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Nutritional and Ingredient Labeling Summary FDA/USDA Regulations 1993

A Guide for Food Processors

Prepared by:
Steve L. Taylor, Ph.D.
Director, Food Processing Center

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The
Food Processing
C E N T E R

Nutritional and Ingredient Labeling Summary FDA/USDA Regulations 1993

A Guide For Food Processors

Prepared by:
Steve L. Taylor, Ph.D.
Director, Food Processing Center

(This summary is presented as a guide to the recently published labeling regulations of the FDA and USDA. The final authority is the wording in the Federal Register and its interpretation by the FDA and USDA plus any additional documents published by either agency relative to these new labeling regulations.)

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On January 6, 1993, the FDA and the USDA released the final versions of the new nutritional and ingredient labeling regulations. The new regulations, which take up nearly 1,000 pages of fine print in the Federal Register, are the most sweeping changes in the food regulations in 35 years. These changes will impact nearly all food processors, and each and every processor has the responsibility to determine the changes that will be necessary on their own food labels. The Food Processing Center is prepared to assist processors in this procedure, so do not hesitate to call for specific advice regarding your products.

Obtaining Your Personal Copy of the New Regulations: Food processors may wish to purchase their own copies of these new regulations. Copies can be obtained from the Superintendent of Documents, Washington, D.C.; telephone: 202/783-3238; fax: 202/512-2250; the document number is 069-001-00045-9; and the price is $4.50 per each 2-volume set (specify Federal Register, Volume 58, No. 3, January 6, 1993). Floppy disks will also be made available from the Superintendent of Documents, P.O. Box 37082, Washington, D.C. 20013-7082 for a cost of $88.50; there are 4 diskettes and the text is in ASCII.

Reading the New Regulations: If you are not an expert in reading new regulations in the Federal Register, it can be a lot easier than drudging through nearly 1,000 pages. The new regulations are divided into sections: the FDA and USDA portions are separate and these major divisions include a series of subdivisions. An example from page 2,302 is a section on "Food Labeling: Nutrient Content Claims". Each of these sections begins with a summary and effective date (which are short and should be read). Each section contains a long preamble where FDA or USDA argue their new positions in light of existing food law and respond to comments received on the proposed regulations. These preambles may be fun for lawyers, but are not very enjoyable for the rest of us. The FDA received over 38,000 comments on the proposed regulations, so the arguments in the preamble get a bit long-winded. Reading the preamble is necessary only if you want to try to understand their logic. After this preamble, you will find sections labeled as Part numbers (e.g. Part 101) which are the actual statements of the new regulations (the important part).

Effective Dates: Most of the new regulations become effective on **May 8, 1994.** A few of the new regulations become effective on **May 8, 1993** and the USDA regulations do not become effective until **July 6, 1994**. Figure 1 displays all of the important dates. The following dates are correct, however, the February 5, 1993 date for comments on the USDA Healthy proposal will very likely be extended to March 8, 1993. Several of the dates in the actual Federal Register document are wrong (many of the dates are given as February 14, 1994 and attempts to change all dates to May 8, 1994 resulted in quite a few errors).

Technically, the FDA was forced to include another 30-day comment period for these final regulations (the explanation is rather complicated). The FDA wishes to receive "technical comments" only and then only those comments which it did not receive following the release of the proposals. FDA does not define "technical comments", but seems to mean they would want to learn of technicalities and imposed difficulties they may have overlooked or ignored as they put together these final regulations. Such comments are to be submitted to the FDA in Washington, D.C. This comment period does not apply to the USDA regulation.

FDA and USDA also released several new **proposed regulations** simultaneously with the release of the final nutritional labeling regulations. These proposals are now open for comment from industry and the public until March 8, 1993. If you would be affected by any of these proposed regulations, you should obtain copies for possible comment. The proposed regulations cover:

- FDA Proposal on Allowed Uses of Term, "Healthy".
- USDA Proposal on Allowed Uses of Term, "Healthy".
- FDA Non-Functional Slack-fill Proposal.
- Several FDA Ingredient Labeling Proposals on:
  Protein Hydrolysates
  Vegetable Broth in Canned Tuna
  "and/or" Labeling for Soft Drinks.

Small Business Exemption: The FDA small business exemption remains unaltered. For FDA-regulated foods, nutritional labeling is not required if the food is offered for sale by a processor, packer or distributor having annual gross sales made or business done in sales to consumers of no more than $500,000, or have such sales of food to consumers of no more than $50,000. Thus, any companies with sales approaching $500,000 per year should make preparations to abide by the new regulations. Also, any companies that have annual sales of more than $50,000 in food and $450,000 in non-food items should prepare to comply with the new regulations or separate the two types of business.

The FDA is very sympathetic to the impact of these new regulations on small businesses. However, the above small business exemption was included in the Nutritional Labeling & Education Act as promulgated by Congress, and can only be changed by Congressional action. Only a very vigorous grass-roots effort is likely to result in any change.

The USDA small business exemption is much more generous. For USDA-regulated foods (those containing any appreciable meat or poultry), a processed consumer product will be exempt from nutrition labeling if the producing firm has 500 or fewer employees and produces less than 100,000 pounds of that particular product per year. The volume exemption will be phased in over a three-year period. As of July, 1994, companies having products with volumes of 250,000 pounds per year or more will be expected to comply. By July, 1995, companies having products with volumes of 175,000 pounds per year or more will be expected

Figure 1.

FDA and USDA FOOD LABELING RULES
PUBLICATION, COMMENT PERIODS AND EFFECTIVE DATES

NOVEMBER 8, 1991
Effective Date for:
- Voluntary Nutrition Labeling for Raw Agricultural Commodities and Raw Fish

NOVEMBER 8, 1992
Effective Date for:
- State Petitions Requesting Exemption From Federal Preemption
- State Enforcement Provisions

JANUARY 6, 1993
Publication of:
- FDA and USDA Proposed and Final Food Labeling Rules

FEBRUARY 5, 1993
Comment Period Ends for:
- Technical Comments on FDA's Final Rules FDA's Revocation of Regulations Considered Final on Nov. 8, 1992
- USDA's "Healthy" Proposal

Period for Filing Objections Ends for:
- Label Statements on Food for Special Dietary Use
- Ingredient Labeling for Dairy Products and Maple Syrup

MARCH 8, 1993
Comment Period Ends for:
- FDA's Nonfunctional Slack-fill Proposal
- Ingredient Labeling for Protein Hydrolysates and Vegetable Broth in Canned Tuna; "and/or" Labeling for Soft Drinks
- FDA's "Healthy" Proposal

MAY 8, 1993
Effective Date for:
- Health Claim Rules
- Total Percentage Juice Labeling
- Ingredient Labeling of Standardized Foods and Certified Colors
- Ingredient Labeling for Dairy Products and Maple Syrup (except stayed provisions following objections, see Feb. 5, 1993)

FEBRUARY 14, 1994
Effective Date for:
- Metric Amendments

MAY 8, 1994
Effective Date for:
- Mandatory Nutrition Labeling and Format
- Reference Daily Intakes and Daily Reference Values
- Nutrient Descriptor Claims, including those for Butter and "Healthy"
- Serving Sizes
- Standardized Foods Named Using a Nutrient Descriptor
- Juice Labeling — Common and Usual Name
- Declaration of Ingredients (except Standardized Foods and Certified Colors, see May 8, 1993)
- Label Statements on Foods for Special Dietary Use (except stayed provisions following objections, see Feb. 5, 1993)

JULY 6, 1994
Effective Date for:
- USDA Nutrition Labeling of Meat and Poultry Products

Prepared by Grocery Manufacturers of America, Washington, D.C.

to comply. By July, 1996, the product volume of 100,000 pounds per year or more will trigger the need for compliance with the nutritional labeling regulation. The USDA was not included in the Congressional NLEA and so was free to set a more reasonable small business exemption.

These small business exemptions do not apply if you make a nutritional claim on the product. If such a claim is made, you are required to adhere to all of the nutritional labeling regulations.

Other Exemptions: There are other exemptions from the requirements of the nutritional labeling regulations. For FDA, these include:

- foods for immediate consumption.

- ready-to-eat foods that are prepared on site (this means delis and in-store bakeries are exempt even when they package products for sale).

- foods sold for use in restaurants.

- foods of no nutritional significance (coffee, tea, black pepper, but not salt [significant sodium]).

- raw fruits, vegetables and fish (but voluntary nutritional information is encouraged at the retail level).

- custom processed fish and game meat.

- bulk foods.

- donated foods (to food banks, etc).

- individual units in multiunit packs.

- infant formulas (separate FDA regulation on these).

- medical foods (separate FDA regulation on these).

- dietary supplements (expect FDA regulation in late 1993).

- small packages (must be less than 12 square inches available for labeling, not counting can tops and bottoms, necks, etc).

- gift packages (but nutritional information must be included in package insert if not on label or on labels of items in package).

- shell eggs (if carton conforms to shape of eggs, then labeling can be on the inside of the carton lid).

For USDA, the other exemptions include:

- small packages but defined as less than 0.5 oz.

- foods prepared, processed, portioned, or packaged at the retail level.

- custom slaughtered products.

- meat and poultry items intended for further processing.

- gift packages (but nutritional information must be included in package insert if not on label).

- raw meat and poultry products (but voluntary labeling at retail establishments through posters, etc., is strongly encouraged).

Serving Sizes: The new FDA regulations establish serving sizes for 139 different categories of foods. Since nutritional information must be presented on a serving size basis, it will be important to know this fact for each of your products. Consult the Federal Register or the Food Processing Center.

Required Nutritional Information: All of the following information must be on the label, unless exempt on a per serving size basis:

- Calories
- Calories from Fat
- Calories from Saturated Fat (voluntary)
- Total Fat Content
- Saturated Fat
- Polyunsaturated Fat (voluntary)
- Monounsaturated Fat (voluntary)
- Cholesterol
- Sodium
- Potassium (voluntary)
- Total Carbohydrate
- Total Dietary Fiber
- Soluble and Insoluble Fiber (voluntary)
- Sugars Content
- Sugar Alcohols (voluntary)
- Other Carbohydrates (voluntary)
- Protein Content
- Vitamin C
- Vitamin A
- Calcium
- Iron
- Other Vitamins and Minerals (voluntary)

Compliance: The accuracy of nutrition labeling information can be evaluated based upon either the nutritional analyses of a composite sample of the food, or by use of an FDA-approved database.

Some segments of the food industry are working to establish approved databases. However, you may not get easy access to such databases unless you belong to the trade association that developed it e.g. the Snack Food Association. FDA has issued guidelines for the development of databases called, "FDA Nutrition Labeling Manual - A Guide for Developing and Using Data Bases". It may be very expensive, however, to develop your own personal database

and FDA may or may not accept existing USDA databases. They are likely to accept these databases for raw products, but they recognize these databases are not very accurate for processed foods. However, FDA may accept inaccurate databases if industry shows progress in development of better data.

The nutritional composition of a food can also be determined through analysis of a composite sample of the product. The composite sample must consist of 12 subsamples, one each taken from 12 different randomly selected and representative shipping cases. FDA also established guidance on the analytical methods that must be used (check with the Food Processing Center).

FDA also established class I, class II and other nutrients. Class I nutrients are vitamins, minerals, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated fat, monounsaturated fat and potassium that are added to fortified or fabricated foods. These same nutrients qualify as Class II nutrients if they occur naturally in foods. A food is misbranded when a class I nutrient is found in the composite sample at a level less than the amount declared on the label, or when a class II nutrient is found at a level less than 80 percent of the declared level. The third group of nutrients is made up of calories, sugars, total fats, saturated fat, cholesterol and sodium. A food is misbranded if one of these nutrients is found in the composite sample at a level greater than 20 percent, in excess of the declared amount.

Some foods have substantial natural variations, particularly in vitamin content, which makes applying the 80-20 rule difficult. In all cases, considerable care must be taken in selecting representative products for the composite sample or you will be wasting your analytical efforts and dollars.

Nutritional Labeling Format. The FDA regulation has established a very specific format for the nutritional label and the USDA format for the nutritional label is identical to FDA for the standard format. Several examples of the required formats are provided on the following pages. The standard or basic format (Figure 2) will be used on most food products. Variations from the basic format are permitted for dual declarations, products containing insignificant levels of nutrients and small packages. Modifications are required for products intended for use by children.

The new nutrition label is entitled "Nutrition Facts" and the listing of nutrient information is prefaced by information about serving sizes and number of servings per container (unless the product is a single serving). Next, the label must list total calories per serving (but the word "total" is not used). This is followed by a declaration of the calories from fat per serving. A declaration of calories from saturated fat is voluntary.

The regulation sets a format for the disclosure of mandatory and voluntary information. The regulation includes detailed typographic requirements; strict adherence to type sizes, etc. is necessary (Figures 3 and 4). Headings, as well as the names of broad nutrient categories and percentages for the macronutrients, must be highlighted in bold typeface while the names for subcomponents such as saturated fat must be indented. Highlighting of other information on the nutrition label is strictly prohibited.

Figure 2. The New Food Label: Standard or Basic Format

Nutrition Facts

Serving Size 1/2 cup (114g)
Servings Per Container 4

Amount Per Serving

Calories 260 Calories from Fat 120

	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**11%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4% • Vitamin C 2%

Calcium 15% • Iron 4%

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

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

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

Figure 3. 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 and 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.

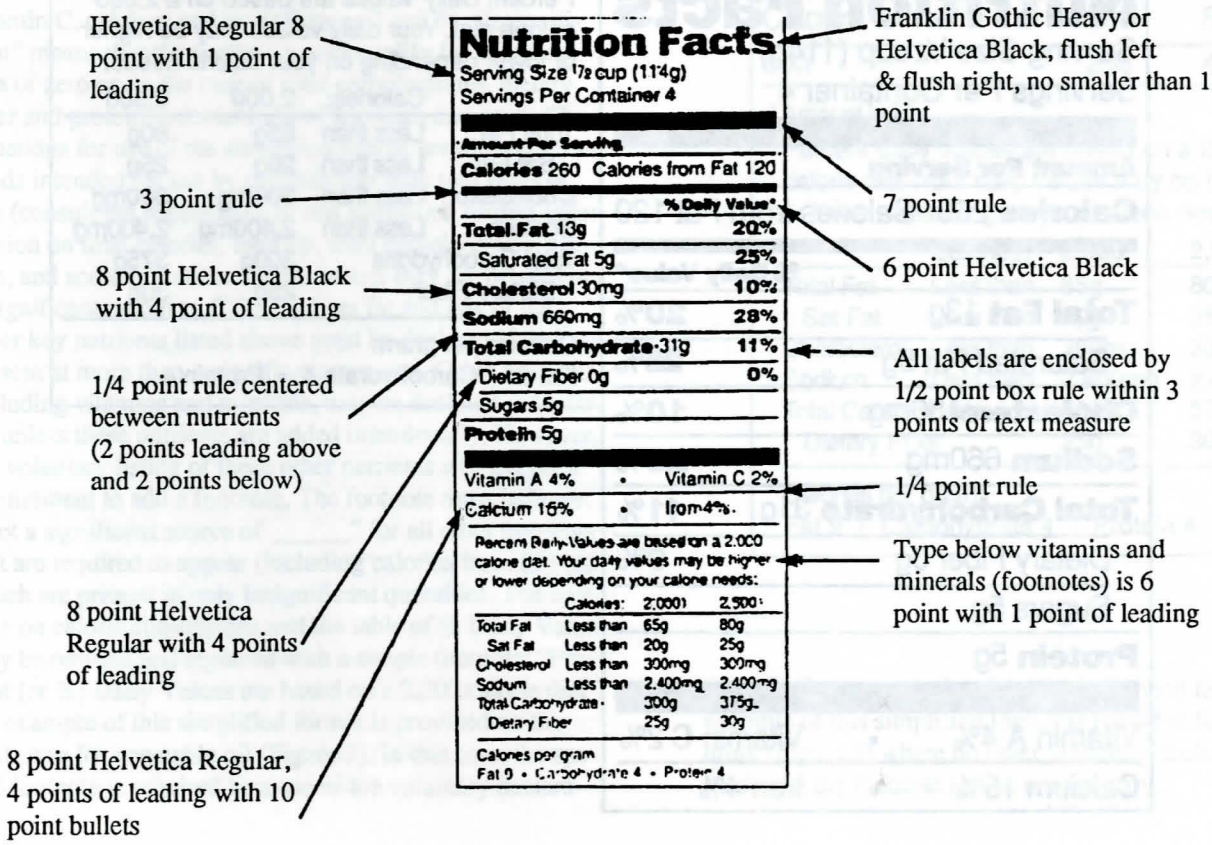
C. Rules

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.

Figure 4. Appearance of Graphic Design of Nutritional Label



As can be seen from the example labels, the specific nutrients are listed in a defined order with the amounts per serving given by weight (either grams or milligrams depending on the nutrient) and the % daily value (except in the case of protein and sugars where no % daily value is required. The % Daily Value would be a favored heading, although abbreviations such as Percent DV and % DV are allowed but must be explained in footnotes on the label.

Daily values refer to the Daily Reference Values (DRVs) for macronutrients established by FDA in the new regulations. % Daily Value declarations expressed to the nearest whole percent (derived from the actual amount of the nutrient divided by the DRV) are required for total fat, saturated fat, cholesterol, sodium, total carbohydrates and total dietary fiber, but not for protein or sugars. A % Daily Value can be voluntarily included for protein, but requires the determination of the biological value of the protein in experimental animals, a very expensive analysis. For other mandatory and voluntarily listed macro-nutrients such as sugars, soluble and insoluble fiber, etc., there are no DRVs so the % daily value column should be left blank in these cases. The exception is potassium which does have a DRV.

Vitamins and minerals are listed below a bold line underneath the macronutrients. Only vitamin A, vitamin C, calcium and iron are required listings. Other vitamins and minerals can be listed voluntarily, except in the case of fortified products where listing is mandatory. The % daily value is used to express the amount of vitamins and minerals in a serving of the product. In these cases, the % daily value is based upon the Reference Daily Intakes (RDIs) which are identical to the old USRDA figures. The FDA promises to change these figures in a separate regulation late in 1993 or early 1994. The percentages of vitamins and minerals must be listed in horizontal pairs, unless more than four entries are included, in which case a vertical arrangement with a percent daily value column would be required.

A footnote is then required on most labels which explains that the percent daily value calculations are based on a 2,000 calorie diet. An example of the required footnote can be seen in the example label on the previous pages. This footnote can appear to the right of the percent daily value information on the label, but only if inadequate space exists beneath the vitamin and mineral information as shown on another example (Figure 5). The footnote is followed by a table illustrating the total daily values for both a 2,000 calorie and 2,500 calorie diet. Since different consumers require different caloric intakes, this modification is intended to help prevent consumers from getting the notion that everyone should exist on a 2000 calorie diet. Presumably, with this information, consumers could re-calculate all of the % daily value information on the label for a 2,500

Figure 5. Example of Nutrition Label with Footnotes on the Right Side.

Nutrition Facts

Serving Size 1/2 cup (114g)
Servings Per Container 4

Amount Per Serving	
Calories 260 Calories from Fat 120	
	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**11%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	
Vitamin A 4% •	Vitamin C 2%
Calcium 15% •	Iron 4%

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

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

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

calorie diet. Finally, another footnote is needed to indicate the basis for caloric calculations from fat, carbohydrate, and protein. There are very specific rules on the appearance of these footnotes and table. The example (Figure 4) provides the ideal format.

Several variations are allowed from the standard format. The dual declaration (Figure 6) is voluntary. Because the nutrient content of some food products will change after purchase, when prepared or when consumed with other foods, a dual declaration may be used to reflect these alterations. The familiar example would be a dry muffin mix versus the muffins made from the mix and the additional egg and milk. An example of a dual declaration label is provided right. The only variation is the inclusion of a second column for % daily value with the combination of ingredients. The two columns must have clearly defined headings as indicated in the example. The weights of the macronutrients, in the prepared or combined form, may be provided to the right of the mandatory weight declarations or in a footnote listing, in the same order, those nutrients affected by the preparation or combination. For example, a breakfast cereal might include in the footnote that follows the declaration of total grams of fat in the dry form the following information: "1/2 cup skim milk contributes an additional 40 calories, 65 mg sodium, 6 g total carbohydrates (6 g sugars), and 4 g protein".

A simplified variation of the standard label format is voluntarily allowed for food products that contain insignificant amounts of **seven** or more of the following nutrients: total calories, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium and iron (Figures 7 and 8). "Insignificant" means that the nutrient would qualify for a declaration of zero or, in the case of total carbohydrates, dietary fiber and protein, a declaration of less than one gram. The situations for use of the simplified format are different for foods intended for use by children less than two years of age (consult the regulation). In this simplified format, information on total calories, total fat, total carbohydrates, protein, and sodium must be listed, even if they are present in insignificant amounts. Calories from fat and any of the other key nutrients listed above must be declared if they are present at more than insignificant amounts. Other nutrients, including vitamins and minerals, may be declared voluntarily unless these nutrients are added intentionally. However, the voluntary listing of these other nutrients will trigger a requirement to add a footnote. The footnote must indicate: "Not a significant source of _____" for all other nutrients that are required to appear (including calories from fat) but which are present in only insignificant quantities. The footnote on caloric conversions and the table of % Daily Values may be omitted and replaced with a simple footnote: "Percent (or %) Daily Values are based on a 2,000 calorie diet". An example of this simplified format is provided on the next page for vegetable oil (Figure 7). In this case, the special footnote is required because of the voluntary declaration of polyunsaturated and monounsaturated fat. Another example of this simplified format is provided for a soft drink (Figure 8) where no other voluntary declarations are made and the footnote is thus unnecessary.

Figure 6. Example of Nutrition Label with Dual Declaration

Nutrition Facts

Serving Size 1/12 cup (45g)
Servings Per Container 12

Amount Per Serving	Mix	Baked
Calories	190	280
Calories from Fat	45	135
	% Daily Value**	
Total Fat 5g*	**13%**	**36%**
Saturated Fat 2g	**10%**	**13%**
Cholesterol 0mg	**0%**	**23%**
Sodium 300mg	**8%**	**9%**
Total Carbohydrate 34g	**9%**	**9%**
Dietary Fiber 0g	**0%**	**0%**
Sugars 18g		
Protein 2g		
Vitamin A	0%	0%
Vitamin C	0%	0%
Calcium	6%	8%
Iron	2%	4%

* Amount in Mix

** 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

Figure 7. Example of Simplified Nutrition Label Format (Vegetable Oil).

Nutrition Facts

Serving Size 1 Tbsp (14g)
Servings Per Container 64

Amount Per Serving	
Calories 130 Calories from Fat 130	
	% Daily Value*
Total Fat 14g	**22%**
Saturated Fat 2g	**10%**
Polyunsaturated Fat 4g	
Monounsaturated Fat 8g	
Sodium 0mg	**0%**
Total Carbohydrate 0g	**0%**
Protein 0g	

Not a significant source of cholesterol, dietary fiber, sugars, vitamin A, vitamin C, calcium, and iron.

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

Figure 8. Example of Simplified Nutrition Label Format (Soft Drink).

Nutrition Facts

Serving Size 1 can (240 ml)

Amount Per Serving	
Calories 145	
	% Daily Value*
Total Fat 0g	**0%**
Sodium 20mg	**1%**
Total Carbohydrate 36g	**12%**
Sugars 36 g	
Protein 0g	**0%**

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

Figure 9. Tabular Nutrition Label Format for Intermediate-Size Packages.

Nutrition Facts

Serv. Size 1/3 cup (56g)
Servings about 3
Calories 80
Fat Cal. 10

*Percent Daily Values (DV) are based on a 2,000 calorie diet.

Amount/serving	% DV*	Amount/Serving	% DV*
Total Fat 1g	**2%**	**Total Carb.** 0g	**0%**
Sat.Fat 0g	**0%**	Fiber 0g	**0%**
Cholest. 10mg	**3%**	Sugars 0g	
Sodium 200mg	**8%**	**Protein** 17g	

Vitamin A 0% • Vitamin C 0% • Calcium 0% • Iron 6%

The regulation also provides for exemptions and simplified formats for small packages. For packages with less than 12 square inches of surface area available for labeling, a total exemption from the nutritional labeling requirements is granted, as long as the label bears no nutrition information or claims and includes an address or telephone number where consumers can request nutrition information. Intermediate-size packages, or those with up to 40 square inches of available surface area for labeling, may use a shortened version of the nutritional label. The information can be presented in a tabular fashion (Figure 9) when vertical columns cannot be accommodated and linear fashion if tabular formats cannot be accommodated. Some abbreviations are allowed on these packages and the explanatory information at the bottom of the label can be omitted.

Finally, a shortened version of the nutrition label format is allowed on certain products which contain 0 percent of one or more of certain macronutrients. In this case, these macronutrients may be included in a footnote rather than in the vertical table. Calories, total fat, sodium, total carbohydrate and protein must always appear on the vertical table

on the label. Other macronutrients, and the required vitamins and minerals, can be included in a footnote as follows, "Not a significant source of _____". An example of the shortened label for a vegetable soup is given in Figure 10.

Daily Reference Values and Reference Daily Intakes. The DRVs are established in the new regulation for several food components considered important in or relevant to the maintenance of good health:

Protein	50 grams
Carbohydrates	300 grams
Fats	65 grams total fat
Saturated Fat	20 grams
Cholesterol	300 mg
Dietary Fiber	25 grams
Sodium	2400 mg
Potassium	3500 mg

These figures must be used in calculating the % daily values for the vertical portion of the nutritional label. These quantities are also used in the table at the bottom of the label for the 2,000 calorie diet column. For the 2,500 calorie diet column, the quantities are increased accordingly, except for cholesterol and sodium, which remain at 300 mg and 2,400 mg, respectively. The listing of potassium on the label and calculation of its % daily value is voluntary.

The Reference Daily Intakes (RDIs) are used for vitamins and minerals. As noted earlier, FDA will only require the listing of vitamin A, vitamin C, calcium and iron except for fortified foods. For now, the FDA is using the USRDA values as the RDIs. FDA intends to publish a regulation sometime after November 8, 1993 to establish revised RDI values.

Food Names. The new regulations have a small, but significant, impact on the basic rules for food naming. The new regulations adopt a new standard for foods whose names combine a nutrient content descriptor, such as "reduced calorie" or "lite", and the name of a standardized food, mayonnaise or cottage cheese, for example. To employ such names as "reduced calorie mayonnaise", the product must meet the requirements for the nutrient descriptor (see below). Ingredients required to be present in the standardized foods can be replaced (e.g. by a fat substitute), as long as the food remains functionally equivalent to the standardized food. If not, the limitations to use must be disclosed on the label. Some special labeling options are possible for such nutrient-modified foods, and the new regulations should be consulted for details.

Nutrient Descriptors. The new regulations establish both general and specific criteria for the use of nutrient content descriptors, both as free-standing claims and as part of brand names. The definitions for various nutrient descriptors (Figure 11), relative claim definitions for meal-type products and main dishes (Figure 12) and relative claim definitions for individual foods (Figure 13) are provided for easy reference.

Figure 10. Example of Alternative Shortened Format for Nutrition Label (Vegetable Soup).

Nutrition Facts

Serving Size 1cup (245g)
Servings Per Container 2

Amount Per Serving

Calories 55 Calories from Fat 20

	% Daily Value*
Total Fat 1g	**2%**
Sodium 800mg	**33%**
Total Carbohydrate 31g	**11%**
Dietary Fiber 4g	**16%**
Sugars 0g	
Protein 2g	

Vitamin A 20% • Vitamin C 4% • Iron 2%

Not a significant source of saturated fat, cholesterol, and calcium.

* 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

Figure 11. NUTRIENT DESCRIPTOR CLAIM DEFINITIONS*

	Individual Foods			Meal-Type and Main Dish Products
Nutrient	**Free**	**Low**	**Other**	**Low**
	Synonyms for "FREE": "Zero," "No," "Trivial Source (Amount) of," "Dietarily Insignificant Source (Amount) of," "Without," "Negligible Source (Amount) of"	Synonyms for "Low": "Little," "Few" for calories, "Contains a Small Amount of," "Low Source of"		Definitions for "Free" are same as for individual foods except per labeled serving
Calories	Less than 5 cal/reference amount	40 cal or less/reference amount +		120 cal or less/100 g
Sodium	Less than 5 mg/reference amount and no added ingredient that contains sodium (unless specific qualification is made after the ingredient statement)	140 mg or less/reference amount +	Very Low: 35 mg or less/reference amount + "Salt Free" must meet criterion for "Sodium Free" "No Salt Added" and "Unsalted" must meet conditions of use and must declare "This Is Not A Sodium Free Food"	140 mg or less/100 g Very Low: 35 mg or less/100 g
Total Fat	Less than 0.5 g/reference amount and no added ingredient that is fat or contains fat (unless specific qualification is made after the ingredient statement)	3 g or less/reference amount +	"__% Fat Free": meets the requirements for "Low Fat"	3 g or less/100 g and no more than 30% of calories from fat
Saturated Fat	Less than 0.5 g/reference amount and 1% or less of total fat is trans fatty acids and no added ingredient containing saturated fat (unless specific qualification is made made after the ingredient statement)	1 g or less/reference and 15% or less of calories from saturated fatty acids	MUST DECLARE THE AMOUNT OF CHOLESTEROL AND TOTAL FAT NEXT TO CLAIM, UNLESS THE FOOD MEETS THE DEFINITION OF "FAT FREE," "LOW FAT" OR "CHOLESTEROL FREE"	1 g or less/100 g and less than 10% of calories from saturated fat
Cholesterol	Less than 2 mg/reference amount and no added ingredient containing cholesterol (unless specific qualification is made after the ingredient statement) When fat exceeds 13 g/serving, reference amount and 50 g, must declare the amount of "Total Fat" next to claim, and must be "Substantially Less" (25% reduction) than reference food with significant market share (5% of market)	20 mg or less/reference amount + When fat exceeds 13 g/serving, reference amount and 50 g, must declare the amount of "Total Fat" next to claim, and must be "Substantially Less" (25% reduction) than reference food with significant market share (5% of market)	CHOLESTEROL CLAIMS ONLY ALLOWED WHEN FOOD CONTAINS 2 G OR LESS SATURATED FAT/ SERVING	20 mg or less/100 g and contains no more than 2 g of saturated fat per 100 g. When fat exceeds 26 g for meal-type products or 19.5 g for main dishes per labeled serving, must declare "Total Fat" next to claim and must be "Substantially Less" (25% reduction than reference food with significant market share (5% of market)
Sugar	Less than 0.5 g/reference amount and no added ingredients are sugars or contain sugars (unless specific qualification is made after the ingredient statement) Food is labeled "low calorie" or "reduced calorie" or bears a relative claim of special dietary use or states that the food is not "low" or "reduced" calorie	Not Defined	"No Added Sugar" is allowed if it meets conditions of use	Less than 0.5 g/serving

Note: For individual foods, if the serving size differs from the reference amount and the nutrient content is more than the maximum amount to make the claim, then the criteria for the claim must follow the claim (e.g., "very low sodium, 35 mg or less per 240 milliliters (8 fl. oz.)").

* Statement "See ____ panel for nutrition information" must accompany all content claims. Disclosure of othe negative nutrient is required as part of statement when levels exceed 13 g fat, 4 g saturated fat, 60 mg cholesterol, and 480 mg sodium per reference amount, labeled serving or for a food with a reference amount of 30 g or less or 2 Tbsp or less per 50 g.

+ And per 50 g, for a food with a reference of 30 g or less or 2 Tbsp or less, per 50 g (nutrient density requirement).

Prepared by Grocery Manufacturers of America, Washington, D.C.

One unique feature of the new regulations is that comparative or relative claims are allowed (Figures 12 and 13). Certain types of comparative claims, such as "pretzels have fewer calories than potato chips", can be made between product categories. All other comparative claims must be made within a food category. For example, a "light" food must be compared with a "representative" food (average or market basket value) in its category. All other comparisons can be made either against a representative food, or an identified food of the same or another manufacturer. For example, a company could make comparative claims such as "Contains more calcium than _____ (competitor's brand)". The regulations should be consulted for rules on the selection of reference foods, as these situations can be rather complex.

Figure 12. Relative Claim Definitions for Meal-Type Products and Main Dishes

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 in the type size required for net contents declaration or one-half the size of the claim, as appropriate, but in no case less than one-sixteenth of an inch. Quantitative comparison of the amount of the nutrient in the product per labeled serving size with that in the reference food must appear either adjacent to the claim or on the information panel.

REDUCED, LESS, AND LIGHT DESCRIPTORS

"Reduced"	Reduced by 25% per 100 g as compared to the reference food when a meal-type product has been reformulated.
"Light/Lite"	Must meet the definition of "low" for calories, fat or both (e.g., "Light _____, Low Calorie and Low Fat"). "Light/Lite in Sodium" — meets the definition for "Low Sodium."
"Less" or "Fewer"	Comparative claims based on 100 g of the food — Products bearing such claims must include a statement indicating the amount of the reduction of the nutrient per specified weight (e.g., Contains 33% less fat per ounce than Brand Y meal product. Fat content has been reduced from 2.5 g/ounce to 1.7 g/ounce.).

OTHER NUTRIENT DESCRIPTOR CLAIMS

"More," "Fortified," "Enriched," or "Added"	Contains 10% or more of the RDI or DRV for protein, vitamins, minerals, dietary fiber or potassium per 100 g of food than the reference food. With respect to fortified foods, fortification is in accordance with FDA's policy.
"Good Source" or "Source," "Contains" or "Provides"	Contains 10-19% of the RDI or DRV per reference amount and the label identifies the food that is subject to the claim (e.g., "The serving of sweet potatoes in this product is a good source of fiber.")
"High," "Rich In" or "Excellent Source"	Contains 20% or more of the RDI or DRV per reference amount and the label identifies the food that is subject to the claim (e.g., "The serving of broccoli in this product is high in Vitamin C.")
Fiber Claims (More, High, Good Source)	If the food is not low in fat as defined, then the level of fat per serving must be disclosed.
"Lean"	Contains less than 10 g of fat, less than 4 g of saturated fat and less than 95 mg of cholesterol per 100 g and per labeled serving
"Extra Lean"	Contains less than 5 g of fat, less than 2 g of saturated fat and less than 95 mg of cholesterol per 100 g and per labeled serving

* Statement "See _____ panel for nutrition information" must accompany all content claims. Disclosure is required for meal-type products when levels exceed 26 g of fat, 8 g of saturated fat, 120 mg of cholesterol or 960 mg of sodium per labeled serving. Disclosure is required for main dishes when levels exceed 19.5 g of fat, 6 g of saturated fat, 90 mg of cholesterol or 720 mg of sodium per labeled serving.

Prepared by Grocery Manufacturers of America, Washington, D.C.

Figure 13. Relative Claim Definitions for Individual Foods

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 in the type size required for net contents declaration or one-half the size of the claim, as appropriate, but in no case less than one-sixteenth of an inch. Quantitative comparison of the amount of the nutrient in the product per labeled serving size with that in the reference food must appear either adjacent to the claim or on the information panel. Relative claims may not be made when the amount of nutrient in the reference food is less than the value for "low".

LIGHT, REDUCED, AND MODIFIED DESCRIPTORS

"Light" / "Lite"	For foods with 50% or more calories from fat, 1/2 less fat per reference amount, or for foods with less than 50% calories from fat, 1/3 fewer calories or 1/2 less fat per reference amount as compared with the reference food., Reference standard: nutrient values for a food or group of foods whose nutrient values are accurately representative of a broad base of individual foods of the same type as those that ear the claim, such as an average value determined from the top three national (or regional) brands of the food, a market basket norm, a representative valid data base or a market leader where its nutrient value is representative of the food type. "Light/Lite" may refer to sodium with a 50% reduction in sodium and meet the definition for "low" in calories and fat. "Light/Lite in Sodium" — 50% reduction in sodium "Lightly salted" — contains at least 50% less added sodium than the regular brand.
"Reduced," "Less"* or "Fewer"	Reduced by at least 25% as compared with the reference food. Reference foods: regular brand or another manufacturer's regular brand or a broad base of foods of a particular type, including those reported in a representative valid data base.
"Modified"	May be used in statement of identity that bears a relative claim, e.g., "Modified Fat Cheesecake, Contains 35% Less Fat Than Our Regular Cheesecake"

OTHER NUTRIENT DESCRIPTOR CLAIMS

"More,"* "Fortified," "Enriched" or "Added"	Contains 10% or more of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) per reference amount to describe protein, vitamins, minerals, dietary fiber or potassium. With respect to fortified foods, fortification is in accordance with FDA's policy.
"Good Source" or "Source," "Contains" or "Provides"	Contains 10-19% of the RDI or DRV per reference amount
"High," "Rich In" or "Excellent Source"	Contains 20% or more of the RDI or DRV per reference amount.
Fiber Claims (More, High, Good Source)	If the food is not low in fat as defined, then the level of fat per serving must be disclosed.
Quantitative nutrient statements	Declarations of absolute amounts of nutrient content (e.g., 25 calories per serving) can be made if consistent with any descriptor for that nutrient (low, reduced, less). If the statement is not consistent with a defined descriptor, a disclaimer must accompany the claim (e.g., 100 calories per serving, not a low calorie food).

FRESH CLAIMS

"Fresh" (used to imply that the food is unprocessed)	A raw food that has not been frozen, heat processed or otherwise preserved.
"Fresh" (not used to imply that the food is unprocessed)	Is not subject to FDA's "Fresh" regulation (e.g., fresh milk, fresh bread).
"Fresh Frozen"	Food was quickly frozen while still fresh.

*The terms "less" and "more" can be used in comparing dissimilar products in the same product category (e.g., potato chips as a reference for pretzels).

Prepared by Grocery Manufacturers of America, Washington, D.C.

The use of nutrient descriptor claims or health claims (see below) on a product will trigger the requirement for a nutritional label, even if the product would otherwise be exempt. The use of such claims, then, should be approached cautiously by small businesses that might otherwise be exempt.

The FDA and USDA regulations also provide definitions for "lean" and "extra lean". "Lean is less than 10 grams fat, 4 grams saturated fat and 95 mg cholesterol per serving and per 100 grams. "Extra lean" figures are 5 grams, 2 grams, and 95 mg, respectively.

Implied Nutrient Claims. The new regulations provide a general discussion of what are, and are not, implied nutrient claims. This may be a difficult point if a specific example is not included in the regulation, as it requires a certain amount of judgment. For example, a non-quantitative statement of identity such as "oat bran muffin" is not an implied nutrient claim. A quantitative statement such as "high in oat bran", however, is an implied fiber claim. Absence claims for ingredients that are not nutrients or that relate to dietary practices or religious beliefs are not implied nutrient claims.

Fresh Claims. The FDA regulations include a definition for the use of the terms "fresh" and "fresh(ly) frozen". FDA has revised its prior position, and limited the definitions to those instances where the use of the term "fresh" would imply or suggest that the food is unprocessed or unpreserved. Where it is readily evident that the food is processed, as in the case of "fresh bread", the use of the term "fresh" is not prohibited unless it is somehow false or misleading. Where the usage would imply that the food is unprocessed or unpreserved, such as "fresh pasta sauce", the use of the term "fresh" is limited to food in its raw state, although certain post-harvest processes are allowed if the food, as presented to the consumer, would be accepted as fresh produce. "Fresh(ly) frozen" can be used to describe processing of fresh, i.e. raw food.

Health Claims. Health claims are allowed on certain types of products. In several cases, the allowed health claims relate to specific nutrients/ components and specific diseases. The only allowed health claims of this type are:

- Calcium and osteoporosis
- Fat and cancer
- Saturated fat and cholesterol and coronary heart disease
- Sodium and hypertension

In a few cases, health claims are allowed for specific categories of food products and specific diseases, but not for the dietary component that may be commonly associated with the beneficial effect of these foods (because FDA currently believes that the scientific evidence does not warrant such a claim). These allowed health claims are:

- Fiber-containing grain products and cancer
- Fruits and vegetables and grain products containing fiber and coronary heart disease
- Fruits and vegetables and cancer

If anyone is interested in making such a health claim, the regulation should be consulted for specific guidance. But, the following important provisions now exist:

(1) The effective date for health claims regulations is **May 8, 1993** rather than 1994. If you are currently making any health claims, you should immediately consult the regulations to determine if your claims are still allowed. Existing, inaccurate labels, posters or leaflets cannot be used after May 8, 1993, although products labeled before that date can remain in commerce after May 8, 1993.

(2) Unapproved health claims, either express or implied, are prohibited. Claims can be made through direct statements, third-party references (e.g. to NIH guidelines), symbols (the heart symbol), vignettes or descriptions.

(3) Implied health claims are prohibited, unless the label meets all of the requirements for an approved health claim. An implied claim is a representation in words or by symbols that would be understood to assert a relationship between the level of a substance in the food and a disease or health-related condition.

(4) Certain foods are disqualified from making a health claim. Disqualifying nutrient levels are prescribed for total fat (13 g), saturated fat (4 g), cholesterol (60 mg) and sodium (480 mg) per reference amount normally consumed and per serving. Foods consumed in small amounts must also meet these levels on a per 50 g basis.

(5) Model language to be used in health claims is provided in the regulations and significant changes should not be considered.

(6) Claims must state that other factors play a role in the specific disease, must be phrased in terms of the daily diet and must use "may" or "might" in describing the relationship between the substance and a disease.

(7) The food must qualify for a "low" descriptor claim if the health claim relates to a decreased dietary intake of a nutrient such as cholesterol, sodium or fat.

(8) The food must qualify for a "high" nutrient claim if the health claim relates to an increased intake of the nutrient such as calcium.

(9) Claims must appear at one place on the label, but the front panel may refer to another place on the label where the claim appears.

(10) Petitions for other health claims are allowed, and a process is defined in the regulations, but this will be a difficult proposition at best.

The grain products industry, which processes many products containing fiber, may wish to consider the use of health claims. Model health claims for those types of products are provided on the following page:

Grain Products that contain fiber and Coronary Heart Disease

"Diets low in saturated fat and cholesterol and rich in fruits, vegetables and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors."

or

"Development of heart disease depends on many factors. Eating a diet low in saturated fat and cholesterol and high in fruits, vegetables and grain products that contain fiber may lower blood cholesterol levels and reduce your risk of heart disease."

Fiber-Containing Grain Products and Cancer

"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."

or

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

The dairy industry may wish to promote the availability of calcium in some of their products. Remember, however, that the product cannot exceed the disqualifying levels of fat, saturated fat or cholesterol. An example of a model health claim for calcium is:

"Regular exercise and a healthy diet with enough calcium help teen and young adult white and Asian women maintain good bone health and may reduce the risk of osteoporosis later in life."

Proposals for Use of "Healthy". Both the USDA and FDA proposed new regulations dealing with the use of the term "healthy" on food labels. These proposals are open for comments (see deadlines on pg. 1), and anyone having an interest in this issue should read the proposal and make comments. Slight differences exist between the USDA and FDA proposals. The FDA proposal would define healthy products as low in fat (<3g) and saturated fat (<1 g) with less than 480 mg of sodium and 60 mg of cholesterol per serving. The FDA proposal, if approved, would essentially mean that almost no meat or poultry products could be labeled as "healthy". The USDA proposal defines healthy products as meeting the definition of lean (<10 g fat, <4 g saturated fat and <95 mg of cholesterol per serving or 100 grams), and also having less than 480 mg of sodium per serving. Currently, these are only proposals. No label changes are needed on this point.

Changes in Ingredient Labeling. With this new regulation, FDA has also announced some rather extensive changes in ingredient labeling, although it decided to withdraw many of the November, 1991 proposal suggestions that created a lot of controversy in industry. The most important of the mandated changes are outlined below:

(1) Standardized foods must now contain a list of ingredients in descending order of predominance, a previous requirement for only non-standardized foods. This change goes into effect on May 8, 1993, and affects virtually all standardized foods such as mayonnaise and ketchup. If you do not have an ingredient statement on your product, one must be in place by May 8, 1993.

(2) Certified color additives must be listed by name e.g. Blue 2, Red 40. Previously, many of these color additives were listed under the collective term "artificial colors", a practice that will no longer be permitted. This regulation also goes into effect on May 8, 1993, so quick action is needed. Simplified names, such as Blue 2, can be used rather than FD&C Blue No. 2. This regulation also applies to the lakes of the certified colors. The regulation also specifies that when noncertified colors are declared by their common or usual name, the declaration should make clear that they are added for coloring purposes only, e.g. "caramel color" rather than just caramel.

(3) Certain collective terms (e.g. "milk and milk fat") continue to be permitted in specific standardized foods such as cheeses, even though these collective terms are not generally allowed with nonstandardized foods.

(4) Sweetener ingredients in standardized foods are permitted to include an identification of the source of the sweetening ingredient, corn sugar monohydrate rather than dextrose monohydrate, for example. This is voluntary.

(5) Protein hydrolysates must now be labeled according to the source or sources of the hydrolysate. Terms such as "hydrolyzed vegetable protein" will be insufficient and must be replaced by terms such as "hydrolyzed soy protein" or "hydrolyzed wheat gluten". Processors may voluntarily use terms such as "partially", "lightly" or "mildly" in the declaration of protein hydrolysates that are not extensively hydrolyzed (i.e. an α-amino nitrogen to total nitrogen ratio of not less than 0.62). This regulation goes into effect on May 8, 1994.

(6) ***Proposal Only:*** The FDA also released a new proposal that would require a parenthetical declaration, "(contains glutamate)", for example, on protein hydrolysates with α-amino nitrogen to total nitrogen ratio of greater than 0.62. Comments on this proposal are due by March 8, 1993, and it is not yet a final rule.

(7) The final FDA regulation also mandates the disclosure, through labeling of the package or via point of sale information if the product is not packaged, of waxes and resins used on fresh fruits and vegetables. The regulation requires only simplified labeling of coatings as having animal, vegetable, petroleum, beeswax and/or shellac sources rather than requiring specific compositional information. This regulation goes into effect on May 8, 1994.

(8) Where caseinates are used as food ingredients, and the food is characterized as "nondairy", the caseinates must be identified in the ingredient listing as being milk derived. This regulation goes into effect on May 8, 1994.

(9) Manufacturers may voluntarily provide ingredient percentage information on the label. These declarations would have to appear in parentheses following the name of the ingredient and be expressed in terms of percentage by weight to the nearest one percent.

(10) Any standardized food that contains a sulfiting agent or combination of sulfiting agents that is functional and provided for in the applicable standard or that is present in the finished food at a detectable level (>10 ppm by a specified test) must include a declaration of the sulfiting agent(s) on the ingredient listing. This regulation goes into effect on May 8, 1994. All nonstandardized foods have been subject to a similar provision for several years.

(11) ***Proposal Only:*** The FDA further proposed to change the ingredient declaration for soft drinks to include an "and/or" declaration for sugar, high fructose corn syrup and any other sweeteners. This is simply a proposal at this point, and open for comment until March 8, 1993.

(12) ***Proposal Only:*** The FDA also proposed that vegetable broth used in canned tuna, if it contains soybeans, must declare that ingredient parenthetically e.g. "vegetable broth (contains soybeans)". This is simply a proposal at this point, and open for comment until March 8, 1993.

Percent Juice Labeling. FDA also adopted regulations implementing the juice percentage labeling requirement. In this case, the declaration is required to be stated separately from other ingredients and "near the top" of the information panel in type as least as large as the brand name. The declaration can be as simple as "___ % juice", but may be expanded to include the names of various juices, although only a total percentage is required. This declaration is required on any beverage that claims to contain juice, regardless of product form (dried, concentrate or ready-to-drink) or whether any juice is present ("0% juice"). This regulation is a bit complex and should probably be consulted by affected companies.

Slack Fill Proposal. FDA has proposed an amendment to its current regulations that would define the circumstances in which slack-fill within a package is non-functional and therefore misleading. This is simply a proposal at this point, open for comments until March 8, 1993. A final rule may be issued by May 8, 1993.

Slack fill is the empty space in a package. The proposal would define non-functional (illegal) slack-fill as empty space in a package for reasons other than (1) protection of the contents, (2) packaging machinery requirements, (3) normal product settling, (4) the need for the package to perform a specific function such as in the preparation or consumption of the food and (5) the product is a gift consisting of a food combined with a reuseable gift container. The FDA did not establish specific slack-fill limits in the proposal.

State Preemption and Enforcement. These new FDA and USDA regulations will preempt any existing state regulations immediately upon their dates of implementation. This means the food industry can assure itself of national uniformity on food labeling for the first time. States can petition the FDA for exceptions to these federal regulations, but the likelihood of successful petitions, given the stipulations in the new regulation, seems slim.

States will be able to enforce the new federal food labeling regulations, and much of the enforcement is likely to occur at the state level. FDA plans to conduct training sessions to inform their own field officers and state regulators about the new regulations. However, these regulations are very complex, and some enforcement mistakes are likely to be made in the first few years.

The USDA Regulations. Most of the information provided above has referred to the FDA regulations. The USDA regulations only differ in a few ways from the FDA regulations, and many of these differences were mentioned. A USDA FSIS Backgrounder is available which provides more information on USDA regulations. It can be obtained by calling the USDA-FSIS Information Office in Washington, D.C. (telephone number: 202/720-9113).

Other Sources of Information. The FDA has also published an issue of its *FDA Backgrounder* which provides a summary of the new labeling regulations. This pamphlet can be obtained by writing to Food and Drug Administration, 200 C Street S.W., Washington, D.C. 20204. Request the December 10, 1992 issue of this newsletter, as it contains two portrayals that summarize the new regulations and illustrate the appearance of the new food labels quite nicely; they are attached here as Figures 14 and 15.

Figure 14. 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
- light
- more
- good source
- high
- low
- reduced
- 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 diseaes, diets low in saturated fat and cholesterol may reduce the risk of this disease."

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 the 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

Source: Food and Drug Administration 1992