Food Labeling

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In June 1990, the American Diabetes Association approved a food labeling position statement (1) that emphasized the following four general points: *1*) food labeling must be truthful, meaningful, understandable, and complete; 2) no food should be designated or promoted as nutritionally good, bad, healthful, or unhealthful for people with diabetes; 3) education, based on principles of good nutrition and use of food labels, is essential for people with diabetes; and 4) specific recommendations for label inclusions.

Since its approval and publication in 1990, this position statement has been used as documentation for comments to the Food and Drug Administration (FDA) concerning proposed food labeling regulations and as guides for critiques of food-related components of American Diabetes Association corporate sponsorships and advertising.

In November 1990, passage of the Nutrition Labeling and Education Act (NLEA) (public law 101–535) mandated the new national food labeling regulations. This act has been implemented by the FDA and the U.S. Department of Agriculture Food Safety and Inspection Service's (FSIS) labeling regulations, published in more than 2,300 pages of the 6 January 1993 *Federal Register* (2). Included in this document were summaries of and responses to over 40,000 comments as well as the actual wording of the final regulations. Regulations were in the form of revisions to the Code of Federal Regulations (CFR) (3,4).

The new regulations expand mandatory nutrition labeling to almost all food products and provide a revised food label format that

- includes a uniform list of nutrients for all products
- establishes new label reference values for nutrients and food components
- defines standard serving sizes for ~140 food product categories
- defines descriptive label words and phrases (such as the term *light*)
- defines health claims that can be made to describe the relationship between a food or food component and a disease or health-related condition
- requires a more informative ingredient listing.

Under the Federal Food, Drug and Cosmetic Act, FDA regulates dietary supplements (vitamins, minerals, herbs, and other similar nutritional substances) as foods, as long as no drug claims are made for them. In early January 1994, FDA issued NLEA-based final regulations for labeling dietary supplements (5). These rules require that dietary supplement labels provide the same basic nutritional information that is found on the labels of nearly all conventional foods. In addition, dietary supplements are subject to the general requirements for health claims that apply to conventional foods, including the NLEA requirement that health claims be supported by significant scientific agreement among qualified experts.

In almost all instances, these national labeling regulations have incorporated the components of the fourth general part of the American Diabetes Association's 1990 position statement (specific label recommendations) as well as emphasizing the first point (truthfulness). Therefore, focuses for a revised American Diabetes Association Food Labeling Position Statement now can shift to the 1990 labeling position points two (no food is nutritionally good or bad) and three (nutrition and labeling education) and the implications of these two points for people with diabetes.

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FDA, Food and Drug Administration; NLEA, Nutrition Labeling and Education Act; FSIS, Food Safety and Inspection Service; CFR, Code of Federal Regulations; DRV, Daily Reference Value; RDI, Reference Daily Intake; RDA, Recommended Dietary Allowance; U.S. RDA, U.S. Recommended Daily Allowance.

LITERATURE REVIEW AND ANALYSIS

— No single food can supply all of the nutrients needed by humans. Individual foods are composed of various amounts of macronutrients, micronutrients, water, and trace elements (6). Even the nutrient composition of one food may vary depending on a number of factors, including harvesting time and location and how the food is stored (7).

Although specific nutrients may be recommended in greater or lesser amounts for healthy individuals (8) and

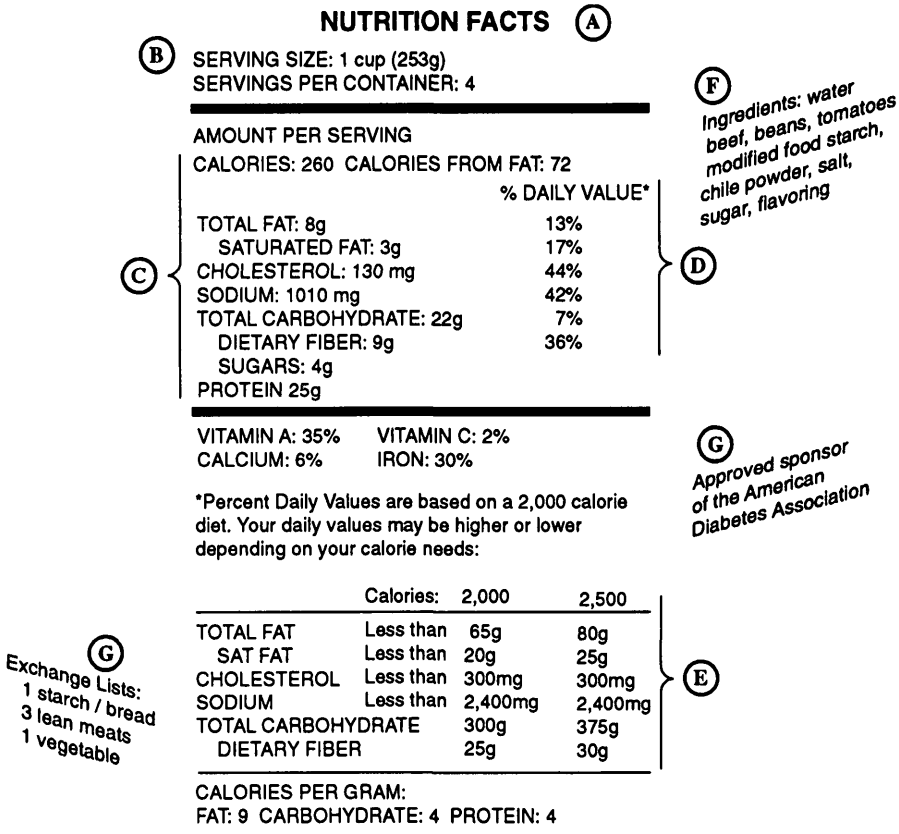

Figure 1—*Sample food label.*

for individuals with diabetes (9,10), no one food by itself can be judged nutritionally adequate or inadequate. It is technically difficult and biologically unnecessary to design a single day's diet that contains all of the Recommended Dietary Allowances (RDAs) for all nutrients (8). Goals are meant to reflect achievement over time. For most nutrients, RDAs are intended to be average intakes over at least three days. For more slowly metabolized nutrients (e.g., vitamins A and B_{12}) they may even be averaged over several months (8). Thus, a component of current federal nutrition guidelines (11,12) recommends that individuals follow a dietary pattern that contains a variety of foods and is adequate in calories, high in complex carbohydrates, and moderate in protein (especially animal protein), while being limited in fat, saturated fatty acids, cholesterol, sodium, added sugars, and alcohol (13,14).

There is no evidence that people with diabetes should follow different general nutritional recommendations than those stated above. Individual nutrient recommendations to reach and maintain glycemic control, however, should follow the guidelines from the 1994 American Diabetes Association Nutrition Position Statement (9).

FOOD LABEL REGULATIONS, 1993— Industry was required to comply with FDA food labeling regulations by 8 May 1994 and with FSIS regulations by 6 July 1994. FDA nutrition labeling regulations cover almost all foods except meat and poultry products and alcoholic beverages. FSIS labeling regulations pertain to meat and poultry products. Although there are many nuances in the regulations (see specifics of self-management section for examples), the basics as defined in the CFR require the food label to include the nutrition label; nutrient content claims; health claims; ingredient listing; other information, e.g., product name declaration, net quantity of contents, total percent juice content (for juice products), name and address of packer and distributor, and country of origin (if imported); and optional information, e.g., sponsorship/fund-raising information or exchange lists serving information.

Nutrition label

In the past, serving sizes for the same food produced by different manufacturers were not necessarily similar; many foods—for example, foods with standards of identity (more than 300 foods for which the federal government has defined composition) or foods that were imported—did not contain nutrient information; and the word *sugar* had many different interpretations. With the 1993 regulations, labels are more uniform and provide comparative nutrition information.

Format specification for labeling is delineated in 21 CFR 101.9(d). The identifying heading NUTRITION FACTS indicates at a quick glance the nutrition label (Fig. 1*A*).

Nutrients and food component quantities are to be declared in relation to a defined serving size (Fig. 1*B*) (21 CFR 101.9[b]), which is determined from the "Reference Amounts Customarily Consumed Per Eating Occasion" (21 CFR 101.12[b]; 2, p. 667, 2294–2298).

Nutrients and food components (e.g., calories) (Fig. 1*C*) that must be included on the nutrition label are delineated in 21 CFR 101.9(c) and include, in order: calories, calories from fat, total fat (with saturated fat indented under total fat), cholesterol, sodium, total carbohydrate (with dietary fiber and sugars indented under total carbohydrate), protein, vitamin A, vitamin C, calcium, and iron. Note that *sugars* is defined as the sum of all free mono- and disaccharides

(21 CFR 101.9[c][6][ii]), whether occurring naturally in foods or added to foods (15). Examples of naturally occurring sugars are glucose, fructose, and sucrose (in fruits and vegetables); lactose (in milk and milk products); and maltose (in cereals, grains, and legumes). Examples of added sugars include sucrose (table sugar), brown sugar, high fructose corn syrup, honey, and fruit juice concentrate. Labels may also include voluntary declaration of calories from saturated fat, polyunsaturated fat, monounsaturated fat, potassium, soluble fiber, insoluble fiber, sugar alcohol, and other carbohydrates (difference between total carbohydrate and the sum of dietary fiber, sugars, and, if declared, sugar alcohol).

Percent daily values for the specific food (Fig. 1*D*) are included, based on 2,000 calories per day, for fat (30% of calories), saturated fat (10% of calories), carbohydrate (60% of calories), fiber (11.5 g fiber/1,000 calories), sodium (2,400 mg/day), and cholesterol (300 mg/day) (21 CFR 101.9[c] and 21 CFR 101.9[g]; 2, p. 2218). Daily value is a new dietary reference value developed to help consumers use label information for planning a healthy overall food intake by declaring on the label the percent daily value for each nutrient that a serving of the food provides (based on 2,000 calories/day) and by providing a threshold that defines descriptive words for nutrient content (e.g., high fiber, low fat). It is not intended to tell people what amounts of nutrients to eat each day. Daily value is actually a combination of two sets of reference values for nutrients, Daily Reference Values (DRVs) and Reference Daily Intakes (RDIs).

DRVs apply to nutrients for which no set of standards previously existed (such as fat and cholesterol). FDA set the DRV for protein at 10% of calories and for fat at 30% of calories. FDA based the DRV for total carbohydrate on the quantitative recommendation from *Diet and Health* (14) that carbohydrate intake be 55% or more of calories. To allow the energy-yielding nutrients to add up to 100% of calories, the carbohydrate DRV was changed to 60% (2, p. 2220, 2222).

RDIs replace the U.S. Recommended Daily Allowances (U.S. RDAs), which were introduced in the early 1970s as a reference value for vitamins, minerals, and protein in voluntary nutrition labeling. U.S. RDAs should not be confused with RDAs (Recommended *Dietary* Allowances), which are set by the National Academy of Sciences (8). The FDA used the RDAs as the basis for setting the U.S. RDAs (now called RDIs) (15a).

To illustrate the use of daily values, Fig. 1*E* shows the goal daily values for target nutrients at two calorie levels, 2,000 and 2,500. Note that the percentage of calories of each of the macronutrients and the goal levels for the other nutrient calculations or figures given by the FDA to calculate DRVs (2, p. 2218) are not necessarily those recommended by the American Diabetes Association Nutrition Position Statement (9).

Nutrient content claims

In the past, nutrient content claims (such as *low cholesterol* or *light*) were undefined and sometimes used in a misleading manner. Definitions for these words now provide a framework on which manufacturers can base their labels and that consumers can use in understanding and interpreting these types of claims.

Specific requirements for nutrient content claims (descriptors) are defined for

- calorie content of food (21 CFR 101.60) (sugars content claims are defined here)
- *light* or *lite* (21 CFR 101.56)
- fat, fatty acid, and cholesterol content of food (21 CFR 101.62)
- sodium content of food (21 CFR 101.61)
- *good source*, *high*, and *more* (21 CFR 101.54).

Table 1 provides examples of meanings of some nutrient content claims descriptors. A more complete set of definitions is included in an educator's resource guide to food labeling (16). General principles, including type size and the wording of referral statements for nutrient content claims, are defined in 21 CFR 101.13.

Foods with standards of identity now may be altered or modified by using water and/or fat replacers (17) to reduce fat, cholesterol, and calories and still use the standard name and a nutrient content claim, rather than having to use a word such as *imitation* (21 CFR 130.10[d][5]). For example, the nutrient composition of sour cream is defined by the federal government. With the new labeling regulations, a product replacing some of the fat with water could call itself light sour cream rather than imitation sour cream.

Health claims

FDA has authorized health claims—any claim on the food label that describes the relation between a food or food component and a disease or health-related condition—for only eight diet and health relationships based on proven scientific evidence. (References for this "proof" of the eight allowed claims are provided in the *Federal Register* [2,5]). The government has provided suggested wording (models) if a health claim is appropriate for use on a food product. The allowed claims are relationships between

- calcium and osteoporosis (21 CFR 101.72)
- fiber-containing grain products, fruits, and vegetables and cancer (21 CFR 101.76)
- fruits and vegetables and cancer (21 CFR 101.78)
- fruits, vegetables, and grain products that contain fiber—particularly soluble fiber—and the risk of coronary heart disease (21 CFR 101.77)
- fat and cancer (21 CFR 101.73)
- saturated fat and cholesterol and coronary heart disease (21 CFR 101.75)
- sodium and hypertension (21 CFR 101.74)
- folate and neural tube defects (21 CFR 101.79).

In addition, a food must satisfy three nutrient criteria categories to qualify for a

Table 1—*Definitions of some words used for nutrient content claims*

Calories
- Calorie free: <5 calories per serving
- Low calorie: ≤40 calories per serving; if the serving is ≤30 g or ≤2 tablespoons, per 50 g of the food
- Reduced or fewer calories: at least 25% fewer calories per serving than reference food

Sugar
- Sugar free: <0.5 g per serving
- No added sugar, without added sugar, no sugar added
  1) No sugars added during processing or packing, including ingredients that contain sugars (such as fruit juices, applesauce, or dried fruit)
  2) Processing does not increase the sugar content above the amount naturally present in the ingredients
  3) The food that it resembles and for which it substitutes normally contains added sugars
  4) If the food does not meet the requirements for a low- or reduced-calorie food, the product bears a statement that the food is not low-calorie or calorie-reduced and directs consumers' attention to the nutrition panel for further information on sugars and calorie content
- Reduced sugar: at least 25% less sugar per serving than reference food

Light, lite: has one-third fewer calories or 50% less fat per reference amount. If more than half the calories are from fat, fat content must be reduced by 50% or more

Fat, saturated fat
- Fat free: <0.5 g of fat per serving
- Saturated fat free: <0.5 g per serving, and the level of trans fatty acids does not exceed 1% of total fat
- Low fat: ≤3 g per serving; if the serving is ≤30 g or ≤2 tablespoons, per 50 g of the food
- Low saturated fat: ≤1 g per serving and not more than 15% of calories from saturated fatty acids
- Reduced or less fat: at least 25% less per serving than reference food
- Reduced or less saturated fat: at least 25% less per serving than reference food

Cholesterol
- Cholesterol free: <2 mg of cholesterol and ≤2 g of saturated fat per serving
- Low cholesterol: ≤20 mg and ≤2 g of saturated fat per serving; if the serving is ≤30 g or ≤2 tablespoons, per 50 g of the food
- Reduced or less cholesterol: at least 25% less and ≤2 g of saturated fat per serving than reference food

Sodium
- Sodium free: <5 mg per serving
- Low sodium: ≤140 mg per serving; if the serving is ≤30 g or ≤2 tablespoons, per 50 g of the food
- Very low sodium: ≤35 mg per serving; if the serving is ≤30 g or ≤2 tablespoons, per 50 g of the food
- Reduced or less sodium: at least 25% less per serving than reference food

From Stehlin D: A little "lite" reading. In *FDA Consumer Special Report: Focus on Food Labeling*, May 1993, p. 32.

health claim. 1) A food must not exceed set nutrient levels for total fat, saturated fat, cholesterol, and sodium; a food product must have no more than 13 g total fat, 4 g saturated fat, 60 mg cholesterol, and 480 mg sodium per reference amount. (Main dish products and meal products may have higher limits.) 2) A food must meet specific nutrient requirements for each of the claims. For example, to make a claim about fiber and coronary heart disease, the food must be or must contain a fruit, vegetable, or grain product; must be low saturated fat, low cholesterol, and low fat; and must contain (without fortification) at least 0.6 g soluble fiber per reference amount, with soluble fiber content listed on the nutrition panel. If all requirements are met, the health claim can state "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." 3) Before any nutrient addition, a food must contain at least 10% of the daily value per serving size of one or more of the following nutrients: protein, dietary fiber, vitamin A, vitamin C, calcium, or iron (2, p. 2573–2574).

Ingredient listing

In the past, many foods did not list ingredients (for example, those with federal standards of identity), and there was confusion about the definition of terms such as *sugar*. People with diabetes should now be able to identify all of a food's components by looking at the ingredient list (Fig. 1*F*).

Ingredients will still be listed in descending order of predominance (by weight from most to least), (21 CFR 101.4[a] [1]). With the advent of the 1993 labeling regulations, federal standards of identity foods (for example, peanut butter and ice cream) must list ingredients, as well (21 CFR 130.3[e]). The word *sugar* in the ingredient list refers specifically to sucrose (21 CFR 101.4[b] [20]). All other ingredient sugars must be listed by their common names (for exam-

ple, lactose or high fructose corn syrup) (2, p. 2858–2859).

Other information

Occasionally, the American Diabetes Association name and/or logo will appear on food labels in conjunction with fund-raising messages. There was concern that this might not be allowed on food labels. The FDA has ruled that sponsorship (for example, "a proud sponsor of the American Diabetes Association") or fund-raising information ("a contribution from the sale of this product has been made to the American Diabetes Association") on food labels is not considered an implied health claim so long as there is neither a nutrient nor a product-specific element in the message (Fig. 1*G*). As such, this information is outside the coverage of NLEA and thus labeling regulations, so long as it is truthful.

FDA also ruled that inclusion of exchange information (Fig. 1*G*) on the food label does not make the label subject to a health claim, as exchanges are provided for educational purposes and relate to many foods rather than to a specific food or nutrient (2, p. 2484). The same applies to the diabetes self-test.

Information (fund-raising, exchanges, diabetes quiz) on the food label should not be interpreted as endorsement of a specific food by the American Diabetes Association, because all foods (albeit some at moderate to low levels) may be incorporated into a meal plan for a person with diabetes.

SELF-MANAGEMENT TRAINING ABOUT FOOD AND NUTRITION LABELING —

Learning self-management techniques for chronic diseases, such as diabetes, is vital. Patient education is successful in improving the course of chronic disease, particularly if knowledge improvement is combined with other behavior-oriented programs for self-management (18–20).

Nutrition has been and continues to remain a cornerstone in the treatment of diabetes (10,21), and nutrition education and counseling continue to play a vital role in diabetes self-management training (9,22–24). Most recently, this was reiterated in the DCCT trial results (25), where support by dietitians was found to be critical to good diabetes control. In addition, nutrition education and counseling are major components of a controlled clinical trial involving practice guidelines and individuals with non-insulin dependent diabetes mellitus sponsored by the American Dietetic Association (24).

Food labels can be useful in helping people with diabetes apply nutrition guidelines to their individualized approach to meal planning; however, it may not be an easy process without assistance from registered dietitians and other diabetes educators. Some points provided in the 1993 food labeling regulations are particularly germane to diabetes meal planning. Education and counseling are needed to help individuals with diabetes apply this information not only to purchasing food but also to incorporating the abstract guidelines into their actual food choices for meals. Some examples of how this information can be applied include

1. using daily values when the person's individualized food intake requirement differs from the standard example on the label (e.g., 1,500 calories rather than the 2,000 or 2,500 on the food label).
2. individualizing the daily values to match a therapeutic recommendation. People with diabetes may have individual nutrient goals (calories, fat, protein) that are different than those used in determining the daily values for labeling information. Linking individualized therapeutic nutrient goals to the label's daily values will be essential for effective use of the NUTRITION FACTS part of the label.
3. using label information to help in various meal planning methods, particularly the counting methods of meal planning (carbohydrate, fat, calorie) (27) and the exchange system. For example, one carbohydrate serving is based on the amount of food (e.g., a fruit, a starch, a milk) that contains ~15 g of carbohydrate. One fat serving is based on the amount of food that contains ~5 g of fat.
4. using sugars (as a component of carbohydrate) information from the nutrition label, the nutrient content claims (Table 1), and the ingredient listing for determining "nutritional value" of a food. In the NUTRITION FACTS section of the label, *sugars* is defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose) (21 CFR 101.9 [c][6][ii]), whether occurring naturally in foods (such as fruits, vegetables, milk) or added to foods. This definition is the same as that used for sugars in nutrient content claims. (Note: Because the words *sugars free* were considered awkward, the nutrient content claim word allowed is *sugar free*). In the ingredient listing, the word *sugar* specifically means sucrose, whereas all other sugars are listed by their common names (i.e., high fructose corn syrup).
5. knowing how to appropriately incorporate sugars and foods containing sugars as part of the total carbohydrate for the day's food choices.
6. understanding the implications when there is a nutrient content claim about sugars made and the product contains sugar alcohol(s). For example, *sugar free* is defined as having <0.5 g sugars per reference amount and containing no ingredient that is a sugar or that is generally understood by consumers to contain sugar, unless marked by an asterisk referring to the statement "adds a trivial amount of sugar," "adds a negligible amount of sugar," or "adds a dietarily insignificant amount of sugar." Although sugar alcohols may be used in foods as sweeteners, they are not defined as sugars by FDA for nutrition labeling purposes; however, if a

product incorporating sugar alcohol(s) makes a claim to be *sugar free* (<0.5 g/serving), the sugar alcohol(s) must be declared on the label.

7. using other carbohydrate information for determining the nutritional value of a food. *Other carbohydrate* is that amount of carbohydrate remaining after subtracting dietary fiber, sugars, and sugar alcohols (if declared) from total carbohydrate. Other carbohydrate includes not only what was previously called *complex carbohydrate* or *starch and related carbohydrate*, but also many substances added to processed foods for technical purposes, such as for texture modification or as bulking agents. This other carbohydrate category may provide a clue as to how foods might have been modified to be lower in calories than their regular counterparts.
8. using grams of fat or grams of saturated fat information (or percent daily value of fat and percent daily value of saturated fat) and interpreting the information *calories from fat*.
9. understanding that there are exemptions to food labeling. Although almost all processed foods will have nutrition labels, the following foods are exempt from the labeling regulations. Note that foods exempt from nutrition labeling must still comply with ingredient, net content, and other regulations.

    - foods of insignificant nutritional value (e.g., plain coffee, tea, and most spices)
    - foods sold in restaurants (although restaurants making nutrient content claims, such as *low fat*, or *low cholesterol*, and health claims about their products must comply with federal government definitions if the claim is made on promotional material, such as posters and table tents)
    - foods sold for immediate consumption (e.g., at hospital cafeterias, or on airplanes)
    - foods prepared in food stores (e.g., deli, bakery, and candy store items)
    - foods sold by food service vendors (e.g., mall cookie counters, sidewalk vendors, and vending machines)
    - bulk foods not for sale to consumers
    - foods in very small packages (manufacturers must provide a phone number or address where individuals may obtain nutrition information)
    - foods manufactured by small businesses
    - medical foods (a medical food is defined as a "food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.") (21 CFR 101.9[j][8]). Examples of medical foods are phenylketonuric formula for infants or food supplements for burn patients
    - alcoholic beverages such as *light* beer, because the Bureau of Alcohol, Tobacco, and Firearms regulates this labeling

10. identifying some of the nuances of serving sizes (including single-serve containers, and meal-in-a-package products). For example, a serving size of sliced bread could be one or two slices, depending on the weight of a slice; although a reference amount for a soft drink is 8 fl oz, a 12-oz can is considered one serving; and the label serving size for a 15-oz can of ready-to-eat soup may be 1 cup or 2 cups.
11. identifying modified forms of the standards of identity foods (such as those reducing calories and fat by use of water or fat replacers), such as *light ice cream*; knowing how to decide whether to use a regular form of food or a *modified* form by using a number of factors including taste, cost, and how much over or under the daily values one is.
12. understanding the meanings of various nutrient content claims and how they relate to other guidelines. For example, *calorie free* on a label means that a food contains <5 calories/reference amount, whereas a *free* food in the exchange meal planning system is defined as <20 calories/serving.
13. learning how to accommodate, in the meal plan, nutrient-modified foods that switch food groups (such as salad dressings that are predominantly modified starch or sugar).
14. learning to integrate other types of food information (e.g., recipes) with food labeling educational concepts.
15. understanding that the use of the American Diabetes Association name and/or logo on a product label does not mean endorsement of the product itself or that the product can be eaten freely.

CONCLUSIONS— The important role that nutrition plays in maintaining and improving the nation's health has been well documented. In particular, self-management training in the area of nutrition is an essential component of the treatment of diabetes.

To make appropriate food choices and to select appropriate portion sizes, consumers must have food label information that is truthful, meaningful, understandable, and complete. This information also must not be misleading. Food labels that include nutrition and ingredient information are the most efficient and practical way to communicate much of these data. However, food labels cannot compensate for inadequate nutrition knowledge. To properly use the information imparted by food labels, consumers must understand basic principles of good nutrition and how to apply them. This necessity is particularly true for people with diabetes, who must be knowledge-

able about foods in relation to their diabetes self-management. This learning process is enhanced and facilitated by the guidance of the registered dietitian and other diabetes educators.

Clinical practice recommendations are contained in the Food Labeling Position Statement (this issue, American Diabetes Association, p. 488–489).

SUGGESTIONS FOR FUTURE RESEARCH— Research should be conducted to evaluate present and proposed methods for food labeling information transfer. Results should provide diabetes educators with the most successful methods for transferring labeling information.

In additon, outcomes research should be conducted to quantify the impact of food labeling education and counseling methods used for self-management training on the quality of the day's total food choices for people with diabetes.

Finally, applications research should be conducted in special populations to determine the cultural appropriateness of food labeling education and counseling methods used for self-management training.

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