of their daily calories from fat.

*Daily Values* - Daily values are also something new. Consumers can use these numbers to evaluate how a food fits into a healthful diet. Because individual dietary needs vary, two daily values are listed on the label as references—one based on a 2,000 calorie diet and the other on a 2,500 calorie diet. The "Daily Values" listing is also an easy way to know at a glance whether the package carries the new food label.

*% Daily Value* - These are numbers consumers can use to evaluate how a food fits into a healthful diet.

## **Compliance**

FSIS monitors labels in the marketplace as part of its regulatory mission. The agency will select products and then analyze the food to make sure the label information is accurate. If the nutrient values of the food do not match the values on the label, FSIS will notify the company, which must either change the label or provide data that support the label information listed. Companies must keep records on their nutrient analyses and/or recipe calculations.

## **Public Education Activities**

A new food label is only as beneficial as the ability of consumers to understand and use it. FSIS and FDA are committed to helping consumers learn how to read the new label and use it to choose a healthful diet.

The agencies are coordinating a public and private sector "National Exchange for Food Labeling Education (NEFLE)" to help educate the American public about nutrition labeling. NEFLE includes representatives from Government, and health, consumer, industry, and educational groups. These groups bring varied resources to the massive public education campaign. For instance, health organizations share information and materials on labeling education activities through a central network at USDA's National Agricultural Library; USDA and FDA conduct periodic surveys to identify consumers' knowledge and attitudes toward health and nutrition; and USDA is developing consumer brochures on the food label through the FSIS Office of Consumer Education.



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**Consumer Inquiries:**

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1-800-535-4555  
(in the Washington, D.C. area,  
call 202-720-3333)



**CHANGES AS A RESULT OF THE  
NEW NUTRITION LABELING REGULATIONS**

**January 6, 1993**

Food Safety and Inspection Service

Department of Agriculture

Washington, DC

**CHANGES AS A RESULT OF THE  
NUTRITION LABELING REGULATIONS**

Rescind Now	Follow Until July 6, 1994*	Follow Until July 6, 1994**
074A	007	016A
085B	039	019A
	046A	114
	049D	121A
	070C	069
	071B	
	078A	
	086A	
	121A	

\* These policy memoranda will be rescinded on July 6, 1994.

\*\* These policy memoranda will be revised on July 6, 1994.



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

6 JAN 1993

To: Branch Chiefs, FLD

Policy Memo 046A

From: Ashland L. Clemons, Director  
Food Labeling Division  
Regulatory Programs

Subject: Percent Fat Free Label Declarations

**ISSUE:** Requirements for the approval of percent fat free declarations.

**POLICY:** This policy memo replaces Policy Memo 046. Percent fat free statements, e.g., "95% Fat Free," are acceptable on product labels if the labels also bear a positive declaration of the product's fat content, e.g., "contains 5% fat." This percent fat statement should be contiguous to the percent fat free statement and be displayed in a prominent manner.

The percent fat free statement and the accompanying statement of the fat content are considered representations of the fat content of the product only and do not necessarily represent the fat free portion as lean material. Thus, concomitant claims of the lean content, such as "95% Lean," will be closely scrutinized.

**RATIONALE:** These guidelines are issued to identify the policy the meat and poultry industry may use for the labeling of percent fat free information during the period between the promulgation of the nutrition labeling regulations (January 6, 1993) and its implementation date (July 6, 1994). The guidelines essentially reflect policy that has been applied to percent fat free labeling for a number of years, with the exception that the requirements for data submission at the time of label approval and the need for a Nutrition Labeling Verification procedure or Partial Quality Control program have been deleted. The Agency believes that it is necessary to remove these requirements so that the industry may devote existing resources to the development of the nutritional information needed to comply with the new nutrition labeling regulations.



6 JAN 1993

To: Branch Chiefs, FLD

Policy Memo 049D

From: Ashland L. Clemons, Director  
Food Labeling Division  
Regulatory Programs

Subject: Sodium Labeling Guidelines

**ISSUE:** What guidelines should be followed in the review and approval of labeling which includes sodium and/or salt information?

**POLICY:** This policy memo replaces Policy Memo 049C.

1. The label of any meat or poultry product may bear quantitative information on the amount of sodium in a serving of the product. When this information is provided, the serving size must appear on the label and must be within the range of serving sizes customarily used for that product. Sodium content information may be included without other nutrition information.
2. Quantitative information on sodium content shall be declared in terms of milligrams (mg) per serving of the product. The sodium content shall be expressed as zero when the serving contains less than 5 mg, to the nearest 5 mg increment when the serving contains 5 to 140 mg of sodium, and to the nearest 10 mg increment when the serving contains greater than 140 mg of sodium.
3. Nutrition labeling does not require the inclusion of sodium content information. However, if sodium content information is included on the nutrition information panel of a meat or poultry product, the sodium content information must immediately follow the information on fat content (or, if provided, any information on fatty acid and/or cholesterol content).
4. When a claim is made about the sodium and/or salt content of a product, the label of the product must bear quantitative information on the sodium content in a serving of the product.
5. "Very Low Sodium" may be applied only to products that contain 35 mg or less of sodium per serving. "Low Sodium" may be applied only to products that contain 140 mg or less

of sodium per serving. "Sodium Free" and similar terms may be applied only to products that contain less than 5 mg of sodium per serving. "Salt Free" and similar terms may be applied only to products that qualify to be labeled "Sodium Free."

6. "Unsalted" or "No Salt Added" or "Without Added Salt" or an equivalent term may be applied to products only if: (1) no salt is added during processing and no ingredient contains salt (sodium chloride), and (2) the product that it resembles and for which it substitutes is normally processed with salt.

7. "Reduced Sodium" may be applied only to those products which have been formulated to serve as and are represented as direct replacements for foods containing at least four times the sodium content (75 percent reduction). The label of the product shall provide quantitative information comparing the sodium content per serving of the reduced product with that of an equivalent serving of the product it replaces. This information should be in immediate conjunction with the claim or referenced by an asterisk.

8. A comparative sodium content claim may not be made unless: (1) a product's sodium content is at least 25 percent less than that of the appropriate product(s) with which it is compared, and (2) the comparative claim is accompanied by (in immediate conjunction with the claim or referenced by an asterisk) an identification of the product(s) with which the comparison is being made and a quantitative statement of the relative or absolute difference in sodium content per serving (using equivalent serving sizes) of the product(s) being compared. Examples of such claims would be "This bologna has 25% less sodium per serving than our regular bologna," or "This bologna contains 125 mg less sodium per serving than the three leading brands of bologna." While a 25 percent reduction in sodium is necessary in order to make such comparative claims, companies are encouraged to decrease the sodium content of their products in lesser amounts and, if necessary, incrementally as experience is gathered.

**RATIONALE:** These guidelines are issued to identify the policy the meat and poultry industry may use for the labeling of sodium information during the period between the promulgation of the nutrition labeling regulations (January 6, 1993) and its implementation date (July 6, 1994). The guidelines essentially reflect the policy that has been applied to sodium information labeling for a number of years, with the exception that the requirements for data submission at the time of label approval and the need for a Nutrition Labeling Verification procedure or Partial Quality Control program have been deleted. The Agency believes that it is necessary to remove these requirements so

that the industry may devote existing resources to the development of the nutritional information needed to comply with the new nutrition labeling regulations.





United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

6 JAN 1993

To: Branch Chiefs, FLD

Policy Memo 070C

From: Ashland L. Clemons, Director  
Food Labeling Division  
Regulatory Programs

Subject: Fat and Lean Claims

**ISSUE:** What are the guidelines for the review and approval of labeling claims relating to the fat and lean content of meat and poultry products?

**POLICY:** This policy memo replaces Policy Memo 070B. Emphatic expressions of the lean content of a meat or poultry product, e.g., "lean," "extra lean," and "low fat," and comparative expressions of lean or fat content, e.g., "leaner," "lower fat," "less fat," may be used in the labeling of meat and poultry products.

"Low Fat" may be used only for those products that contain no more than 10 percent fat. "Lean" may be used only for those products that contain no more than 10 percent fat except for ground beef and hamburger. "Extra lean" may be used only for those products that contain no more than 5 percent fat except for ground beef and hamburger. In each case, the actual amount of fat in the product must be disclosed, e.g., "contains 4 percent fat" and either accompany the claim or be referenced by means of an asterisk and placed elsewhere on the principal display panel, on the information panel, or be included as a part of other nutrition information.

When ground beef and hamburger are labeled as "lean" or "extra lean," they must have at least a 25 percent reduction in fat from the regulatory standard of 30 percent fat (i.e., they can contain no more than 22.5 percent fat). In each case, the actual fat percentage and the lean percentage must either accompany the claim or be referenced by means of an asterisk and placed elsewhere on the principal display panel. For example, 20 percent fat ground beef could be labeled "Lean Ground Beef, Contains 80 percent Lean and 20 percent Fat." Ground beef or hamburger, not labeled as "lean" or "extra lean," may continue to be labeled with a fat percentage (i.e., Contains 20 percent Fat). However, ground beef and hamburger may not be labeled

with only a lean percentage. A fat percentage must accompany any claim about the lean content. In all cases, the fat percentage must be in lettering of the same size, type, and on the same background as the lean percentage.

Comparative expressions of the lean or fat content of products may be used only if there is at least a 25 percent reduction or difference in fat or lean content from (1) the amount of fat permitted by an applicable standard if the amount of fat identified by the standard is representative of the majority of the products in the marketplace, e.g., a comparison to the pork sausage standard would not be permitted because market-basket surveys have shown that the average fat content of pork sausage is approximately 40 percent and not close to the 50 percent fat allowed by the standard, (2) the amount of fat in a market-basket survey of comparable products, or (3) the amount of fat in a similar product or class of products as found in recent applicable references such as the revised editions of Composition of Foods - Agriculture Handbook No. 8. An explanation that includes quantitative information about the fat or lean content of the lower fat product and a comparison of its fat or lean content to any of the above references must also be included on the labeling. For example, the explanation for a product labeled "Leaner Italian Sausage" might be "This product contains 24 percent fat, which is 30 percent less fat than allowed by the USDA standard for Italian Sausage."

Fanciful names, brand names, and trademarks often include lean terms. In the case of frozen dinners and entrees, the terms are assumed to represent these products as useful in the reduction or maintenance of body weight. An example is "Lean Cuisine." When such terms are used for this purpose, the products must be nutritionally labeled in accordance with Policy Memo 039. In other situations where the terms are included in fanciful names, brand names, and trademarks to convey the leanness of a product or a substantial reduction in fat, the explanation for comparative expressions of lean or fat content described therein is required unless the products meet the definitions for "lean," "extra lean," or "low fat."

All products with claims about the lean content will be closely examined to assure that the products became leaner due to the replacement of fat by lean material, i.e., indigenous meat or poultry protein and the natural moisture associated with the protein. In situations where a fat content declaration would not accurately reflect the lean content of the product, a statement that discloses the actual amount of lean material in the leaner product expressed as the percent lean material or percent protein may be needed, e.g., "50 percent leaner than average \_\_\_\_\_ -- contains 25 percent protein." These statements may accompany the claim or be referenced by means of

an asterisk and placed elsewhere on the principal display panel or on the information panel.

Generally, the emphatic claims "lean" and "extra lean" will be limited to products composed solely of fat and lean material with no added substances such as water or extenders. In those limited situations where it can be demonstrated that the product before and after the addition of any added substances contained no more than 10 percent or 5 percent fat, as the case may be, the emphatic claims may be used. For example, a ham and water product could not be labeled "lean" if it contained 10 percent fat, since the product became lean by dilution with water and other added substances. However, if the meat portion contained no more than 10 percent fat before processing, the product could be labeled "lean."

The policy of allowing on the labeling of whole cuts or parts of meat or poultry terms such as "lean" and "extra lean" if stated in the possessive and accompanied by a guarantee statement has been withdrawn. These products must meet the definitions for use of these terms. Comparative terms, e.g., "leaner," "lower fat," etc., may be used if there is at least a 25 percent decrease in fat or increase in lean content of the product. In this case, a comparative explanation as described above is required.

The terms "lean," "50/50," and other similar designations which are used as meat industry trade terms to designate the leanness of meat for further processing are acceptable without an explanation as required by this policy memo. However, when the lean or fat content is expressed as a true percentage, the company must either add contiguous to the product name the phrase, "For Further Processing," or some similar designation that indicates the product is to be further processed.

**RATIONALE:** These guidelines are issued to identify the policy the meat and poultry industry may use for the labeling of fat and lean claims during the period between the promulgation of the nutrition labeling regulations (January 6, 1993) and its implementation date (July 6, 1994). The guidelines essentially reflect the policy that has been applied to fat and lean claims for a number of years, with the exception that the requirements for data submission at the time of label approval and the need for a Nutrition Labeling Verification procedure or Partial Quality Control program have been deleted. The Agency believes that it is necessary to remove these requirements so that the industry may devote existing resources to the development of the nutritional information needed to comply with the new nutrition labeling regulations.

Labeling claims concerning a product's fat or lean content can be informative and useful to consumers in making food choices. Processors producing products with reduced amounts of fat or using leaner meat or poultry ingredients should be able to label their products to indicate this characteristic. A claim alone without some explanation of its meaning may be misleading and, in most cases, does not provide the information necessary to make a value judgment. The explanation accompanying most claims must be designed to enable the consumer to make a comparison. In some cases, a disclosure of only the fat or lean content will provide the necessary information.

Definitions are being established for "lean" and "extra lean" (except for ground beef and hamburger) as well as "low fat" since they are absolute terms which have taken on increasing importance to the consumer in recent years. "Lean" and "low fat" are comparable in meaning and are given the same definition. "Extra lean" is given a more strict definition because consumers would expect a product so labeled to have less fat than a product labeled "lean" or "low fat."

Because of the history of successful State and local regulation of the meaning of "lean" and "extra lean" ground beef and hamburger, the absolute definitions established are not considered necessary. The State and local requirements do vary, but by stating the fat and lean content of the product, such labeling will assure that consumers do not mistakenly believe that "lean ground beef" contains no more than 10 percent fat.

The policy allowing only a reduction to 25 percent fat (a 17 percent reduction) for products that may contain no more than 30 percent fat has been withdrawn. It was recognized that this was an anomaly and it is preferable to be consistent with other policies both within this Agency and the Food and Drug Administration that require a 25 percent reduction in some component before a claim can be made.

The longstanding policy of allowing the use of fat and lean claims if stated in the possessive and accompanied by a guarantee statement has been withdrawn. The widespread interest in fat and its relation to diet demands that quantitative information be available to the consumer. Furthermore, the policy had only limited application, and it is important to have a consistent approach for all products in order to avoid confusion and promote consumer understanding.

The comparisons to leading brands, a leading brand, or the company's regular product are not being permitted in the interest of eliminating comparisons that have limited value. In some cases, the leading brand or regular product was not marketed in the same areas as the "leaner" or "lower fat"

product and these comparisons were of limited value to consumers. Also, the leading brand or regular product comparisons provide information which often is not representative of most products in the marketplace.

The term "Lean," when used by industry to describe red meat should not be confused with other uses outlined in this policy memo. We have recognized that this usage of lean is very common among industry and is instrumental as both an inhouse means of identifying product and as a way to describe product shipped to other plants to be further processed into a formulated product. Indicating fat and lean by use of a ratio (e.g., 50/50) is also a practice which has been used by industry for years. We have always regarded this as an estimate of the amount of lean material, and have never imposed the requirements of supportive data or quality control.

Percent labeling of an ingredient or component will no longer require implementation of a quality control program to assure ongoing accuracy of the label information. However, addition of a qualifier showing that the product is to be used for further processing should satisfy industry's need for the term, while distinguishing it from retail product marketed as "Lean."



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and Inspection  
Service

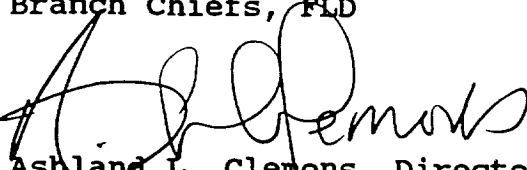
6 JAN 1993

To:

Branch Chiefs, FLD

Policy Memo 071B

From:

  
Ashland L. Clemons, Director  
Food Labeling Division  
Regulatory Programs

Subject:

Lite and Similar Terms

**ISSUE:** What are the guidelines for the review and approval of labeling terms such as "Lite," "Light," "Lightly," and similar terms?

**POLICY:** This policy memo replaces Policy Memo 071A. Terms such as "Lite," "Light," "Lightly" may be used on the labels of meat and poultry products. Such terms generally imply that a product has significantly fewer calories than expected in a similar product but often are used to relate that a product has significantly less fat, salt, sodium, breeding and/or other components than a similar product. A significant reduction is considered to be at least 25 percent. In the case of a salt reduction, the sodium content must also be reduced by at least 25 percent (see Policy Memo 049D).

If used, the terms generally must be explained either adjacent to the term or referenced by means of an asterisk and placed elsewhere on the principal display panel or on the information panel. The explanation must provide to the purchaser quantitative information about the amount of calories, fat, salt, sodium and/or other components in the product and include a quantitative comparison to (1) the amounts permitted by an applicable standard if the amount identified by the standard is representative of the majority of the products in the marketplace, e.g., a comparison to the fat content of the pork sausage standard would not be permitted because market-basket surveys have shown that the average fat content of pork sausage is approximately 40 percent and not close to the 50 percent fat allowed by the standard, (2) the amounts found in a market-basket survey of comparable products, or (3) the amounts in a similar product or class of products as found in recent applicable reference sources such as the revised editions of Composition of Foods -- Agriculture Handbook No. 8.

For products that are unquestionably low in calories, fat, salt, breading, or sodium, the explanation required to accompany such terms need only consist of a disclosure of the actual amount in the product. For this purpose, the amount of calories can be no more than 40 calories per serving and no more than 0.4 calories per gram of product. For fat and breading, the product can contain no more than 10 percent. For salt and sodium, the product can contain no more than 35 mg of sodium per 100 grams of product.

Fanciful names, brand names, and trademarks often include lite terms. In the case of frozen dinners and entrees, the terms are assumed to represent these products as useful in the reduction or maintenance of body weight. An example is "Dining Lite." When such terms are used for this purpose, the products must be nutritionally labeled in accordance with Policy Memo 039. In other situations where the terms are included in fanciful names, brand names, and trademarks to convey the leanness of a product or a substantial reduction in fat, the explanation for comparative expressions of fat content described above is required. Those products containing no more than 10 percent fat may provide a declaration of fat content as the explanatory statement.

**RATIONALE:** These guidelines are issued to identify the policy the meat and poultry industry may use for the labeling of "Lite" and similar terms during the period between the promulgation of the nutrition labeling regulations (January 6, 1993) and its implementation date (July 6, 1994). The guidelines essentially reflect the policy that has been applied to "Lite" and similar terminology for a number of years, with the exception that the requirements for data submission at the time of label approval and the need for a Nutrition Labeling Verification procedure or Partial Quality Control program have been deleted. The Agency believes that it is necessary to remove these requirements so that the industry may devote existing resources to the development of the nutritional information needed to comply with the new nutrition labeling regulations.

Labeling claims that include terms such as "Lite," "Light," "Lightly," and similar terms which imply that a product has reduced levels of various components can be informative and useful to consumers in making food choices. Processors making products with reduced amounts of various components should be able to indicate this characteristic on labeling. A claim alone without some explanation of its meaning may be misleading and certainly does not provide the information necessary for consumers to make informed judgments. The explanation accompanying most claims must be designed to enable the consumer to make a comparison. In some cases where a product is

unquestionably low in various components, a disclosure of only the absolute amount will provide the necessary information.

The policy of allowing a reduction to only 25 percent fat (a 17 percent reduction) for products that may contain no more than 30 percent fat is being withdrawn. It is recognized that this was an anomaly and it is preferable to be consistent with other policies both within this Agency and the Food and Drug Administration that require a 25 percent reduction in some components before a claim may be made.

The comparisons to leading brands, a leading brand, or the company's regular product are no longer being permitted in the interest of eliminating comparisons that have limited value. In some cases, the leading brand or regular product was not marketed in the same areas as the "lite" product and these comparisons were of limited value to consumers. Also, comparisons to the leading brand or regular product provide information which often is not representative of most products in the marketplace.

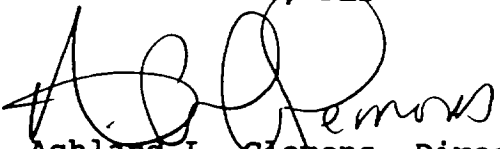




6 JAN 1993

To: Branch Chiefs, FLD

Policy Memo 078A

From:   
Ashland L. Simons, Director  
Food Labeling Division  
Regulatory Programs

Subject: Potassium Labeling Guidelines

**ISSUE:** What guidelines should be followed in the review and approval of labeling which includes potassium information?

**POLICY:** This policy memo replaces Policy Memo 078.

1. The label of any meat or poultry product may bear quantitative information on the amount of potassium in a serving of the product. When this information is provided, the serving size must appear on the label and must be within the range of serving sizes customarily used for that product. Potassium and sodium content information may be included without other nutrition information. Labels may not bear nutrition information on potassium content alone.
2. Quantitative information on potassium content shall be declared in terms of milligrams (mg) per serving of the product. The potassium content shall be expressed as zero when the serving contains less than 5 mg, to the nearest 5 mg increment when the serving contains 5 to 140 mg of potassium, and to the nearest 10 mg increment when the serving contains greater than 140 mg of potassium.
3. Nutrition labeling does not require the inclusion of potassium content information. However, if potassium content information is included on the nutrition information panel of a meat or poultry product, the potassium content information must immediately follow the information on sodium content.

**RATIONALE:** These guidelines are issued to identify the policy the meat and poultry industry may use for the labeling of potassium information during the period between the promulgation of the nutrition labeling regulations (January 6, 1993) and its implementation date (July 6, 1994). The guidelines essentially reflect the policy that has been applied to potassium information labeling for a number of years, with the exception that the requirements for data submission at the time of label

approval and the need for a Nutrition Labeling Verification procedure or Partial Quality Control program have been deleted.  
The agency believes that it is necessary to remove these requirements so that the industry may devote existing resources to the development of the nutritional information needed to comply with the new nutrition labeling regulations.



6 JAN 1993

To: Branch Chiefs, FLD

Policy Memo 086A

From: Ashland L. Clemons, Director  
Food Labeling Division  
Regulatory Programs

Subject: Nutrition Labeling

**ISSUE:** What are the guidelines for the approval of nutrition labeling on meat and poultry products?

**POLICY:** This policy memo replaces Policy Memo 086 dealing with nutrition labeling. The following guidelines are currently being used in the review and approval of nutrition label information when it is voluntarily provided by the processor or when it is required due to the presence of labeling claims or features relating to calorie content and weight control (see Policy Memo 039). Nutritional information may appear on the label's principal display panel or information panel (see Policy Memo 007 on uses of the information panel).

Nutrition information may be presented in the format and style provided by FDA regulations prior to recently issued nutrition labeling regulations (see enclosed example). The format includes the following information presented in this order: the size of one serving presented in common household measures or recognized portions such as cups, ounces, slices, pieces, etc.; the number of servings or portions per container; the number of calories per serving/portion, the number of grams of protein, carbohydrates, and fat per serving/portion; and the percent of the U.S. Recommended Daily Allowance (U.S. RDA) of protein, vitamin A, vitamin C, thiamine, riboflavin, niacin, calcium, and iron per serving/portion. Inclusion of the B vitamins (thiamine, riboflavin, and niacin) in the FDA nutrition format is optional for labeling meat and poultry products.

An abbreviated format is also accepted for labeling meat and poultry products. This format includes the number of calories and the number of grams of protein, carbohydrate, and fat in a specified serving or portion of the product and the servings or portions per container.

Both nutrition labeling formats may be supplemented with information on other nutrients that may be of interest to consumers. Examples include: fatty acid composition reported in grams per serving/portion, milligrams of cholesterol reported in 5mg increments and sodium information reported according to the guidelines in Policy Memo 049D. When the FDA nutrition labeling format is used, information on the percent of the U.S. RDA of additional vitamins and minerals, such as vitamin D and vitamin E, may be included. Other means of presenting nutrition information will also be considered.

**RATIONALE:** On January 6, 1993, the Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) published final regulations setting forth requirements for the mandatory nutrition labeling of most foods under their respective jurisdictions. Among other things, these regulations provide for the voluntary disclosure of the B vitamins (thiamine, riboflavin, and niacin) because public health concerns for deficient intakes of these vitamins have lessened over the last 20 years. Thus, inclusion of these three nutrients in nutrition labeling is not considered necessary to assist consumers in maintaining healthy dietary practices.

FSIS has historically disseminated its nutrition labeling guidelines for meat and poultry products through the issuance of various policy memoranda by its Food Labeling Division (FLD). Policy Memo 086 entitled Nutrition Labeling, which is the subject of this revision, provided for the disclosure of nutrition information in the format and style described in FDA regulations prior to the recent issuance of nutrition labeling regulations for required components. This memorandum also permitted an abbreviated labeling format for the nutrient content of meat and poultry products that included, calories, protein, carbohydrates, fat, and/or sodium. This revision continues this practice until the effective date of the aforementioned final rule, which is July 6, 1994.

The policy memos that relate in whole or in part to nutrition-related information will be rescinded or revised because of this final rule. Policy Memo 074A, dated November 1986, Exemptions from NLV or PQC, and Policy Memo 085B, dated January 1988, NLV Procedures, will no longer be in effect upon promulgation of this final rule. Policy Memo 086, dated May 1985, Nutrition Labeling, Policy Memo 046, dated April 1982, Percent Fat Free Label Declarations, Policy Memo 049C, dated June 1984, Sodium Labeling Guidelines, Policy Memo 070B, dated November 1987, Fat and Lean Claims, Policy Memo 071A, dated March 1986, Lite and Similar Terms, Policy Memo 078, dated November 1984, Potassium Labeling Guidelines, and Policy Memo 121, dated May 1991, Labeling of Low Fat Ground Beef and Low Fat Hamburger Containing Added Ingredients, will remain in effect during the 18-month

period between the date of publication and the effective date of this final rule, except that the provisions relating to data requirements and requirements for an NLV procedure or Partial Quality Control Program will not be enforced. Policy Memo 007, dated August 1980, Information Panel, and Policy Memo 039, dated January 1982, Caloric Claims/Weight Reduction, will remain in effect during the interim period but will be rescinded just before or upon the effective date of this final rule. Policy Memo 016A, dated March 1981, Combinations of Ground Beef or Hamburger and Soy Products, Policy Memo 069, dated March 1984, Labeling for Substitute Products, Policy Memo 019A, dated May 1987, Negative Labeling, and Policy Memo 114, dated July 1988, Point of Purchase Materials, will remain in effect during the interim period but will be revised just before or upon the effective date of this final rule. Thus, companies desiring to continue declaring nutrition-related information on labels in accordance with existing policy memoranda may do so until the effective date, which is July 6, 1994.

Official establishments desiring to continue declaring nutrition-related information on labels in accordance with the above policy memoranda may do so until the effective date of the final nutrition labeling regulation. At or before that time, all of the memoranda listed above will be rescinded or revised and any new labels or other labeling would then be required to conform to the provisions of the final rule. During this interim period, however, labels must conform either to policies established in the above-cited policy memoranda or the new regulations, but not both. In other words, no combinations may be allowed.

Enclosure

Enclosure

**Nutrition Information Per Serving/Portion**

**Serving/Portion Size:**  
**Servings/Portions Per Container:**  
**Calories:**  
**Protein:**  
**Carbohydrate:**  
**Fat:**  
**Sodium:**

**Percentage of U.S. Recommended  
Daily Allowance (U.S. RDA)**

<b>Protein</b>	<b>Riboflavin (optional)</b>
<b>Vitamin A</b>	<b>Niacin (optional)</b>
<b>Vitamin C</b>	<b>Calcium</b>
<b>Thiamine (optional)</b>	<b>Iron</b>



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

6 JAN 1993

To: Branch Chiefs, FLD

Policy Memo 121A

From: Ashland L. Clemons, Director  
Food Labeling Division  
Regulatory Programs

Subject: Labeling of Low Fat Ground Beef and Low Fat  
Hamburger Containing Added Ingredients

**ISSUE:** How should low fat products which substitute for ground beef and hamburger be labeled, and what other requirements are necessary to obtain label approval and use of final labels?

**POLICY:** This policy memo replaces Policy Memo 121.

Low fat products which combine hamburger or ground beef and other nonfat ingredients may be descriptively labeled, e.g., "Low Fat Ground Beef With a X% Solution of ..." or "Low Fat Hamburger, Water, and Carrageenan Product." A combination product which is not low fat is to be labeled as Imitation Ground Beef (or Hamburger) or Beef Patty or Beef Patty Mix in accordance with 9 CFR Section 317.2(j)(1) and Section 319.15(c), respectively. Descriptively labeled low fat combination products should comply with the following guidelines:

(1) The finished product may contain no more than 30 percent of a combination of fat and added substances and no more than 10 percent fat.

(2) The product includes nutrition labeling that provides, at a minimum, serving (portion) size, servings (portions) per container (if appropriate), total calories, calories from fat, protein, carbohydrates, total fat, saturated fat, and sodium.

(3) Words in the descriptive name may be of a different size, style, color, or type but, in all cases, the words must be prominent, conspicuous, and legible. Moreover, no word in the descriptive name should be printed in letters that are less than one-third the size of the largest letter used in any other word in the descriptive name. The solution statement, when used, is considered to be part of the descriptive product name and must comply with descriptive name sizing requirements.

(4) If percentage labeling is included as part of the product name, e.g., "Low Fat Ground Beef With a X% Solution of ...," a Partial Quality Control (PQC) program for the addition of solutions must be approved before the label can be used.

**RATIONALE:** These guidelines are issued to identify the policy the meat and poultry industry may use for the labeling of low fat ground beef products containing added ingredients during the period between the promulgation of the nutrition labeling regulations (January 6, 1993) and its implementation date (July 6, 1994). The guidelines essentially reflect the policy that has been applied to the labeling of low fat ground beef products containing added ingredients for a number of years, with the exception that the requirements for data submission at the time of label approval and the need for a Nutrition Labeling Verification procedure have been deleted. The Agency believes that it is necessary to remove these requirements so that the industry may devote existing resources to the development of the nutritional information needed to comply with the new nutrition labeling regulations.

This policy allows flexibility in developing and marketing low fat products that may be substituted for ground beef and hamburger while maintaining the product's nutritional quality. The policy provides labeling that informs the public of the actual characteristics of the products and is in keeping with the Department's policy on descriptive labeling. Since the combination foods differ from regular hamburger and ground beef with regard to moisture content and fat content, it is important that nutrition information be included with labeling so that the consumer can make better comparative nutritional judgments.

This policy memo provides further guidance for compliance with Section 317.2(b). The intent of this policy is consistent with Policy Memo 087A regarding word size in labeling of product names.

The need for a Partial Quality Control program is consistent with the Department's policy regarding percentage labeling.

The policy permits the use of added nonfat ingredients as fat replacement.





**NUTRIENT  
CONTENT  
CLAIMS**

## Nutrient Content Claims

### "Added" ("More")

Contains at least 10% or more of the RDI for protein, vitamins, or minerals, or the DRV for dietary fiber or potassium

#### Brand names

1. Nutrient content claims not defined cannot be used.
2. Nutrient content claims not defined but used in the brand name before November 26, 1991 may continue to be used, provided they are not false or misleading.
3. Defined nutrient content claims must meet definition.

### "Contains" ("Good Source"/"Provides")

10-19% of the RDI or DRV.

### "Excellent source of" ("High"/"Rich in")

20% or more of the RDI or DRV.

#### Expressed nutrient content claim

Any direct statement about the level (or range) of a nutrient in the food ("low sodium" or "contains 100 calories").

### "Extra Lean"

Less than 5 grams fat,  
Less than 2 grams saturated fat,  
Less than 95 milligrams cholesterol;

Per 100 grams and RACC for individual foods

Per 100 grams and labeled serving for meal-type products

### "Fewer"- ("Less")

- relative claim
- 25% reduction
- reference food may be a dissimilar food within a product category that can generally be substituted for one another, or a similar food
- the nutrient value for the reference food may be from a valid data base, an average value from the top three national (or regional) brands, a market basket norm, a market leader, or the manufacturer's regular product.
- label must state the identity of the reference food and the percentage (or fraction) the nutrient has changed must appear in immediate proximity to the most prominent claim
- quantitative information comparing the levels of the nutrient may appear next to the most prominent claim, or on

the information panel

### Fiber

If a claim is made on a food that is not "low" in total fat, the label shall disclose the level of total fat per labeled serving in immediate proximity to the claim in type size no less than one-half the size of the claim.

### "Good Source" ("Contains"/"Provides")

10-19% of the RDI or DRV

### "High" ("Rich in"/"Excellent source of")

20% or more of the RDI or DRV

### Implied nutrient content claim

1. Describes the food or an ingredient in a manner that suggests that a nutrient is absent or present in a certain amount.
2. Suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices.

### "Lean"

Less than 10 grams fat,  
Less than 4 grams saturated fat,  
Less than 95 milligrams cholesterol;

Per 100 grams and RACC for individual foods

Per 100 grams and labeled serving for meal-type products

### "Less"- ("Fewer")

- relative claim
- 25% reduction
- reference food may be a dissimilar food within a product category that can generally be substituted for one another, or a similar food
- the nutrient value for the reference food may be from a valid data base, an average value from the top three national (or regional) brands, a market basket norm, a market leader, or the manufacturer's regular product.
- label must state the identity of the reference food and the percentage (or fraction) the nutrient has changed must appear in immediate proximity to the most prominent claim
- quantitative information comparing the levels of the nutrient may appear next to the most prominent claim, or on the information panel

### "Light" ("Lite") -

- relative claim
- reference food shall be a similar food
- \* - the nutrient value for the reference food may be from a valid data base, an average value from the top three national (or regional) brands, a market basket norm, or a market leader.
- label must state the identity of the reference food and the percentage (or fraction) the nutrient has changed must appear in immediate proximity to the most prominent claim
- quantitative information comparing the levels of the nutrient may appear next to the most prominent claim, or on the information panel

Definition for individual foods-

1.  $\geq$  50% calories from fat, fat content reduced by 50%
2.  $<$  50% calories from fat, fat content reduced by 50% and calories reduced by 33%
3. A "low" calorie ( $\leq$ 40), "low" fat ( $\leq$ 3g), sodium reduced by 50%.

Definition for meals-

1. "Low in calories"
2. "Low in fat"
3. "Light" in the brand name of foods may describe the sodium content if the sodium is reduced by 50% and the term "light" is qualified by the statement "light in sodium".

"Meal-type Product"

Makes a significant contribution to the diet by weighing at least 6 but no more than 12 oz., contains ingredients from 2 of the 4 food groups, and is represented as, or is in a form commonly understood to be a breakfast, lunch, dinner, meal, main dish, entree, or pizza.

"More" - ("Added")

Contains at least 10% or more of the RDI for protein, vitamins, or minerals, or the DRV for dietary fiber or potassium.

Prominent Location -

1. A claim on the PDP adjacent to the statement of identity.
2. A claim elsewhere on the PDP.
3. A claim on the information panel.
4. A claim elsewhere on the label or labeling.

"Provides"("Good source"/"Contains") - 10-19% of the RDI or DRV.

"Reduced" -

- relative claim
- 25% reduction
- reference food shall be a similar food

the nutrient value for the reference food may be from a valid data base, an average value from the top three national (or regional) brands, a market basket norm, a market leader, or the manufacturer's regular product.

- label must state the identity of the reference food and the percentage (or fraction) the nutrient has changed must appear in immediate proximity to the most prominent claim
- quantitative information comparing the levels of the nutrient may appear next to the most prominent claim, or on the information panel

#### Relative claims -

- includes "light", "reduced", and "less" (or "fewer")
- label must state the identity of the reference food and the percentage (or fraction) the nutrient has changed must appear in immediate proximity to the most prominent claim
- quantitative information comparing the levels of the nutrient may appear next to the most prominent claim, or on the information panel

#### Type size -

1. Nutrient Content Claim - type size and style no larger than two times that of the statement of identity.
2. Reference Statement (the identity of the reference food and the percent or fraction that the nutrient was reduced)- easily legible boldface print or type, in distinct contrast to other printed or graphic matter, that is no less than that required for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch.
3. "Light" in the brand name

#### "Rich in" ("Excellent source of"/"High")

20% or more of the RDI or DRV.

## NUTRIENT CONTENT CLAIMS IN MEALS

NUTRIENT	FREE	LOW	REDUCED/LESS/FEWER	OTHER
	<p>Synonyms for "Free": "Free of," "No," "Zero," "Without," "Trivial source of," "Negligible source of," "Dietarily insignificant source of"</p> <p>Exception: "Sugarless," "Nonfat"</p>	<p>Synonyms for "Low": "Contains a small amount of," "Low source of," "Low in"</p> <p>Exception: "Little sodium," "Few" for calories, "Little fat," "A little saturated fat," "Little cholesterol"</p>	<p>Synonyms for "Reduced/Less/Fewer": "Reduced in," "Lower," "Lower in"</p>	
Calories	Not Defined	≤120/100 grams	≥25% fewer/100 grams	
Sodium	<p>&lt;5mg/Labeled Serving</p> <p>"Salt Free" may be used if food is "Sodium Free"</p>	≤140mg/100 grams	≥25% fewer/100 grams	<p>"Very Low Sodium"</p> <p>"Very Low in Sodium"</p> <p>≤35 mg/100 grams</p>
Total Fat	<0.5g/Labeled Serving	<p>≤3 g/100 grams</p> <p>and &lt; 30% calories from fat</p>	≥25% fewer/100 grams	<p>"__% Fat Free" must meet "low fat" criteria</p> <p>"__% Lean" must meet "low fat" criteria</p>
Saturated Fat	<p>&lt;0.5g/Labeled Serving</p> <p>and Level of trans fatty acids &lt;1% Total Fat</p>	<p>≤1 g/100 grams</p> <p>and &lt;10% calories SFA</p>	≥25% fewer/100 grams	
Cholesterol	<p>&lt;2 mg/Labeled Serving</p> <p>and ≤2g SFA/Labeled Serving</p>	<p>&lt;20 mg/100 grams</p> <p>and ≤2g SFA/100 grams</p>	<p>≥25% fewer/100 grams</p> <p>and ≤2g SFA/100 grams</p>	
Sugar	<0.5g/Labeled Serving	Not defined	≥25% fewer/100 grams	<p>"No added sugar," "Without added sugar," "No sugar added" if no amount of sugar, or ingredient that functionally substitutes for added sugars, is added, the product does not contain ingredients containing added sugars, and the food declares (unless it meets definition that) it is not "low calorie" or "reduced calorie."</p>

## NUTRIENT CONTENT CLAIMS FOR FOODS

NUTRIENT	FREE	LOW	REDUCED/LESS/FEWER	OTHER
	<p>Synonyms for "Free": "Free of," "No," "Zero," "Without," "Trivial source of," "Negligible source of," "Dietarily insignificant source of"</p> <p>Exception: "Sugarless," "Nonfat"</p>	<p>Synonyms for "Low": "Contains a small amount of," "Low source of," "Low in"</p> <p>Exception: "Little sodium," "Few for calories," "Little fat," "A little saturated fat," "Little cholesterol"</p>	<p>Synonyms for "Reduced/Less/Fewer": "Reduced in," "Lower," "Lower in"</p>	
Calories	<5/RACC	<p>Reference Amount &gt;30g or &gt;2T: ≤40 cal/RACC</p> <p>Reference Amount ≤30g or ≤2T: ≤40 cal/RACC &amp; /50g</p>	≥25% fewer/RACC	
Sodium	<p>&lt;5 mg/RACC</p> <p>"Salt Free" may be used if food is "Sodium Free"</p>	<p>Reference Amount &gt;30g or &gt;2T: ≤140 mg/RACC</p> <p>Reference Amount ≤30g or ≤2T: ≤140 mg/RACC &amp; /50g</p>	≥25% fewer/RACC	<p>"Very Low Sodium" "Very Low in Sodium"</p> <p>Reference Amount &gt;30g or &gt;2T: ≤35 mg/RACC</p> <p>Reference Amount ≤30g or ≤2T: ≤35 mg/RACC &amp; /50g</p>
Total Fat	<0.5g/RACC	<p>Reference Amount &gt;30g or &gt;2T: ≤3g/RACC</p> <p>Reference Amount ≤30g or ≤2T: ≤3g/RACC &amp; /50g</p>	≥25% fewer/RACC	<p>"__% Fat Free" must meet "low fat" criteria</p> <p>"__% Lean" must meet "low fat" criteria</p>

Note: RACC=Reference Amount Customarily Consumed



## NUTRIENT CONTENT CLAIMS FOR FOODS

NUTRIENT	FREE	LOW	REDUCED/LESS/FEWER	OTHER
Saturated Fat	<0.5g/RACC and Level of trans fatty acids <1% of total fat	≤1g/RACC, ≤15% calories SFA	≥25% fewer/RACC	
Cholesterol	<2mg/RACC and ≤2g SFA/RACC	Reference Amount >30g or >2T: ≤20mg/RACC, ≤2g SFA/RACC  Reference Amount ≤30g or ≤2T: ≤20mg/RACC & /50g, ≤2g SFA/RACC	≥25% fewer/RACC and ≤2g SFA/RACC	
Sugar	<0.5g sugar/RACC	Not defined	≥25% fewer/RACC	"No added sugar," "Without added sugar," "No sugar added" if no amount of sugar, or ingredient that functionally substitutes for added sugars, is added, the product does not contain ingredients containing added sugars, and the food declares (unless it meets definition that) it is not "low calorie" or "reduced calorie."

Note: RACC=Reference Amount Customarily Consumed



NUTRITION LABELING

REVIEW OF FDA'S & FSIS'S

NEW FOOD LABEL

**NUTRITION LABELING**  
**Review of FDA's and FSIS's New Food Label**

FDA Final Rule

FSIS Final Rule

**Implementation**

May 8, 1994

July 6, 1994

**Mandatory Labeling**

Processed foods (other than meat and poultry) including fresh/frozen fish packaged at the plant  
Single-ingredient fish or game meat products may provide nutrition information "as consumed" in lieu of "as packaged"

Most meat and poultry products (i.e., basted turkey, chicken franks, corned beef, meat burritos) other than single-ingredient raw meat and poultry products

Nutrition information provided "as packaged" (may additionally list nutrition information "as consumed")

Same

"As packaged" means nutrition information based on of packaged product before consumer preparation

Compliance - industry accountable for determining nutrient content of product: Agency will periodically sample products for nutrition analysis to ensure compliance

Same, in addition, FSIS permits the use of data base values, recipe analysis based on data base values, direct analyses, and combinations of these methods

**Voluntary Labeling**

Raw produce and seafood unpackaged or packaged at retail (final regulation published November 1991)

Single-ingredient raw meat and poultry products (i.e., ground beef, chicken breasts, whole unbasted turkey) fresh or frozen

"As consumed " for raw fish;  
"As packaged" for raw fruits  
and raw vegetables

Same

"As packaged" or "As  
consumed"

"As packaged" means nutrition  
information provided on  
serving size of the product  
in the package, without  
further preparation, such as  
cooking

Same

"As consumed" means nutrition  
information provided on  
cooked meat and poultry,  
using common cooking methods  
that do not add fat, flour,  
salt, etc., which could alter  
nutrient profile

Allows use of point-of-purchase  
materials (e.g., large placards,  
pamphlets, brochures, videos)

Same

60% of retailers surveyed must be  
in compliance for at least 90%  
of the 20 most frequently consumed  
raw fruits, raw vegetables and raw  
fish (60 total) by May 1993; if not,  
will develop regulations for manda-  
tory program; if in compliance, will  
survey stores every two years to  
ensure compliance, so next compliance  
survey completed in May 1995

Significant participation  
means 60% of stores surveyed  
provided nutrition informa-  
tion for at least 90% of  
major cuts (45 total). FSIS  
will begin surveying  
retailers to determine  
levels of participation in  
July, 1994. Agency will  
report results in May, 1995.  
If participation deemed un-  
satisfactory, FSIS will in-  
vestigate courses of  
regulatory action.

Allows use of data provided by FDA;  
products using FDA-approved data  
bases will not be subject to  
compliance procedures

Allows use of USDA Handbook  
#8 for representative  
nutrient values; products  
using USDA Handbook #8 data  
will not be subject to  
compliance procedures, unless  
a nutrient content claim is  
made

## Mandatory Disclosures

Calories	Same
Calories from fat	
Total fat (grams and % DV)	
Saturated fat (grams and % DV)	
Cholesterol (milligrams and % DV)	
Sodium (milligrams and % DV)	
Total carbohydrate (grams, and % DV, includes dietary fiber)	
Dietary fiber (grams and % DV)	
Sugars (grams and % DV)	
Protein (grams)	
Vitamin A (% of Daily Value)	
Vitamin C (% of Daily Value)	
Calcium (% of Daily Value)	
Iron (% of Daily Value)	

## Voluntary Disclosures

Calories from saturated fat	Same
polyunsaturated and monounsaturated fats (grams) - (unless a claim is made about fatty acid or cholesterol content)	Same, plus stearic acid
Potassium (milligrams and % DV)	Same
Soluble and insoluble fiber, sugar alcohols and other carbohydrate (grams)	Same
Protein as % of DV for foods other than foods for infants and children under 4	Same
Thiamin, riboflavin, niacin, and other vitamins and minerals (% DV)	Same
Voluntary nutrients become mandatory if a claim is made about them, except "calories from from saturated fat" and "other carbohydrates"	Same

## **Simplified Label Format**

May be used when a food contains insignificant amounts of more than one-half (more than 7) of the nutrients required to be listed

May be used when any of the required nutrients; except for the 5 core nutrients: calories, total fat, total carbohydrate, protein, and sodium; are present in insignificant amounts

Insignificant amount is that amount that may be rounded to zero, except for carbohydrate, dietary fiber, and protein, which is the amount that can be declared as 1 gram

Same

Nutrients present in insignificant amounts should be listed in the following statement: "Not a significant source of \_\_\_\_\_"

## **Exemptions from Mandatory Rule**

Products for export

Same

Custom slaughter products

Same

Restaurants and institutional food service (e.g., hospitals, prisons) provided a claim is not made (except on menus)

Restaurants and institutional food service, even if a claim is made. Menus are exempt from the labeling rule.

### **Unless a nutrient content claim is made:**

Small businesses with less than \$ 500,000 in food and other merchandise sales or less than \$ 50,000 in sales of food alone

Small businesses with 500 or fewer employees, and 100,000 pounds or less production of a particular product( phase in process - begin with 250,00 pounds and in two years 100,000 pounds)

Small packages - a total surface area of less than 12 square inches available to bear labeling

Small packages - individually wrapped packages of less than 1/2 ounce net weight

Products not for sale to retail consumers (e.g. institutional pack)

Same

Ready-to-eat foods primarily prepared or processed at retail establishments

Foods prepared, processed, portioned, packaged, or served at retail establishments

Products intended for further processing

Same

### Serving Sizes

The amount customarily consumed per eating occasion by persons 4 years of age or older

Same

139 food product categories with reference amounts

23 meat, 22 poultry product categories with reference amounts

Serving size for raw fish is 3 ounces cooked

Serving size for single ingredient raw meat and poultry is 3 ounces cooked

Household measures (cups, tablespoons, and teaspoons)

Same

When household measure is ounces, visual representation required

Not required

Meals - weigh 10 ounces or more, contain 3 components from 2 or more to food groups

Meal-type products (dinners, entrees) weigh 6-12 ounces, contain ingredients from 2 of 4 food groups, and be labeled in their entirety

Main dish items - weigh 6 or more ounces, contain 2 components from 2 or more food groups

Units/pieces that vary in size (i.e. seafood, pickles) to be labeled in the number of ounces closest to the reference amount, plus the approximate number of pieces

Units/pieces to be labeled in the number of whole units closest to the reference amount

Individual units that weigh between 67 and 200 percent must use 1 as their serving size

Same



## Reference Daily Intakes (RDI) and Daily Reference Values (DRV)

Establishes RDIs and DRVs, which are meant to serve as reference values, to help consumers compare how nutrient levels in foods contribute toward a healthy diet

Same

RDIs established for protein, 19 vitamins and minerals

Same

DRVs established for total fat, saturated fat, cholesterol, protein, total carbohydrate, dietary fiber, sodium and potassium

Same

Percent of Daily Values and daily values (represent RDIs and DRVs) will appear on food labels

Same

### Descriptors

FDA has general requirements for the use of descriptors and definitions for several nutritional components (e.g., calories, fat, saturated fat, sodium, and cholesterol). Listed below are some of the definitions

FSIS adopts FDA's requirements for the use of descriptors and definitions for several nutritional components

High: product contains 20 % or more per Reference Amount of the DRV or RDI

Same

Good Source: product contains 10 - 19 % of the DRV or RDI per Reference Amount

Same

Fat Free: product contains less than 0.5 g of fat per reference amount for individual foods and per labeled serving for meal-type products, and no added ingredient that is fat or oil unless identified as trivial in the ingredient statement

Same

<p><b><u>Low Fat:</u></b> product contains 3 grams or less of fat per Reference Amount for individual foods and per 100 g and per labeled serving for meal-type products with not more than 30 % of calories from fat</p>	<p>Same</p>
<p><b><u>Light or lite:</u></b> if product derives 50 % or more of its calories from fat, its fat content is reduced by 50 % or more compared to the reference food. If the product derives less than 50 % of its calories from fat, the fat is reduced by 50 % or more or the number of calories is reduced by at least one-third compared to the reference food</p>	<p>Same</p>
<p><b><u>Reduced/Less fat:</u></b> product has reduced fat content by 25 % or more and that contain no added fat</p>	<p>Same</p>
<p><b><u>More/Added/Enriched:</u></b> amount of nutrient in the product exceeds the amount in the reference food by at least 10 % of the DRV or RDI per Reference Amount</p>	<p>FSIS will adopt the descriptors "more" and "added"</p>
<p><b><u>Percent Fat Free:</u></b> only used on products that meet low fat definition</p>	<p>Same, permit <u>percent lean</u> claims, synonymous with percent fat free claims</p>
<p><b><u>"Lean" and "extra lean"</u></b></p>	<p><b><u>"Lean" and "extra lean"</u></b></p>
<p>Same, as USDA-regulated single-ingredient, raw meat and poultry product for use with FDA-regulated seafood or game meat products. Same as USDA regulated multi-ingredient, meat and poultry meal-type products for use with all FDA regulated meal-type products</p>	<p>Descriptors for use with all meat and poultry products including meal-type, multi-ingredient products and raw single ingredient meat and poultry cuts</p>

Lean: Meat or poultry products with less than 10 grams of fat, less than 4 grams of saturated fat, and less than 95 milligrams cholesterol per 100 grams, and per Reference Amount for individual foods, and per 100 grams and labeled serving size for meal-type products

Extra-lean: Meat or poultry products with less than 5 grams of fat, less than 2 grams of saturated fat, and less than 95 milligrams cholesterol per 100 grams and Reference Amount for individual foods, and per 100 grams and labeled serving for meal-type products

### Health Claims

Seven health claims are permitted on foods only where claims are specifically provided for by regulations and where no other nutrient is present in an amount that increases the risk of disease. The claim must be supported by publicly available scientific evidence and there must be significant scientific agreement among qualified scientists

No provisions in November 1991 proposal; will publish proposal in 1993

### "Healthy" Proposal

Must meet definition for low fat and low in saturated fat; cholesterol and sodium cannot exceed established risk levels. Sodium risk level changes between "main dishes" and "meals".

Allows use of term for products meeting definition of "lean" and containing less than 480 milligrams sodium per 100 grams and the reference amount for individual foods, and per 100 grams and labeled serving for meal-type products.



# **FDA/FSIS DIFFERENCES**

## FDA/FSIS DIFFERENCES

ISSUE	FDA	FSIS
<b>IMPLEMENTATION</b>		
Effective date	May 8, 1994	July 6, 1994
Codification of Final Rules	Final Rule published with full codification	cross references to FDA final rule, full codification of final rules expected in Spring of 1993
<b>MANDATORY LABELING</b>		
Protein quality	use of specific factors to convert amino acid to protein	only use general factor (6.25 x nitrogen) to convert amino acid to protein
Calorie Measurement	allow use of "bomb calorimetry" to measure calories	FSIS will not use of bomb calorimeter to measure calories (manufacturers may use any method)
Data bases	FDA will approve	FSIS will not approve
Compliance/data bases	label to a 95% confidence level	label to the average
<b>VOLUNTARY LABELING</b>		
Compliance measurement	allows use of data provided by FDA	will allow use of databases, recipe analysis, direct analysis, or a combination of methods
"As consumed" or "As packaged"	as consumed for raw fish; as packaged for raw fruits or vegetables	as packaged or as consumed for single-ingredient raw meat or poultry

Voluntary program significant participation	will measure for significant compliance, if not found will develop mandatory regulations	will measure for significant participation, if not found will investigate the development of mandatory regs.
Voluntary program compliance	no compliance check with data provided by FDA	no compliance check when using USDA Handbook # 8
USDA Handbook 8	do not accept average values from Hdbk 8 as suitable for nutrition labeling in all cases	will allow product to be labeled with Hdbk 8 average values

**VOLUNTARY DISCLOSURES**

Stearic Acid	will not permit voluntary listing	will allow the voluntary declaration of stearic acid content on the label
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**FORMAT**

Simplified Format	used when 7 or more nutrients are present in insignificant amounts (does not include calories from fat) Footnotes not required	used when any nutrient, other than a core nutrient, is present in an insignificant amount (FDA refers to this as the "shortened" format and requires the use of footnotes)
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**EXEMPTIONS**

Restaurants	exempt unless a claim is made (except on menus)	menus are exempt
Retail product exemption	Ready-to-eat products prepared, processed or packed to consumer specification at a retail estab.	products packaged, portioned or processed at a retail establishment

Small Business < \$500,000 total annual sales of food or other merchandise sales, or < \$50,000 annual sales of food 500 or fewer employees, and 100,000 pounds or less of production per product per year

Small Package total surface area available to bear labeling of less than 12 square inches individual packages of less than 1/2 ounce net weight

**SERVING SIZE**

Product Categories 139 product categories 23 for meat products, 22 for poultry products

Handbook 8 Yields FDA has no comparable provision some product categories have an additional column listing a reference amount based on Hdbk 8 yields for products that undergo significant composition changes prior to consumption

RACC Charts "Label Statement" Column column that gives information on how the serving size should be stated on the label does not have a comparable column

Meal Products separate definitions: Meal:3 or more foods from 2 different groups, 40 g each, product weighs at least 10 oz Main dish:2 or more foods from 2 different groups, 40 g each, product weighs at least 6 oz weighs between 6 and 12 ounces, food from 2 of 4 food groups, represented as a meal/entree

Serving Size for Units/Pieces (that vary in size) expressed in ounces followed parenthetically by gram weight and the approximate number of pieces or dimension expressed as the # of units/pieces, label to the average

**NUTRIENT CONTENT CLAIMS**

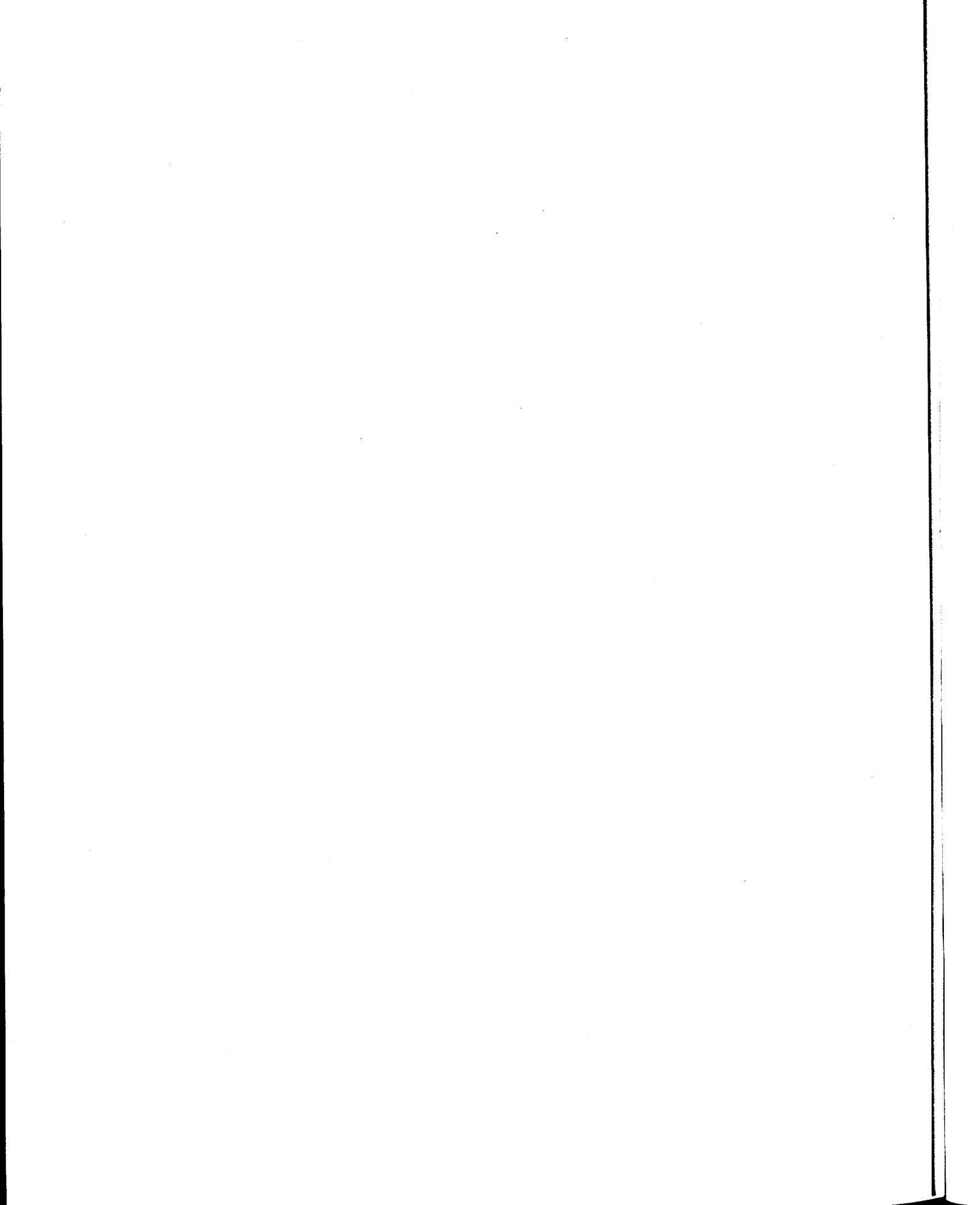


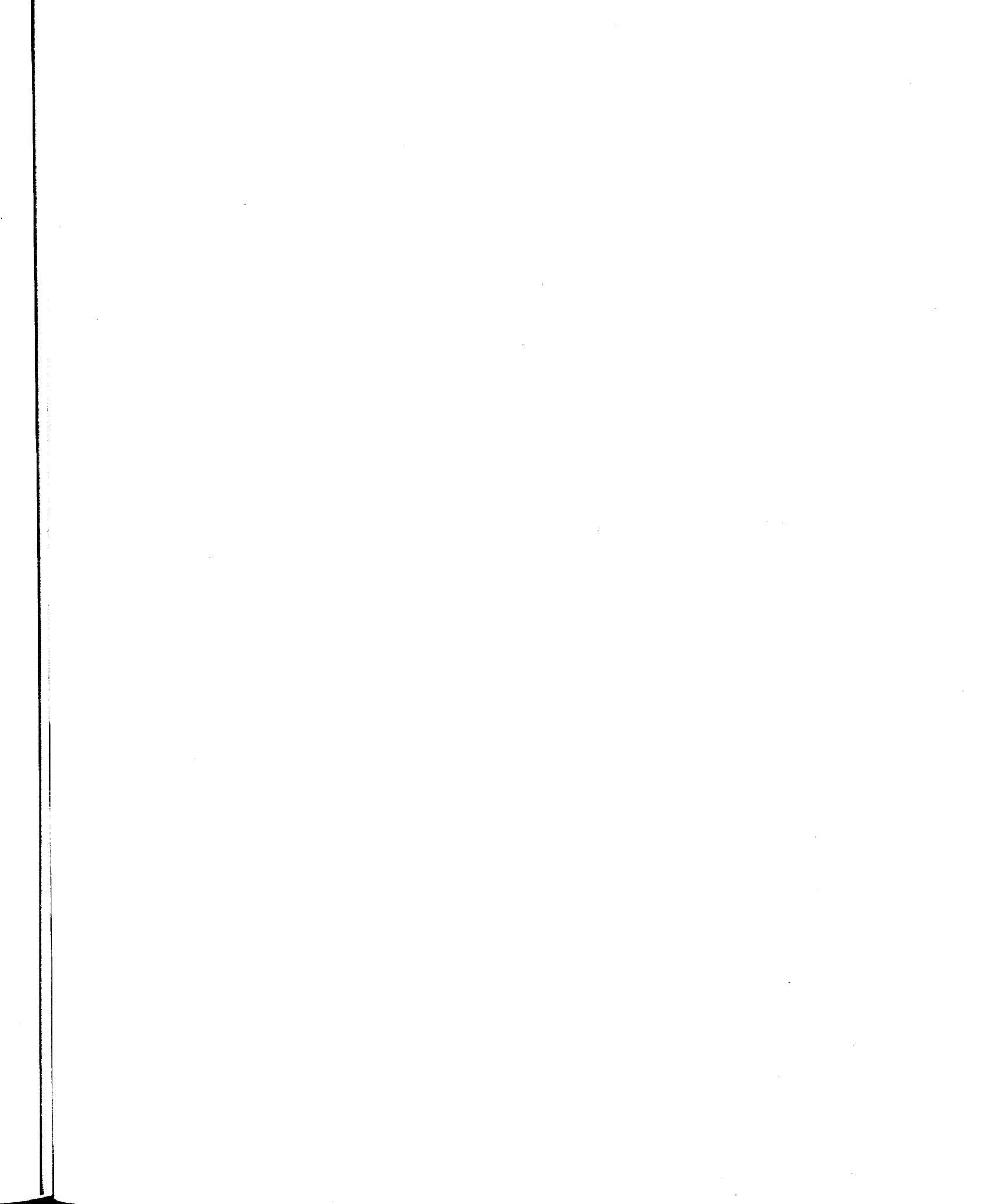
More, Added, Enriched	FDA defined these terms	FSIS only defined "more"/"added" terms, will not approve fortification
Lean, Extra Lean	approved for use on seafood, game meat, and meal products only	approved for use on all products
_____ % Lean	this claim not approved for use; only _____% Fat Free, must meet definition for "low fat"	claim approved for use; terms are synonymous; must meet definition for "low fat"
Disclosure/Disqualifier	for individual foods: more than 20% of DRV for fat, sat fat, cholesterol, or sodium, for main dish items >30% DRV, for meals > 40% DRV	no disclosure or disqualifying levels or statements required
Referral Statements	required when a nutrient exceeds a disqualifying level	no statement required
Light in sodium for brand names	Must meet sodium criteria, appear contiguous to the brand name, uniform in type, size, color, and prominence as the brand name	must meet sodium criteria, appear contiguous to the brand name, uniform in type, size, color, and prominence as the product name
Claims as part of a Brand Name	allowed if not defined in the final rule, not false or misleading and in use prior to Oct. 25, 1989	allowed if not defined in the final rule, false, or misleading and in use prior to Nov. 27, 1991
<b>OTHER DIFFERENCES</b>		
Healthy/Proposals	must be low in fat and sat fat and not above the disclosure level in cholesterol and sodium	allowed if product meets the definition of lean and contains < 480 mg of sodium

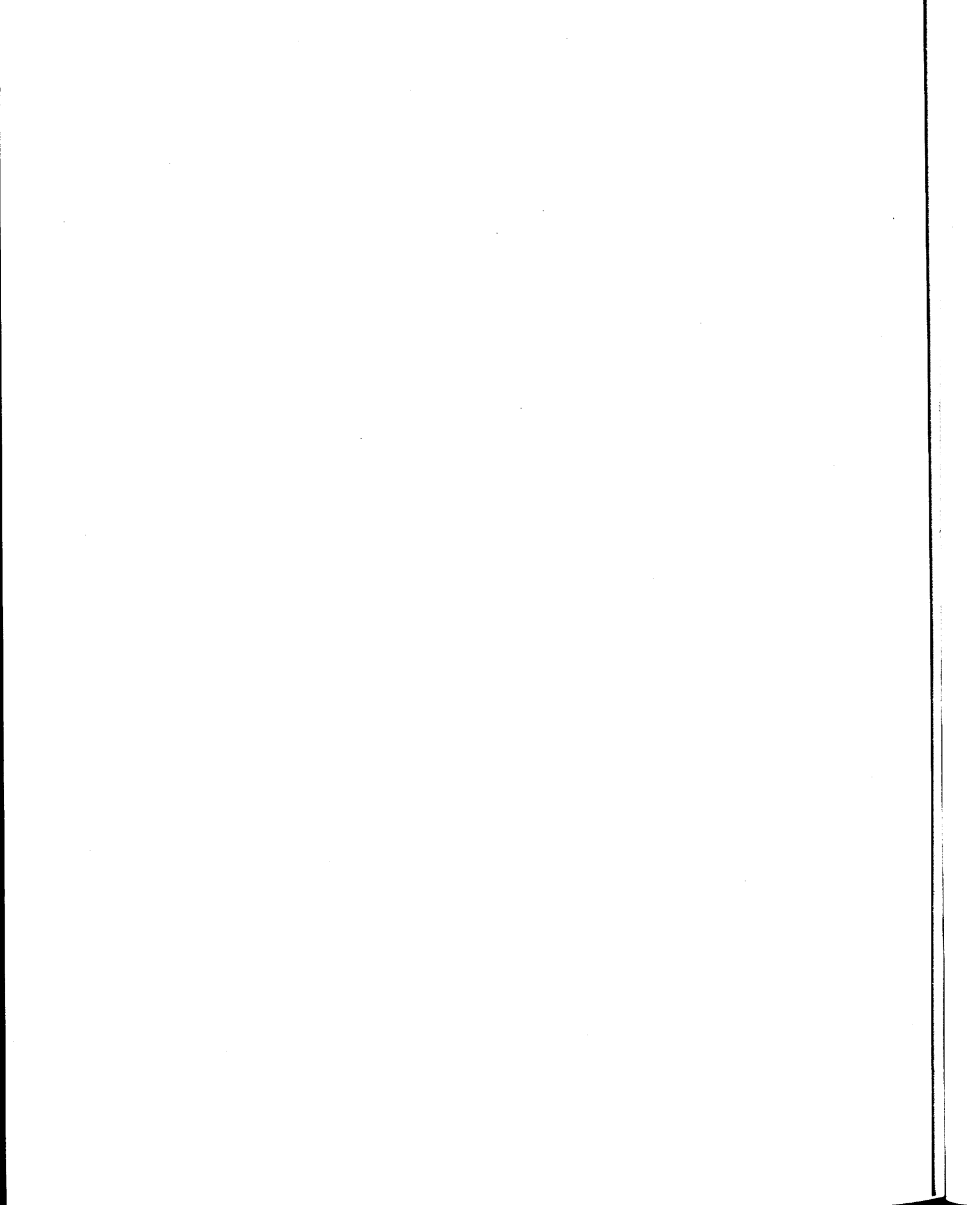
3rd party  
endorsements

will be judged in "context";  
will be permitted in certain  
context; if a fee is paid, must  
be disclosed

will be addressed as part of  
the proposed rule for health  
claims







List of Voluntary  
and Mandatory  
Nutrients

TABLE 2 MANDATORY/VOLUNTARY NUTRIENTS

NUTRIENTS	MANDATORY (M) VOLUNTARY (V)	CORE NUTRIENT	UNITS	INCREMENTS ROUNDING	INSIGNIFICANT AMOUNT	DEFINITION	OTHER
Calories	M	X	calories	5 cal < = 50 cal 10 cal > 50 cal	< 5 cal		may be listed on label as kilojoules [k] or [energy] in addition to calories
Calories from fat	M		calories	5 cal < = 50 cal 10 cal > 50 cal	< 5 cal		
Calories from sat fat	V		calories	5 cal < = 50 cal 10 cal > 50 cal	< 5 cal		
Total Fat	M	X	gn	nearest .5 gram below 3 grams nearest gram above 3 grams	< .5 gn	total lipid fatty acids	
Saturated Fat	M		gn	nearest .5 gram below 3 grams nearest gram above 3 grams	< .5 gn	sum of all fatty acids without double bonds	
Stearic Acid	V		gn	nearest .5 gram below 3 grams nearest gram above 3 grams	< .5 gn		
Polyunsaturated fat and monounsaturated fat	V		gn	nearest .5 gram below 3 grams nearest gram above 3 grams	< .5 gn		
Cholesterol	M		mg	nearest 5 mg	< 2 mg		2-5 mg may state "less than 5 mg"
Sodium	M	X	mg	5 mg < = 140 mg 10 mg > 140 mg	< 5 mg		
Potassium	V		mg	5 mg < = 140 mg 10 mg > 140 mg	< 5 mg		
Total Carbohydrate	M	X	gn	nearest gram	< 1 gn	all carbohydrates including dietary fiber	
Dietary Fiber	M		gn	nearest gram	< 1 gn	sum of soluble and insoluble fiber	

TABLE 2 MANDATORY/VOLUNTARY NUTRIENTS

Soluble Fiber	V		gm	nearest gram	< .5 gm		
Insoluble Fiber	V		gm	nearest gram	< .5 gm		
Sugars	M		gm	nearest gram	< .5 gm	sum of all free mono and disaccharides	
Sugar Alcohols	V		gm	nearest gram	< .5 gm	sum of all approved sugar alcohols	
Other Carbohydrate	V		gm	nearest gram	< .5 gm	all carbohydrates except sugars, sugar alcohols (if not declared), and dietary fiber	
Protein	M	X	gm	nearest gm	< 1 gm		voluntarily state as % of RDI or DRV, becomes mandatory for foods for infants and children less than 4 years
Vitamin A	M		% RDI	nearest 2% <= 10% nearest 5% > 10% <= 50% nearest 10% > 50%	< 2% RDI		
Vitamin C	M		% RDI	nearest 2% <= 10% nearest 5% > 10% <= 50% nearest 10% > 50%	< 2% RDI		
Calcium	M		% RDI	nearest 2% <= 10% nearest 5% > 10% <= 50% nearest 10% > 50%	< 2% RDI		
Iron	M		% RDI	nearest 2% <= 10% nearest 5% > 10% <= 50% nearest 10% > 50%	< 2% RDI		

Note: All voluntary nutrients become mandatory if a claim is made regarding the nutrient or one of its subcomponents.

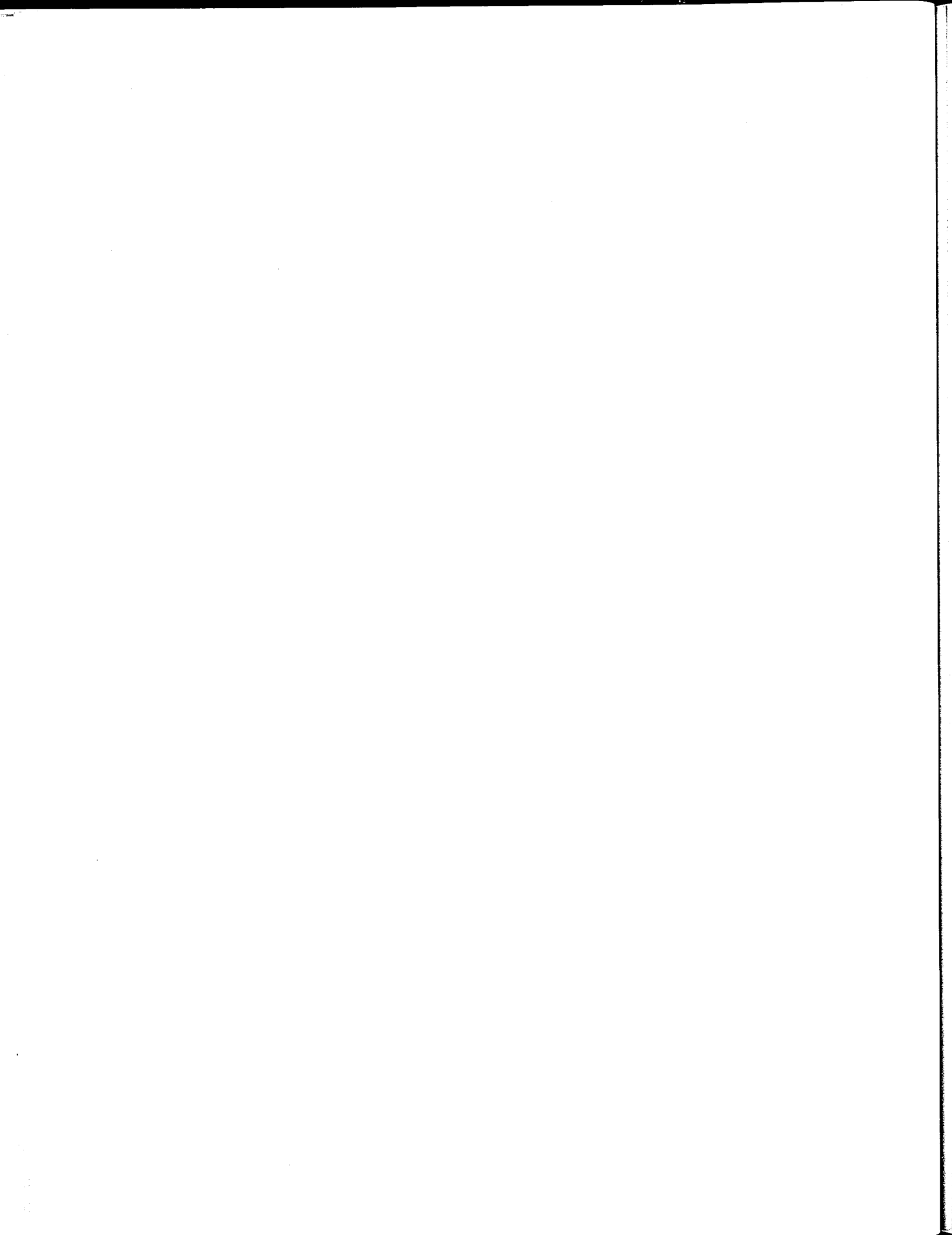


TABLE 3  
MANDATORY/VOLUNTARY RDI CHART

NUTRIENT	Mandatory (M) Voluntary (V)	UNIT OF MEASUREMENT	RDI
	VITAMIN A	M	INTERNATIONAL UNITS
VITAMIN C	M	MILLIGRAMS	60
CALCIUM	M	GRAM	1.0
IRON	M	MILLIGRAMS	18
VITAMIN D	V	INTERNATIONAL UNITS	400
VITAMIN E	V	..DO...	30
THIAMIN	V	MILLIGRAMS	1.5
RIBOFLAVIN	V	..DO...	1.7
NIACIN	V	..DO...	20
VITAMIN B6	V	..DO...	2.0
FOLATE	V	..DO...	0.4
VITAMIN B12	V	MICROGRAMS	6.0
BIOTIN	V	MILLIGRAMS	0.3
PANTOTHENIC ACID	V	..DO...	10
PHOSPHORUS	V	GRAM	1.0
MAGNESIUM	V	MILLIGRAMS	400
ZINC	V	..DO...	15
IODINE	V	MICROGRAMS	150
COPPER	V	MILLIGRAMS	2.0

- Notes:**
- o All voluntary nutrients are required if a claim is made regarding that nutrient.
  - o The declaration of all vitamins and minerals will be as a percent of the RDI.





# **Sample**

## *Label Formats*

**FSIS/USDA  
January 1993**

**Sample Label**

**Nutrition Facts**

Serving Size 1 cup (253 g)  
 Servings Per Container 4

**Amount Per Serving**

**Calories** 260      **Calories from Fat** 70

**% Daily Value\***

**Total Fat** 8g      **13%**

Saturated Fat 3g      **17%**

**Cholesterol** 130mg      **44%**

**Sodium** 1010mg      **42%**

**Total Carbohydrate** 22g      **7%**

Dietary Fiber 9g      **36%**

Sugars 4g

**Protein** 25g

Vitamin A 35%      •      Vitamin C 2%

Calcium 6%      •      Iron 30%

\* 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

(Consult FDA regulation for specific requirements on type size, spacing and other graphic elements.)

**Modified  
Format**

<b>Nutrition Facts</b>		* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:	
Serving Size 1/2 cup (114 g) Servings Per Container 4		Calories: 2,000    2,500	
<b>Amount Per Serving</b>			
<b>Calories 260</b>	<b>Calories from Fat 120</b>		
		<b>% Daily Value*</b>	
<b>Total Fat 13g</b>			<b>20%</b>
Saturated Fat 5g			<b>25%</b>
<b>Cholesterol 30mg</b>			<b>10%</b>
<b>Sodium 660mg</b>			<b>28%</b>
<b>Total Carbohydrate 31g</b>			<b>11%</b>
Dietary Fiber 0g			<b>0%</b>
Sugars 5g			
<b>Protein 5g</b>			
Vitamin A 4%	•	Vitamin C 2%	
Calcium 15%	•	Iron 4%	

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

(Consult FDA regulation for specific requirements on type size, spacing and other graphic elements.)

## Simplified Format

### Nutrition Facts

Serving Size 1 cup (253 g)  
Servings Per Container 4

#### Amount Per Serving

Calories 260      Calories from Fat 70

#### % Daily Value\*

Total Fat 8g      13%

Saturated Fat 3g      17%

Cholesterol 130mg      44%

Sodium 1010mg      42%

Total Carbohydrate 22g      7%

Protein 25g

Vitamin A 35%      • Vitamin C 2%

Calcium 6%      • Iron 30%

Not a significant source of dietary  
fiber and sugars.

\*Percent Daily Values are based  
on a 2,000 calorie diet.

(Consult FDA regulation for  
specific requirements on type  
size, spacing and other graphic  
elements.)

## Tabular Display

<b>Nutrition Facts</b>	<b>Amount Per Serving % DV*</b>		<b>Amount Per Serving % DV*</b>	
	<b>Serving Size X cup (XX g)</b> <b>Servings about X</b>	<b>Total Fat Xg</b>	<b>XX%</b>	<b>Total Carbohydrate XXg</b>
<b>Calories XX</b> <b>Fat Cal. XX</b>	<b>Sat. Fat Xg</b>	<b>XX%</b>	<b>Dietary Fiber Xg</b>	<b>X%</b>
	<b>Cholest. XXXmg</b>	<b>XX%</b>	<b>Sugars Xg</b>	
	<b>Sodium XXXmg</b>	<b>XX%</b>	<b>Protein XXg</b>	
	<b>Vitamin A XX% • Vitamin C X% • Calcium X% • Iron XX%</b>			

(Consult FDA regulation for specific requirements on type size, spacing and other graphic elements.)



**Medium-Size  
Package Label**

**Nutrition Facts**

Serv. Size 1 cup (253 g)  
Servings Per Container 4

**Amount Per Serving**

**Calories** 260 Fat Cal. 70

**% Daily Value\***

**Total Fat** 8g 13%

Sat. Fat 3g 17%

**Cholesterol** 130mg 44%

**Sodium** 1010mg 42%

**Total Carb.** 22g 7%

Fiber 9g 36%

Sugars 4g

**Protein** 25g

Vitamin A 35% • Vitamin C 2%

Calcium 6% • Iron 30%

\*Percent Daily Values are based  
on a 2,000 calorie diet.

(Consult FDA regulation for  
specific requirements on type  
size, spacing and other graphic  
elements.)

**Format for foods  
for children less  
than 4 years of  
age.**

## **Nutrition Facts**

Serving Size X cup (XXX g)  
Servings Per Container X

### **Amount Per Serving**

Calories XXX      Calories from Fat XX

	<b>Amount</b>
<b>Total Fat</b>	<b>XXg</b>
Saturated Fat	<b>XXg</b>
<b>Cholesterol</b>	<b>XXg</b>
<b>Sodium</b>	<b>XXg</b>
<b>Total Carbohydrate</b>	<b>Xg</b>
Dietary Fiber	<b>XXg</b>
Sugars	<b>XXg</b>
<b>Protein</b>	<b>Xg</b>

Vitamin A XX%      •      Vitamin C X%

Calcium X%      •      Iron XX%

(Consult FDA regulation for specific requirements on type size, spacing and other graphic elements.)

**Format for same  
food represented  
to be specifically  
for children less  
than 2 years of  
age.**

(Consult FDA regulation for  
specific requirements on type  
size, spacing and other graphic  
elements.)

## **Nutrition Facts**

Serving Size X jar (XXX g)  
Servings Per Container X



### **Amount Per Serving**

**Calories XXX**



**Amount**

**Total Fat XXg**

**Sodium XXg**

**Total Carbohydrate Xg**

Dietary Fiber XXg

Sugars XXg

**Protein Xg**



Vitamin A XX% • Vitamin C X%

Calcium X% • Iron XX%

**Dual  
Declaration**

# Nutrition Facts

Serving Size X cup (XXX g)  
Servings Per Container X

Amount Per Serving	Raw	Cooked
<b>Calories</b>	XXX	XXX
Calories from Fat	XXX	XXX

	% Daily Value*	
<b>Total Fat</b> Xg	XX%	XX%
Saturated Fat Xg	XX%	XX%
<b>Cholesterol</b> XXXmg	XX%	XX%
<b>Sodium</b> XXXmg	XX%	XX%
<b>Total Carbohydrate</b> XXg	X%	XX%
Dietary Fiber Xg	XX%	XX%
Sugars Xg		

**Protein** XXg

Vitamin A	XX%	XX%
Vitamin C	X%	XX%
Calcium	X%	XX%
Iron	XX%	XX%

\* 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	XXg	XXg
Sat Fat	Less than	XXg	XXg
Cholesterol	Less than	XXXmg	XXXmg
Sodium	Less than	XXXmg	XXXmg
Total Carbohydrate		XXXg	XXXg
Dietary Fiber		XXg	XXg

Calories per gram:  
Fat X • Carbohydrate X • Protein X

(Consult FDA regulation for specific requirements on type size, spacing and other graphic elements.)

**Dual declaration  
with footnote of  
nutrients added  
by combination  
of foods.**

# Nutrition Facts

Serving Size X cup (XXX g)  
Servings Per Container X

Amount Per Serving	Soup	Soup w/ 1/2 cup Skim Milk
<b>Calories</b>	XXX	XXX
Calories from Fat	XXX	XXX

	% Daily Value*	
<b>Total Fat</b> Xg	XX%	XX%
Saturated Fat Xg	XX%	XX%
<b>Cholesterol</b> XXXmg	XX%	XX%
<b>Sodium</b> XXXmg	XX%	XX%
<b>Total Carbohydrate</b> XXg	X%	XX%
Dietary Fiber Xg	XX%	XX%
Sugars Xg		

## Protein XXg

Vitamin A	XX%	XX%
Vitamin C	X%	XX%
Calcium	X%	XX%
Iron	XX%	XX%

\* Amount in soup mix. One half cup sim milk contributes an additional XX calories, XX mg sodium, Xg total cabohydrate (Xg sugars), and Xg protein.

\*\* 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	XXg	XXg
Sat Fat	Less than	XXg	XXg
Cholesterol	Less than	XXXmg	XXXmg
Sodium	Less than	XXXmg	XXXmg
Total Carbohydrate		XXXg	XXXg
Dietary Fiber		XXg	XXg

Calories per gram:  
Fat X • Carbohydrate X • Protein X

(Consult FDA regulation for specific requirements on type size, spacing and other graphic elements.)

# Appendix B to Part 101

Helvetica Regular 8 point with 1 point of leading

Franklin Gothic Heavy or Helvetica Black, flush left & flush right, no smaller than 13 point

3 point rule

7 point rule

8 point Helvetica Black with 4 point of leading

6 point Helvetica Black

1/4 point rule centered between nutrients (2 points leading above and 2 points below)

All labels are enclosed by 1/2 point box rule within 3 points of text measure

8 point Helvetica Regular with 4 points of leading

1/4 point rule

8 point Helvetica Regular, 4 points of leading with 10 point bullets

Type below vitamins and minerals (footnotes), is 6 point with 1 point of leading

<b>Nutrition Facts</b>		
Serving Size 1/2 cup (114g)		
Servings Per Container 4		
<b>Amount Per Serving</b>		
<b>Calories 260</b> Calories from Fat 120		
		<b>% Daily Value*</b>
<b>Total Fat</b> 13g		<b>20%</b>
Saturated Fat 5g		<b>25%</b>
<b>Cholesterol</b> 30mg		<b>10%</b>
<b>Sodium</b> 660mg		<b>28%</b>
<b>Total Carbohydrate</b> 31g		<b>11%</b>
Dietary Fiber 0g		<b>0%</b>
Sugars 5g		
<b>Protein</b> 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
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		

# Appendix B to Part 101

## Graphic Enhancements used by the FDA

### A. Overall

1. Nutrition Facts Label is boxed with all black or one color type printed on a white or neutral ground.

### B. Typeface and size

1. The "Nutrition Facts" label uses 6 point or larger Helvetica Black and/or Helvetica Regular type. In order to fit some formats the typography may be kerned as much as -4, (tighter kerning reduces legibility).
2. Key nutrients & their % Daily Value are set in 8 point Helvetica Black (but "%" should be set in Helvetica Regular).
3. "Nutrition Facts" is set in either Franklin Gothic Heavy or Helvetica Black to fit the width of the label flush left and flush right.
4. "Serving Size" and "Servings per container" are set in 8 point Helvetica Regular with 1 point of leading.
5. The table labels ( for example; "Amount per Serving") are set 6 point Helvetica Black.
6. Absolute measures of nutrient content ( for example; "1g") and nutrient subgroups are set in 8 point Helvetica Regular with 4 points of leading.
7. Vitamins and minerals are set in 8 point Helvetica Regular, with 4 points of leading, separated by 10 point bullets.
8. All type that appears under vitamins and minerals is set in 6 point Helvetica regular with 1 point of leading.

### C. Rules

1. A 7 point rule separates large groupings as shown in example. A 3 point rule separates calorie information from the nutrient information.
2. A hairline rule or 1/4 point rule separates individual nutrients, as shown in the example. Descenders should not touch rule. The top half of the label (nutrient information) has 2 points of leading between the type and the rules, the bottom half of the label (footnotes) has 1 point of leading between the type and the rules.

### D. Box

1. All labels are enclosed by 1/2 point box rule within 3 points of text measure.

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