DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 101

[Docket Nos. 90N-0135, 91N-0162, 78P-0091, 87P-0194/CP, AND 90P-0052]

RIN 0905-AD08

Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to: (1) Require nutrition labeling on most foods that are regulated by FDA, (2) revise the list of required nutrients and food components and the conditions for declaring them in nutrition labeling, (3) specify a new format for declaring nutrition information, (4) allow specified products to be exempt from nutrition labeling, and (5) prescribe a simplified form of nutrition labeling and the circumstances in which such simplified nutrition labeling may be used. This final rule also responds to citizen petitions on the declaration of dietary fiber in nutrition labeling and on methodologies for determining protein content.

DATES: Effective February 14, 1994. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 101.9(c)(1)(i)(A), (c)(1)(i)(B), (c)(1)(i)(C), (c)(1)(i)(E), (c)(6), (c)(7)(ii), (c)(7)(ii)(B), and (g)(2), effective (February 14, 1994).

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SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 19, 1990 (55 FR 29847), FDA published a proposed rule entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" (hereinafter identified as "the mandatory nutrition labeling proposal") to amend its food labeling regulations to require nutrition labeling on most food products that are meaningful sources of nutrients FDA also proposed to revise the list of nutrients and food components that must be included in nutrition labeling by adding calories from fat, saturated fatty acids, cholesterol, and dietary fiber to that list. It proposed to make the listing of thiamin, riboflavin, and niacin optional rather than mandatory. In addition, FDA addressed the conditions under which other nutrients could be, or are required to be, included in nutrition labeling and proposed to allow manufacturers to voluntarily include a nutrition profile of selected food components in nutrition labeling.

During the comment period for these proposed regulations, Congress passed, and the President signed into law, the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101-535, November 8, 1990). The 1990 amendments amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 403(q) (21 U.S.C. 343(q)) which specifies, in part that: (1) With certain exceptions, a food is to be considered misbranded unless its label or labeling bears nutrition labeling, (2) certain nutrients and food components are to be included in nutrition labeling, although the Secretary of Health and Human Services (the Secretary) can add or delete nutrients by regulation if he finds such action necessary to assist consumers in maintaining healthy dietary practices, (3) nutrition labeling is to be provided for the most frequently consumed varieties of raw produce (fruits and vegetables) and raw fish according to voluntary guidelines or, if necessary, regulations, (4) a simplified nutrition label is to be used when the food contains insignificant amounts of most nutrients, and (5) FDA is to develop regulations governing labeling of foods to which section 411 of the act (21 U.S.C. 350) applies.

In response to these requirements of the 1990 amendments, FDA published in the **Federal Register** of November 27, 1991 (56 FR 60366; as amended (57 FR 8178, March 6, 1992)) a proposal (hereinafter identified as the supplementary proposal) to modify its July 19, 1990, proposal by: (1) Adding sugars and complex carbohydrates to the list of required nutrients in nutrition labeling, (2) prescribing a simplified form of nutrition labeling and the circumstances in which such simplified nutrition labeling must be used, (3) allowing specified products to be exempt from nutrition labeling, and (4) establishing regulations for the nutrition labeling of vitamin and mineral supplements. The agency also responded to a citizen petition regarding methodologies for determining protein quality. Interested persons were given until February 25, 1992, to comment.

Subsequently, FDA published in the **Federal Register** of July 20, 1992 (57 FR 32058; amended at 57 FR 37190, August 18, 1992), a proposal (hereinafter identified as the format proposal) to adopt a new format, specifically the PERCENT DV (Daily Value) with DRV (Daily Reference Value) format, for use in presenting nutrition information on the food label. Interested persons were given until August 19, 1992, to comment. In addition, on July 23, 1992, a notice was published in the **Federal Register** (57 FR 32750) of a public meeting to be held on the format proposal in Bethesda, MD, on August 17, 1992.

On October 6, 1992, Congress passed the Dietary Supplement Act of 1992 (H.R. 6181) (hereinafter referred to as the "DS Act") that, in section 202(a)(1), establishes a 1 year moratorium on the implementation of the 1990 amendments with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances. Section 202(a)(2) requires the Secretary, and by delegation FDA, to issue new proposed regulations that are applicable to dietary supplements no later than June 15, 1993, and final regulations by December 31, 1993. In addition, section 203 instructs FDA to not promulgate regulations that require the use of, or are based upon, recommended daily allowances of vitamins or minerals before November 8, 1993 (other than regulations establishing the United States Recommended Daily Allowance (U.S. RDA) specified in 21 CFR 101.9(c)(7)(iv) as in effect on October 6, 1992).

FDA received approximately 1,500 responses to its July 19, 1990, mandatory nutrition labeling proposal, approximately 3,000 responses to the November 27, 1991, supplementary proposal, and approximately 1,000 responses to the July 20, 1992, format proposal, each of which contained one or more comments. Responses were received from consumers, health professionals, health promotion organizations, trade and retail associations, State and local governments, foreign governments, professional societies, consumer advocacy organizations, industry, and universities. The comments generally supported the proposals. Several comments addressed issues covered by other proposals that are a part of this overall food labeling initiative, and they will be addressed in those final documents, while other comments were outside the scope of these proposals and will not be discussed here. Many

comments dealt with issues pertaining to meat and poultry products whose labeling is regulated by the U.S. Department of Agriculture (USDA). Of those comments, comments pertaining to the content or format of the nutrition label are included in the following discussions. However, comments pertaining to issues covered exclusively by USDA, such as specific exemptions applicable to meat and poultry products, were considered to be outside the scope of this document.

A number of comments to both the July 19, 1990, and November 27, 1991, proposals suggested modifications in, or were opposed to, various provisions of the proposals. A summary of the suggested changes, the opposing comments, and the agency's responses follow.

II. Mandatory Nutrition Labeling—Legal Authority

1. Most comments agreed that the 1990 amendments clearly established FDA's authority to mandate nutrition labeling on most foods. One comment, however, argued that a requirement that labels say or not say certain things curtails freedom of the press.

The agency disagrees. FDA's authority to regulate the content of food labels has been broadly upheld against First Amendment challenges. This issue is discussed at length in both the final rule on nutrient content claims entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms" and the final rule on health claims entitled "Food Labeling; General Requirements for Health Claims for Food," both of which are published elsewhere in this issue of the Federal Register. Those discussions are incorporated in this document by reference. As those discussions make clear, there is no merit to this comment. Therefore, FDA is taking no action on the basis of this comment.

2. One comment objected to FDA being given authority to mandate nutrition labeling on most foods on the basis that current nutrition labeling rules were legally questionable.

The question of FDA's authority to require nutrition labeling was a fundamental issue that led Congress to pass the 1990 amendments. As discussed in the legislative history, Congress concluded that legislation was needed to strengthen FDA's authority to require nutrition labeling on foods and to avoid the possibility of protracted litigation over the comprehensive nutrition labeling regulations that the agency adopts (Ref. 16). Therefore, there can be no question about FDA's authority to require nutrition labeling on most food products.

III. Content of the Nutrition Label

A. General Issues

1. Voluntary Declaration of Additional Information

3. A number of comments objected to the voluntary declaration of nutrients beyond those required in nutrition labeling. Numerous comments stated that the declaration of additional information on the food label would be confusing, or that it might mislead the consumer into believing that a product with additional nutrients listed is more nutritious or has greater public health significance than is the case. Some comments objected on the basis that the additional information would clutter the label and diminish the consumer's focus on mandatory nutrients. A few comments expressed concern that voluntary declaration of additional nutrients on the label will require smaller print on the food label to accommodate the inclusion of all the mandatory and voluntary information, and that the smaller type size would compromise the usefulness of the label information to the elderly or visually impaired.

A number of comments supported the voluntary listing of additional nutrients, pointing out that the 1990 amendments require that the regulations permit the label or labeling of food to include nutrition information, which is in addition to the information required by section 403(q) of the act and which is of the type described in subparagraph (1) or (2) of that section. A few comments supported the view that voluntary listing of additional nutrients may provide valuable information to an individual or aid the consumer in making an informed choice in food selection. Other comments supported voluntary listing of additional nutrients stating that some nutrients may satisfy nutrient needs of some individuals or pose a health risk to others. One comment pointed out that the Institute of Medicine (IOM) report (Ref. 1) recommends that regulations allow the declaration of all micronutrients for which Recommended Dietary Allowances have been established by the National Academy of Sciences.

Numerous comments that basically supported listing of additional information also supported limiting the information allowed. Some comments supported allowing voluntary information, but they suggested that FDA standardize the manner in which it is included on the label to the extent of requiring that it be separate from the nutrition label or in different type size. Five comments requested voluntary listing of specific nutrients including: Potassium; vitamins E, K, and B6; copper; manganese; iodine; maltodextrin; and L-glutamate, L-cysteine, and L-tryptophan. Two comments supported the listing of additional nutrients but recommended restricting the allowed nutrients to those for which Recommended Dietary Allowances have been set by the National Academy of Sciences (Ref. 23) or for which Reference Daily Intakes (RDI's) have been determined by FDA. One of these comments further suggested restricting the allowed nutrients to exclude nutrients that do not have Recommended Dietary Allowances but only have Estimated Safe and Adequate Daily Dietary Intakes (ESADDI's), which are also set by the National Academy of Sciences (Ref. 23). One comment suggested that additional information on the food label be restricted to information permitted by the Council of the European Communities (EC).

FDA, in its mandatory nutrition labeling proposal of July 19, 1990, proposed to allow the voluntary declaration of several nutrients (e.g., potassium and soluble fiber) and any naturally occurring vitamins and minerals for which RDI's had been proposed in § 101.9(c)(10)(iv) (21 CFR 101.9(c)(10)(iv)), which was redesignated as § 101.9(c)(11)(iv) in the November 27, 1991, proposal. Additionally, section 2(b)(1)(C) of the 1990 amendments states that regulations shall permit the label or labeling of food to include nutrition information that is in addition to the information required by section 403(q) of the act and that is of the type described in subparagraph (1) or (2) of that section. Section 403(q)(2) of the act refers to information that will assist consumers in maintaining healthy dietary practices.

FDA believes that it is required by statute to allow additional information on the food label insofar as it assists consumers in maintaining healthy dietary practices. However, the agency raised questions in the supplementary proposal about how the presence of these additional nutrients on the label would be interpreted by consumers, and whether the listing of some voluntary nutrients would actually be misleading (56 FR 60366 at 60372). The comments confirmed that unlimited additional information on the nutrition label would have the potential of being confusing or misleading.

FDA requested comments on whether it is necessary to include limits on the voluntary information that may be

provided on the nutrition label. The comments that FDA received on this issue have lead the agency to conclude that it has a responsibility to limit the number of nutrients permitted to be voluntarily listed on the food label. Such a limitation reflects the statement in the House report (Ref. 16, p. 18) that the regulations that FDA adopts should assure that the information that is included voluntarily does not interfere with the consumer's understanding of the information that is required to be included on the nutrition label. The agency finds that limits are necessary so that the emphasis is on the required information, and that the additional information does not clutter the food label or mislead or confuse the consumer.

Therefore, to limit the information that may be provided on the nutrition label, FDA is amending the proposed regulations to delete "calories from unsaturated fat," "calories from carbohydrates," "calories from protein," and quantitative declarations of "unsaturated fat" from the list of nutrients that are allowed to be declared voluntarily on the nutrition label. Each of these deletions is detailed below. FDA has decided to permit the voluntary declaration on the nutrition label of "calories from saturated fat," "polyunsaturated fat," "monounsaturated fat," "soluble fiber," "insoluble fiber," "sugar alcohol," "other carbohydrate," "potassium" and those vitamins and minerals for which RDI's have been established.

With respect to other nutrients suggested by individual comments for consideration for voluntary listing on the food label, the agency has not been persuaded that there are large numbers of consumers who desire a voluntary listing of the food components in question (e.g., maltodextrin or single amino acids. Therefore, FDA will not allow voluntary listing of these other substances or food components on the nutrition label. To implement this section, FDA has added a sentence to § 101.9(c) that states that no nutrients or food components other than those set forth in that section as either mandatory or voluntary may be included in the nutrition label. The inclusion of any other nutrient or food component would violate section 403(q) of the act and misbrand the food.

Also, while FDA supports efforts toward international harmonization of food labeling where possible, the 1990 amendments direct FDA to permit that a broad spectrum of nutrients be on the food label unless the agency finds that the information is not necessary to assist consumers in maintaining healthy dietary practices, a finding that FDA has generally not made. As a result, the spectrum of required and permitted nutrients exceeds those permitted by the EC.

FDA is not requiring that additional nutrients declared voluntarily be put in separate boxes or a different type size because it believes these actions would confuse consumers and would complicate and clutter the label needlessly. In some instances additional nutrients, whose declaration is usually voluntary, will be required to be declared. For example, in the case of fortified foods, enriched pasta must declare amounts of thiamin, riboflavin, and niacin, and margarine must declare vitamin D when it is added. In other cases, if certain claims are made, additional nutrients will be required to be declared. For example, when nutrient content claims are made about cholesterol, declaration of poly- and monounsaturated fats are required (see § 101.9(c)(2) (i) and (ii). Placing these nutrients in the principal box for nutrition labeling when required, and in a separate box (or different type size) when voluntarily added to the nutrition label would easily confuse consumers. Also, separating subcomponents that can voluntarily be declared, such as soluble and insoluble fiber, from the primary component, dietary fiber, for which declaration is mandatory, would unduly complicate the label.

However, in response to comments concerned that information on additional nutrients would clutter the label and to comments on the format proposal, FDA is providing in new § 101.9(d)(8) for a linear array of vitamins and minerals. This form of presentation, which is discussed in more detail in section V. of this document, is similar to that recommended in the IOM report (Ref. 1) which places more emphasis on the macronutrients.

2. Order of Nutrients

4. Several comments from industry, health promotional organizations, and academia supported the order of nutrients proposed by FDA in § 101.9(c) (56 FR 60366 at 60386 through 60390). One industry comment stated that the proposed sequence fairly prioritized the Dietary Guidelines for Americans (Ref. 4) and placed the proper emphasis on those dietary factors that affect the health of consumers. This comment, along with one from a health promotion organization, also endorsed the separation of vitamins and minerals from other nutrients seen in proposed formats (57 FR 32058), stating that this feature represented a logical break in the list of nutrition information and would both improve label readability and facilitate consumers' search for specific nutrient data. Another comment supporting the proposed order endorsed the listing of nutrients from those most important to consumers to those least important to consumers but questioned whether protein should be included.

On the other hand, several comments argued that the proposed order of nutrients has features that would mislead consumers. One comment characterized the proposed order as "an unwarranted effort to overemphasize some nutrients, such as fat, at the expense of the other important label components" and suggested that the decision on whether to emphasize one nutrient over another should be left to nutrition education programs that consider the total diet over a long period of time. Other industry comments criticized the proposed order of nutrients, stating that it would be consistent with the "good food/bad food" concept and would convey a negative impression to consumers. One industry comment supporting the current order of nutrients argued that protein should not be listed near the end, stating that beneficial nutrients should be listed at the beginning of the nutrient list. The comment suggested that from an educational standpoint, it is more positive to educate on the good points of nutrition labeling than to focus on negative aspects.

A number of comments advocated that the current order of nutrients be maintained, or that any modified order resemble the current order as closely as possible. Several comments supporting the current order of nutrients stated that consumers are already accustomed to the current order, and that changing the order would lead to unnecessary confusion and diminish consumers' understanding of the nutrition label.

A few comments suggested alternative nutrient orders. A comment from a professional organization stated that those nutrients whose overconsumption is related to increased risk of disease should be placed at the top of the list of required nutrients. One industry comment recommended that nutrients be regrouped to first list those nutrient whose Daily Value is dependent on calorie intake (i.e., total fat, saturated fat, carbohydrate, dietary fiber, and protein), followed by those whose Daily Value remains the same for varying calorie intakes (i.e., cholesterol and sodium). Another comment requested that sodium be listed with the vitamins and minerals rather than among the organic macronutrients.

A comment from a manufacturer addressed the issue of where to place the voluntary nutrients on the label. The comment suggested that voluntary nutrients should be sequenced in a logical manner with respect to the nutrients whose declaration is mandatory. The following examples were cited: Unsaturated fat should follow saturated fat (both should be indented), potassium should follow sodium, soluble and insoluble fiber should follow dietary fiber, and vitamins and minerals should follow those that are mandatory.

The agency is not persuaded by arguments stating that listing nutrients in order of public health importance will cast foods as either "good foods" or "bad foods." Listing nutrients in this manner will instead facilitate selection of an overall diet that is consistent with dietary guidelines based on what nutrients are present in a particular food and in what amounts. No data were presented to show that use of this nutrient order on the nutrition label is likely to be confusing to consumers.

The agency also does not agree with the request that sodium be placed with vitamins and minerals rather than with the organic macronutrients. Sodium is an electrolyte that is distinct from both organic nutrients and vitamins and minerals. However, excessive intake is associated with a potential increase in the risk of chronic diseases, as are excessive intakes of the other mandatory organic nutrients (i.e., macronutrients such as fat) in the nutrition label. Vitamins and minerals generally are associated with deficiency diseases. The agency believes this categorization supports the continued placement of sodium with the organic nutrients.

FDA agrees that the placement of voluntary nutrients should be sequenced in a logical manner with respect to the mandatory nutrients. FDA has provided in new § 101.9(c) that voluntary nutrients that are subcomponents are to be declared immediately beneath the primary components, and that potassium (the second electrolyte) is to be declared adjacent to sodium.

The agency believes that a revised order according to the public health significance of a nutrient will adequately convey nutrient information with no appreciable increase in consumer effort. This action is based on the order provided in section 403(q)(1) of the act (see Ref. 16, p. 13) and the comment recommending that nutrients whose overconsumption is related to increased risk of disease should be placed at the top of the list of required nutrients

Accordingly, new § 101.9(c) is modified to require mandatory and voluntary nutrients to be arranged in the following order: Calories, calories from fat, calories from saturated fat, total fat, saturated fat, polyunsaturated fat, monounsaturated fat, cholesterol, sodium, potassium, total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, sugars, sugar alcohol, other carbohydrate, protein, vitamin A, vitamin C, calcium, iron, and other vitamins or minerals in the order listed in proposed § 101.9(c)(11)(iv), redesignated as § 101.9(c)(8)(iv). This order deviates from that provided in section 403(q)(1) of the act only by reversing dietary fiber (and its subcomponents) and sugars. The reason for this reversal is discussed in comment 58 of this document.

Consequently, the paragraphs in § 101.9(c) are renumbered as discussed below for each nutrient. Redesignations also occur as a result of moving paragraphs (c)(1) and (c)(2) pertaining to serving size and servings per container, respectively, to new paragraph (d).

The agency believes that this amended order of nutrients, which lists them in order of public health significance, will benefit consumers. The agency's decision is a reasonable outgrowth of its commitment to present nutrition information in the context of a total daily diet, and it reflects the agency's commitment to link nutrient information with the dietary guidance considered important to public health (Ref. 4).

B. Calories

1. Total Calories

5. The majority of comments supported the proposal for mandatory declaration of calories with voluntary use of metric terminology (i.e., declaration of the number of kilojoules in addition to calories in proposed § 101.9(c)(3), redesignated as § 101.9(c)(1), and voluntary use of the term "energy" parenthetically as a synonym for calories, as provided in § 101.9(c)(11)(v), redesignated as § 101.9(c)(8)(v)).

Other comments expressed a preference for metric labeling. The comments argued that American consumers should become accustomed to the metric system of measurement and recommended the exclusive use of metrics to ensure compatibility with European markets. The comments suggested that the avoirdupois system of measurement used in the United States is outmoded and impedes international commerce and the exchange of scientific information. Several comments suggested that "energy" should be used in lieu of calories and requested that the conversion factor for calories to kilojoules be stated on each label.

Still other comments, taking the opposite position, suggested that metric units be disallowed to avoid consumer confusion and for the sake of simplicity.

Although FDA agrees that efforts should be made to familiarize consumers with metric units, the agency disagrees with the comments that urged the exclusive, mandatory conversion to metrics at this time. The technical amendments (August 3, 1992) to the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq., Pub. L. 102–329) require the use of the most appropriate units of both the customary inch/pound system of measure and the metric system on food labels for measuring quantity. These amendments do not require that kilojoules be declared in lieu of calories. Upon implementation, this act should further an awareness of metric measurement among American consumers and permit a greater concordance in units of measurement with the international market and scientific community. Until that time, the agency is not persuaded that the mandatory use of metric terminology, or the declaration of factors to convert calories to kilojoules, is justified. Accordingly, the agency is not making the requested changes.

2. Calories From Fat

6. Many comments were received from consumers, state and local governments, universities, professional associations, consumer groups, manufacturers, and health associations on the issue of calories from fat. The majority agreed with the proposal that the declaration of calories from fat should be mandatory on the nutrition label.

Several other comments suggested that calories from fat be voluntarily listed or disallowed because this information might be confusing or misleading to consumers and might establish artificial "good food" and "bad food" categories. These comments stated that consumers may tend to exclude foods with a significant amount of calories from fat, possibly creating nutritional deficiencies. Further, these comments stated that it is important that consumers view fat as part of a day's diet rather than in the context of individual foods. A few comments suggested that declaring the calories from fat is unnecessary because calories from fat can be easily calculated by multiplying the number of grams (g) of fat by nine, the number of calories per g of fat. A few comments suggested that

there be further study of the effectiveness of the declaration of calories from fat in nutrition labeling as a nutrition education tool. One comment suggested that low fat foods, such as fruits and vegetables that contain less than 2 g of fat, be exempted from the requirement to list calories from fat.

FDA is not persuaded by the arguments that the declaration of calories from fat should be voluntary or disallowed. The declaration of calories from fat is required by section 403(q)(1)(C)(ii) of the act. While section 403(q)(2)(B) of the act allows the Secretary to delete nutrient information that is not necessary to assist consumers in maintaining healthy dietary practices, no data were presented that would support making such a finding with respect to the declaration of calories from fat.

It is well established that diets that are high in fat pose significant health risks. Dietary fat contributes more than twice the calories per g than does protein or carbohydrate. Overconsumption of fat is associated with higher rates of obesity (Refs. 2 and 3), and there is evidence from epidemiological and animal studies that high fat intakes are associated with some types of cancer (Refs. 2 and 3). The most common and consistent dietary recommendation for the general population is for calories from total fat to be reduced to less than or equal to 30 percent of total calories (Refs. 3 and 4).

Currently, the consumption of total fat in the general population is approximately 37 percent of total calories, an amount well above the recommended level (Ref. 2). Further, consumption of total fat in the United States is significantly higher than that consumed in countries with much lower rates of coronary heart disease, such as Japan, China, and the Mediterranean countries (Ref. 2).

Based upon this body of evidence, FDA believes that reducing total fat intake is an important public health priority. The agency is not persuaded that the declaration of calories from fat will automatically lead to consumers viewing foods in strict "good food," "bad food" categories, or that consumers cannot make appropriate decisions regarding the consumption of foods that may have a significant number of calories from fat in their diets. No evidence was presented demonstrating a relationship between the declaration of calories from fat in nutrition labeling and nutritional deficiencies.

Although calories from fat can, in fact, be readily calculated (FDA is requiring that information on the number of calories per g of fat, carbohydrate, and protein, be included as part of the nutrition label (see § 101.9(d)(10)), the declaration of calories from fat will be beneficial in assisting consumers to moderate their fat intake by providing an additional method, other than g of fat, for monitoring their fat intake.

However, the agency concurs that fat should be viewed as a part of the complete daily diet. Foods that may have a significant number of calories from fat may readily be included in the daily diet when the overall fat intake for the day is moderate. The agency intends to build this concept into its consumer education program, discussed later in this document. Further, FDA welcomes further study on the health implications of overconsumption of calories from fat and the effectiveness of this method of depicting fat content.

7. Many comments advocated the mandatory declaration of the percent of calories from fat. Other comments suggested that calories from total fat should be replaced by the percent of calories from fat. The comments stated that the process of determining the percent of fat is time consuming and unfamiliar to many consumers. Further, the comments argued that it is unlikely that substantial numbers of consumers would or could keep running totals of their fat intake in order to calculate the percent of daily fat consumed. The comments argued that the best way to determine whether a food is high or low in fat is to have fat content declared by percent of total calories.

A few comments suggested that percent of calories from fat for individual foods is incomplete information, while the percent of calories from fat for a complete meal or the daily diet is useful information. These comments suggested that the percent of calories from fat be voluntary and limited to meal-type products, such as frozen dinners, and disallowed for other foods.

The agency is not persuaded by the comments that the declaration of percent calories from fat is warranted. As discussed in the July 19, 1990, mandatory nutrition labeling proposal (55 FR 29487 at 29493 and 29494), information on the percent of calories from fat is only valuable in the context of a total daily diet. Recommendations from various health organizations to limit dietary fat intake to 30 percent or less of calories pertain not to individual foods but to the entire day's intake.

In addition, the percent of calories from fat in low calorie foods can be quite misleading. For instance, in radishes, over 25 percent of calories are from fat. Despite this relatively high percentage, radishes contain very low amounts of fat and readily fit within a daily diet that meets current dietary recommendations.

The agency agrees that calculating the percent of calories from fat consumed in a day may be difficult for many consumers. The agency notes that the PERCENT DV format (see section V.G.2) facilitates monitoring of dietary fat because the Daily Value for fat is set at 30 percent of calories from fat. Consumers need only add the percent DV for total fat with a target of no more than 100 percent or a target percentage adjusted for their individual caloric intake. Alternatively, consumers can determine the maximum number of g of fat recommended per day at their calorie level and track the number of g of fat. There are several publications listing recommended daily maximum amounts of fat according to caloric intake or that have simple arithmetical methods for deriving this information (Refs. 26 through 29). In a similar fashion, the DRV for fat, which is established in the companion document entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values" (hereinafter identified as the "RDI/DRV proposal") published elsewhere in this issue of the Federal Register, can be used as a guide, with levels being adjusted upward or downward depending on caloric intake. The agency encourages other organizations to develop and publish similar approaches.

8. One comment objected to that section of § 101.9(c)(3)(i) in the July 19, 1990, mandatory nutrition labeling proposal that allowed "calories from fat" to be omitted and replaced with the statement "Not a significant source of calories from total fat" if the product contains less than 1 g of fat per serving. The comment objected to similar provisions for saturated fat, cholesterol, and dietary fiber on the basis that it made the regulations complex and confusing. These provisions were carried forward in the November 27, 1991, supplementary proposal with the 1-g criterion being changed to ½ g, and similar provisions being added for complex carbohydrates and sugars.

These provisions were included in the July 19, 1990, mandatory nutrition labeling proposal (55 FR 29487 at 29502), which was published before the adoption of the requirement in section 403(q)(5)(C) of the act for a simplified format, to minimize the space required for nutrition labeling. This provision is similar to that allowed in current § 101.9(c)(7)(i) for vitamins and minerals that are present in amounts less than 2 percent of the U.S.

Recommended Daily Allowance (U.S. RDA). FDA did not delete these provisions in the November 27, 1991, supplementary proposal because the agency believed they might be helpful in minimizing space requirements on foods that do not qualify for the simplified format under proposed § 101.9(f).

FDA finds that the added flexibility that these provisions provide outweighs any added complexity they may create. USDA's final nutrition labeling regulations, which are being published simultaneously with these final rules, include similar provisions. Under FDA's regulations, with the exception of the core nutrients (i.e., calories, total fat, total carbohydrate, protein, and sodium), nutrients that are present in insignificant amounts may be omitted from the list of nutrients and grouped in a summary statement (e.g., "Not a significant amount of calories from fat, saturated fat, and cholesterol"). Therefore, the agency is retaining in § 101.9(c)(3)(i), redesignated as § 101.9(c)(1)(ii), for calories from total fat; in § 101.9(c)(4)(i), redesignated as § 101.9(c)(2)(i), for saturated fat; in § 101.9(c)(5), redesignated as § 101.9(c)(3), for cholesterol; in § 101.9(c)(6)(ii)(A), redesignated as § 101.9(c)(6)(ii), for sugars; in § 101.9(c)(7), redesignated as § 101.9(c)(8)(i), for dietary fiber; and in § 101.9(c)(11)(iii), redesignated as § 101.9(c)(8)(iii), for vitamins and minerals a provision that allows the nutrients to be omitted and replaced with a statement "Not a significant source of _____" when present in insignificant amounts. An example of this shortened format is given in appendix A of this document.

3. Calories From Saturated Fat

9. Several comments agreed with the proposal that declaration of calories from saturated fat should be voluntary. A few comments suggested that this information should be mandatory and referred to national dietary guidelines recommending that saturated fat be limited to less than 10 percent of total daily calories. A few comments requested that declaration of percent of calories from saturated fat be made mandatory.

Several comments believed that the declaration of calories from saturated fat should be disallowed. The comments argued that this information is redundant, confusing, and misleading.

FDA acknowledges that research has established the role of saturated fats in the etiology of atherosclerotic vascular disease and recognizes that there are national consensus recommendations regarding the levels of intake for saturated fat. However, section 403(q)(2)(A) of the act permits the Secretary to require the inclusion of information on additional nutrients in nutrition labeling if he determines that such information "will assist consumers in maintaining healthy dietary practices." The agency is not persuaded that the mandatory declaration of calories from saturated fat or the percentage of calories from saturated fat meet this criterion.

First, this information may be obtained by simple calculation if needed (i.e., calories from saturated fat can be calculated by multiplying the g of saturated fat by nine, the number of calories per g of fat; the percentage of calories from saturated fat can then be determined by dividing the number of calories from saturated fat by the total calories). Secondly, concerns have been expressed in comments that consumers will be faced with so much information that they will avoid using any of it. To minimize the possibility of this happening, FDA believes that it is preferable to have consumers concentrate on the number of calories from total fat. By controlling dietary intake of calories from fat, intake of calories from saturated fat will also be controlled.

However, in recognition of dietary recommendations that Americans should consume less than 10 percent of calories from saturated fat (Refs. 3, 4, and 30) FDA is continuing to allow voluntary declaration of calories from saturated fat in § 101.9(c)(3)(ii)(A), redesignated as § 101.9(c)(1)(iii).

4. Calories From Unsaturated Fat

10. Several comments agreed with proposed § 101.9(c)(3)(ii)(B) that the declaration of calories from unsaturated fat should be voluntary. A few comments suggested that the declaration of calories from unsaturated fat should be mandatory. These comments stated that caloric information on unsaturated fat would be helpful in monitoring unsaturated fat intake to maintain consumption of unsaturated fat at not more than the 20 percent of total calories.

Several other comments suggested that this information be disallowed because it will not be useful to the consumer in evaluating a total day's food intake, and because the information is potentially confusing.

A few comments requested that declaration of calories from monounsaturated and polyunsaturated fats be mandatory. One comment requested that declaration of the percent of calories from monounsaturated and polyunsaturated fats be mandatory. These comments stated that caloric or percentage information on monounsaturated and polyunsaturated fats would be helpful in limiting consumption of each of these two classifications of fatty acids to not more than 10 percent of total calories each.

The agency has decided not to permit declarations regarding calories from unsaturated fats because there is considerable uncertainty and controversy about the term "unsaturated fat" and its definition, specifically whether the "*trans*" isomers of monounsaturated fat should be included in this category of fats. These isomers have been implicated in the development of coronary heart disease and cancer (Ref. 31) and are discussed in the subject health claims rules published elsewhere in this issue of the Federal Register.

Further, the agency is not persuaded that it should allow the voluntary declaration of calories from monounsaturated and polyunsaturated fats. Definitions of monounsaturated and polyunsaturated fats include *cis* isomers only. *Trans* isomers are excluded. The declaration of calories from monounsaturated and polyunsaturated fats would therefore underrepresent the total caloric value of these fats because of the exclusion of the *trans* isomers. Such an underrepresentation would be misleading to consumers. Therefore, the agency is not allowing the declaration of calories from polyunsaturated and monounsaturated fats in the nutrition label.

11. One comment suggested that § 101.9(c)(3)(ii)(A) and (c)(3)(ii)(B) be modified to clarify that when the declaration of calories from saturated fat is declared adjacent to the declaration of g of saturated or unsaturated fat, that it be in a column headed "calories" as was stated in § 101.9(c)(3)(i) for calories from total fat.

The agency has reconsidered the proposed format in the supplementary proposal that would have allowed a separate column for listing calories. As discussed in section V. of this document, FDA is incorporating additional columns into the nutrition label to declare the percent of daily value and the daily value list. For this reason, the agency believes a column headed "calories" would add to label clutter and, therefore, has not made the suggested change. FDA has modified § 101.9(c)(1)(ii) to delete the option that calories from total fat be declared in a column headed "calories."

5 Calories From Carbohydrate

12. Several comments requested that the declaration of calories from carbohydrates be made mandatory so that consumers can monitor and adjust their intake of calories from carbohydrate to approach the recommended 50 to 60 percent of total calories A few comments requested that the declaration of percent of calories from carbohydrate be made mandatory. Several comments agreed with the proposal to allow the voluntary listing of calories from carbohydrate. Several other comments requested that FDA not permit the declaration of calories from carbohydrate because this information is potentially confusing to consumers. These comments suggested that this information would not be helpful in evaluating a total day's food intake. A few comments argued that too much information is burdensome to the consumer, and that if it results in the manufacturer using smaller type size, it could make the information more difficult for the elderly to read. Further, the comments suggested that there was a danger of "information overload" and "label clutter."

Based on the comments to the July 19, 1990 and November 27, 1991, proposals, the agency has reconsidered its proposal to permit the voluntary declaration of calories from carbohydrate and has decided not to permit this declaration. As discussed in the mandatory nutrition labeling proposal of July 19, 1990 (55 FR at 29493), FDA's intent is to require the listing of only those nutrients that present public health concerns and for which quantitative intake recommendations have been made. FDA proposed to permit the voluntary declaration of calories from carbohydrate because of general recommendations that suggested that intake of carbohydrate should be increased to 50 to 60 percent of total calories but recognized that carbohydrate is not of pressing public health significance.

Based on its evaluation of the comments, FDA has become concerned that it will overemphasize the public health significance of carbohydrate if it allows the declaration of calories from this nutrient. Additionally, the legislative history of section (2)(b)(1)(C) of the 1990 amendments (Ref. 16) makes clear that while FDA must allow the declaration of additional nutrients in nutrition labeling, it must ensure that such information does not interfere with the consumer's understanding of the information required by the act. Thus, FDA considers it important to ensure the comprehensibility of the nutrition label.

The 1990 IOM report "Nutrition Labeling: Issues and Directions for the 1990s" (Ref. 1) emphasizes the importance of considering information quantity and complexity when determining the components of the food label (Ref. 1). The report suggests that too much information compromises the ability of many consumers to understand the label.

The agency is persuaded that because the amount of calories from carbohydrate is not of pressing public health significance, it should not provide for inclusion of this information in nutrition labeling. Accordingly, FDA has deleted proposed § 101.9(c)(3)(ii)(C) from the final regulation.

Consumers interested in determining the calories from carbohydrate for the vast majority of individual foods may simply multiply the number of g of carbohydrate by four, the number of calories per g of carbohydrate. Consumers attempting to compare their intake of carbohydrates to the recommended amounts of 50 to 60 percent of total caloric intake can use the Percent Daily Value format in the same way described for monitoring fat intake. Because the Daily Value for carbohydrate is set at 60 percent of calories, consumers need only add the percent DV for total carbohydrate with a target of 100 percent or a target of a percentage adjusted for their individual caloric intake. Alternatively, consumers can sum the g of carbohydrate consumed for the day, multiply the total by four, divide the result by the total calories consumed in that day, and multiply by 100 to obtain percent.

13. Although FDA chose not to propose the declaration of calories from sugars and complex carbohydrates, a few comments addressed this topic. Some of these comments stated that the declaration of calories from sugars and complex carbohydrates should be voluntary, and that this information, especially for sugars, was of interest to consumers. Other comments felt that the declaration of calories from sugars and complex carbohydrates should be mandatory. Both sets of comments felt that this information is potentially valuable to diabetics and parents of young children who are concerned about dental caries and excessive sugar intake. A few additional comments argued that the declaration of calories from sugars and complex carbohydrates is unnecessary and should not be permitted.

Interest in having calories from sugars and complex carbohydrates declared in the nutrition label was slight, and no data were presented to support the requests for such information. Further, dietary guidelines have not recommended specific quantitative amounts for caloric intake from sugars or complex carbohydrates. Therefore, the final rules do not permit the inclusion of such information in the nutrition label. FDA advises that the calculation of calories from sugars, which was of the most interest to the comments, can be easily calculated by multiplying the number of g of sugars present by four, the number of calories per g of sugars.

6. Calories From Protein

14. A few comments requested that the declaration of calories from protein as well as the percent of calories from protein be made mandatory to permit consumers to evaluate the quality of the food. Other comments agreed with the proposal for the voluntary declaration of calories from protein. On the other hand, additional comments suggested that this information would be confusing and misleading. These comments pointed out that concerns about protein intake are of limited public health significance in the United States and suggested that the declaration of calories would not be helpful in evaluating a total day's diet. The comments urged, therefore, that this declaration should not be permitted. One comment suggested that consumers would be tempted to overconsume protein if calories from protein were listed.

Upon consideration of the comments, FDA has reassessed its position. The agency agrees that the declaration of calories from protein and the percent of calories from protein are of limited usefulness to the consumer because the diets of the majority of Americans exceed the Recommended Dietary Allowances (Ref. 23) for protein. This lack of usefulness appears to outweigh any of the potential benefits of allowing the declaration of calories from protein. For this reason, and in an effort to reduce unnecessary information that might interfere with the consumer's understanding of required information, FDA is amending the final regulations by deleting proposed § 101.9(c)(3)(ii)(D) which allowed for the voluntary declaration of calories from protein.

Consumers interested in determining the calories from protein for an individual food may simply multiply the number of g of protein by four, the number of calories per g of protein. Consumers interested in determining the percent of calories from protein consumed in one day may add the g of protein consumed for the day, multiply

the total by four, divide the result by total calories consumed that day, and multiply by 100 to obtain percent.

7. Increments for Calories

15. The agency received only a few comments concerning the proposed change in § 101.9(c)(3) to delete the use of 2-calorie increments for expressing caloric content up to and including 20 calories per serving. Most of the comments agreed with the proposal which would express caloric content to the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increment above 50 calories. While one comment disagreed with the proposed change to delete the 2-calorie increments on the basis that it would permit less accurate information for very low calorie foods, another comment considered 2-calorie differences as inconsequential to the consumer. Another suggestion was made to round all calorie levels to the nearest 5-calorie increment.

FDA is not persuaded by the comments that there is sufficient reason to maintain the use of 2-calorie increments for foods containing 20 or fewer calories or to use only 5-calorie increments. FDA acknowledges the concern expressed about very low calorie products. However, only a relatively small number of products will be affected by the change. In fact, the agency traditionally has been tolerant of slight differences in the declared and actual amounts of calories. Current § 101.9(e)(6), redesignated as § 101.9(g)(6), states that "Reasonable deficiencies of calories * * * under labeled amounts are acceptable within current good manufacturing practice." Thus, FDA is adopting this aspect of § 101.9(c)(3), redesignated as § 101.9(c)(1), as proposed.

C. Total Fat, Fatty Acids, and Cholesterol

1. Total Fat

In the mandatory nutrition labeling proposal, FDA proposed to require the declaration of fat, saturated fat, and cholesterol. In addition, FDA proposed definitions for saturated fat, unsaturated fat, polyunsaturated fat, and monounsaturated fat. The agency did not define "fat" (i.e., total fat) for nutrition labeling purposes. For compliance purposes, FDA has used as its definition the sum of compounds with lipid characteristics that are extracted by the Association of Official Analytical Chemists International (hereinafter referred to as AOAC) methods or by other reliable and appropriate analytical procedures (current § 101.9(e)(2)).

16. The agency received a number of comments concerning the agency's standards for assessing total fat. A few comments from food manufacturers and trade associations agreed with the customary method of estimating dietary fat. Comments from other food manufacturers, trade associations, college and university nutrition professionals, consumer advocate groups, other Government agencies, and foreign governments, disagreed with the agency's position regarding the determination of fat content. Some of these comments expressed uncertainty about what current declarations of fat represent. It became evident that some persons considered that the agency had implied a definition of total fat as the sum of all triglycerides by stating in current § 101.25(c)(2)(ii) that the amount of fatty acids was to be calculated as triglycerides. This statement led some comments to assume that mono- and diglycerides did not need to be included in the declaration of total fat.

Several comments suggested that the definition of fat should include all dietary lipids, especially mono-, di-, and triglycerides, phospholipids, and free fatty acids. These comments pointed out that advances in food technology have led to the development of fats and oils that reduce the triglyceride content found in foods by replacing triglycerides with mono- and diglycerides and phospholipids. These new forms of fats provide calories and should be included in total fat values declared in nutrition labeling.

One comment suggested changing the definition of fat to "substances possessing the physiological properties of fat." This comment stated that this definition would encompass all types of dietary fats. Another comment suggested that the definition be the "sum of fatty acids from a total lipid extraction." These comments pointed out that dietary lipids not only contribute to the total dietary caloric intake but have other physiologic functions attributable to fats. These functions include transporting of lipids and fat soluble vitamins in the body and structural functions in cell membranes, as well as serving as essential fatty acids and as precursors of certain hormones and eicosanoids.

Several comments suggested that FDA's position on total fat is not consistent with the definition found in Codex Alimentarius or with that used by the Canadian government and the EC. According to the comments, the international definition of fat is not restricted to triglyceride-releasable fatty acids but includes total free fatty acids and other lipids, including phospholipids.

A couple of comments suggested that the definition of fat should exclude some types of lipids (i.e., phospholipids, plant sterols, and novel lipids) because these lipids constitute only a small portion of total fat consumed, and, according to the comments, these types of lipids have not been reported as having a causal role in disease.

The agency is concerned about the obvious confusion caused by the lack of a precise definition for total fat. Because of the importance given to dietary recommendations to reduce the intake of total dietary fat, it is critical that all parties (i.e., Government agencies, food manufacturers, health professionals, nutrition scientists, and consumers) clearly understand what the values declared on the nutrition label represent.

Concerns that the total fat value not be underrepresented have persuaded the agency that it is not adequate to continue only using a reference to AOAC methods or "other reliable, appropriate analytical procedures." Such an approach allows for the use of many methods that measure different analytes. For example, according to AOAC procedures, "fat" content can be determined by ether or chloroform-methanol extraction. In the case of an ether extraction, results yield a value for neutral lipids which are primarily triglycerides (a complex lipid composed of glycerol and three fatty acids) and some mono- and diglycerides. In contrast, the chloroform-methanol extraction method extracts all classes of lipids. The two methods, which are both acceptable according to current regulations, may result in different values for total fat being obtained for the same product and different values being declared on the nutrition label.

The agency believes that the use of the implied definition of total fat as the sum of triglyceride fatty acids from saturated, polyunsaturated, and monounsaturated fatty acids, would in some cases underestimate both total g of fat and the caloric intake from fat. The agency agrees that all forms of fatty acids that contribute to energy intake of foods should be included in the calculation of total fat, particularly in view of dietary recommendations that target total fat intakes at 30 percent or less of calories.

For these same reasons, the agency disagrees with the suggestion that some lipids (e.g., mono- and diglycerides and phospholipids) be excluded from the definition of fat.

Therefore, the agency has decided to define total fat as total lipid fatty acids, that is, the sum of fatty acids from mono-, di-, and triglycerides, free fatty acids, phospholipid fatty acids, and sterol fatty acids. This definition includes all sources of fatty acids that provide energy, preventing underestimates of energy from total fat. It also acknowledges that certain lipid components, such as cholesterol and other sterols, do not contribute metabolizable calories and constitute only a very small amount of the total weight of lipids.

This definition represents all fatty acids obtainable from a total lipid extraction. The definition does not require that a single extraction method be used. The extraction method will depend upon the type of lipid being sought in the food and the type of food (i.e., the food matrix). Analytical procedures are discussed further in section IV. of this document.

The agency finds that this definition is more consistent with, although not identical to, international definitions for dietary fat. The Codex Alimentarius considers any source of dietary energy to be a nutrient (that would include nontriglyceride sources of fatty acids), and declaration of dietary fat would reasonably include all sources of fatty acids. The EC definition of fat is total lipids, including mono- and diglycerides and phospholipids. The difference between the EC definition and the agency's definition is that the agency excludes the sterol fraction, not a large difference in quantitative terms. Furthermore, the agency's definition reflects dietary goals for consumption of only 30 percent of calories from fat, because the sterols are not absorbed and therefore do not contribute calories.

However, the agency also recognizes that the definition of total fat as total lipid fatty acids does not account for the weight of glycerol to which the fatty acid chains are linked in the formation of mono-, di-, and triglycerides. Unless the glycerol is included in the weight of the total fat, it will be reported as carbohydrate. In this case, foods in which the fat is mostly triglyceride, e.g., corn oil and lard, will appear to have 95 percent total fat and 5 percent carbohydrate, while other products such as muscle meats which have never been reported to contain carbohydrate may now contain measurable amounts. These values would conflict with common perceptions of food composition because nutrient data bases and food composition tables routinely include the weight of glycerol in the declaration of total fat.

Therefore, the agency has decided to require that the declaration of total fat be expressed as the amount of triglyceride that would provide the analytically measured amount of total lipid fatty acids in the food. This position is supported by a recent report in The Referee, a publication of the AOAC International (Ref. 32). Likewise, because food composition data bases do not include glycerol in the declaration of fatty acids (i.e., values represent free fatty acid), the agency is not requiring that the amount of saturated fatty acids or other classes of fatty acids be expressed as triglycerides (see comment 30 of this document).

While the inclusive term "total lipid fatty acids expressed as triglycerides" would be the more accurate term to use in the nutrition label, the agency will continue to require use of the term "total fat" to be consistent with the terminology used in dietary recommendations and to avoid consumer confusion.

17. Several comments from manufacturers, trade associations, a consumer advocacy group, and a research firm addressed the issue raised in the preamble to the supplementary proposal (56 FR 60366 at 60371) of the increased use of fats containing very long (longer than 18 carbons) chain fatty acids in the food supply. These compounds provide the potential for marketing novel compounds in which fatty acids are linked to carbon structures in a manner that reduces their digestibility. As a result, these compounds have the technical effect of fat with less calories than traditional fats.

Comments requested that fat be defined to exclude various types of very long chain fatty acids because of their poor absorbability and reduced digestibility. A recent article was cited as evidence of the poor absorption of the very long chain fatty acids (Ref. 33). One comment stated that the definition of fat should exclude extractable compounds that do not have the physiological effects of fatty acid compounds. Two comments suggested the omission of these fatty acids from fat and calorie declarations similar to the omission of insoluble dietary fiber from calorie declarations. According to these comments "total fat" should be defined as "total 'digestible' fat" to allow for the use of fat-type ingredients that have reduced digestibility and therefore fewer calories than the fats they replace. The declared amount of fat would then be the total analytically determined fat times the fat digestibility coefficient.

FDA acknowledges the effect that the use of certain very long (longer than 18 carbons) chain saturated fatty acids with reduced digestibility have on the fat and calorie content of foods. In an effort to encourage innovation in the creation of products that provide lower fat and lower calorie contents to enable the consuming public to have a healthier diet and thus to meet one of the primary objectives of the Surgeon General's report on Nutrition and Health (Ref. 2), the agency is willing to consider the digestibility of novel fat compounds. However, the agency has concluded that because of the diversity of possible products, it is not appropriate to modify the definition of total fat in § 101.9(c)(2) to allow for alternate values because of reduced digestibility of very long chain fatty acids. Rather, the agency will address the digestibility of new ingredients containing these fatty acids on a case-by-case basis.

Because the digestibility of a substance is one of the identifying characteristics of the substance, the agency requests that manufacturers who wish to declare adjusted values of total fat based on reduced digestibility include information on the digestibility of the compound, analytical assay procedures for the compound, and data on interference with required methods of analysis in food additive petitions (21 CFR part 171) or in petitions for affirmation that the use of the substance is GRAS (21 CFR 170.35). The agency will include the specific digestibility coefficients that can be used in determining the quantitative declaration of fats and the caloric contribution from fats as part of the statement of identity for the substance in the listing regulation in part 172 for food additives and in part 184 for substances whose use is affirmed as GRAS. However, FDA recognizes that mechanisms other than food additive or GRAS petitions may be appropriate to bring issues involving the digestibility of a substance to the attention of the agency. Interested persons may wish to use the mechanism in § 101.9(g) to request to use specific digestibility coefficients.

18. Several comments said that there is a need for adequate analytical methods for assaying novel forms of fat in new low-fat foods. They noted the difficulty of isolating new ingredients by the traditional or AOAC determinations for fat. As one comment stated, the current acid hydrolysis analysis may not be appropriate for these type of substances.

FDA agrees with the concern about analytical methodology and is aware that different methods might be needed for each product or type of product. Because of this concern, and as noted in the preceding comment, the agency

finds that it is necessary that manufacturers delineate, in the documentation submitted to FDA in support of the lower fat content declarations, the methodology needed to assay for the novel fat compound. Use of the method by the manufacturer and the agency in lieu of conventional methods found in the AOAC or other recognized sources should alleviate labeling compliance concerns.

19. One comment urged the agency to allow manufacturers to use calculations from product formulas to arrive at the calorie or fat content of products containing these alternate ingredients.

As discussed in previous comments, the supporting documentation submitted to the agency to substantiate different caloric levels for novel fats should contain adequate information regarding the digestibility coefficient, analytical methodology, and other factors to ascertain an accurate label value for the fat and calorie declarations. FDA will use the information and analytical methodology for each such fat to determine whether the values for fat and calories stated on the label are correct. Manufacturers may use other methods, such as calculations from product formulas, to determine fat and calorie values if they have a reasonable basis on which to believe that the values so obtained will be consistent with values determined analytically. However, they do so at the risk that FDA will disagree.

2. Saturated Fat

a. *Definition.* FDA proposed (55 FR 29487 at 29495) to make the amount of fat, saturated fatty acids, and cholesterol mandatory elements of nutrition labeling. At the same time, FDA proposed in § 101.9(c)(4)(i) to continue to define saturated fatty acids as the sum of lauric (C12:0), myristic (C14:0), palmitic (C16:0), and stearic (C18:0) acids, the major saturated fatty acids in the U.S. food supply. FDA requested comments on the questions of what fatty acids should be considered as saturated fatty acids, and on what basis these decisions should be made (55 FR 29487 at 29495).

20. Many comments, including comments from food manufacturers and distributors, trade associations, professional organizations, nutritionists, and state health departments agreed with FDA's proposal to include only the four saturated fatty acids with 12 to 18 carbons (lauric, myristic, palmitic, and stearic acids) in the definition of saturated fat for labeling purposes. The reasons given included: (1) Lauric, myristic, palmitic, and stearic acids comprise the vast majority of saturated fatty acids in the American diet; (2) C12:0–C16:0 fatty acids raise total and low density lipoprotein (LDL)-cholesterol; (3) although some clinical and metabolic evidence suggests that C18:0 fatty acid (stearic acid) does not have the same blood total and LDL-cholesterol-raising effect as C12:0–C16:0 saturated fatty acids, the effect of C18:0 on blood total and LDL-cholesterol is not conclusive enough to warrant deletion of C18:0 from the definition; (4) stearic acid may be associated with other risk factors of cardiovascular disease such as thrombosis and platelet aggregation; and (5) a separate analysis for stearic acid would be costly.

Many other comments, including comments from other food manufacturers, trade associations, and health professionals, suggested that FDA include only lauric acid (C12:0), myristic acid (C14:0), and palmitic acid (C16:0) in the definition of saturated fat for labeling purposes. These comments stated that there is no evidence that stearic acid has a cholesterol-raising effect, and that the postulated role of stearic acid in thrombosis is open to dispute. With regard to the latter point, the comments cited the conclusion of a workshop on Dietary Fatty Acids and Thrombosis that there is no direct evidence of a prothrombotic effect of long chain fatty acids (e.g., C18) in humans (Ref. 34).

One comment from a trade association suggested that FDA not include palmitic acid in the definition of saturated fat because palmitic acid does not raise blood total and LDL-cholesterol. The comment cited recent research articles (Refs. 35 and 36) as the evidence.

A comment from a major food manufacturer suggested that FDA not include saturated fatty acids with less than 10 carbons in the saturated fat category. Other comments suggested FDA exclude lauric acid or myristic acid from the saturated fat category for labeling purposes. The reasons given were: (1) That the medium chain fatty acids (C6:0–C10:0), lauric acid (C12:0), and myristic acid (C14:0) are readily absorbed and oxidized and may not raise blood total and LDL-cholesterol, and (2) that medium chain fatty acids are minor sources of saturated fat in the American diet. In contrast, a consumer and a state agency suggested that FDA include saturated fatty acids with carbon numbers less than 12 in the saturated fat category because they may elevate blood cholesterol.

Some comments from a major food manufacturer and a state public health department stated that saturated fatty acids with carbon chains longer than 18 (i.e., C20–C24) should not be categorized as saturated fatty acids. The reasons given included: (1) These fatty acids compose a small part of saturated fat content in the U.S. diet, and (2) these fatty acids are poorly absorbed, have no or little physiological effects, and therefore do not contribute to heart disease.

Several comments, from a food manufacturer, a consumer, and foreign governments, suggested that FDA use a chemical definition of saturated fatty acids for labeling purposes. Two other comments from the meat industry suggested that FDA use a chemical definition if it is not possible to set a definition on the basis of the relationship of saturated fatty acids to the risk of cardiovascular disease. The reasons included in these comments were:

(1) Underrepresentation of the content of saturated fat. Several comments stated that the proposed definition, limiting saturated fat to only the four saturated fatty acids with 12 to 18 carbons, would result in underrepresentation of the saturated fatty acid content of foods, particularly of those foods that contain significant amounts of saturated fatty acids with less than 12 carbons or more than 18 carbons. They further stated that this underestimation of saturated fat contradicts the current dietary recommendation that Americans consume less than 10 percent of calories as saturated fats. The examples that they presented of foods in which the definition of saturated fat as C12–C18 would underrepresent saturated fat were milk, underrepresented by 8 percent; coconut oil, by 14 percent; and palm kernel oil, by 7.2 percent.

(2) Oversimplification. A consumer stated that FDA's proposal is an oversimplification and suggested that all saturated fatty acids be included.

(3) International harmonization. The Canadian Government and the EC stated that FDA's proposal to restrict the definition of saturated fat to only lauric, myristic, palmitic, and stearic acids is at variance with the Codex Alimentarius Commission, EC, and Canadian definitions. They stated that the proposed deviations from international definitions present serious problems for food companies in the EC and would be confusing for consumers. They suggested that FDA include all saturated fatty acids without double bonds in the saturated fat definition. A major food manufacturer also stated that it already had encountered minor problems with different definitions in labels for Canada and the United Kingdom and suggested that FDA consider international

harmonization in its decision on the definition of saturated fat.

FDA is persuaded by the comments that there is substantial controversy regarding the inclusion or exclusion of specific fatty acids in a definition of saturated fat that is based on effects on blood total and LDL-cholesterol.

Therefore, the agency has reconsidered its position of linking the definition of saturated fatty acids to effects of particular fatty acids on blood total and LDL-cholesterol levels and has determined that a chemical definition is appropriate for the following reasons.

First, a chemical definition avoids much of the controversy regarding the blood cholesterol effects of palmitic acid, very long (longer than 18 carbons) chain fatty acids, and short and medium chain fatty acids, because the definition is not subject to changes in knowledge about the physiologic effects of particular fatty acids. The chemical definition also avoids uncertainties about physiologic effects other than those regarding blood total and LDL-cholesterol, such as effects on thrombosis, and other possible health effects of very long chain, medium chain, and short chain saturated fatty acids.

Secondly, FDA agrees that the amount of saturated fat in some foods could be underrepresented when the definition of saturated fat is confined to the sum of four fatty acids. This underreporting of saturated fat may be increased as new foods containing saturated fatty acids less than C12 and more than C18 appear in the marketplace.

Thirdly, the agency also notes that the chemical definition is in line with EC and Canadian definitions of saturated fat and, hence, will promote international harmonization.

Finally, the agency notes that the chemical definition of saturated fat is more consistent with dietary recommendations to reduce fat consumption to 30 percent of calories and saturated fat consumption to less than 10 percent of calories. Food composition data tables have generally been used in epidemiologic investigations that relate diet to risk of chronic diseases, and these tables group all the chemically defined saturated fatty acids together as a class. Thus, the term "saturated fat" used in these dietary recommendations pertains to the chemical classification of fatty acids, not FDA's current, more restricted definition.

Accordingly, FDA has amended § 101.9(c)(4)(i), redesignated as § 101.9(c)(2)(i), to define saturated fat as the sum of all fatty acids containing no double bonds.

b. *Voluntary declaration of specific saturated fatty acids.* 21. Some comments specifically requested that the agency provide for labeling that distinguishes those fatty acids associated with increased blood total and LDL-cholesterol levels from those not associated with increased cholesterol. One approach that was identified in the comments and in a published commentary (Ref. 13) would allow a declaration of "cholesterol-raising fatty acids," so that a manufacturer could show that a particular food contained little or none of these fatty acids.

The agency recognizes that there is substantial uncertainty as to which saturated fatty acids are cholesterolemic and which are not. Conclusions of authoritative documents and review papers are not consistent on this issue (Refs. 2, 3, 37 through 41). The effects of most individual saturated fatty acids on blood total and LDL-cholesterol are not fully understood. The agency finds that the only saturated fatty acid that has been consistently reported as cholesterol-raising is myristic acid. The effects of palmitic acid and lauric acid are not as clearly associated with increased blood cholesterol, although the prominence of palmitic acid in the diet makes any contribution of this fatty acid important in the control of blood cholesterol. On the other hand, it has consistently been reported that stearic acid, when substituted for other saturated fatty acids in the diet, has a neutral effect on blood total and LDL-cholesterol concentration (Refs. 37 through 40). As a result, the agency is concerned that there is not an adequate basis for deciding which fatty acids should be included in the term "cholesterol-raising fatty acids."

In addition, the agency is concerned that the term "cholesterol-raising fatty acids" will be confusing to consumers. Since consumers are unfamiliar with the term "cholesterol-raising fatty acids," there is a possibility that they would misinterpret it and would avoid foods with such a declaration on the nutrition label, even if the intent of the labeling was to indicate the absence of these fatty acids. Also, given that the only fatty acid declaration the agency is requiring is saturated fat (defined as the sum of all saturated fatty acids), any added declaration of "cholesterol-raising fatty acids" would be on a voluntary basis. Under these circumstances, manufacturers could be expected to only include this declaration when the level of such fatty acids is low to emphasize the absence of such components from the product.

A variation of this term that avoids the negative connotation and applies positively to the composition of the product is the term "noncholesterol-raising fatty acids." However, this term suffers from the other problems with respect to cholesterol-raising fatty acids (i.e., the scientific uncertainty concerning what fatty acids to include and the likelihood of increased consumer confusion).

FDA is also concerned that either of the terms "cholesterol-raising fatty acids" or "noncholesterol-raising saturated fatty acids" could be seen as a health claim. Section 403(r)(1) of the act states that information that is required or permitted under 403(q) of the act to be included in the nutrition label is not a nutrient content or health claim. Because of the relationship between fatty acids and increased blood cholesterol and, thereby, heart disease, however, the agency is concerned that the use of either of the subject terms goes beyond the factual reporting of nutrients that is characteristic of the nutrition label.

For the reasons enumerated above, FDA has concluded that it is not appropriate to distinguish among fatty acids by the terms "cholesterol-raising fatty acids" or "noncholesterol-raising saturated fatty acids."

Another approach to distinguishing among fatty acids is to declare specific saturated fatty acids without any reference to effects on blood total and LDL-cholesterol. This approach is consistent with the agency's intention of providing factual information on the nutrition label. Because some comments strongly opposed the inclusion of stearic acid in the declaration of saturated fat because of the consumer's association of saturated fat with increased blood cholesterol levels, it is reasonable to indicate the extent of the saturated fat content of the food that is stearic acid and, thus, not associated with increased blood cholesterol. As noted above, a consensus that seems to be emerging is that stearic acid, when substituted for other saturated fatty acids, does not raise or lower blood total and LDL-cholesterol level. Consumer education programs could advise consumers that when a large portion of the saturated fat in a product consists of stearic acid, the fat content of the food is not likely to increase blood total and LDL-cholesterol levels.

The agency, however, has some reservations about allowing for the voluntary labeling of stearic acid in that: (1) Other saturated fatty acids that may raise blood total and LDL-cholesterol are not addressed; (2) only one risk factor of cardiovascular disease, blood

cholesterol level, is addressed; (3) it may complicate and overcrowd the label; and (4) it would require a consumer information program to have any meaning to consumers.

In addition, recognizing particular saturated fatty acid effects on blood cholesterol may require that the agency redefine the saturated fat threshold criterion for cholesterol claims in § 101.62(d) (cholesterol claims are not allowed on foods containing more than 2 g saturated fat, defined as the sum of all fatty acids containing no double bonds, per serving), as described in a companion document on nutrient content claims published in this issue of the **Federal Register**. Because of the agency's reservations about the meaningfulness of labeling of individual fatty acids and the need to reconsider criteria for cholesterol claims if such action was to be taken, the agency concludes that more information, including public comment, is necessary before taking further action on this approach. The agency intends to further address this issue at a later date, and would welcome submission of information and views on this question.

3. Polyunsaturated and Monounsaturated Fat

a. *Use of the term "unsaturated fat"*. FDA proposed in both the July 19, 1990, and November 27, 1991, documents in § 101.9(c)(4)(ii) to permit the voluntary declaration of the quantitative amount of unsaturated fat in nutrition labeling. The agency proposed to make the declaration of unsaturated fat mandatory if claims were made about fatty acid or cholesterol content or if the manufacturer voluntarily declared the number of calories from unsaturated fat. Alternatively, the agency proposed to allow separate declarations of polyunsaturated and monounsaturated fats.

22. The agency received comments that either agreed or disagreed with the proposed defini ion and voluntary use of the term "unsaturated fat". Comments that supported the use of the inclusive term did so because neither monounsaturated nor polyunsaturated fats have been shown to increase the risk of coronary heart disease, and because both types of unsaturated fats decrease the risk of coronary heart disease relative to saturated fat.

Comments objecting to the term "unsaturated fat" argued that the term is not useful, that it offers no additional information that could not be obtained by subtracting the saturated fat content from total fat, and that it obscures the presence of essential fatty acids. Other comments were concerned that the term was misleading in that it suggests that all unsaturated fats are synonymous by including both *cis* and *trans* isomers and both poly- and mono-unsaturated fats together. These comments argued that in light of the current uncertainty and controversy surrounding the physiological effects of *trans* fatty acids (which are a particular type of unsaturated fatty acid having some physical properties of saturated fatty acids), use of the term "unsaturated fat" would not only be misleading to the consumer but possibly could have an adverse effect on the health of some individuals. This opposition to the inclusion of *trans* isomers in the definition of "unsaturated fat" was the most frequently repeated concern.

Comments suggesting that it would be misleading to group poly- and mono-unsaturates together argued that this action would imply that the two types of fatty acids are the same and have similar effects on blood total and LDL-cholesterol when, in fact, they do not. It has been reported that monounsaturates do not effect blood total and LDL-cholesterol levels and do not reduce high density lipoprotein-cholesterol when substituted for saturated fats. On the other hand, polyunsaturates have often been reported to reduce blood total and LDL-cholesterol levels and to decrease blood pressure.

A few comments suggested that if the term "unsaturated fat" is permitted, the declaration of the *cis* forms of polyunsaturates and monounsaturates should either be permitted or required at the same time. Comments also argued that there is no scientific consensus supporting the use of the inclusive term, and that it was not a term used in international trade.

FDA is persuaded by these comments that the use of the term "unsaturated fat" is potentially confusing to consumers, does not provide useful information, and could result in consumer deception. Accordingly, the agency is revising the regulation by not providing for the voluntary declaration of unsaturated fat in nutrition labeling. As a result, the proposed listings of polyunsaturated fat and monounsaturated fat in § 101.9(c)(4)(ii)(A) and (c)(4)(ii)(B), respectively, are redesignated as § 101.9(c)(2)(ii) and (c)(2)(iii). In addition, each paragraph has been modified to incorporate provisions that had been included in proposed § 101.9(c)(4)(ii). The revised listings provide that the disclosure of the level of polyunsaturated fat and monounsaturated fat is voluntary unless claims are made on the label about fatty acid or cholesterol content, and that, if either polyunsaturated or monounsaturated fat is declared, the other must also be declared.

b. *Trans Fatty Acids*. In its July 19, 1990 proposal on mandatory nutrition labeling (55 FR 29487 at 29496), the agency tentatively concluded that there is no basis for declaring *trans* isomers of fatty acids on the nutrition label. This conclusion was based on a consensus report that noted that current evidence does not support a blood cholesterol-raising effect for *trans* isomers when they are substituted for saturated fatty acids in the diet. The agency requested comments on this issue. Later that year new research and commentary was published (Refs. 12 and 13) which led FDA to request in the supplementary proposal (56 FR 60366 at 60371) comments on the significance of the new findings and a reevaluation of any comments submitted on *trans* fatty acids in response to the July 19, 1990 proposal.

23. Several comments, from a major food manufacturer, health professionals, a professional health organization, a state agency, a trade association, and a consumer, suggested that FDA include *trans* fatty acids in the saturated fat category because research suggests that *trans* fatty acids raise blood total and LDL-cholesterol. On the other hand, several comments were against the inclusion of *trans* fatty acids in the saturated fat category because the evidence of a cholesterol-raising effect of *trans* fatty acids is not conclusive. Several comments suggested that *trans* fatty acids should be declared separately because it may increase blood cholesterol.

FDA disagrees that there is sufficient evidence that indicates that *trans* fatty acids raise blood total and LDL-cholesterol. In 1985, a report of the Federation of American Societies for Experimental Biology on "Health Aspects of Dietary *trans* Fatty Acids"(Ref. 42) concluded that human studies indicate that *trans* isomers are little, if any, more cholesterolemic than *cis* isomers. In animals (rabbits, swine, and monkeys), *trans* fatty acids are cholesterolemic but not atherogenic. Since the publication of the Federation of American Societies for Experimental Biology report, a scientific review article, (Ref. 40) concluded that reports are inconsistent regarding the effects of *trans* unsaturates on blood total and LDL-cholesterol levels in humans.

Recently, two studies in The Netherlands (Refs. 12 and 43) have shown that a high intake of *trans* fatty acids may elevate blood total and LDL-cholesterol concentration. Concerns

have been raised about the applicability of these studies to U.S. diets because of certain methodologic limitations, because the level of *trans* fatty acid tested was 2–3 times higher than the current average consumption of the U.S. population, and because the methods for generating *trans* fatty acids might have been different from those used in the United States.

In contrast, another study (Ref. 44) seems to indicate that *trans* fatty acids do not raise blood total and LDL-cholesterol in mildly hypercholesterolemic, normotensive men, although diet differences other than *trans* fatty acids may have been responsible for the effects.

Finally, the agency is aware of preliminary results from a very recent unpublished study designed to address the criticisms of the studies from The Netherlands (Ref. 45) that suggests that *trans* fatty acids raise LDL-cholesterol.

In the absence of the fully analyzed data from this study, the agency considers it premature to require the labeling of *trans* fatty acids because of their effects on total or LDL-cholesterol. However, even if there was a need for labeling of *trans* fatty acids, the agency does not agree that *trans* fatty acids should be included in the category of saturated fats. The agency has argued against inclusion or exclusion of particular saturated fatty acids in the definition of saturated fat solely on the basis of their effect on blood total and LDL-cholesterol. In addition, the agency recognizes that inclusion of *trans* fatty acids in the definition of saturated fat is not consistent with the EC, Codex, or Canadian definitions of saturated fat.

Because of the current uncertainties, the agency does not agree that a separate declaration of *trans* fatty acids is appropriate at this time. Because new data are rapidly emerging (Ref. 45) that imply that *trans* fatty acids raise LDL-cholesterol, however, the agency recognizes that it may be necessary to readdress the labeling of *trans* fatty acids in the near future.

24. One comment suggested that not all foods voluntarily declaring levels of monounsaturates and polyunsaturates need to be analyzed to differentiate *cis* and *trans* fatty acids because only those containing hydrogenated fats would contain *trans* isomers.

The agency agrees with this comment in the case of vegetable oils and other plant lipids. However, naturally occurring *trans* fatty acids are found in some animal lipids (e.g., dairy products). If there is adequate and reliable reason to believe that a nutrient is not present in a food, there is no need to analyze for that nutrient. However, a manufacturer is responsible for ensuring that its labeling is truthful and not misleading.

c. *Definition of polyunsaturated fatty acids.* FDA proposed in §§ 101.9(c)(4)(ii)(A) and (c)(4)(ii)(B) in July 19, 1990 and November 27, 1991 to define polyunsaturated and monounsaturated fats as *cis, cis*-methylene interrupted polyunsaturated fatty acids and cis-monounsaturated fatty acids, respectively. These definitions exclude *trans* isomers. The definition of polyunsaturated fat is consistent with current § 101.25(c)(2)(ii)(*a*). FDA has not previously defined monounsaturated fat for labeling purposes.

25. Comments from food manufacturers, trade associations, health promotion organizations, consumer groups, and international agencies supported the agency's definition for polyunsaturated fat. However, some comments urged FDA to change the definition to reflect the various physiological roles of specific types of polyunsaturated fats, in particular to allow for the identification of omega-3 (n–3) and omega-6 (n–6) fatty acids, indicating that these are essential in the diet and that the ratio of consumption of these fatty acids can be important.

FDA is not persuaded that there is a need to require further breakdown of polyunsaturated fats in the nutrition label. As discussed above, FDA is concerned that additional information on the nutrition panel may confuse consumers and interfere with their understanding of other required information.

However, the agency agrees that there are valid reasons to consider the voluntary labeling of omega-3 and omega-6 fatty acids. These chemical distinctions are important nutritionally, because the omega-3 fatty acids (with the first double bond at the third carbon from the methyl end of the fatty acid) and omega-6 fatty acids (with the first double bond at the 6th carbon from the methyl end) are not interchangeable during metabolism in the body; rather each must be supplied by diet. Each subcategory has members that are considered essential nutrients (α-linolenic acid and linoleic acid, for the omega-3 and omega-6 classes, respectively) (Ref. 23). Dietary omega-3 and omega-6 fatty acids are precursors for biologically active compounds, e.g., prostaglandins, eicosanoids, and the nutritional balance of omega-3 and omega-6 fatty acids modulates the production of many of these biologically important substances. Furthermore, omega-3 and omega-6 fatty acids are important components of cell membranes.

Although the National Research Council has not yet established a Recommended Dietary Allowance for omega-3 and omega-6 fatty acids, they recognized in 1989 that "[T]he possibility of establishing Recommended Dietary Allowance's for these fatty acids should be considered in the near future." (Ref. 23)

FDA agrees that information on the amount of omega-3 and omega-6 fatty acids may be useful to allow interested consumers to select foods that provide these fatty acids. It is not difficult to consume a diet rich in omega-6 fatty acids because vegetable oils are rich in these fatty acids. However, vegetable oils vary widely in their content of omega-3 fatty acids, and labeling may be useful to identify those foods that contain substantial amounts of omega-3 fatty acids to encourage a balanced intake of these two classes of fatty acids.

However, FDA is not fully persuaded about the usefulness of additional label information on omega-3 and omega-6 fatty acids, and whether there are many consumers who desire this information. As discussed above, the agency is concerned that additional information on the nutrition panel may confuse consumers and interfere with their understanding of other required information. Because of these concerns, FDA concludes that it is not appropriate to allow for the voluntary declaration of these subcomponents of polyunsaturated fats at this time. The agency intends to address this issue at a later date and would welcome submission of information and views on this issue.

26. The majority of comments supported the voluntary declaration of polyunsaturated fats. However, a few comments suggested that their declaration be mandatory rather than voluntary. One of these comments was concerned with possible safety issues associated with increased consumption of polyunsaturated fats. The comment alleged that polyunsaturated fats convey a potential source of free-radical peroxidation products, and that consumers should be informed of the amounts of polyunsaturated fat present in a food. Other comments merely stated that mandatory declaration of polyunsaturated fat would provide consumers with valuable and more complete nutritional information.

FDA is not persuaded that there is need to require the inclusion of polyunsaturated fats on the nutrition label. These fatty acids do not meet the criteria for mandatory declaration set forth in the mandatory nutrition

labeling proposal (55 FR 29487 at 29493) that the nutrient or food component be of particular public health significance, and that quantitative intake recommendations for the nutrient be given in major scientific consensus reports. The comments largely support this view, and the agency therefore rejects the suggestion that the declaration of polyunsaturated fats be mandatory.

The agency disagrees with the contention that commonly consumed amounts of polyunsaturated fats would pose any safety concerns. While the potential exists for formation of oxidative products as a result of the increased number of double bonds—present in polyunsaturated fats, any risk would only occur at very exaggerated levels of consumption.

d. *Monounsaturated fats.*

27. Comments both agreed and disagreed with the proposed definition of "monounsaturated fat." Those opposed generally requested that the definition not exclude *trans* fatty acids on the basis that they have not been proven to have an adverse effect on health or disease in humans, or that *cis* and *trans* isomers have similar metabolic and physiologic properties. One comment asked the agency to include *trans* fatty acids in the definition of monounsaturated fats until an expert panel can determine if *trans* or unusual *cis* isomers formed as components of commercial hydrogenation increase the risk for coronary heart disease or other health related conditions.

Comments from medical associations, trade associations, a consumer advocacy group, the Canadian government, and the EC supported the proposed definition, focusing particularly on two considerations. First, *trans* fatty acids or unusual *cis* isomers formed during commercial hydrogenation of unsaturated fats may increase the risk of coronary heart disease, and, second, monounsaturated fats, as defined in the proposal, may reduce blood total and LDL-cholesterol and reduce the risk of coronary heart disease. Comments also suggested that the inclusion of *trans* fatty acids may mislead consumers, who perceive monounsaturates as healthful or at least as not harmful.

FDA concludes that there is no need to amend the proposed definition of "monounsaturated fat." The comments received, the scientific reports they discuss (Refs. 12 and 43), and the concerns addressed in the preceding discussion of *trans* fatty acids establish that to include *trans* isomers in the definition of "monounsaturated fat" would be misleading and will not assist consumers in maintaining healthy dietary practices. The agency is not willing to include *trans* isomers in the label definition of "monounsaturated fat" until there is further consensus based on publicly available, well-designed, and well-conducted studies. However, as more data concerning the action and safety of *trans* fatty acids become available, the agency may reconsider its decisions to define monounsaturates as the usual *cis*-monounsaturated fatty acids.

28. One comment also objected to the proposed definition of "monounsaturated fat" because it would require manufacturers to conduct a further analysis of lipids to differentiate between *cis* and *trans* isomers. The comment argued that this extra analysis was not justified by available scientific data and would cause a financial burden.

The agency disagrees with the comment. The declaration of poly- and mono-unsaturates is voluntary. Therefore, an analysis of unsaturated isomeric forms is only required if the manufacturer chooses to declare poly- or mono-unsaturates or to make fatty acid or cholesterol claims. In such cases, given the controversy on the effect of *trans* fatty acids, the additional analysis is necessary to ensure that the declaration or claims are not misleading.

29. One comment suggested that the agency should include stearic acid in the definition of monounsaturated fat by virtue of its effects on blood total and LDL-cholesterol. The comment stated that scientific data suggests that stearic acid does not increase blood LDL-cholesterol, and that it is rapidly converted to oleic acid, an unsaturated fat that does not raise blood total and LDL-cholesterol levels.

FDA does not agree that stearic acid should be included in the definition of monounsaturated fat. Chemically, stearic acid is a saturated fat, and the agency, therefore, finds that it would be inappropriate to include it with monounsaturated fats. The agency has acknowledged above that some studies and some consensus statements suggest that stearic acid does not increase LDL-cholesterol relative to other saturated fats. However, stearic acid does increase LDL-cholesterol relative to monounsaturates and polyunsaturates (Refs. 12 and 43). Accordingly, the agency is not including stearic acid in the definition of monounsaturated fat.

4. General Issues Related to Declaration of Fats and Fatty Acids

a. Calculation of fatty acids as triglycerides.

30. A comment was received that disagreed with proposed § 101.9 (c)(4)(i) and (c)(4)(ii), which would require saturated fat and unsaturated fat content to be calculated as triglycerides. The comment noted that values in current data bases are reported as the free fatty acids.

Current § 101.25(c)(2)(ii) requires that fatty acids be calculated as triglycerides. This requirement dates back to the initial nutrition labeling regulation promulgated in 1974. This requirement was a result of comments from industry at that time.

To provide consumers with nutrition information that can readily be used for comparison to available nutrient data bases, FDA agrees that saturated and poly- and mono-unsaturated fat should be declared as free fatty acids instead of as triglycerides. As a consequence of the change in method of reporting, slightly lower values for the various fatty acid declarations will appear on the label because the weight of the glycerol molecule in triglycerides is not included when free fatty acids are declared. Also, fatty acids from mono- and di-glycerides used as a source of fat in many products will be included using this revised means of reporting fatty acids. Accordingly, FDA is amending § 101.9(c)(2)(i) for saturated fat and § 101.9(c)(2) (ii) and (iii) for polyunsaturated and monounsaturated fat, respectively, to remove the requirement that the fatty acids be "calculated as triglycerides."

b. Increments for declaring fats and fatty acids. The mandatory nutrition labeling proposal retained the current requirement for the declaration of fat in g and added, as a requirement, the amount of saturated fatty acids in g (55 FR 29487 at 29495). In the supplementary proposal, FDA proposed to change the increments for declaring fats and fatty acids (56 FR 60366 at 60380). The agency proposed to require the declaration of total fat, saturated fat, unsaturated fat, polyunsaturated fat, and monounsaturated fat in 0.5 (½)-g increments. The agency made this change in the proposed provisions to make the increments in which these nutrients are declared more consistent with the levels at which these substances will have nutritional significance. FDA believed the proposed change would consequently provide consumers with more precise information and a greater ability to discriminate among products. In this context, a level of less than 0.25 g per serving was established as the level at which saturated and unsaturated fat content would be expressed as zero.

31. Over 25 responses concerning fat increments were received in response to the request for comments. Almost twice the number of comments disagreed with the proposal to declare total fat and fatty acids in 0.5-g increments as those who agreed with the proposal to do so. The rationale given by essentially all who disagreed with the proposed change was the lack of analytical methods that are adequate and sensitive enough to provide data to that degree of precision. Several comments recommended that the fat content of foods containing 3 or less g fat be declared in 0.5 (½)-g increments, and the fat content of foods containing more than 3 g be declared in whole g increments. These comments suggested that the precision of 0.5 g increments for fat declarations is less important for higher fat foods. Additionally, these comments stated that the variability of some fat assays warrants whole-g increments, especially for moderate and high levels of fat. It should be noted, however, that several comments stated that methodology does exist to support the 0.5-g increment declaration. One comment noted the desirability of keeping all macronutrients, including fat, in whole-g increments. Several comments cited the cost of assaying to the 0.5 (½)-g level of precision as a reason for retaining the whole-g increment declarations for these nutrients.

FDA has given careful consideration to the comments. The agency recognizes that labeling requirements must not only convey desired nutrition information for the consumer but must also be enforceable. Because of concerns about analytical precision, variability, and the effect of product matrices on the methods necessary to quantify total fat, saturated fat, and poly- and mono-unsaturated fat declarations in 0.5-g increments, FDA has concluded that such precision is not necessary for amounts of fat above 3 g per serving of food. Consequently, the agency is modifying § 101.9(c)(2) and (c)(2)(i) through (c)(2)(iii) to require that levels below 3.0 g per serving be declared in 0.5 (½)-g increments and levels above 3.0 g be declared in g increments.

The agency disagrees that cost, although a factor, is a sufficient reason in and of itself to retain the current whole-g increments for total fat, saturated fat, and poly- and mono-unsaturated fats. The public health benefits attributed to decreasing dietary intakes of fat (Refs. 2, 3, 4, and 47) justify the use of 0.5-g increments to allow consumers to differentiate between products containing low levels of fats.

32. A few comments urged that fats not be declared in 0.5 (½)-g increments to improve the legibility of the label.

The agency is concerned about the legibility of the label. However, because of the public health significance of dietary intake of fats, FDA believes it is important to provide the increased precision at low levels of fat. Inasmuch as legibility is more dependent upon factors such as type size and color contrast than the addition of a decimal point and digit, FDA urges manufacturers to consider the readability factor and use great care to ensure that the information is legible.

33. Two comments requested that the agency permit the declaration of total fat and saturated fat in tenths of a g.

FDA does not agree. It is not possible to require the declaration of total fat and saturated fat in tenths of g increments because this degree of precision cannot be reliably obtained in all foods with available methodology.

34. Comments stated that the change from whole-g increments would be confusing and cumbersome to consumers. One comment requested that the agency adopt a consistent rule for all macronutrients by rounding values to the nearest g.

FDA does not agree that the use of different increments for different nutrients will be confusing and cumbersome. These final rules allow for calories to be declared to the nearest 5 or 10 calorie increment depending on amount, for fats to the nearest 0.5 (½) or whole g, for cholesterol to the nearest 5 milligram (mg) amount, for carbohydrates and protein to the nearest g and for sodium to the nearest 5 or 10 mg increment. The rationale for each of these increments was explained when the increments were proposed.

c. *Amounts of fatty acids to be rounded to zero.*

35. A few comments disagreed with 0.25 g as the cut-off level at which fatty acids could be declared at zero. The primary reason given for disagreeing with the 0.25 g cut-off was that the analytical methods are not sensitive and precise enough to detect that level with any degree of reliability. One of the comments noted that FDA had, in its proposal on serving sizes, referenced consumer complaints about fractional numbers. The comment felt it was contradictory to introduce a potentially confusing requirement for the proposed 0.25 g cut-off. Other comments stated it would be confusing to consumers if, because of the rounding requirements, a product containing either 0.4 g or 0.45 g total fat and 0.3 g saturated fat is declared as "0" g total fat and 0.5 g saturated fat.

The agency is persuaded that the level of 0.25 g as the cutoff for a zero declaration for saturated, polyunsaturated, and monounsaturated fat content implies unwarranted precision. The ability to distinguish 0.24 g as zero and 0.26 g as a 0.5 g increment is presently unsubstantiated. Therefore, FDA is amending § 101.9(c)(2)(i) through (c)(2)(iii), to require that when a serving contains less than 0.5 g of saturated fats, polyunsaturated fats, or monounsaturated fat, the content of the fatty acids will be expressed as zero.

5. Cholesterol

36. The majority of comments agreed with the proposal for the mandatory declaration of cholesterol content. A few comments disagreed stating that dietary cholesterol does not play a significant role in the etiology of atherosclerotic vascular disease. Some comments stated that the declaration of cholesterol would mislead consumers into believing that a food free of, or low in, cholesterol would be effective in lowering serum cholesterol levels no matter how much saturated fat or total fat it contained. These comments suggested that declarations of cholesterol content should be either voluntary or not permitted.

FDA disagrees that the declaration of cholesterol should be voluntary or not permitted. The declaration of cholesterol content is required by section 403(q)(1)(D) of the act. While section 403(q)(2)(B) of the act allows the Secretary to delete nutrient information that is not necessary to assist consumers in maintaining healthy dietary practices, FDA does not believe that this is the case for cholesterol. There is a strong scientific consensus that high dietary intakes of total fat, saturated fatty acids, and cholesterol are associated with an increased risk of atherosclerotic cardiovascular disease, most notably with elevations in blood LDL-cholesterol and increased risk of coronary heart disease (Refs. 2, 3, 4, and 30).

Further, numerous controlled experiments, in both animals and humans, verify that dietary saturated fats and cholesterol elevate blood LDL-cholesterol. For this reason, current recommendations suggest limiting cholesterol to 300 mg per day as a means of lowering blood LDL-cholesterol and thereby reducing the risk of atherosclerotic vascular disease (Refs. 2, 3, 30, and 48). Accordingly, the agency concludes that the declaration of cholesterol is warranted and will be beneficial to many individuals in the general population in the monitoring of their cholesterol intake. Therefore, no

changes have been made in § 101.9(c)(5), redesignated as § 101.9(c)(3).

37. A few comments requested the mandatory declaration of a cholesterol-saturated fat index. This index provides a single number for individual foods that describes their cholesterol and saturated fat content. The index indicates the potential of a given food, diet, or menu to raise blood cholesterol levels.

The agency is not persuaded that the declaration of a cholesterol-saturated fat index on the nutrition label is warranted. There currently exists no consensus on the efficacy of this index. Therefore, FDA believes that the declarations of cholesterol and saturated fat, as required by the 1990 amendments, are sufficient for those who wish to moderate their intake of these nutrients.

38. Several comments disagreed with the proposal to declare "not a significant source of cholesterol" if cholesterol is present at less than 2 mg per serving. One comment suggested that the label declare zero cholesterol only if the product is virtually devoid of cholesterol. The comments stated that it is misleading to have even minute quantities of a food component in a product when the label declares that the product is free of that component.

The agency is not persuaded by these arguments. As discussed in the July 19, 1990, tentative final rule on cholesterol (55 FR 29460 at 29461), FDA purposely selected a value, less than 2 mg of cholesterol per serving, that is dietarily insignificant yet that can be detected with reasonable analytical reliability. A quantitative declaration other than zero would not necessarily be more correct because methodological limitations do not generally permit precise quantification of cholesterol content within the 95 percent confidence level below 2 mg amounts. It is also extremely unlikely that sufficient quantities of foods containing less than 2 mg of cholesterol per serving would be consumed on a daily basis to represent a significant level of cholesterol intake.

39. A few comments requested that foods having less than 5 mg of cholesterol per serving be permitted to indicate "not a significant source of cholesterol" so that skim milk, at 4 mg cholesterol per cup, and similar foods could use the statement. Proposed § 101.9(c)(5) only allows its use on labels of foods containing less than 2 mg of cholesterol per serving.

FDA disagrees. The agency believes that the statement "not a significant source of cholesterol" is only appropriate on foods that contribute truly insignificant amounts of cholesterol to the diet. In the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register**, the agency has determined that foods that contain less than 2 mg of cholesterol per serving are dietarily insignificant sources, and that foods that contain larger amounts, both individually and collectively, contribute significantly to a person's daily cholesterol intake. Therefore, FDA is taking no action on the basis of these comments.

D. Sodium

40. The majority of comments supported the proposal for the mandatory declaration of sodium. A few comments requested alternate methods of declaring sodium, such as a sodium to potassium ratio and a sodium balance system.

The agency has no data, nor were any submitted, that demonstrate that these alternative methods would more effectively present sodium content. Accordingly, FDA has not revised the provision for the declaration of sodium content.

41. A few comments questioned potential beneficial effects of sodium restriction in nonhypertensive populations. The comments suggested that there is still debate within the scientific community as to whether it is appropriate for the general population to reduce its overall sodium consumption. Further, these comments stated that control of sodium intake is only relevant for those segments of the population that are sodium sensitive. These comments requested that the agency not permit the declaration of sodium, or that it make the declaration of sodium voluntary.

The agency disagrees. Section 403(q)(1)(D) of the act requires the declaration of sodium. While section 403(q)(2)(B) of the act allows the Secretary to delete nutrient information that is not necessary to assist consumers in maintaining healthy dietary practices, the bulk of the accumulated evidence strongly supports the prevailing consensus that it would be prudent for the general population to reduce sodium consumption, even though not all people display increased blood pressure in response to high sodium intakes.

The Surgeon General's report (Ref. 2) asserts the need for moderation in sodium consumption, not only because there is a benefit to persons whose blood pressures do rise with sodium intake, but also because there is no biological marker for individual sodium sensitivity. Additionally, the report notes that there is no apparent harm from moderate sodium restrictions (Ref. 2). Accordingly, § 101.9(c)(9), redesignated as § 101.9(c)(4), will continue to require sodium declaration.

42. One comment from a national manufacturer of carbonated soft drink syrups explained that these syrups must be mixed with local water supplies, and that, therefore, the final products vary in sodium content. The comment suggested that the sodium in these products be declared as an average value, such as "less than 35 mg," even though the product contains slightly more, or slightly less, than that amount. Further, the comment suggested that the manufacturer be allowed to make a claim, such as "very low sodium," based on that range.

Data on the sodium content of the United States water supplies were previously submitted, reviewed, and discussed in the April 18, 1984, final rule on the declaration of sodium content (49 FR 15524). FDA's evaluation of these data revealed that a single label would accurately reflect the sodium content of all but 10 percent of soft drink products bottled in the United States, and that a second label could apply to the remainder without severely overstating the sodium content.

Further, the agency stated that the manufacturer had the option of using a single nationwide label with the highest possible sodium level declared. This approach would result in the sodium content being overstated by about 50 mg for a majority of products. While 50 mg is not an insignificant amount of sodium, it represents a relatively small portion of the daily sodium intake for all but those persons on extremely restricted sodium diets. Even if sodium were declared based on the highest level of sodium found in any source of water, all regular and diet soft drinks would fall into the "low sodium" category.

FDA is not persuaded by the comment to the July 19, 1990 or November 27, 1991, proposals that an average value representing a range of sodium levels, such as "less than 35 mg," is appropriate for these products. Sodium content may be underrepresented by this method.

Inasmuch as the declaration of sodium is required by section 403(q)(1)(D) of the act, and no new data were presented with the comment, the agency is denying the request that a range of sodium content be declared on the nutrition label or be allowed as a basis to support a nutritional claim.

E. Potassium

43. Several comments supported the proposal for the voluntary declaration of potassium. One comment, however,

requested that the agency not allow any declaration of potassium content. The comment suggested that the general population is unaware of the dietary role of potassium, and any declaration of potassium content would only serve to confuse the consumer. No data were provided to support this argument.

FDA is not persuaded that it should not permit the voluntary declaration of potassium content. As discussed in the mandatory nutrition labeling proposal (55 FR 29500 at 29501), beneficial effects of potassium intake relative to reducing mortality from stroke have been reported. Data from animal studies suggest that dietary potassium may lower blood pressure and the risk for heart disease and may also protect against vascular damage and stroke (Ref. 3).

In addition, epidemiological evidence for humans suggests that diets with high levels of potassium—but also low levels of sodium—may be beneficial in lowering blood pressure (Ref. 3). Moreover, the IOM report concluded that even though deficits or excesses of potassium intake do not pose public health concerns, the voluntary declaration of potassium would be beneficial to consumers (Ref. 1). Based on the foregoing evidence, FDA concludes that the declaration of potassium in nutrition labeling may assist in maintaining healthy dietary practices. Accordingly, in § 101.9(c)(10), redesignated as § 101.9(c)(5), FDA will allow potassium to be declared in nutrition labeling on a voluntary basis.

44. Comments from several health and professional associations, consumers, consumer groups, and universities supported mandatory declaration of potassium content. The comments stated that this information is potentially helpful to persons with kidney disease. Others referred to epidemiological evidence of a positive association among high potassium intake, low sodium intake, and lower blood pressure.

Although potassium has been acknowledged as a potential public health issue (Refs. 1 and 49), no specific, quantitative recommendations have been made by national consensus reports. Accordingly, potassium does not meet FDA's criteria for inclusion as a mandatory element of nutrition labeling, as discussed in FDA's mandatory nutrition labeling proposal (55 FR 29487 at 29493 and 29500).

Until such time as quantitative recommendations are made, the agency does not believe there are sufficient grounds to require labeling of potassium content. Therefore, FDA is continuing to permit potassium content labeling in nutrition labeling on a voluntary basis in § 101.9(c)(5).

45. One comment suggested that the declaration of potassium content should be mandatory only if magnesium is not required as a reference nutrient. The comment stated that potassium and magnesium are abundant in whole grain cereals, legumes, nuts, and other unprocessed foods. Further, the comment suggested that if magnesium is required, potassium should be voluntary.

The agency is not persuaded that the mandatory declaration of magnesium is warranted, or that the declaration of potassium should be mandatory because the declaration of magnesium is not required. Magnesium is not a nutrient for which there are significant public health concerns (Ref. 23).

Further, while magnesium and potassium are found together in many foods, using magnesium as a reference nutrient for potassium in food labeling is questionable because there are many fruits and some vegetables that are excellent sources of potassium but poor to moderate sources of magnesium (Ref. 23). The agency does not believe that a mandatory declaration of magnesium content is warranted at this time.

46. One comment suggested that information on potassium should be available from manufacturers' toll-free telephone numbers. The comment explained that consumers who must monitor their potassium intake, such as renal dialysis patients, often have difficulty determining how much potassium is in a product. The comment suggested that manufacturer's toll-free numbers would provide easy access to more detailed nutrient content information.

While FDA encourages manufacturers to make additional information available to consumers, this request is beyond the authority of the agency. Toll-free telephone numbers for product information may or may not be supplied according to the preference of the manufacturer.

F. Total Carbohydrate, Dietary Fiber, Sugars, Sugar Alcohol, and Other Carbohydrate

1. Total Carbohydrate

47. Comments from trade associations, manufacturers, professional societies, and another federal agency recommended that FDA reconsider proposed § 101.9(c)(6) which excludes dietary fiber from total carbohydrate. As noted in several comments, dietary fiber traditionally has been included as part of the carbohydrate content of food, is considered part of carbohydrate in current nutrition labeling regulations, is included within total carbohydrate for nutritional labeling by Canada, and is included in the Atwater method of determining "carbohydrate by difference." Other comments pointed out that excluding dietary fiber from total carbohydrate is consistent with definitions for labeling used by Codex Alimentarius Commission and the European Community (EC), which include only metabolized carbohydrate. A comment remarked that to exclude dietary fiber from total carbohydrate is inconsistent with all major data bases and U.S. publications on food composition and is different from the way carbohydrate has been presented to the consumer in nutrition labeling for the past two decades. This comment suggested that inconsistency in definitions will contribute to consumer confusion.

In the 1990 mandatory nutrition labeling proposal, FDA proposed mandatory declaration of total digestible carbohydrate, which excluded dietary fiber, the nondigestible portion of carbohydrate. Several comments noted that while the intent of this definition for total carbohydrate was to include only energy yielding components, in fact there is evidence that fermentation of dietary fiber yields available energy. Comments noted that dietary fiber content was accounted for in deriving both the general energy factor of 4 calories per g of carbohydrate and the specific Atwater factors for calculation of energy value of carbohydrate in foods. The comments stated that total carbohydrate (excluding dietary fiber) content as defined in proposed § 101.9(c)(6) is not appropriate for calculating calories from carbohydrate as proposed in § 101.9(c)(3). As a result, two different values for "total carbohydrate" would be required to comply with nutritional labeling: (1) Total carbohydrate (excluding dietary fiber) for the content declaration, and (2) total carbohydrate (including dietary fiber) for calorie calculation.

In the mandatory nutritional labeling proposal, FDA stated that the reason for declaration of carbohydrate content was, in part, to allow consumers to determine the percentage of calories from carbohydrate (55 FR 29487 at 29497). Several comments argued that departing from the established use of the term "carbohydrate" (i.e., including dietary fiber) used in determining carbohydrate calories by the Atwater method, will be confusing and thereby detract from the value to consumers of the caloric information. Several comments suggested that in separating dietary fiber

from "energy yielding" components of carbohydrate, FDA's logic was faulty for two reasons. First, carbohydrate fractions are not clearly delineated as digestible or nondigestible fractions. Rather, there exists a continuum of digestibility among carbohydrate substances. Second, dietary fiber is appropriately included in total carbohydrate for calculation of energy content with use of Atwater factors.

Many comments noted that, except for lignin, substances comprising dietary fiber are carbohydrates. Comments pointed out that dietary guidelines (Ref. 4) urge increased consumption of types of foods rich in both dietary fiber and complex carbohydrate and stated that separating these carbohydrate components in nutrition labeling will mislead consumers as to the nature of dietary fiber.

FDA is persuaded by the comments that the separation of dietary fiber from carbohydrate is inconsistent with established methods of reporting food composition and confuses the issue of calculating energy content. Further, the agency agrees that the separation of dietary fiber from carbohydrate will decrease consumer understanding of label information and its application to dietary recommendations that link dietary fiber and complex carbohydrate together in advising increased consumption of foods high in both. Accordingly, FDA is modifying § 101.9(c)(6) to include dietary fiber in the declaration of total carbohydrates. This action results in the inclusion of both digestible and nondigestible carbohydrates under total carbohydrates.

Section 101.9(c)(6) is also modified to state that total carbohydrate content is to be calculated by subtracting the sum of crude protein, total fat, moisture, and ash from the total weight of food. Additionally, since total carbohydrate now includes dietary fiber, the paragraphs relating to dietary fiber are redesignated under § 101.9(c)(6)(i) rather than under § 101.9(c)(7). Consequently, the remaining paragraphs within § 101.9(c) are renumbered.

2. Dietary Fiber

48. Comments from consumers, health professionals, health promotional organizations, and manufacturers agreed that declaration of dietary fiber should be mandatory. Other manufacturers, trade associations, and a university food science department disagreed and urged voluntary, rather than mandatory, declaration of dietary fiber. The arguments against required listing of dietary fiber included: (1) Analytical methods for dietary fiber in foods are not yet routine, are expensive, and lack precision in some types of foods; (2) mandatory declaration imposes an unnecessary analytical burden on producers of foods that are not significant sources of fiber; and (3) mandatory declaration will likely encourage fiber supplementation of foods.

The agency does not agree that the specified methods for fiber analysis are difficult and expensive. The operations involved and equipment required for the methods are standard in analytical laboratories. The agency recognizes that the official AOAC method for dietary fiber analysis is relatively recent. However, as a validated method, it should be included in current nutrition labeling regulations.

In regard to the analytical burden on producers of foods with insignificant amounts of fiber, the agency advises that if there is adequate and reliable reason to believe that fiber is not present, there is no need to analyze for it; it can be declared as "0". Additionally, § 101.9(c)(6)(i) provides for expression of dietary fiber in 1 g increments in recognition of the precision of analytical methods. For foods that contain less than 1 g of dietary fiber per serving, manufacturers may choose to state "contains less than 1 g" or to omit dietary fiber from the list of nutrients and to state at the bottom of the nutrition label "Not a significant source of dietary fiber."

There have always been concerns that nutrition labeling will encourage the supplementation (i.e., fortification) of foods. In part for this reason, FDA published a policy statement on the addition of nutrients to food on January 25, 1980 (45 FR 6314). The statement was issued to promote the rational addition of nutrients to foods to preserve a balance of nutrients in the diet of American consumers. In the statement, FDA established guidelines in § 104.20, which the agency urges manufacturers to follow if they elect to add nutrients to a food.

FDA intends to continue to monitor the marketplace through the Food Labeling and Packaging Survey, consumer and industry complaints, and other means to determine if inappropriate fortification is occurring. If the agency finds that there is a problem with inappropriate fortification of foods with dietary fiber or any other nutrients, it will take steps to ensure that overfortification does not result in the imbalance of essential nutrients in the diet of American consumers or the presence of excessive amounts of particular nutrients that have the potential for toxicity.

Thus the agency is not persuaded that there is a compelling cause not to require declaration of dietary fiber in nutrition labeling. Section 403(q)(1)(D) of the act requires dietary fiber to be included in nutrition labeling. Section 403(q)(2)(B) of the act allows a required nutrient to be deleted if the Secretary determines that the nutrient is not necessary to assist consumers in maintaining healthy dietary practices, but no information contained in the comments would lead to such a conclusion. In fact, most comments supported the usefulness of mandatory declaration of dietary fiber. Accordingly, § 101.9(c)(6)(i) will require the declaration of dietary fiber in nutrition labeling.

This action represents the final disposition of two petitions regarding label declaration of carbohydrates, including dietary fiber. One petition from the Kellogg Co. dated May 14, 1978 (Docket No. 78P-0091), requested, in part, permission to list under "carbohydrate" the amounts of "starches and related carbohydrates" and "sucrose and other sugars." The other petition from the Center for Science in the Public Interest dated June 1, 1987 (Docket No. 87P-0194/CP) requested that dietary fiber be a mandatory component of nutrition labeling, and that regulatory letters be sent to all manufacturers making misleading claims about fiber content.

49. Comments from nutritionists representing state cooperative extension services and from one manufacturer cautioned that declaration of soluble and insoluble subcomponents of dietary fiber should be prohibited because the methodology for separating soluble from insoluble fiber is inadequate, and because there is no scientific agreement as to the health effects of the subgroups of dietary fiber.

The agency advises that analytical methods for the measurement of soluble and insoluble dietary fiber are now part of an official AOAC method for dietary fiber (Ref. 50). While experience with these methods is limited, they will allow for accurate separation of these subcomponents.

In regard to scientific agreement as to the health effects of soluble or insoluble fiber, FDA has evaluated the health effects of the dietary fiber subgroups and has concluded that there is sufficient scientific agreement to issue a final rule permitting health claims relating to the effects of intake of soluble dietary fiber on heart disease. This decision is discussed in a companion document entitled "Food Labeling; Health Claims; Dietary Fiber and Cardiovascular Disease" published

elsewhere in this issue of the Federal Register.

Accordingly, § 101.9(c)(7)(i), redesignated as § 101.9(c)(6)(i)(A) and (c)(6)(i)(B), will continue to allow the voluntary declaration of soluble and insoluble dietary fiber in nutrition labeling, except that when a claim is made about either type of fiber, label declaration of that type of fiber will be required. To clarify that soluble and insoluble fiber are to be indented under dietary fiber rather than under total carbohydrate, FDA has modified § 101.9(c)(6)(i)(A) and (c)(6)(i)(B) to state "indented under dietary fiber." FDA has also modified these two sections to remove the requirement that whenever one type of fiber is declared, the other type must also be declared. Because total dietary fiber is a mandatory component of nutrition labeling, the amount of an undeclared subcomponent (i.e., soluble or unsoluble fiber) can be calculated simply by subtracting the amount of the declared subcomponent from the amount of dietary fiber. This change will minimize space requirements caused by the voluntary declaration of additional nutrients.

3. Sugars

a. *Definition of sugars.*

50. Comments from consumers, consumer interest groups, state governments, trade associations, food retailers, and a manufacturer concurred with the agency's proposed definition for sugars as the sum of all free mono- and oligo-saccharides through four saccharide units and their derivatives having similar sweetening, nutritional, and metabolic effects. Consumer interest in the sugars content of food, and concern that "sugars" should include all forms of carbohydrate sweeteners added to foods, were cited as reasons for support for the proposed definition. Comments from many consumers, state governments, and a health promotion association stated that information on content of both sugars and of sugar derivatives is important to assist consumers to moderate intake of sugars and to assist diabetics in maintaining healthy dietary practices. Consumer interest groups argued that underreporting of the sugars content in products rich in corn syrups is an appropriate justification for an expanded definition for sugars. A comment noted that the agency has a precedent for considering sugar alcohols as sugars in § 100.130(d)(4), which states that "sugar-free" type statements cannot be made on labels of diet beverages containing "sorbitol mannitol, or other hexitols."

Other comments from a wide variety of manufacturers, trade associations, foreign and state governments, professional associations, and a Federal agency objected to the proposed sugars definition. Most of these comments recommended that the sugars definition be limited to monosaccharides and disaccharides. One argument for limiting the sugars definition to mono- and di-saccharides is that this is the traditional and widely accepted use of the term "sugars." They pointed out that it is also the definition of the term in the IOM report "Nutrition Labeling: Issues and Directions for the 1990s" (Ref. 1). Many comments noted that for conformity with international regulatory definitions for nutrition labeling (EC, Codex Alimentarius Commission, and Canada) sugars should be defined as mono- and di-saccharides.

Another argument, brought forth in comments, for limiting the sugars definition to mono- and di-saccharides is that there are no compelling health or nutritional reasons for including tri- and tetra-saccharides as "sugars." The comments pointed out that the 1986 "Report From FDA's Sugars Task Force" (Ref. 51) concluded that the only public health concern from sugars consumption in the United States is the promotion of dental caries. The IOM report (Ref. 1) concurred with this conclusion. The comments argued that, in the absence of a clear relationship between number of saccharide units and carcinogenicity, the proposal to include tri- and tetra-saccharides within sugars is not relevant to the public health concern of dental caries.

Several comments questioned the agency's logic in including tri- and tetra-saccharides with sugars. FDA had stated in the 1990 mandatory nutrition labeling proposal (55 FR 29487 at 29497) that the intent of including tri- and tetra-saccharides as sugars was to preclude potential underdeclaration of the sugars content of foods containing corn syrups. Several comments noted that mono- and di-saccharides are logically grouped in that they are sweet, naturally occurring, and rapidly absorbed, but that these characteristics are, for the most part, not in common with tri- and tetra-saccharides. Comments also noted that most corn syrup used in sweetening is in the form of high fructose corn syrup, which is composed of 95 percent monosaccharides, and that high fructose corn syrup accounts for two thirds of total U.S. corn syrup consumption. Comments noted that corn syrups with greater proportions of higher saccharides are used for technical purposes other than sweetness. Thus, the comments argued that underestimation of simple sugars from corn syrups is not of sufficient importance to warrant imposing a unique sugars definition for labeling purposes that would differ from common usage of the term.

Many comments objected to the proposed sugars definition on methodological grounds, in that they claimed that the proposed definition is not compatible with standardized analytical methods for measuring sugars. The comments acknowledged that validated methods for measuring mono- and di-saccharides in foods exist but argued that there are not collaboratively validated methods for the measurement of tri- and tetra-saccharides. The comments noted that measurement in foods of oligosaccharides larger than disaccharides is difficult, costly, and inaccurate. The comments asserted that the lack of validated analytical methodology appropriate for the definition would result in compliance difficulties and inaccurate information on the label.

FDA has evaluated all comments in favor of the proposed expanded sugars definition and those opposed to this definition. FDA is persuaded that compliance with nutrition labeling will be impeded by adopting a definition for sugars that is not supported by validated analytical methods. FDA is also persuaded that the usefulness of nutrition labeling will be hindered by adopting a definition that is inconsistent with commonly accepted use, and with the international use of the term.

FDA finds that these factors outweigh any public health benefit from including tri- and tetra-saccharides in the definition of "sugars" for nutrition labeling purposes. The public health concern associated with sugars consumption is the promotion of dental caries. While simple sugars are the most cariogenic carbohydrates, all fermentable carbohydrates, including starches, are capable of promoting dental caries. Factors such as the characteristics of the food that contains the sugar (e.g., stickiness), the frequency of consumption, and the sequence in a meal, appear to be as important in the etiology of dental caries as the sugars themselves (Refs. 2 and 3). As such, the inclusion of tri- and tetra-saccharides with sugars would not improve the ability of the label to assist consumers in maintaining healthy dietary practices with respect to dental health.

Therefore, the agency is modifying the definition of "sugars" in § 101.9(c)(6)(ii)(A), redesignated as

§ 101.9(c)(6)(ii), to include only free monosaccharides and disaccharides.

51. Several comments recommended that lactose be specifically excluded from the sugars definition for nutrition labeling. These comments asserted that the listing of lactose with sugars in nutrition labeling may mislead some consumers who may equate the lactose sugar content of dairy products with "empty calories" of products high in added sugar. The comments expressed a fear that dietary guidelines to moderate sugars consumption may lead some consumers to forego the important nutritional benefit of dairy products if lactose is included in sugars content. Comments also noted that intestinal digestion of lactose is inefficient. As such, the digestion and absorption of lactose more closely resembles complex carbohydrate than simple sugars. Furthermore, comments argued that lactose is not sweet nor used as a sweetener and could logically be separate from sugars used as sweeteners.

FDA disagrees with the comments. As discussed in the preceding comment, the agency has been persuaded of the need to define "sugars" for nutrition labeling purposes to be consistent with standard analytical methodologies and in conformity with the traditional usage of the term. Lactose, a di-saccharide, is clearly a sugar by conventional standards and is identified with all other mono- and di-saccharides in routine analytical procedures. The nutritional significance of the sugars content of certain types of foods, such as lactose in dairy products and natural sugars in fruit, and the importance of such foods as sources for other important nutrients, needs to be addressed through the consumer education program discussed below.

Accordingly, the agency is not making the recommended change to exclude lactose in the definition of sugars.

52. Several comments suggested alternative definitions for "sugars" based upon physiological characteristics rather than the number of saccharide units. Among these alternatives were suggestions for definitions based on digestibility, caloric value, glycemic index, and serum insulin response.

FDA finds that such alternative approaches are not feasible from a compliance standpoint because validated analytical methods to quantitate sugars defined in these ways do not exist. In addition, use of any of hese definitions for sugars would be unique to U.S. nutrition labeling and would thus likely impede foreign trade. Moreover, because these definitions do not correspond to the commonly recognized meaning of the term, the resulting labeling information would be of limited usefulness.

53. FDA received comments that suggested alternative terminology for the "sugars" component of carbohydrate. The agency's longstanding use of "sugar" as synonymous with sucrose in ingredient labeling was cited as evidence of the need for an alternative term. Several comments felt that FDA's distinction between "sugar" and "sugars" would not be clearly understood by consumers. Alternative terms suggested included "sweeteners" and "simple carbohydrates."

FDA considered these comments but has concluded that it is best to maintain the proposed terminology. The agency advises that the term "sweeteners" would logically include the noncarbohydrate intense sweeteners, which would not be appropriately declared as a part of carbohydrate content. In addition, the term appears to apply more to added sugars than to total sugars and, therefore, would cause compliance problems because it is not possible, in most foods, to differentiate between added and naturally present sugars.

"Simple carbohydrates" may have been a good term for the originally proposed definition (i.e., mono-, di-, tri-, and tetra-saccharides). However, the agency finds it is too broad a term to encompass only the traditional sugars (i.e., mono- and di-saccharides).

b. *Total sugars versus added sugars.*

54. Some comments recommended mandating declaration of added sugars only rather than total sugars. The comments noted that consumers need to be made aware of added sugars because dietary recommendations urge use of sugars in moderation, while at the same time recommending increased consumption of fruits which are sources of naturally occurring sugars. Other comments recommended either mandatory or voluntary declaration of both added and naturally occurring sugars. One comment suggested that added sugars be required in addition to total sugars in foods containing more than 2 g of added sugar.

The agency is not persuaded that there is a need for mandatory disclosure of added sugars in place of, or in addition to, total sugars. There is no scientific evidence that the body makes any physiological distinction between added sugar molecules and those naturally occurring in a food. In addition, the agency believes that it should not promulgate regulations that it cannot enforce. When a product is sampled for compliance, laboratory analysis yields a value for total sugars. For most foods, as stated above, it is not possible to differentiate between added and naturally occurring sugars. Accordingly, the agency would not be able to determine the accuracy of a label declaration of added sugars.

Furthermore, declaration of only added sugars may significantly underrepresent the sugars content of many foods that are high in naturally occurring sugars. For example, in some fruits canned in heavy syrup, added sugars may represent only about 50 percent of total sugars. Disclosure of only the added sugars could be misleading to consumers who are concerned with total sugar intake. Therefore, the agency is retaining the provision of § 101.9(c)(ii)(A), redesignated as § 101.9(c)(ii), to declare total sugar content, e.g., that added as well as that naturally present.

While FDA is not distinguishing, on the nutrition label, between added and naturally present sugars, the agency does intend to include information about this distinction in the consumer education program that it is preparing. This information will help consumers: (1) Use the information on the nutrition label to differentiate between sugar-containing foods with high versus low levels of other important nutrients, (2) use the ingredient statement to distinguish foods with naturally occurring versus added sugars, and (3) appreciate the important role in the total daily diet of foods, such as fruits and dairy products, with naturally occurring sugars.

c. *Mandatory declaration of sugars.*

55. In the 1991 supplementary proposal, FDA requested specific comments as to the utility, appropriateness, and feasibility of requiring declaration of sugars content, particularly as such declaration relates to, and is supported by, public health goals (56 FR 60366 at 60369). Comments received were relatively evenly divided on the issue of whether the declaration of sugars should be mandatory in nutrition labeling. In general, consumers and health professionals and their associations supported mandatory declaration of sugars. Several state attorneys general and a few industry groups also agreed that consumers have a right to know the amount of sugars present. Comments argued that section 403(q)(2)(B) of the act only allows FDA to delete sugars as a mandatory component of nutrition labeling if such information "is not necessary to assist consumers in maintaining healthy dietary practices," and that such information is vital to this end. Comments from many consumers, state governments, and a health promotion

association stated that information on sugars content is important to diabetics in assisting them to maintain healthy dietary practices and to consumers in general in selecting diets that will moderate the intake of sugars. One comment urged mandatory declaration of sugars as a way to inform consumers of the content of new foods that are being marketed as "low fat" and "fat free" in which fats are being replaced by sugars.

Most industry groups as well as a few health professional associations and the IOM report (Ref. 1) recommended allowing sugars declaration to be voluntary. They argued that dietary guidance recommendations have not specified quantitative goals for sugar consumption, and that sugar declaration should not be required until a definition has been recognized by scientific communities that reflects physiological effects. They also pointed out that data bases do not generally contain information on sugars composition, so a substantial investment of time and money is needed for analysis and data base update. The comments argued that such an expenditure would be inappropriate for a nutrient of little public health concern. There was also a concern expressed that because total sugars would be declared rather than only added sugars, consumers would be confused by the amount of sugars in fruits and reduce their consumption of these foods. Despite these concerns, industry generally conceded that if sugars information is needed, requiring sugars declaration in the nutrition label is a better approach than mandating grouping of sweeteners in the ingredient statement, as the agency proposed in a document on ingredient labeling (56 FR 28593, June 21, 1991). Final action on the issue of grouping sweeteners in the ingredient statement is addressed in the final rule on declaration of ingredients published elsewhere in this issue of the Federal Register.

FDA is persuaded that mandatory declaration of sugars is of great interest to consumers, and that it will assist consumers in planning diets that conform to current dietary guidelines for Americans to avoid too much sugars (Ref. 4). As discussed above, FDA is modifying its proposed definition of "sugars" to be in conformity with general usage and international definitions for this term. The use of this definition will minimize the costs associated with necessary laboratory analyses and update of data bases.

Therefore, FDA is requiring in § 101.9(c)(6)(ii) that declaration of sugars be included in nutrition labeling.

4. Sugar Alcohol

56. Comments from a wide variety of manufacturers, trade associations, foreign and State governments, professional associations, and a Federal agency were opposed to inclusion of saccharide derivatives, specifically sugar alcohols, within the proposed "sugars" definition. The agency's proposed definition included in its coverage saccharide derivatives that have sweetening, nutritional, and metabolic effects similar to simple sugars. The comments stated that sugar alcohols are inappropriately included with sugars because sugar alcohols have many different chemical and physiological properties than sugars. Comments noted that it is these differences that motivated the development of uses for these substances and makes them useful as sugar substitutes. Comments pointed out that a salient distinction between sugar alcohols and sugars lies in their digestion and absorption, which is slower for sugar alcohols. Also, intestinal absorption of monosaccharide sugar alcohols occurs only by passive diffusion, not by active or facilitated monosaccharide absorptive mechanisms. As a result, significant portions of ingested sugar alcohols remain unabsorbed and pass into the colon, where they are fermented, similar to fiber and complex carbohydrate. Thus, the caloric value, insulin response, and glycemic index for some sugar alcohols are less than for sugars.

Several comments also claimed that sugar alcohols have reduced cariogenic potential compared to sucrose or other sugars. The comments noted that FDA proposed in § 101.13(o)(8) in the document on the general principles for nutrient content claims to permit chewing gums sweetened with sugar alcohols to be labeled as "sugar free" or "sugarless" as a means of indicating that these products do not promote tooth decay. The comments argued that declaring sugar alcohols as sugars would deny manufacturers the means to promote the reduced cariogenic potential of other sugar alcohol sweetened products relative to sugar containing products.

Comments also noted that international regulatory definitions for nutrition labeling (EC, Codex Alimentarius Commission, and Canada) exclude sugar alcohols and provide for a separate declaration of sugar alcohols under carbohydrates. As a result, the comments stated that a definition for sugars that includes sugar alcohols for U.S. nutrition labeling could be seen as an obstruction to international trade.

The IOM report (Ref. 1) recommended that sugar alcohols not be grouped with sugars in ingredient labeling. Some comments argued that in the absence of any quantitative dietary guidelines concerning sugar alcohols, it is inappropriate to require any declaration of sugar alcohols in nutrition labeling.

FDA is persuaded that sugar alcohols have metabolic effects different than sugars, have a history of being considered to be sugar substitutes rather than as sugars, and have a role in contributing to dental health. FDA also acknowledges that the proposal to define sugar alcohols as sugars for nutrition labeling purposes is inconsistent with the nutrition labeling practices of other countries. Thus, FDA is modifying § 101.9(c)(6)(ii) to remove sugar alcohols from the definition of "sugars" for nutrition labeling. The agency is doing so in recognition of their usefulness as sugar substitutes in reducing the cariogenic potential of foods.

However, FDA continues to believe that the content of nutritive carbohydrate sweeteners used as sugar substitutes is of interest and importance to consumers. Therefore, FDA is retaining § 101.9(c)(6)(ii)(B), which provides for the voluntary declaration of sugar alcohols except when a claim is made on the label or in the labeling about sugar alcohol or sugars (e.g., "sugar free") and sugar alcohols are present in the food, in which case their declaration is mandatory. Because sugar alcohols will no longer be a subcomponent of sugars, FDA is redesignating § 101.9(c)(6)(ii)(B) as § 101.9(c)(6)(iii).

Removing sugar alcohol from the definition of sugars necessitates a change in the definition of sugar alcohol. The proposed definition included a criterion that sugar alcohols "meet the definition of sugars as described in paragraph (c)(6)(ii)(A)." Accordingly, FDA has revised the definition for sugar alcohol in § 101.9(c)(6)(iii) to use a chemical definition, namely that sugar alcohols be defined as "saccharide derivatives in which a ketone or aldehyde group is replaced by a hydroxyl group, and whose use in food is listed by FDA (e.g., mannitol) or is GRAS (e.g., xylitol, sorbitol)."

57. Comments from trade associations and manufacturers stated that the term "sugar alcohol" is potentially confusing in that consumers may assume such components contain a sugar and ethyl alcohol. The comments requested that the term "polyol," which has been recognized by the EC, be used in lieu of "sugar alcohol." Another comment from

the Canadian government included a copy of their nutrition labeling regulations which allow for declaration of the specific sugar alcohols by name (i.e., sorbitol, mannitol, and xylitol).

FDA advises that the term "polyol," a contraction of "polyalcohol" or of "polyhydric alcohol," is neither uniquely descriptive of the alcohol derivatives of saccharides used as sugar substitutes, nor is it a term that FDA expects consumers to recognize or understand. While the agency recognizes that it is a term that may be used voluntarily on labeling in the EC, it is unlikely that American consumers will have any concept of what it represents. As such, the agency considers the term "polyol" to be potentially more confusing to consumers than would be "sugar alcohol."

Despite this fact, FDA acknowledges that many consumers also may not be familiar with the term "sugar alcohol." Thus, FDA has decided to adopt the approach used by the Canadian Government, which allows manufacturers to use the specific name of the sugar alcohol in the nutrition label. The names of sugar alcohols that are listed or GRAS for use in food, (e.g., sorbitol § 184.1835, mannitol § 180.25, and xylitol § 172.395) are currently used in ingredient statements on labels of food packages and, hence, should be recognized by many consumers.

The primary disadvantage to this option is the introduction of the name of an ingredient into the nutrition label. While FDA is generally opposed to such a result, the agency concludes that the arguments opposed to the term "sugar alcohol" and the desire to harmonize with Canadian labeling regulations are more compelling in this instance than the need to maintain a clear separation between the nutrition label and ingredient list. However, to avoid cluttering the nutrition label and confusing consumers, if more than one sugar alcohol is used in a food, § 101.9(c)(6)(iii) provides that the term "sugar alcohol," and not the names of the ingredients, must be used in the nutrition label.

Accordingly, FDA is modifying § 101.9(c)(6)(iii) to specify the continued use of the term "sugar alcohol" or, alternatively, if only one sugar alcohol is present in the food the name of the specific sugar alcohol present in the food may be used.

5. Other Carbohydrate

a. *Definition.*

58. In the supplementary proposal, FDA noted that the term "complex carbohydrate" has not been clearly or consistently defined, and that consensus reports that have associated increased consumption of dietary complex carbohydrate with health benefits have not attempted to define this food component. The agency solicited suggestions on appropriate chemical definitions and analytical methodology for complex carbohydrate (56 FR 60366 at 60369). Many comments from trade associations, food manufacturers, professional societies, and state and foreign governments expressed opposition to the agency's proposed definition for the term complex carbohydrate as the sum of dextrins and starches that contain ten or more saccharide units (56 FR 60366 at 60388). A majority of these comments also recommended as an alternative that "complex carbohydrate" be defined as the difference between total carbohydrate and sugars. Comments that argued for changing the definition pointed to the lack of existing analytical methodology to support the proposed definition. Thus, these comments raised concerns about the feasibility of compliance and the economic burden of developing methods and data bases. These comments also pointed out that complex carbohydrate content defined as the difference between total carbohydrate and sugars could readily be calculated.

Another criticism of the proposed complex carbohydrate definition was that the cutoff at 10 saccharide units is arbitrary. These comments noted that there are no known nutritional or physiological differences, nor a methodological justification, to make a distinction between polysaccharides smaller than 10 saccharide units and those with 10 or more saccharide units. Several comments were concerned that there is the potential for consumer confusion regarding total carbohydrate because neither of the subcomponents for total carbohydrate included the 5 to 9 saccharide unit polysaccharides.

Several comments suggested that the commonly accepted usage of "complex carbohydrate" includes all carbohydrates larger than disaccharides. Other comments suggested that complex carbohydrate should be defined as all digestible polysaccharides (e.g., dextrins, starch, and glycogen) rather than on the basis of the number of saccharide units. Comments emphasized that while there is not a consensus on a precise definition for "complex carbohydrate," the agency's proposed definition is not commonly recognized, nor is it consistent with the use of the term in the IOM report (Ref. 1).

One comment from a State government recommended that to avert undue emphasis on complex carbohydrate substances added to foods and to avoid the potential for misleading claims about complex carbohydrates, the term "other carbohydrate" should be used rather than "complex carbohydrate."

The agency noted in the supplementary proposal (56 FR 60366 at 60368) that identification of a specific benefit for complex carbohydrate is confounded by the fact that diets high in complex carbohydrate are usually mixed diets that contain significant amounts of cereal grains, fruits, and vegetables which are high in fiber, vitamins, and minerals and low in fats (Ref. 2). Thus the extent to which complex carbohydrate provides health benefits separate from those provided by fiber, vitamins, minerals, and reduced fat is unclear. FDA has evaluated comments concerning the complex carbohydrate definition and concludes that there is not sufficient consensus on the meaning of the term to justify adopting a specific definition for "complex carbohydrate."

In response to the comments that suggested defining this term as "digestible polysaccharides," FDA advises that carbohydrate digestibility is not clear cut. Some soluble dietary fiber is relatively digestible, whereas some oligosaccharides are relatively nondigestible. At this time there is not a consensus regarding the most reliable methods for determining carbohydrate digestibility nor for distinguishing energy derived from intestinal digestion from that derived from colonic fermentation. As a result, the agency feels that it is inappropriate to base a regulatory definition upon digestibility.

FDA, therefore, is modifying the definition it proposed for "complex carbohydrates" (§ 101.9(c)(6)(i), redesignated as § 101.9(c)(6)(iv)) to provide that it is the difference between total carbohydrate and the sum of dietary fiber and sugars or, if sugar alcohol is declared, the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol. This modified definition accommodates quantification of the remaining carbohydrates by calculation rather than by requiring additional laboratory analysis, and it resolves concerns that the defined components of total carbohydrate were not inclusive of all carbohydrates.

In addition, because there is no consensus on a clear definition for the term "complex carbohydrate" as it relates to physiological effects, health benefits, or dietary guidelines, the

agency concurs with the recommendation from a state government that the term "other carbohydrate" be used rather than "complex carbohydrate." The agency recognizes that the new definition will include many substances added to processed foods for technical purposes, such as for texture modification or as bulking agents. To declare these substances as complex carbohydrates would be misleading. The intent of dietary recommendations to increase the consumption of complex carbohydrates and dietary fiber is to select diets with plenty of fruits, vegetables, and grain products, not foods that have complex carbohydrates as added texturizers or bulking agents. Accordingly, FDA is modifying § 101.9(c)(6)(iv) to change the terminology from "complex carbohydrate" to "other carbohydrate." In addition, FDA is modifying § 101.9(g)(4) and (g)(6) to reflect this change in terminology.

Finally, because "other carbohydrate" will be calculated as that amount of carbohydrate remaining after subtraction of the amount of dietary fiber, sugars, and sugar alcohols (when declared) from total carbohydrate, it is logical to rearrange the subcomponents of total carbohydrate to place "other carbohydrate" at the bottom of the list. This reordering should help to reduce any potential confusion over the meaning of the term "other carbohydrate." Accordingly, dietary fiber is designated as § 101.9(c)(6)(i), sugars as § 101.9(c)(6)(ii), sugar alcohol as § 101.9(c)(6)(iii), and other carbohydrates as § 101.9(c)(6)(iv).

b. *Voluntary declaration of "other carbohydrate".*

59. In the supplementary proposal, FDA requested specific comment on the utility, appropriateness, and feasibility of mandatory declaration of complex carbohydrate content, particularly as it relates to, and is supported by, public health goals (56 FR 60366 at 60369). Based on the comments and information that it received in response to the supplementary proposal, the agency said it would decide, under section 403(q)(2) of the act, whether to include complex carbohydrate in the required list of nutrients in nutrition labeling. Several comments from consumers, health professionals, a manufacturer, and state governments supported mandatory listing of complex carbohydrates on the grounds that this information will be helpful to persons attempting to follow dietary recommendations. However, a much larger number of comments from health professional associations, academia, manufacturers, trade associations, and foreign governments supported voluntary listing of complex carbohydrates. The overriding factors cited in these comments were the lack of an accepted definition for "complex carbohydrates" and the lack of reliable analytical methods for determining amounts present. Comments also stated that dietary recommendations do not specify amounts of complex carbohydrates to be consumed; therefore quantitative information in nutrition labeling is not necessary to assist consumers in maintaining healthy dietary practices. Additionally, comments noted that the IOM report (Ref. 1) recommended voluntary listing of complex carbohydrate. Comments also pointed out that currently available data bases do not contain information on complex carbohydrates, and that there would be an inherent variability in amounts present in minimally processed foods.

In light of these comments, the agency's decision to drop the term "complex carbohydrate" because of the lack of a consensus on the meaning of the term, and the lack of methods for reliably determining the amounts present, FDA has reassessed the requirement in section 403(q)(1)(D) of the act to declare complex carbohydrates. Section 403(q)(2)(B) of the act allows the Secretary to determine whether information relating to nutrients specified in section 403(q)(1)(C), (q)(1)(D), (q)(1)(E), or (q)(2)(A) of the act is necessary to assist consumers in maintaining healthy dietary practices. If not, the Secretary may delete such nutrients from the list of those required to be included in nutrition labeling. FDA concludes that, without a specific definition for "complex carbohydrates," it is not possible to include quantitative information in the nutrition label that would assist consumers in maintaining healthy dietary practices. Therefore, under the provisions of section 403(q)(2)(B) of the act, FDA is deleting the requirement for the listing "complex carbohydrate" in the nutrition label and is allowing for declaration of "other carbohydrate" on a voluntary basis.

When "other carbohydrate" is omitted from the label, the declared subcomponents of total carbohydrate (i.e., dietary fiber and sugars) will not add up to the value for total carbohydrate in most foods. Consumer education programs should inform interested persons that other forms of carbohydrate beyond those declared on the label are in the food product. This situation is analogous to the fat category where the sum of saturated, polyunsaturated, and monounsaturated fatty acids often do not add up to 100 percent of the value for total fat because *trans* fatty acids are not included in the definition of the fatty acids but are included in the value for total fat.

G. Protein

1. Quantitative Protein Content

60. Several food manufacturers agreed with the proposed provision requiring that if the protein in foods represented or purported to be for adults and children 4 or more years of age has a protein digestibility-corrected amino acid score (PDCAAS) of less than 20 percent, and if foods represented or purported for children below 4 years have a protein quality value less than 40 percent of casein, the protein content statement must be modified by an adjacent statement, "not a significant source of protein," regardless of the actual amount of protein present. However, other food manufacturers objected to this provision of the proposal. These comments argued that the statement has little value in terms of the total dietary protein intake, and that there is no evidence of protein malnutrition in this country. These comments argued that, therefore, the statement is unnecessary. One food manufacturer stated that the statement should only be required if a claim is made. Another comment stated that the declaration of the percent of the RDI for protein should be required instead of the statement.

FDA disagrees with the comments that state the statement is unnecessary. Information on protein quantity alone can be misleading on foods that are of low protein quality. As stated in the supplementary proposal, dietary protein serves as a source of essential and nonessential amino acids, the building blocks of body protein. Because excess amino acids are not stored in the body, humans need a constant supply of good quality dietary protein to support growth and development. The determination of the quality of a protein is dependent upon the proportion and availability of essential amino acids (i.e., those amino acids that the human body cannot manufacture but must obtain through the diet) as well as the quantity of protein present. Foods that contain proteins that are low in one or more of the essential amino acids are known as incomplete proteins and are lower quality proteins than those that contain all the essential amino acids in sufficient quantities to support growth and development.

The agency believes that nutrition labeling must inform consumers when the quality of the protein is below

minimum specified levels. The majority of comments supported this position. Although the agency agrees that protein deficiency is not common in the United States, protein quality is still of concern for certain segments of the population, such as the very young and the elderly. Accordingly, the agency concludes that nutrition labeling must allow consumers to readily identify foods with particularly low quality protein to prevent them from being misled by information on only the amount of protein present.

Nonetheless, in the case of foods for adults and children over 1 year of age, the agency agrees with the comment that the percent of the reference value for protein (discussed below) is a satisfactory alternative to the statement, "not a significant source of protein," to allow consumers to readily identify foods of low protein quality. However, as discussed in the final rule entitled "Food Labeling: Reference Daily Intakes and Daily Reference Values" published elsewhere in this issue of the Federal Register, the label reference value for protein for adults and children 4 or more years of age has been established as a DRV rather than an RDI. As discussed in that document, this change to a DRV is necessary because the agency is no longer basing the label reference value for protein for this group on the Recommended Dietary Allowances for protein. Rather, they are now being based on percent of calories. However, because FDA did not propose DRV's for infants, children less than 4 years of age, pregnant women, and lactating women, the protein label reference values for these groups remain as RDI's.

Accordingly, the agency is amending § 101.9(c)(8), redesignated as § 101.9(c)(7), to permit the optional declaration of percent of the DRV or RDI for protein, as appropriate, expressed as "Percent Daily Value," in lieu of the statement "not a significant source of protein" when the food is represented or purported to be for use by adults and children 4 or more years of age and the protein quality value is a PDCAAS of less than 20 expressed as a percent, or when the food is represented or purported to be for use by children under 4 years of age and the protein quality value is a PDCAAS of less than 40 expressed as a percent.

FDA is not requiring declaration of percent DRV or RDI for protein instead of the subject statement, as requested in the comment, because of cost considerations. If a manufacturer is aware that the protein in a particular food product represented or purported to be for adults and children 4 or more years of age has a PDCAAS of less than 20 percent, or that the protein in a food represented or purported for children below 4 years has a protein quality value less than 40 percent of casein, and the manufacturer does not want to go to the expense of determining the precise percent of the label reference value present in the food, the agency has no objection to the use of the statement "not a significant source of protein."

In conjunction with this change, FDA is making a parallel modification in proposed § 101.9(c)(8)(i), redesignated as § 101.9(c)(7)(i), by deleting the prohibition on the declaration of percent of the RDI for protein on foods represented or purported to be for use by adults and children 4 or more years of age with a PDCAAS of less than 20 percent, or on foods represented or purported to be for use by children under 4 years of age with a protein quality value of less than 40 percent of the reference standard. That prohibition is no longer necessary because the PDCAAS method for assessing protein quality is more exact in measuring the protein quality for humans one year of age and above than the protein efficiency ratio (PER) which was previously used for all age groups. Because the PER is being retained to measure protein quality for infant foods, FDA has retained this prohibition for declarations on foods represented or purported to be for use by infants with a protein quality value of less than 40 percent of the reference standard of casein.

61. One comment requested that the food-specific conversion factors used by AOAC, and permitted in proposed § 101.9(c)(8), to convert amounts of nitrogen to protein content should be allowed in calculating the PDCAAS whenever such factors are available. The comment stated that in some cases (e.g., peanut butter) the amino acid score used in calculating the PDCAAS is artificially reduced when a conversion factor of 6.25 must to be used to calculate protein content rather than a food-specific conversion factor.

FDA agrees that there is an inconsistency in proposed § 101.9(c)(8) pertaining to the factors for converting g of nitrogen to g of protein when calculating protein content and when calculating the PDCAAS. While the method for calculating the PDCAAS described in the Report of the Joint Federation of Agriculture Organization and the World Health Organization (FAO/WHO) Consultation (Ref. 8) specifies a conversion factor of 6.25 (i.e., g of nitrogen x 6.25 = g of protein), the agency finds it appropriate to use more specific conversion factors for those foods where the official AOAC procedures require them. Therefore allow for consistent methods of calculating g of protein, the agency is modifying § 101.9(c)(7)(ii) to state that food-specific conversion factors required by the AOAC are to be used when calculating the PDCAAS.

2. Protein Content as a Percentage of the RDI/DRV

62. Several comments opposed the voluntary (in the absence of a claim) declaration of protein as percent of the RDI on the labels of foods intended for adults and children 4 or more years of age. The comments contended that mandatory declaration of protein as percent RDI for all groups would provide the consumer with information on how amino acid and protein needs are met and would assist consumers in appreciating that protein is an important part of the diet.

FDA disagrees with these comments. In the preamble of the mandatory nutrition labeling proposal, FDA stated that current evidence suggests that the diet typically consumed in the United States provides for an adequate protein intake of sufficiently high biological quality to meet the nutritional needs of adults and children 4 or more years of age (55 FR 29487 at 29499). Because protein intakes generally are adequate and not a public health concern for this population group, FDA finds that the additional costs associated with determination of the PDCAAS, which are necessary to calculate the percent of the DRV for protein, are not warranted on foods for this group unless protein claims are made. Therefore, while declaration of the quantitative amount of protein will continue to be required on all foods, § 101.9(c)(7)(i) allows voluntary declaration of the percent of the DRV for protein, expressed as "Percent Daily Value," for foods intended for adults and children 4 or more years of age unless a protein claim is made for the product.

63. Two baby food manufacturers suggested that the protein content expressed as percent of the RDI for protein should be voluntary for all foods, including those for infants and children less than four years of age, unless the food is infant formula or a protein claim is made. The comments stated that data show that breast or cow milk and formula are the main contributors of protein during the first 18 months, and that other foods are not sole sources of protein for infants above 4 months. One manufacturer provided survey data on the protein intake of children 2 to 18 months of age. The comments also stated that recent

evidence shows that the protein intake of children 1 to 4 years of age is 100 percent of the RDI, that nutrition information expressed as percent of the RDI would not be helpful to the parents, and that the requirement is burdensome. Other comments supported mandatory declaration of protein content expressed as percent of the RDI for children less than 4 years of age.

FDA rejects the suggestion that protein content expressed as the percent of the RDI should be voluntary for foods specifically intended for infants and children under 4 years of age. As noted in the preamble of the mandatory nutrition labeling proposal, mandatory declaration of the percent RDI is warranted for this age group because of the importance of protein quality in diets derived from a limited number of foods (55 FR 29487 at 29499). FDA acknowledges that breast or cow milk and formula are the major sources of protein during the first 18 months. However, as seen in the data provided in the comment, foods specifically intended for infants and young children, other than infant formula, do make a significant contribution to total protein intake. For example, at 6 to 7 months of age, infants are receiving approximately one-third of the total protein intake from baby foods (Ref. 52).

The agency recognizes that required declaration of the percent of the RDI for protein for foods for infants and children less than 4 years of age presents a burden to manufacturers. However, protein nutriture is critical during this period of life which is marked by rapid growth and development. Both protein quantity and quality are major factors in the utilization of protein. Because of the importance of adequate high quality protein in the diets of infants and young children, FDA considers the declaration of percent of the RDI for protein necessary. Moreover, with the information on digestibility the agency is providing in appendix B (see comment 66 in this document), declaring the percent of the RDI for protein should not be overly costly or difficult.

64. Several comments suggested the use of a system similar to the current approach of expressing the percent of the U.S. RDA for protein. Recommendations were made for the use of a single RDI or two RDI's (i.e., an RDI for proteins of high quality and another RDI for those of low quality) to calculate the percent RDI as long as the food is not intended for infants and toddlers. Three baby food manufacturers favored establishment of specific low and high protein quality-based RDI's to calculate the percent RDI for foods intended for infants.

FDA disagrees with the use of a system similar to the current approach of expressing protein as percent U.S. RDA. The use of breakpoints, as found in the existing regulation, creates artificial differences in apparent protein nutritive values of some foods when significant differences do not exist.

3. Protein Quality

65. One comment questioned FDA's authority to change the proposed protein quality methodology. The comment contended that the 1990 amendments did not require a change in methodology, and that the proposal must be reevaluated pursuant to President Bush's directive in his State of the Union address on January 28, 1992, and set forth in his memorandum on Reducing the Burden of Government Regulations (Ref. 53).

FDA stated in the supplementary proposal that while not directed to do so by the 1990 amendments, it was proposing to modify the approach for determination of protein quality in the mandatory nutrition labeling proposal. The agency did so in response to a citizen's petition submitted by Protein Technologies International Inc. (Docket No. 90P–0052), requesting that the agency accept an amino acid method that is corrected for digestibility as an alternative method for evaluating protein quality. FDA tentatively decided that the petition had merit, and that some of the concepts in the petition should be integrated into the rulemaking since protein quality is an important part of nutrition labeling. The agency has the authority under sections 201(n) of the act (21 U.S.C. 321(n), 403 (a) and (q) of the act, and 701(a) of the act (21 U.S.C. 371(a)) to modify the original proposed protein quality methodology to reflect expanding scientific knowledge. This final rule represents the final disposition of the subject petition.

66. Several comments commended the agency for acceptance of the PDCAAS method for assessing the protein quality of foods for regulatory purposes. Comments stated that the PDCAAS method was entirely appropriate and consistent with the FAO/WHO Consultation on protein quality evaluation (Ref. 8). Other comments from food manufacturers and a trade association conditionally supported the PDCAAS method. Several comments recommended that PDCAAS not be used as the sole method for measuring protein quality of foods intended for adults and children 4 or more years of age until more technical knowledge on the amino acid reference pattern and methodology is gained, and until manufacturers gain more practical experience in its application across a broad spectrum of foods. Two comments stated that compliance problems necessitate a transition period of 2 to 5 years to ease the logistical and economic burdens. Several comments supported the method but recommended that the current PER method also be permitted.

One manufacturer recommended: (1) Manufacturers be permitted to use calculated PDCAAS values for common foods and food ingredients; (2) that FDA issue a list of estimated digestibility values and PDCAAS values for major foodstuffs and ingredients before issuing the final regulation; and (3) that FDA convene an expert group to produce a data base on digestibilities and PDCAAS values and to make provision to update such a list.

Another manufacturer requested that FDA allow any valid methodology for determining protein quality for adults and children more than 1 year of age.

FDA disagrees with the recommendations that the PDCAAS method not be used as the sole method until more technical and practical knowledge is gained on its application to a broad spectrum of foods and disagrees that a transition period is needed. FDA advises that since most food products in the market place are intended for adults and children above 4 years of age, on which the declaration of percent DRV of protein is voluntary, a delay in the implementation of the PDCAAS as the sole method is not necessary.

The agency also rejects the recommendation that the PER method continue to be permitted for foods for adults and children 1 or more years of age as an option to the PDCAAS method for the following reasons: (1) The PDCAAS is based on human amino acid requirements and, therefore, is inherently more appropriate for evaluating the protein content of foods intended for human consumption than the PER which is based on the amino acid requirements of the rat (Ref. 8), (2) the PDCAAS method is recommended for regulatory purposes by a recognized international organization experienced in establishing such standards (Ref. 8), and (3) values obtained by the two methods differ so that their simultaneous use on different foods would not allow for comparison of food products.

FDA considered the recommendation that manufacturers be permitted to calculate PDCAAS values. The two pieces of information that are needed for

this calculation are the amino acid content and the digestibility of the food. FDA has concluded that current representative amino acid data bases on raw and processed food products are not sufficiently reliable to allow for calculated PDCAAS values. Current data bases often lack information on key essential amino acids, and the information that is there was often obtained using methodology that is now outdated. In addition, food processing, i.e., the chemical, biological, or physical treatment of foods, can reduce the amino acid content of the food, so that only data from a food that underwent similar processing or treatment should be utilized in calculating the PDCAAS. In time, the agency believes it will be possible to calculate PDCAAS values using representative amino acid data backed by periodic analytical spot checks, but, at the current time, more and better data are needed.

FDA does agree, however, that a data base on digestibility values could be of assistance in implementing the PDCAAS method and in reducing the expense of implementing this new methodology by eliminating the need for a bioassay. Therefore, FDA is providing a limited data base on published true digestibility values (determined using humans and rats) of commonly used foods and food ingredients, which manufacturers may use to calculate the PDCAAS for food products. The agency has decided not to publish the digestibility values in the Code of Federal Regulation at this time because the values are interim and subject to change on a frequent basis. The data base is being published in Appendix B to this document and is also available from the Division of Nutrition, Center for Food Safety and Applied Nutrition (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

Appendix B lists foods from nine major food groups. In the development of this data base, the agency examined scientific data that included reports by national and international organizations, review articles and other scientific articles. In examining the data, FDA first considered true digestibility values of protein foods obtained using adult subjects, followed by data using the rat as an animal model. The agency did not consider digestibility data obtained using *in vitro* methods or other animal species. Comparative reviews of digestibility of some protein using humans and the rat model suggest that the true digestibility of a variety of foods is similar in humans and rats.

There are gaps in knowledge of the digestibility of protein in common food sources. Therefore, the data in Appendix B of this document are tentative. FDA believes that with the implementation of this regulation, better data will be forthcoming, and that, in due course, it will be able to revise the data base. The agency encourages industry to submit additional data to enable FDA to expand the assortment of foods included in the data base and to update current data.

FDA concludes that it would be premature to convene an expert group to develop a data base on digestibilities and PDCAAS values. There is a need to allow time for the compilation of reliable data based on digestibility and amino acid analyses obtained by the methods specified in this regulation. FDA will reconsider the idea of convening of an expert group on protein quality as such data become available.

The agency advises that manufacturers are not precluded from using other analytical methods for their own quality control purposes as long as they assure themselves that such unofficial methods compare adequately with the official methods. For compliance purposes the methods specified in the regulation will be used by FDA.

67. Several comments recommended that the proposed new method (PDCAAS) for the evaluation of protein quality be eliminated from the regulation. Some comments stated that the PDCAAS method will not provide flexibility and will be unnecessarily burdensome and expensive, because it requires that digestibility and amino acid analysis be performed on every product for which a declaration of the percent of the RDI for protein is made. One comment stated that foods are often reformulated, creating an ongoing cost. Several comments expressed concern that, because of the costs, the PDCAAS could have unintended negative effects on the competitive position of smaller companies and on the willingness of manufacturers to provide complete nutrition information to the consumer.

A few comments argued that for some foods, the PDCAAS will result in lower values being declared for the percent of the RDI than current methodologies using the PER, and that this will effect the ability of the foods to make claims about protein content. Another manufacturer opposed the change to new methodology and commented that the PDCAAS methodology should be reviewed and scrutinized by the AOAC before application.

FDA does not agree that the PDCAAS should be eliminated. FDA wishes to clarify that declaration of the percent DRV for protein (which uses the PDCAAS method) is voluntary for foods intended for adults and children 4 or more years of age unless a protein claim is made for the product. Therefore, for this age group, the burden and expense of the PDCAAS method are voluntarily assumed by the manufacturer.

FDA acknowledged in the preceding comment that values obtained for percent of label reference value differ when calculated using the PDCAAS rather than the PER. However, the PDCAAS, based on human requirements, is inherently more appropriate for assessing protein quality of foods intended for human consumption than the PER which is based on the amino acid requirements of the rat (Ref. 8). Accordingly, label claims based on these values will more accurately describe the role of the protein product in meeting human nutrition requirements.

FDA advises that the analytical methodologies for amino acid analyses involved in the calculation of the PDCAAS method have undergone collaborative studies and have been published in the Journal of the Association of Official Analytical Chemists.

68. One comment expressed uncertainty about the proposed amino acid scoring pattern used in calculating the PDCAAS and stated that the WHO/FAO recommended further research to confirm the currently accepted values of preschool children.

FDA acknowledges that the WHO/FAO Consultation (Ref. 8) recommended further research on the proposed scoring pattern to confirm and reinforce the existing information. The Consultation concluded, however, that the proposed scoring pattern is robust and represents the best available estimate of indispensable amino acids for this age group. Because of the high protein requirements of the preschool age group for adequate growth and development, protein foods and diets with an amino acid pattern that effectively meets the needs of the preschool child will adequately meet the needs of older children and adults, whereas the reverse may not be true (Ref. 10). Therefore, FDA concludes that the proposed amino acid scoring pattern for preschool age children is at present the most suitable pattern for use in the evaluation of dietary protein quality for all age groups, except infants.

69. Comments agreed that the amino acid pattern for 1 to 4 year old children should be the same as the amino acid reference pattern for 2 to 5 year old children when calculating the PDCAAS. According to the data presented in the comments: (1) There is little difference

in the portion of protein and amino acids needed for maintenance and growth between the two age groups; (2) there is no sound nutrition rationale for using 70 percent of casein as the reference standard for 1 to 3 year old children as recommended by the Codex Committee on Nutrition and Foods for Special Dietary Uses (Ref. 10a); and (3) there is no evidence that the pattern of intake of amino acids for 1 to 3 year old children differs from, or that the pattern is inadequate compared to, the pattern for 2 to 5 year old children. The comments also confirmed that there is sufficient overlap between the age groups to render one standard adequate.

In the preamble to the supplementary proposal, FDA specifically requested comments on the inconsistency between the FAO/WHO and the Codex Committee on Nutrition and Foods for Special Dietary Uses standards for the protein quality of foods intended for children 1 to 3 years old. The data presented in the comments (Refs. 54 and 55) supported the agency's tentative conclusion to use the amino acid scoring pattern for preschool 2 to 5 year old children for determining the PDCAAS of foods intended for children over 1 year of age. Therefore, the agency is maintaining the requirement in § 101.9(c)(7) that the PDCAAS be used to measure protein quality in foods for children above 1 year of age.

However, the agency inappropriately left a parenthetical notation in proposed § 101.9(c)(8) that indicated that casein was to be used as the reference standard for determining the PDCAAS for children greater than 1 but less than 4 years of age. Because by definition the PDCAAS uses an amino acid scoring pattern based on human requirements as the standard, the agency has modified proposed § 101.9(c)(8), redesignated as § 101.9(c)(7), to remove the reference to casein for that age group.

70. Two comments disagreed with retaining the PER method and the casein standard for assessing protein quality for infants. The comments asserted that the requirement was not consistent with the FAO/WHO Consultation recommendation for the use of the amino acid pattern of breast milk for this age group.

FDA acknowledges that the FAO/WHO Consultation (Ref. 8) recommended that the amino acid composition of human breast milk should be the basis of the scoring pattern to evaluate protein quality in foods for infants under the age of one. However, in the same document, the Consultation stated that further data on the amino acid profile of human breast milk using standardized methods of analysis are required to confirm the pattern for calculating the chemical score of infant formulas (Ref. 8).

Because of the uncertainties expressed in the FAO/WHO report (Ref. 8) and the inconsistencies in reported amino acid patterns of human breast milk (Ref. 56), the agency finds that it is premature to use the FAO/WHO reference pattern for infants, especially since this population group relies on relatively few foods for nutrients. Until further data become available, the safer course is to continue to use the current PER method using casein as a standard. When more data become available, FDA would be willing to reconsider this position in response to a petition.

71. A few comments stated that the use of the PDCAAS will understate the biological quality of vegetable proteins consumed in a mixed diet. Another comment requested that FDA provide manufacturers with ways to communicate the complementary nature of different proteins from different sources.

FDA agrees that use of the PDCAAS does not indicate the value of individual proteins consumed as part of a mixed diet. However, this is true with any method used to measure quality of proteins in individual foods. The calculation of the corrected amount of protein of a food does not take into account the complementary potential of the food in a mixed diet, i.e., how a food rich in a particular essential amino acid can "complement" a food low in that amino acid to result in a total diet that provides sufficient amounts of the amino acid. What the method does is allow for a greater awareness of the value of protein sources when consumed alone.

While FDA acknowledges that more consumer education would be helpful on the complementary effects of individual foods in mixed diets, providing such information is beyond the scope of nutrition labeling. Space limitations within the nutrition label generally prevent the addition of information to communicate the complementary nature of different proteins. However, FDA advises that the regulation does provide in § 101.9(e) for the voluntary inclusion of a second column to declare the nutrient content of common combinations of foods (e.g., milk and cereal, peanut butter and bread). It would be possible to declare in this column the percent of the DRV or RDI for protein, as appropriate, for the combination of foods. Also, the manufacturer may include nonmisleading statements about the complementary nature of protein sources in materials outside the nutrition label.

72. Several comments expressed concern over the amino acid analytical methodology and urged that high performance liquid chromatography (HPLC) technology be incorporated into the methodology, and that hydrolysis time be tailored for specific foods. One comment suggested that FDA appraise the use of plasma aminograms as indicators of protein quality.

FDA agrees that the HPLC technology should be incorporated into the suitable methodology for amino acid analyses. In the preamble of the supplementary proposal, the agency stated that the analytical methodology for PDCAAS is described in the Report of the Joint FAO/WHO Consultation, section 5.4.1 (Ref. 8). The analytical methodology includes HPLC and provides flexibility in the hydrolysis of specific foods.

The agency has evaluated the merits of using plasma aminograms for protein quality evaluation. FDA believes that the method is not appropriate for this purpose. Current methodologies using plasma amino acids for predicting the protein quality of foods are highly variable, nonstandardized, and expensive. Consequently, it is not practical on a routine basis to conduct tests using plasma amino acid changes in humans as a basis for estimating protein quality.

73. One comment requested information on how to implement the PDCAAS method and on whether commercial testing laboratories have the necessary capabilities to determine the PDCAAS value.

FDA advises that the methods for determining a food product's PDCAAS is found in "Protein Quality Evaluation, Report of a Joint FAO/WHO Expert Consultation" which is being incorporated by reference into the final rule. As stated in § 101.9(c)(7)(ii), this report is available from the Division of Nutrition, Center for Food Safety and Applied Nutrition (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or is available for inspection at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. To assist persons in using this report, FDA has modified § 101.9(c)(7)(ii) to add the specific sections of the FAO/WHO report in which the methodology is found. These sections are 5.4.1, 7.2.1, and 8.00.

For those foods for which the digestibility factors are known and found in FDA's interim data base, commercial testing laboratories will be able to calculate the PDCAAS after running an amino acid analysis as

described in the FAO/WHO report, section 8.00 (Ref. 8). The equipment necessary for amino acid analyses is commonly used by commercial laboratories and should be widely available.

For those foods for which the digestibility factor is not known, digestibility values must be determined in laboratories according to methods in the FAO/WHO Report, sections 7.2.1 and 8.00 (Ref. 8).

74. A comment noted that the agency had not specified increments for reporting the "Percent Daily Value" for protein as had been done in proposed § 101.9(c)(11)(iii) for reporting the "Percent Daily Value" for vitamins and minerals.

FDA acknowledges the oversight and is modifying § 101.9(c)(7)(i) by specifying that the "Percent Daily Value" for protein is to be declared to the nearest whole percent as it is for fat and carbohydrate in § 101.9(d)(7)(ii).

4. Conclusion

In all other respects, § 101.9(c)(8), redesignated as § 101.9(c)(7), remains unchanged except that § 101.9(c)(7)(iii) has been reserved in this document. That paragraph is included in the companion document entitled "Food Labeling: Reference Daily Intakes and Daily Reference Values" published elsewhere in this issue of the Federal Register in which the DRV for protein for adults and children over 4 years of age and the RDI for protein for infants, children less than 4 years of age, pregnant women, and lactating women are established.

H Vitamins and Minerals

75. Retaining the requirement for mandatory listing of vitamin A, vitamin C, calcium, and iron on the food label was supported by a large number of comments representing a broad spectrum of consumers and consumer organizations, public health organizations, health care professionals, industry representatives, and trade associations. These comments agreed with the rationale stated in the proposal for continuing the mandatory declaration of these nutrients in nutrition labeling.

There were, however, some comments that did not support the mandatory listing of these nutrients. Some comments suggested that vitamin A and vitamin C should not be mandatory but should be allowed on the food label on a voluntary basis. One comment questioned whether inadequate intake of these vitamins is a public health issue, noting that some milk is fortified with vitamin A and stating the belief that consumers are aware that citrus fruits are sources of vitamin C. One comment noted that the IOM report (Ref. 1) recommends that vitamin A and vitamin C should be allowed on the food label rather than required. Additionally, a few comments recommended voluntary rather than mandatory declaration of calcium and iron.

In view of the strong support for the mandatory listing of vitamin A, vitamin C, calcium, and iron on the food label, and in the absence of strong opposition to the agency's proposal to require the listing of these nutrients on the label, FDA is not persuaded that voluntary listing of these nutrients is desirable and in the interest of the public health. While the IOM report does suggest that vitamin A and vitamin C could be allowed, rather than required, on the food label, it identifies vitamin A and vitamin C as potential public health issues and states that certain subpopulations are still at risk for deficiencies of these vitamins (Ref. 1). The report states that inadequate dietary intake of vitamin A is found in children under 5 years of age, and that two segments of the population are at risk for vitamin C deficiency (infants fed cow's milk exclusively and elderly individuals on inadequate diets).

FDA continues to believe that public health concerns exist for vitamin A in these at-risk groups and for the general public. While fortification of certain foods, such as low fat and skim milk, has helped to improve intakes of this vitamin among healthy persons consuming a balanced diet, the inclusion of adequate vitamin A in the diet still requires care and effort on the part of a consumer in selecting good food sources of this vitamin. Vitamin A is found in a relatively limited number of foods within the food supply, and these foods must be selectively chosen by consumers on a regular basis to ensure adequate intake.

FDA also continues to believe, as supported by numerous comments, that vitamin C is a nutrient with public health significance, in that, even with fortification efforts and greater year-round availability of citrus fruits and dark green vegetables, certain subpopulations are considered at risk (see 55 FR 29487 at 29501).

In the case of calcium and iron, these minerals are identified as public health issues in the IOM report (Ref. 1) and by numerous other sources, including the Surgeon General's report (Ref. 2), Diet and Health (Ref. 3), and the report on "Nutrition Monitoring in the United States" (Ref. 49).

Therefore, § 101.9(c)(11)(ii), redesignated as § 101.9(c)(8)(ii), requires vitamin A, vitamin C, calcium, and iron as mandatory elements of nutrition labeling.

76. Many comments were received from persons at risk of iron overload, particularly hemochromatotics, supporting mandatory labeling of iron and requesting that the food label declare both added and naturally occurring iron.

FDA has carefully considered these comments. The agency recognizes that a segment of the population is at risk of iron overload. In deciding whether the declaration of a nutrient or component on the food label should be mandatory, however, the agency must consider the broad public health significance of its action. Inadequate intakes of dietary iron are responsible for the most prevalent form of iron deficiency in the United States. Iron deficiency remains a risk for certain segments of the U.S. population, notably young children, adolescents, women of childbearing age, and pregnant women, especially those with low incomes (Refs. 2, 3, 23, and 49). Thus, public health concerns relative to iron, as stated in the National Nutrition Goals for the Year 2000 (Ref. 47), center on the prevention of iron deficiency and support increased dietary intake of iron among children 1 to 2 years of age, women 20 to 44 years of age, and low-income pregnant women. The agency believes that the listing of iron on the food label aids the consumer in making individual food selections in structuring the total diet, and that this total diet has significant effects on health.

However, as discussed in comment 54 of this document concerning added sugars, the agency has taken the position that it should not attempt to regulate actions that it cannot enforce. Because available laboratory analytical methods do not differentiate between added and naturally occurring iron, the agency would not be able to determine compliance with declared amounts of added iron.

Therefore, the agency is denying the request that manufacturers declare on their labels separate quantitative amounts of added and naturally occurring iron.

For the segment of the U.S. population at risk of iron overload, the agency notes that the food label will provide quantitative declaration of iron and vitamin C content of a food, as well as a listing of ingredients (including iron compounds if iron is added to the food). As absorption of nonheme iron may be enhanced by consumption of vitamin C containing foods, those at risk

of iron overload can decrease their simultaneous consumption of foods containing iron and vitamin C by using the information on the iron and vitamin C content of foods found on the food label.

77. The majority of comments that the agency received from consumers, health care professionals, public health agencies, universities, industry, and trade associations agreed with FDA's proposal to allow thiamin, riboflavin, and niacin to be listed voluntarily unless a claim is made, or unless these nutrients are added to a food. Most comments based their position on the decline of public health concern for deficiencies of these vitamins over the past 20 years.

On the other hand, there were some comments that advocated continued mandatory listing of these vitamins on the food label. Several comments expressed the opinion that mandatory inclusion of thiamin, riboflavin, and niacin within nutrition labeling contributed to the reduction of the incidence of deficiencies of these vitamins in the United States. One comment stated that these vitamins continue to be important to a significant portion of the U.S. population, that listing these vitamins on the label provides information on the nutritional properties of a food, and that the 1990 amendments direct FDA to mandate declaration of any vitamin that the agency deems to be important for the maintenance of healthy dietary practices.

FDA does not agree that the listing of thiamin, riboflavin, and niacin on the food label has been the major cause of the declining incidence of deficiencies of these vitamins. Rather, the agency believes that the variety and abundance of the food supply and the enrichment of many standardized foods with these vitamins are the primary factors responsible for reducing the occurrence of deficiencies of these vitamins (Ref. 57).

FDA acknowledges that these vitamins continue to be important nutrients, and that listing these vitamins on the label provides information on the nutritional properties of a food. However, the agency notes that while the 1990 amendments direct the agency to include in the nutrition label information that will assist consumers in maintaining healthy dietary practices, not all information related to maintaining healthy dietary practices can be included on the food label. If all such information were included, all essential nutrients would be declared on the nutrition label. Not only would space constraints not allow for this, but the large amount of information would interfere with consumers' abilities to use the information of the greatest public health significance (see discussion in response to comment 3 of this document). Such a result would be contrary to the intent of Congress (Ref. 16).

For this reason, FDA developed criteria in its mandatory nutrition labeling proposal to assist it in determining which nutrients to require in nutrition labeling (55 FR 29487 at 29493). These criteria specify that nutrients should be required when quantitative intake recommendations have been made in scientific consensus documents, and when the nutrient is of particular public health significance. Based on the preponderance of comments that agreed with FDA's assessment that thiamin, riboflavin, and niacin are no longer of particular public health significance, FDA has decided to provide in § 101.9(c)(11)(ii), redesignated as § 101.9(c)(8)(ii), for the voluntary declaration of thiamin, riboflavin, and niacin.

78. Several comments requested that FDA clarify whether thiamin, riboflavin, and niacin are required to be listed on the nutrition label of a product made with enriched flour, a standardized food, if no claim is made about these enrichment nutrients other than their listing in the ingredient statement as part of enriched flour. Similarly, another comment suggested that FDA explicitly state, as in current § 101.9(h)(7), that labeling of voluntary nutrients will not become mandatory if present in a food product as part of an enriched ingredient that has a standard of identity. The comment also requested that nutrients added strictly for a technological effect not be required to be declared in nutrition labeling, in a similar fashion to current § 101.9(h)(6).

Proposed § 101.9(c)(11)(ii) stated that vitamins and minerals (other than vitamin A, vitamin C, calcium, and iron which must be declared) need only be declared in the nutrition label when they are added as a nutrient supplement, or when a claim is made about them. FDA's intent in this section, which is redesignated as § 101.9(c)(8)(ii), was that when a food product is made with enriched flour as an ingredient, but the label does not make an "enriched" claim or use "enriched" in the name of the food, the nutrition label need not declare the enrichment nutrients. If, however, the product is made with unenriched flour and supplemented with nutrients as ingredients to achieve the equivalent of a product made with enriched flour, the product's label must list the enrichment nutrients in the nutrition label. Information on the amount of the enrichment nutrients is also required if an "enriched" claim is made on the label, or if "enriched" is used in the name of the food. Section 101.9(c)(8)(ii) is modified to clarify this requirement.

FDA agrees with the comment that nutrients that are not required to be declared in the nutrition label and are added to a food strictly for a technological effect need not be declared if the nutrient is declared solely in the ingredient statement and is otherwise not referred to on the label or in labeling or advertising. This provision, similar to current § 101.9(h)(6), is added to § 101.9(c)(8)(ii).

79. Several comments stated that listing of other vitamins and minerals should be required, even without a claim, such as vitamin D, magnesium, and phosphorus. One comment supported the listing of all vitamins (even those absent from the food or food product).

FDA notes from these comments consumer interest in a variety of nutrients but points out that not all nutrient information related to maintaining healthy dietary practices can be included on the food label. As discussed in comment 3 of this document, the agency must be selective with regard to the information that it requires to be listed on the label. Thus, it emphasizes nutrients or components of particular public health significance. FDA does not believe that all vitamins and minerals are of equal public health significance, a view that is supported by the IOM and Nutrition Monitoring reports (Refs. 1 and 49). The agency is also aware that space limitations on the food label require that it use discretion in deciding which nutrients it requires to be listed there.

FDA does not agree that vitamin D, magnesium, or phosphorus are of particular public health significance in the United States. Because the human requirement for vitamin D can be met with sufficient exposure to sunlight, and because milk and other foods are fortified with vitamin D, deficiencies in this vitamin are very rare (Ref. 23). Magnesium and phosphorus are cited in both the Nutrition Monitoring and IOM reports as food components that are not currently public health issues (Refs. 1 and 49). FDA, therefore, is not requiring mandatory listing of vitamin D, magnesium, or phosphorus in the nutrition label.

80. Some comments suggested not requiring any vitamins or minerals on the food label unless claims are made, or the nutrient is added to the food, in

order to minimize the space requirements of nutrition labeling.

As discussed in the supplementary proposal (56 FR 60366 at 60368), FDA interprets section 403(q)(1)(E) of the act to require the inclusion of vitamins and minerals currently required in § 101.9(c)(7)(iii) if the Secretary (or FDA, by delegation) determines that such information will assist consumers in maintaining healthy dietary practices. For the reasons discussed above, FDA, has determined that vitamin A, vitamin C, calcium, and iron meet the criterion in section 403(q)(1)(E) of the act and, therefore, must continue to be required elements of nutrition labels. The 1990 amendments did not provide for nutrients to be omitted to save space. Therefore, § 101.9(c)(8)(ii) continues to require declaration of vitamin A, vitamin C, calcium, and iron.

81. One comment requested that the final regulations allow for the voluntary identification of foods that are important sources of beta-carotene, either as a subset of vitamin A or through an independent designation. The comment stated that beta-carotene may reduce the risk of chronic diseases and appears to have its own independent biological functions in addition to serving as a source of vitamin A. The comment also noted that "Recommended Dietary Allowances" (10th ed.) states that "For food products containing large quantities of carotenoids, it would be advisable in nutrition labeling to distinguish between retinol, which in large amounts is toxic, and carotenoids, which are not" (Ref. 23).

The agency has carefully reviewed the relationship of beta-carotene to cancer in the companion document entitled "Food Labeling: Health Claims and Label Statements: Antioxidant Vitamins and Cancer," published elsewhere in this issue of the Federal Register. Based on that review and the stated recommendations in "Recommended Dietary Allowances," FDA has concluded that there should be a method within nutrition labeling to voluntarily distinguish the amount of beta-carotene present in food products. Accordingly, FDA is adding § 101.9(c)(8)(vi), which states that the percent of vitamin A that is present as beta-carotene may be declared to the nearest 10-percent increment immediately adjacent to or beneath the nutrient name (e.g., "Vitamin A (90 percent as beta-carotene)," see example in appendix C).

82. A few comments objected to FDA's proposed deletion of the synonyms vitamin B1 and B2 for thiamin and riboflavin, respectively. The comments argued that many consumers continue to use these terms and understand them better than the "scary-sounding chemical" names. Similar comments were received in response to proposed § 101.36 *Nutrition labeling of dietary supplements of vitamins and minerals.*

Based on the comments, the agency has reassessed its position on this issue. FDA believes that for consistency the chemical name of the nutrient (i.e., thiamin and riboflavin) must always be given when the nutrient is declared in nutrition labeling, or when claims are made (e.g., "high in thiamin"). However, the agency will not object to the voluntary parenthetical listing of "vitamin B1" or "B1" following "thiamin" and "vitamin B2" or "B2" following "riboflavin." Accordingly, FDA has modified § 101.9(c)(11)(v), redesignated as § 101.9(c)(8)(v), by adding vitamin B1 and vitamin B2 as synonyms for thiamin and riboflavin, respectively. While FDA believes a similar change is appropriate in proposed § 101.36, given the requirements of the DS Act, FDA is taking no action with respect to dietary supplements, and thus is not acting on proposed § 101.36 at this time.

83. One comment suggested that other synonyms be allowed, namely "pyridoxine" as a synonym for vitamin B6 and beta-carotene for vitamin A when the vitamin A is solely beta-carotene.

FDA rejects this comment. Pyridoxine is only one of three different forms of vitamin B6 (Ref. 23). In addition, the agency believes that it would be a more difficult term for consumers to use and understand. In regard to vitamin A, FDA believes new § 101.9(c)(8)(vi) (see comment 81 of this document) is a preferable course because in most foods, beta-carotene is only a fraction of the total vitamin A content.

84. FDA received a few comments that addressed increments for those nutrients that are expressed as a percent of a reference standard. One comment proposed a more complex incremental scheme than that in the proposed rules, suggesting 1-percent increments up to and including the 5-percent level, 2-percent increments from 6 percent up to and including the 12-percent level, 5-percent increments from 15 percent up to and including 50 percent, and 10-percent increments above the 50 percent level. Another comment suggested increments of 5 percent up to the 50-percent level and 10-percent increments thereafter. This comment suggested that FDA not permit the use of 2-percent increments because the necessary measurements are not accurate enough to allow for such small increments.

FDA proposed to maintain the current increments for vitamins and minerals, i.e., percentages are expressed in 2-percent increments up to and including the 10-percent level, 5-percent increments above 10 percent and up to and including the 50-percent level, and 10-percent increments above the 50-percent level. FDA considered both the comment suggesting a more complex incremental system and the comment suggesting omission of the 2-percent increments. Neither suggestion provided sufficient justification for the change. One appears to believe that an accuracy of 1 percent of the RDI is necessary, the other that an accuracy at 5 percent of the RDI is sufficient. Inasmuch as the agency has experienced no problems with the increments that have been in use since the early 1970's, and given that so few comments addressed this issue, the agency sees no need to modify the incremental scheme in proposed § 101.9(c)(11)(iii), redesignated as § 101.9(c)(8)(iii).

85. One comment noted that regulations specified that all nutrients except vitamins and minerals were to be expressed to the "nearest" unit of increment (e.g., total carbohydrates are to be expressed to the nearest g, and sodium to the nearest 5-mg increment between 5 and 140 mg of sodium and to the nearest 10-mg increment above 140 mg of sodium). The comment asked for direction on reporting amounts of vitamins and minerals.

To clarify the regulations and promote consistency, FDA is modifying § 101.9(c)(8)(iii) to specify that vitamins and minerals are to be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level.

86. A comment objected to the provision in proposed § 101.9(c)(11)(iii) that allows vitamins and minerals that are not present to be represented by an asterisk that refers to a statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)." The comment stated that consumers might be misled into thinking that small amounts of the vitamin or mineral are present when they are not.

FDA considered this comment and has concluded that the flexibility the use of the asterisk provides in allowing manufacturers to reduce the space needed for nutrition labeling outweighs any slight misunderstanding about the amount of a vitamin or mineral present

in a food that might result. Amounts of either zero or less than 2 percent of the RDI (declared as Percent Daily Value) for these nutrients are physiologically insignificant.

The RDI's are provided in § 101.9(c)(8)(iv) which has been reserved in this document. That paragraph is included in the companion document entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values" (hereinafter referred to as the RDI/DRV final rule) published elsewhere in this issue of the **Federal Register**. In accordance with section 203 of the DS Act that prohibits FDA from promulgating regulations based upon recommended daily allowances of vitamins and minerals other than the U.S. RDA's currently specified in § 101.9(c)(7)(iv) until November 8, 1993, § 101.9(c)(8)(iv) includes values for only one age group (i.e., adults and children 4 or more years of age) rather than the 5 proposed groups (i.e., adults and children 4 or more years of age, children less than 4 years of age, infants, pregnant women, and lactating women). FDA intends to adopt in accordance with section 203 of the DS Act, appropriate RDI's for all groups. Therefore, FDA has adopted the references to such groups in §§ 101.9 (a)(4), (c)(8)(i), (e), and (1) of this final rule, even though such values do not exist at this time. In the meantime, suggested RDI values for other age groups, which, to be consistent with the DS Act, are based on the 1968 RDA's are presented as guidance in the preamble of the RDI/DRV final rule.

IV. Analytical Procedures

A. General Issues

87. Several comments asserted that FDA should explicitly state the methods to be used for the analysis of various nutrients. Some comments expressed the opinion that the agency should not mandate listing of any nutrient when there are serious issues with the reliability of the analytical method. Dietary fiber was specifically cited as one example. One comment added that FDA must specify the method of analysis for analytes not available in the AOAC.

The agency acknowledges the concern expressed in the comments. In the mandatory nutrition labeling proposal (55 FR 29487 at 29498), FDA discussed the analytical methodologies for sugars and dietary fiber. The agency noted that in the 17 years since the promulgation of § 101.9, it had acquired substantial experience under the regulation, and techniques for analyzing foods for their nutrient content have greatly improved. The agency considers it is inadvisable to explicitly state a method for a particular nutrient. The applicability of a specific method to products of different matrices varies. As noted in several comments, values for some nutrients, such as fat, are dependent upon the procedure used. If a specific method is cited, it may give the erroneous impression that other methods that are more appropriate to the matrix or that utilize newer techniques could not, or would not, be acceptable. It is FDA's policy and practice that any method used to support a nutrient declaration value requires appropriate validation if it has not been collaborated for that nutrient in a specific matrix. Validation procedures are a necessary component of sound analytical technique and are frequently used even with official, collaborated methods.

The agency agrees that no nutrient should be a required component in nutrition labeling if there is no satisfactory analytical method for determining its level in a food. In fact, this view was a major factor in the agency's decision not to require declaration of complex carbohydrates. FDA believes that there is adequate methodology to assay for the nutrients that it has made mandatory elements of the nutrition label, even, as explained below, for dietary fiber.

Analysis is not needed for nutrients, however, where reliable databases or scientific knowledge establish that a nutrient is not present in the product. For example, there is no need to analyze for cholesterol in fruits and vegetables or for dietary fiber in seafood. Costs associated with nutrition labeling will be contained by not analyzing for a nutrient where there is no reasonable expectation that the nutrient occurs in the food.

88. Some comments noted that analytical variability—which ranges from 1 percent to as high as 20 percent according to one comment—may be a function of the method selected and its inherent variability, the laboratory performing the analysis, the level of nutrient in the food, and the ability to obtain a homogeneous sample composite. A few comments specifically cited the difficulty in measuring levels of complex carbohydrates or vitamin C in potatoes. These comments observed that the nutrient levels may differ between the time of harvesting and processing, as well as after a period of storage. One comment recommended that FDA allow flexibility in selecting analytical methodology such that there would be a broadened range of methods used to generate nutritional information.

FDA advises that manufacturers are free to use methods of their choice for ascertaining the quantity to declare on the label as well as for screening purposes as part of their quality control procedures. However, when questions arise as to the validity of the data, the agency will utilize the methods of the AOAC or other validated procedures.

Given the analytical problems in determining values for complex carbohydrates, the agency has deleted the requirement for declaring complex carbohydrates and is eliminating the term "complex carbohydrate" from the nutrition label. As discussed above, it is using instead the term "other carbohydrate." The term "other carbohydrate" is defined as the difference between total carbohydrates and the sum of dietary fiber, sugars, and sugar alcohols (when declared). Because a specific method of analysis is no longer required for complex carbohydrates, the concern about measuring this food component in potatoes has been addressed. In regard to the concern about the analysis for vitamin C in potatoes, FDA advises that in this situation vitamin C is a naturally occurring, or Class II, nutrient. Thus, the declaration is in compliance if the nutrient is present at a level of 80 percent or more of the declared label value. It should be noted that current regulations and § 101.9(g)(6) permit reasonable excesses within current good manufacturing practice for both vitamin C and other carbohydrate.

As more nutritional analyses are performed in support of label values, more methodologies will be validated. As a result, the number of methods that manufacturers may use in determining the amount of a nutrient will increase. Moreover, products that heretofore had not been labeled with nutrition information will now be subjected to testing. These new matrices will create new challenges for both the food industry and the agency. However, these challenges should not impede the development of full, accurate nutrition information on food labels. The agency is committed to working with industry to provide valid nutrition label information that will promote selection of healthier diets by U.S. consumers.

89. Some comments suggested that FDA work with trade associations and industry on the analytical techniques required to prepare nutrition labels. One comment recommended that designations be made as to which food matrices are appropriate for existing methods and which ones are not.

FDA agrees it should be actively involved in the review of suitable methods to be used in the

implementation of mandatory nutrition labeling. The AOAC Task Force on Nutrient Labeling Methods was established early in 1992 by AOAC for the purpose of assisting its membership in meeting the requirements of the agency's regulations. The agency worked closely with the Task Force, participating in meetings as well as in evaluating appropriate methods for various matrices. The Nutrient Labeling Task Force Report on Analytes for Nutritional Labeling is available from the agency or AOAC. The report lists the methods that are adequate for various nutrients and various matrices. As pointed out in the official AOAC publication, The Referee (Ref. 58), not all analyte/matrix combinations in the report have been fully collaboratively studied, however.

In this context, it should also be noted that § 101.9(g)(2) of these final rules allows for the use of other reliable and appropriate analytical procedures if no AOAC method is available or appropriate. Sources of such methods include FDA's "Lipid Manual" (Ref. 59) and FDA's Food Additive Analytical Manual, vol. I and vol. II (Ref. 60). Additional methods may be found in "Approved Methods of the American Association of Cereal Chemists" and "Official Methods and Recommended Practices of the American Oil Chemists Society."

The method of analysis used must be suitable to achieve the purpose for which it is used. For example, the method used to quantify vitamin C for nutrition labeling must be able to determine whether ascorbic acid or isoascorbic acid is present in the food. Isoascorbic acid and sometimes ascorbic acid are used as antioxidants in food processing. Only ascorbic acid, however, is an active form of vitamin C and considered in the determination of vitamin C content of the food. Thus, the method must be able to distinguish ascorbic acid from isoascorbic acid.

90. FDA received several comments regarding the use of the Official Methods of Analysis of the AOAC. One comment stated that the latest edition of this reference should be cited to avoid obsolescence when new editions are issued.

FDA does not have authority to not reference a particular edition of the Official Methods. The Office of the Federal Register requires that each statement of incorporation by reference into the Code of Federal Regulations contain specific information, including the date and edition of the publication Accordingly, FDA has not modified § 101.9(g)(2).

91. A comment supported a policy whereby FDA would verify laboratory analysis results on file at a firm to substantiate the nutrition label information in lieu of doing nutrient analysis from a limited sample of products. The comment expressed the opinion that FDA should be required to perform additional sampling and testing and to consider the statistical variation inherent in test procedures before initiating a legal action, such as a seizure.

The agency disagrees with the comment. FDA is a law enforcement agency, and its mission is consumer protection. To support a misbranding charge for inaccurate nutrient content information, FDA must have accurate, reliable, and objective data to present in a court of law. To obtain that information, FDA relies upon the work performed by its trained employees because it does not have legal authority in most instances to inspect a food manufacturing firm's records.

The practice of performing nutrient analysis from a composite of 12 subsamples is well established. Compositing the contents of the twelve containers yields a numerical result essentially equivalent to what would be obtained if each container were analyzed, and the results averaged. Thus, the composite value is considered to be the same as the average of a sample of twelve containers. As noted in § 101.9(g)(4) and (g)(5), FDA will not take regulatory action based on a determination of a nutrient value that fails to meet appropriate levels by a factor inherent in the variability generally recognized for the analytical method used on that food at the level involved.

B. Calories

92. Comments stated that the regulations should clarify how calories are to be calculated. Several comments recommended adding "caloric content may be determined by the Atwater method" to proposed § 101.9(c)(3). Some comments objected to the use of the specific Atwater food factors published in "USDA Handbook 74" which have not been updated since 1955. Another comment noted that if a food item is a commodity-type product for which a specific Atwater factor is available, the caloric content for these products should be required to be calculated using the specific Atwater factors.

Several comments disagreed with the proposal to subtract dietary fiber from the amount of carbohydrate before applying the general factor of 4 (i.e., 4 calories per g of carbohydrate). These comments contended that the general factor is intended to apply to total carbohydrate including fiber. Because the gastrointestinal effects of dietary fiber were taken into account in the derivation of the general factors, these comments did not consider it to be legitimate to exclude fiber from carbohydrate content when calculating caloric content.

One comment suggested that calories be calculated from carbohydrate-plus-dietary fiber if the general factor of 4 calories per g of carbohydrate is used. Alternatively, the comment suggested that calories be calculated from available carbohydrate if the general factor of 3.75 calories per g of carbohydrate is used. The factor of 3.75 calories per g for carbohydrate is used by the United Kingdom for calculation of available carbohydrate energy (Ref. 61).

One comment suggested that both total dietary fiber and other nondigestible carbohydrate should be subtracted from the total carbohydrate content before calculating calories contributed by carbohydrates. As noted in the comments, many new food ingredients such as reduced-calorie fats, fat substitutes, and modified carbohydrates have been developed in recent years. Some of these ingredients have caloric values substantially less than the general factors of 4, 4, and 9 for protein, carbohydrate, and fat, respectively. Comments requested specific allowances for ingredients used as reduced calorie replacements for conventional ingredients to permit methods for calculating the available calories other than use of the general factors.

The agency recognizes that confusion may exist about methods for calculating caloric content because of the proposed changes in how total carbohydrate content has been defined in § 101.9(c)(6) and because of the changes in the treatment of dietary fiber. Therefore, the agency is modifying § 101.9(c)(1) to clarify how caloric content is calculated by providing five options for calculating the energy value of foods in § 101.9(c)(1)(i).

The first option, which is set forth in § 101.9(c)(1)(i)(A), is the use of specific Atwater factors that are found in Table 13 in "Energy Value of Foods—Basis and Derivation" by A. L. Merrill and B. K. Watt, USDA Handbook No. 74 (1955) FDA disagrees with the comment that suggested requiring the use of specific Atwater food factors for those foods for which such factors exist. The agency does not believe that there is any need to limit a manufacturer's flexibility in selecting a method for determining

caloric content. Current regulations do not require the use of specific Atwater food factors, and no data were presented to support a change in current practices.

The second and third options utilize the general factors of 4, 4, and 9 calories per g for protein, carbohydrate, and fat, respectively. In § 101.9(c)(1)(i)(B), which provides for calculating calories by general factors, dietary fiber is included in total carbohydrate. FDA also recognizes, however, that doing so can result in significant error for the caloric value of some foods because of the relatively low energy value of dietary fiber. Adjustments for dietary fiber content are therefore appropriate for nutrition labeling of some foods.

However, because some soluble dietary fiber can make a significant contribution to a food's energy value (Ref. 61), FDA does not consider it appropriate to allow an absolute exclusion of all dietary fiber from caloric calculation. Recognizing that there can be significant levels of available energy in some soluble fiber, and that official AOAC methods for dietary fiber now provide for separation of soluble and insoluble fiber, the agency considers it appropriate to permit exclusion of the insoluble component of dietary fiber alone from calculation of carbohydrate calories. Accordingly, FDA has added § 101.9(c)(1)(i)(C) in the final rule to permit calculation of caloric contribution from the carbohydrate portion of food by multiplying carbohydrate content minus insoluble dietary fiber content by the general factor of 4 calories per g.

In addition, § 101.9(c)(1)(i)(D) permits manufacturers or users of soluble dietary fiber additives or other food additive substances with reduced available energy to petition for use of alternative energy factors in nutrition labeling through established procedures for food additive or GRAS petitions. Soluble dietary fiber substances are frequently added to foods to replace fully caloric nutrients in formulating reduced calorie foods. In such cases, the burden for establishing the actual energy value of the food is appropriately with the manufacturer.

The calculation of the caloric contribution of novel fats and carbohydrates has been discussed in section III. of this document. The agency has stated that it will consider digestibility of new products on a case-by-case basis as requested. In support of this action, the agency requests that manufacturers who wish to declare adjusted values for the energy contribution of a substance, based on reduced digestibility, submit information on digestibility of the substance, analytical assay procedures for the substance, and data on interference with required methods of analysis. As stated in section III. of this document, this information should be included in a food additive petition or a petition for affirmation that the use of a substance is GRAS. The agency will then publish the specific digestibility coefficients in 21 CFR part 172 for food additives and in 21 CFR part 184 for GRAS substances. These coefficients can be utilized in determining the caloric value of specific food ingredients.

Other procedures may be required for particular foods and will be addressed by other appropriate means. FDA is allowing for this contingency in § 101.9(c)(1)(i)(D) by adding "or other means, as appropriate." For example, in the voluntary nutrition labeling program for raw fish, data were presented to FDA supporting a value of fat and calories for the fish "orange roughy" that omits a portion of the total fat since more than 90 percent of the fat in the product is in a wax ester that is not metabolized (Ref. 62). FDA published these corrected values for available fat and calories in Appendix B "Nutrition Labeling Provided by FDA for the 20 Most Frequently Consumed Fish" (57 FR 8175; March 6, 1992).

To afford even more flexibility in determining caloric content, FDA is including § 101.9(c)(1)(i)(E), to provide for the use of bomb calorimetry. The agency notes that the caloric value so obtained must be corrected for nonmetabolizable protein by subtracting 1.25 calories per g of protein to correct for incomplete digestibility, as discussed in Energy Value of Foods, Basis and Derivation, "USDA Handbook No. 74" (Ref. 63). The caloric value determined by bomb calorimetry may give a higher value than the other allowed methods. However, because it would produce an over-estimation of the caloric content of the food, FDA would not consider it to be disadvantageous to the consumer. A primary consideration in selecting which method to use must be the accuracy of the declaration of the caloric content in light of the agency's compliance criteria in § 101.9(g).

The agency is aware that some manufacturers have developed their own specific factors for conventional food ingredients that they use in calculating the caloric content of their products. FDA views this practice as analogous to using data bases to determine nutrient label values, in that the manufacturer assumes the responsibility for ensuring that the values obtained are consistent with those obtained analytically by FDA. As such, the agency does not believe it needs to provide for this option in § 101.9(c)(1)(i).

In summary, the agency is amending § 101.9(c)(1) to permit five optional methods for calculation of caloric content of foods: (1) Specific Atwater food factors (i.e., the Atwater method) given in Table 13, "Energy Value of Foods—Basis and Derivation," A.L. Merrill and B.K. Watt, USDA Handbook No. 74 (1955), (2) general factors of 4, 4, and 9 calories per g of protein, total carbohydrate including dietary fiber, and total fat, respectively, as described in USDA Handbook No. 74, (3) general factors of 4, 4, and 9 calories per g for protein, total carbohydrate, and total fat, respectively, as discussed in USDA Handbook No. 74, except that insoluble dietary fiber content may be subtracted from total carbohydrate content before calculating the caloric contribution of the carbohydrate portion of the food; (4) specific factors for particular food ingredients approved by FDA through incorporation in 21 CFR parts 172 or 184 or other means, as appropriate, or (5) bomb calorimetry data after subtraction of 1.25 calories per g protein to correct for incomplete digestibility, as described in USDA Handbook No. 74, p. 10.

By providing for these varied means of calculating caloric content, FDA is giving manufacturers flexibility in how they determine calorie content in a variety of foods, both conventional foods and new foods developed to meet changing marketing strategies.

93. A recommendation was made in one comment that products with a negligible amount of dietary fiber (suggested as less than 2.5 percent) should not be required to have dietary fiber analysis for determination of caloric content.

The agency advises that because revised § 101.9(c)(6) now includes dietary fiber in total carbohydrate content, separate analysis for dietary fiber is no longer required for calculation of either carbohydrate content or calories from carbohydrate. Therefore, the concern expressed in this comment has been addressed.

94. Several comments asked for clarification on the discussion in the mandatory nutrition labeling proposal (55 FR 29487 at 29493 and 29503) of the possible caloric contribution of macronutrient substitutes or other ingredients such as certain types of soluble fibers or gums. While one comment agreed with the agency's position that manufacturers of these ingredients should be asked to provide

evidence that these substances do not contribute to the energy value of food, another comment found the concern unwarranted and opposed the use of any correction factors for calories from soluble fibers (e.g., gums). One comment noted that more research is needed in this area.

In the mandatory nutrition labeling proposal, the agency expressed concern that available energy of soluble dietary fiber food additives (e.g., gums) would not be included under the agency's proposed method for caloric calculation, which excluded energy contribution of all dietary fiber. Innovations in food technology have resulted in reduced calorie foods that utilize various soluble dietary fibers and other modified carbohydrates, proteins, and fats for technical effects that allow reduction of total fat content. The agency considered it inappropriate to automatically assign a zero energy value to all soluble dietary fiber additives when some of these substances may have available energy. Likewise, some modified carbohydrate additives may have less available energy than the 4 calorie per g assigned by the general energy factor for carbohydrate but still have available energy. The agency has determined that petitions regarding specific caloric values for these types of food ingredients are appropriate. FDA's new policy is discussed in comment 92 of this document.

C. Fats, Fatty Acids, and Cholesterol

95. As discussed in section III. C. of this document, comments raised many questions about analytical procedures to be used to measure fat and their reliability. In addition, several comments expressed concern regarding the adequacy of methods for measuring cholesterol. One comment cited a published article on a method for measuring cholesterol that is undergoing collaborative study under the auspices of the AOAC.

The agency believes that its new definition for total fat in § 101.9(c)(2) (i.e., total lipid fatty acids expressed as triglycerides) will help to clarify what analytical procedures are to be used by clarifying what compounds are to be included in the declaration of total fat. As with all nutrient analyses, consideration must be given to the analyte and matrix when selecting a method to determine total fat content. To that end, the AOAC has established methods for analyzing for total lipid fatty acids in a variety of product matrices. A recent publication of the AOAC, The Referee (Ref. 32), contains a compilation of these methods. Other reliable and appropriate methods are also cited in comment 89 of this document.

FDA notes that issues exist about the reliability of methods for measuring low levels of fat. As discussed in a recent article, fat determinations are reliable down to concentrations of 1 to 5 g per 100 g, provided a large enough test portion is taken to obtain at least 50 mg of weighable residue (Ref. 64). The premise is that accuracy generally increases when larger amounts are used for analysis so that there is always a minimum quantity of extracted fat available for weighing.

Although official analytical methodologies for determining cholesterol content are somewhat limited at the present time, the agency is pleased to note that comments indicate that this is an area of active research. FDA, as a member of the AOAC Task Force on Nutrient Labeling Methods, looks forward to the development of additional collaborated methods for a range of matrices.

D. Dietary Fiber

In proposed § 101.9(c)(3) of the mandatory nutrition labeling proposal and proposed § 101.9(c)(7)(ii) of the supplementary nutrition labeling proposal, FDA specified that total, soluble, and insoluble dietary fiber content are to be determined by the method "Total Dietary Fiber in Foods, Enzymatic Gravimetric Method."

96. One comment noted that satisfactory analytical procedures for measuring dietary fiber are available and cited the American Association of Cereal Chemists Method No. 32–21 and the proposed AOAC method. This comment stated these methodologies were at least as accurate as certain other sanctioned procedures. It acknowledged that research should continue, however, to improve the utility and standardization of analytical methods for fiber. Another comment noted that the precision of the proposed method may cause difficulties at low levels, typical of that found in some fruits and vegetables (more than 1 percent to 5 percent) and especially when fat is present in the sample. The comment stated that because of questions concerning the accuracy of methods for measuring dietary fiber, companies may elect not to declare low levels of fiber in their products. The comment stated that there is a more accurate method for use in these situations.

Two comments from the meat industry expressed concern that the proposed method for fiber had only been evaluated on cereals, grains, and breads. They questioned the applicability of the method to other types of products. According to another industry comment, currently approved methods for analyzing dietary fiber seriously underestimate dietary fiber content of high moisture foods, which leads to inaccurate and misleading label information. This comment said that a current analytical method for high moisture products is unavailable. A comment expressed the hope that the tests adopted to measure dietary fiber would not falsely exclude low molecular weight bulking agents, such as polydextrose.

The few comments that addressed analytical methods for soluble and insoluble fibers were split on whether available methods are adequate or inadequate. One comment to the supplementary proposal noted that the agency's cited method does not measure soluble fiber directly. The comment said that the method measures total dietary fiber and insoluble dietary fiber, then calculates soluble dietary fiber as the difference between the two.

With the currently available AOAC methods for dietary fiber and its components, FDA believes that suitable methodology exists for the analysis of dietary fiber for nutrition labeling purposes. Since the issuance of the supplementary proposal, two additional methods for dietary fiber have been accepted by the AOAC, based upon the collaborative data. One new method (AOAC 15, 991.43) permits the discrete analysis of total dietary fiber and of each subcomponent, i.e., soluble and insoluble dietary fiber. The concern expressed by the comments as to the availability of validated methods for measuring dietary fiber is therefore alleviated. Because methods for measuring dietary fiber are now included in the Official Methods of Analysis of the AOAC, § 101.9(c)(7)(ii) of the supplementary proposal, which described dietary fiber methodology, and § 101.9(g)(2), which directs compliance by official AOAC methods, are redundant. As such, § 101.9(c)(7)(ii) has not been included in the final rule.

The enzymatic-gravimetric method (AOAC 15, 985.29) cited in proposed § 101.9(c)(7)(ii), is valid for high-moisture foods and those with fat present in the product. The method specifies drying conditions, as well as defatting procedures, that are to be performed before analysis for total dietary fiber. If drying conditions are a part of the analysis, analytical results must incorporate the loss on drying to obtain the total dietary fiber content of the "as received" product. Likewise, any loss of weight from fat or sugar removal must also be compensated for in the calculations.

Regarding the comment on the appropriateness of including low molecular weight bulking agents in dietary fiber, in the absence of a consensus on a chemical definition for dietary fiber, the available analytical methods dictate classification of such ingredients. Some manufactured low molecular weight, carbohydrate based, bulking agents, such as polydextrose, do not analyze as dietary fiber in the official AOAC methods for measuring dietary fiber. Such food ingredients, while not reported as dietary fiber in nutrition labeling, would be included in total carbohydrate and reported as "other carbohydrate."

97. A few comments recommended that dietary fiber be listed in 0.5-g increments, believing it to be a meaningful quantity to declare. Other comments concurred with the agency's proposal of whole-g declaration for dietary fiber on the basis that 0.5 g requires greater analytical precision than is possible for measuring dietary fiber.

The agency disagrees with the first comment. No data were presented to support a change to 0.5-g increments. Therefore, FDA continues to believe that the precision of the analytical methodology for determining quantitative amounts of dietary fiber does not allow for accuracy to the 0.5 g level. Accordingly, § 101.9(c)(6)(i) will require that dietary fiber be expressed to the nearest g.

98. One comment recommended use of the word "fiber" in lieu of "dietary fiber." The comment stated that consistency with the 1990 amendments was not needed and was far less important than using terms that consumers understood. The comment also contended that insertion of the word "dietary" into each term of fiber content would clutter the label.

The agency disagrees with the comment. No data were presented to support the contention that the term "dietary fiber" would confuse consumers. FDA believes that it is important to distinguish between dietary fiber and crude fiber to ensure that there is no question as to what fiber components are declared.

99. One comment took exception to the agency's citation of USDA Handbook 74 (1955) as the reference for the subtraction of dietary fiber in the calculation of total carbohydrate at § 101.9(c)(6) of the supplementary nutrition labeling proposal. In the cited reference, dietary fiber is not a part of the calculation. The comment noted that, as a defined, analyzable entity, dietary fiber was unknown in 1955.

FDA acknowledges the accuracy of the comment in regard to the concept of what dietary fiber was in 1955. As noted previously, the agency has modified § 101.9(c)(6) so that dietary fiber is no longer subtracted from the weight of the total food in the calculation of total carbohydrate content for nutrition labeling purposes. Therefore, the concern expressed by this comment has been addressed.

E. Sugars and Other Carbohydrate

In the mandatory nutrition labeling proposal, FDA discussed the analytical methodologies for sugars and dietary fiber (55 FR 29487 at 29498). The agency acknowledged in the supplementary proposal (56 FR 60366 at 60369) that analytical problems were a concern for the mandatory declaration of sugars and complex carbohydrate.

100. Essentially all of the comments stated that current methodology is inadequate to determine the levels of sugars and complex carbohydrate, as defined. Other comments described the methodology as unavailable, costly, difficult, and imprecise. One comment noted that there are no current analytical standards for measuring complex carbohydrates as defined in FDA's proposed rule. There were no comments that provided references for available, validated analytical methodology for these food components. Another comment noted that assay techniques for the quantitative determination of polysaccharides of 10 and higher saccharide units are beyond the reasonable capabilities of many in the food industry.

One comment included an evaluation of two liquid chromatographic procedures for monosaccharides through pentasaccharides and delineated disadvantages of each. The technique of high performance ion chromatography was identified by the comment as the technique that could provide the most accurate values for sugars. This technique has not however, been studied collaboratively by the AOAC.

Concerns expressed in regard to the analytical determination of sugars and complex carbohydrates have been alleviated by the revision of the definition of "sugars" to include only the sum of mono- and disaccharides and of "other carbohydrate" as the difference between total carbohydrates and the sum of dietary fiber, sugars, and sugar alcohols (when declared). There is established methodology in the Official Methods of Analysis of the AOAC for the determination of mono- and disaccharides in several food groups with a high degree of confidence. Continued analytical work will be necessary to validate methodology for a wider, more diverse food supply.

The agency will use the technique of HPLC in monitoring compliance with label statements concerning sugars content. The agency's use of this technique will not preclude the use of emerging technologies such as high performance ion chromatography or supercritical fluid chromatography as they are developed and validated.

F. Vitamins

101. A comment stated that the agency should list those carotene fractions that can be included in the declaration of vitamin A for labeling purposes. It noted that a variety of HPLC methods for vitamin A and carotene are available and currently in use by industry and FDA. The comment also stated that analytical reagents required for AOAC official methods for determining vitamin A content are no longer available.

In its RDI/DRV proposal, the agency proposed that vitamin A content is to be expressed in retinol equivalents (55 FR 29476 at 29485). One retinol equivalent was established to be equivalent to 1 microgram (μg) retinol or 6 μg beta-carotene. The nomenclature for vitamin A as retinol equivalents was carried forward in the supplementary proposal at § 101.9(c)(11)(iv). FDA is aware of literature data where alpha-carotene is present in some carrots in significant amounts. To account for this and other carotene fractions, the agency also recognizes the National Academy of Sciences' definition of retinol equivalents as 12 μg of provitamin A carotenoids other than beta-carotene (Ref. 23).

As noted above, the agency worked closely and actively with the AOAC Task Force on Nutrient Labeling Methods to judge the adequacy of AOAC methods to meet nutrition labeling needs. The decreased availability of the analytical reagents for some methods for determining vitamin A content has caused both industry and the agency to rely more on HPLC procedures. For example, the yellow OB dye (formerly FD&C Yellow No. 4) used for standardizing the alumina column in the AOAC method for determining the vitamin A content in margarine is no longer readily available. However, FDA advises that the Nutrient Surveillance Branch (HFF-266), Center for Food Safety and Applied Nutrition, FDA, can provide limited quantities of the dye upon request to the address listed at the beginning of this document.

V. Format

A. Legal Authority for an Improved Nutrition Label Format

Congress clearly intended that nutrition information be presented to the public in a manner that facilitates understanding of the information and that assists consumers in maintaining healthy dietary practices. This fact is evidenced by at least two provisions of the 1990 amendments. Section 403(q)(1) of the act, which was added by the 1990 amendments, states:

> The Secretary may by regulation require any information required to be placed on the label or labeling by this subparagraph or subparagraph (2)(A) (section 403(q)(1) or (2)(A)) to be highlighted on the label or labeling by larger type, bold type, or contrasting color if the Secretary determines that such highlighting will assist consumers in maintaining healthy dietary practices.

In addition, section 2(b)(1)(A) of the 1990 amendments states that the implementing regulations shall:

> * * * require the required information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.

Consistent with the authority vested in the Secretary (and FDA, by delegation) to determine if specific label information will assist consumers in maintaining healthy dietary practices, the House report accompanying the 1990 amendments directs FDA to consider a variety of format options, including: "information about the recommended daily intake, the use of descriptive terms such as 'high,' 'medium,' and 'low' or use of universal symbols to indicate desirable or undesirable levels of particular nutrients." The report goes on to state: "While the bill does not mandate any particular approach, it does require the Secretary to specify requirements that would permit the consumer to understand the nutrition information pertaining to a particular food in relation to recommended dietary information" (Ref. 16).

B. The Role of the Nutrition Label

The 1990 amendments provide several descriptions of the role of the nutrition label. Section 403(q)(1) of the act, which was added by the 1990 amendments, uses the language "assist consumers in maintaining healthy dietary practices." Section 2(b)(1)(A) of the 1990 amendments uses the language "enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet." In the format proposal, FDA requested comment about how the nutrition label can best assume the information role mandated by the 1990 amendments.

102. A number of comments from food manufacturers, trade associations, health promotion organizations, and consumer groups identified more than one role for the nutrition label in assisting consumers in maintaining healthy dietary practices. One illustrative comment from a health professional organization described two different roles of the food label as: (1) Helping consumers choose appropriate foods and (2) helping consumers to understand the "importance of diet and proper dietary behaviors to a healthy life." Similarly, a comment from a trade association made the distinction between the food label "contributing to the consumer's understanding of the relative significance of the food in the context of a total daily diet" and providing "guidance on how to use information in the food label to make appropriate food choices." Many comments made similar distinctions between the food label helping to place the particular product in the context of a daily diet and the food label providing guidance on how to maintain healthy dietary practices. A number of comments from industry questioned whether the act mandated an explicit educational role for the nutrition label to provide guidance to consumers on how to maintain healthy dietary practices.

Many comments argued that the nutrition label cannot by itself provide all the information important to maintaining healthy dietary practices but reached different conclusions about the relevance of this limitation for the nutrition label format. A number of comments, particularly from industry, pointed out that because of the limited space available on the food label, the nutrition label cannot be expected to adequately convey all the information consumers need to understand the importance of nutrition information in maintaining healthy dietary practices. These comments concluded that the role of the nutrition label should be limited to providing factual, product-specific information, and that the broader dietary guidance role should be reserved to off-label activities of public and private nutrition education programs. These comments asserted that these programs will have sufficient time and space to inform consumers about the concepts of flexibility and personal choice necessary to maintain healthy dietary practices.

Other comments, primarily from consumer organizations and health professional groups, acknowledged the necessity of off-label consumer education to help consumers understand how to use the nutrition information to maintain healthy dietary practices but saw the nutrition label as a useful food selection tool that needs to be integrated with off-label educational programs.

FDA agrees that the nutrition label can and should help consumers make informed food choices, and that it can also contribute to helping consumers maintain healthy dietary practices. The two roles are by no means inconsistent. To help consumers make appropriate food choices contributes undoubtedly to maintaining healthy dietary practices. Among those choices are choices that will assist the consumer in maintaining healthy dietary practices. Maintaining healthy dietary practices, however, is a larger and more complex goal than informing food choices, and one that requires motivation and knowledge of how to combine and balance the many different kinds of foods and eating occasions that constitute a total diet. The 1990 amendments require the agency to take both senses of the possible role of the nutrition label into account in evaluating alternative formats for the nutrition label. However, the agency also agrees that the mandated role of the nutrition label to assist consumers in maintaining healthy dietary practices does not encompass an explicit educational role for the nutrition label to provide dietary guidance to consumers.

The agency believes that the nutrition label format needs to give first consideration to helping consumers make informed food choices by enabling them to both comprehend the nutritional value of the food and to understand its relative significance in the context of the total daily diet as called for in section 2(b)(1)(A) of the 1990 amendments.

The agency's view is that the basic format elements that best serve the mandated role of the nutrition label must be identified and justified on the basis of consumer research. Therefore, the implications of format elements for the use of the nutrition label in assisting consumers to understand the nutritional value of the food and to understand the food in the context of the total daily diet were extensively examined in the agency's format research.

C. Need for Consumer Research

Section 2(b)(1)(A) of the 1990 amendments specifies criteria for an acceptable format for nutrition label information. The operative terms in this section, "readily observe and

comprehend" and "understand its relative significance in the context of a total daily diet," are goals stated in terms of consumer perception and understanding. The consequences of various formats and format elements on consumer perception and understanding can only be measured objectively in terms of behavior (i.e., in terms of how well consumers use a format for a specific task). Formats and format elements can be assessed subjectively by asking consumers or experts to judge the usefulness of various formats. Behavior-based performance measures, however, rather than subjective judgment, are generally accepted as the more reliable and valid way to evaluate the consequences of information displays on consumer perception and understanding.

Major scientific groups (Refs. 1, 65, and 66) urged FDA to subject possible nutrition label formats to consumer testing to objectively determine which formats can be used most effectively by consumers. FDA has placed considerable emphasis on the importance of consumer research in developing a new format for the nutrition label because of this advice and because the techniques of consumer research (surveys, focus groups, experiments, and preference polls) provide the best and perhaps the only possible bases for evaluating alternative nutrition label formats against the consumer perception and understanding criteria specified in the 1990 amendments.

103. A number of comments argued that virtually any nutrition label format, even the current format, can serve to help consumers put foods in the context of a total daily diet depending on the knowledge and understanding of the person reading the label. To the same point, many comments recommended nutrition education activities to supplement the public's understanding of label information. Some comments suggested that nutrition education activities can be an alternative to including one or more information elements, such as a listing of DRV's for certain macronutrients, on the nutrition label.

FDA agrees that each person's knowledge is the necessary context for understanding label information, and that nutrition education activities can be an important complement to the public's understanding of label information. FDA disagrees with the implication sometimes drawn from these facts that FDA is thereby relieved from the burden of adopting a format based in part on the available evidence about what kind of format does the best job at achieving the objectives of the 1990 amendments. Although various considerations bear on the selection of a final nutrition label format, FDA believes that an essential criterion is how well a format conveys information that Congress expected would be provided by the nutrition label. Congress expected that such information would allow people to decide whether, based on the nutrition content of the food, they would want to buy the food (Refs. 67 and 68) and to understand the relative significance of the food in the context of the daily diet (section 2(b)(1)(A) of the 1990 amendments). FDA has sought to measure, and has sought other information that measures, the ability of various formats to achieve these objectives.

D. Consumer Research Submitted as Comments or Referenced in Comments to the Format Proposal

1. Background

The agency reviewed a number of qualitative studies (i.e., five focus groups, seven preference polls) and quantitative studies (i.e., five surveys, seven experiments,) that were submitted as comments or referenced in comments to the format proposal. Consumer research studies about format issues were conducted by FDA, food industry groups, individual food companies, consumer groups, public health organizations, health professionals, and academic researchers.

Much of this work was done in response to FDA requests for additional information, and became available only in comments submitted in response to such requests. For example, FDA published an advance notice of proposed rulemaking in the Federal Register of August 8, 1989 (54 FR 32610), soliciting public comment on a wide range of food labeling issues, including: (1) Whether to revise requirements for nutrition labeling and (2) whether to change the nutrition label format. FDA subsequently held four public hearings on food labeling, the last of which was held in Atlanta, Georgia on December 13, 1989. This last public hearing focused on the nutrition label format.

Additionally, in the Federal Register of May 20, 1991 (56 FR 23072), FDA published a notice announcing the availability of a report on research on alternative nutrition label formats that had been conducted by the agency and inviting comments on the report. The comments on this notice were used in the design and execution of subsequent consumer research conducted by the agency. In the Federal Register of July 1, 1991 (56 FR 29963), FDA announced a plan for a cooperative pilot program with industry to test alternative nutrition label formats that led to several industry sponsored nutrition label format studies. In the Federal Register of April 2, 1992 (57 FR 11277), FDA gave notice of a meeting for industry, including small businesses, at which the agency presented the results of its research studies related to the format and design of the nutrition label, so that comments to the proposed format rule (57 FR 32058) could be as informed as possible.

In a number of instances, FDA staff provided materials, information, support, and consultation on technical aspects of study design and label format to researchers. In addition, FDA received many comments from the general public in response to articles in newspapers and newsletters that solicited consumer opinions in the form of informal polls based on examples of possible nutrition label formats provided by FDA. Table 1 presents a summary of the various research studies received in response to the format proposal and the format research conducted by FDA.

Table 1.—Research Studies Submitted as Comments or Referenced in Comments to Docket Number 91N-0162: Food Labeling: Format of Nutrition Label; Proposal

A. Experimental Studies Submitted

1. Frito-Lay Study (Ref. 74)

a. Design: Between subjects; five format cells.

b. Subjects: Central location test; adults, age 18+ who purchased and/or ate salty snacks in the past 4 weeks, one site, N=750.

c. Formats tested: Same as FDA Study 1 on actual product.

d. Key dependent measures: (1) Scale based on seven questions, three number-of-serving type and four dietary-judgment type; (2) rating of single format based on helpfulness, ease of use and adequacy of information.

e. Assessment/comments: All subjects saw same product. Well controlled study.

2. GMA/NFPA Industry Study (Ref. 71)

a. Design: Between subjects; seven format cells.

b. Subjects: Shopping mall intercept/central location test; adults 18+ who did at least half of household food shopping, quota controls on age, income, education and race; 36 sites, N=5,600.

c. Formats tested: Same as FDA Study 2 on realistic product mockups.

d. Key dependent measures: (1) Product comparison task identical to FDA task, (2) four-product comparison task with specific nutrient probes, (3) dietary judgment task with specific nutrient probes, "if you were trying to get more/limit (NUTRIENT) in your diet, how would you feel about eating this

(FOOD)?"; (4) rating of single format based on adequacy of information and ease of use, (5) self-report of whether subjects knew how to use the DRV information.

e. Assessment/comments: Each subject worked with only one format executed in a variety of ways. Products are confounded with tasks. Format executions are inconsistent across products. Percent DRV formats are sometimes executed with 1, 3, or 4 column displays depending on product, while other formats have either one- or two-column displays. This complex execution for Percent DRV formats may explain why they show poor product comparison performance and are rated more negatively than other formats. Exposure to formats on early tasks may affect responses on later tasks.

3. FDA Format Study 1 (Ref. 69)

a. Design: Repeated measures within subjects; subjects assigned to one row of a 5(formats) X 5(products) Greco-Latin Square.

b. Subjects: Shopping mall intercept/central location test, adults 18+ who did at least half of household food shopping, quota controls on age, income, education and race; eight sites in seven states, N=1,560.

c. Formats tested: Five formats (see format proposal (57 FR 32058)).

d. Key dependent measures: (1) Product comparison task, measured both accuracy and time; (2) preference rating for most liked/least liked format among the five seen in the study, and reasons for choices.

e. Assessment/comments: Formats presented as two dimensional nutrition labels of realistic size but not on packages.

4. FDA Format Study 2 (Ref. 70)

a. Design: Repeated measures within subjects; subjects assigned to one row of one of three 4(formats) X 4(products) Greco-Latin Squares.

b. Subjects: Shopping mall intercept/central location test, adults 18 + who did at least half of household food shopping, no quota controls; 8 sites, N=1,232.

c. Formats tested: seven formats (see format proposal (57 FR 32058)).

d. Key dependent measures: (1) Product comparison task, measured both accuracy and time; (2) judgments of front panel nutrition claims; (3) judgments of nutrients that need to be balanced in the diet after eating product; (4) product healthfulness ratings before and after seeing nutrition label; (5) estimate of how many servings of product needed to meet daily requirement; (6) preference for most liked/least liked format out of the four seen, with stated reasons for choices.

e. Assessment/comments: Formats presented as two dimensional nutrition labels of realistic size but not on packages. All formats not tested on product comparison task. FDA Study 1 data used to impute product comparison performance for Control and Adjective formats. Percent DV/With DRV used as proxy for Percent DV/Without DRV on product comparison task.

5. Geiger Study (Ref 72)

a. Design: Repeated measures within subject; subjects assigned to one of two format sets of either five or six formats.

b. Subjects: Shopping mall intercept/central location test, one site, eligibility requirements not specified, N=243.

c. Formats Tested: 11 formats including versions of Control, Control/DRV, Percent DV/With DRV, Percent DV/Without DRV and versions with adjectives, bar graphs and various combinations of these design features.

d. Dependent measures: (1) Reading accuracy; (2) number-of-serving type questions; (3) perceived usefulness of various formats based on a conjoint measurement procedure-equivalent to preference for large choice set.

e. Assessment/comments: All formats executed on same product. Learning effects across repeated measures may confound format effects on performance measures—the same information is available on all formats. Correct answers to number-of-serving type questions are not clearly defined.

6. Byrd-Bredbenner (Ref. 73)

a. Design: Repeated measures within subject; seven format cells.

b. Subjects: Supermarket intercept, 15 sites in same geographic area, food shoppers 18+, age and education quota controls, health and nutrition-related workers excluded, N=309.

c. Formats tested: seven formats including versions of Percent DV, Adjective, DRV Listing and Control in various combinations.

d. Key dependent measures: (1) Hybrid scale consisting of number-of-serving type questions and product comparison questions; (2) scale consisting of product comparison questions; (3) preference ratings of most helpful/least helpful with stated reasons.

e. Assessment/comments: Products confounded with formats. Order of format presentation partially confounded with amount of information in format.

7. Burton (Ref. 75)

a. Design: Between subjects, 4(formats) X 3(reference values: none/daily/meal) X 2(high/low nutrient values).

b. Subjects: Recruited for a university sponsored project by letter, cross-section of adults, n=500.

c. Formats tested: Versions of Control, Adjective and Percent DV with and without different versions of a DRV listing.

d. Key dependent measures: (1) Product ratings: bad-good, not nutritious/very nutritious, purchase intentions; (2) number-or-serving type measure; (3) rank ordering of formats on quantity and quality of information.

e. Assessment/comments: Well controlled study.

B. Survey Studies Submitted

1. AHA Quantitative Study (Ref. 87)

a. Design: Central location test, details unspecified.

b. Subjects: N=405

c. Relevant format topics: Frequency of reading back of food labels, magnitude estimation of amount of fat in product, awareness of calorie base for fat, knowledge of how to adjust Fat DRV if person eats less than 2,350, likelihood of using information on food label to help reduce fat intake.

d. Assessment/comments: Most of the survey is devoted to issues related to use of the word "healthy" on food labels.

2. CSPI Study (Ref. 95)

a. Design: National probability sample of telephone households.

b. Subjects: N=2,008 adults, assigned to one of eight versions of magnitude estimation question.

c. Relevant format topics: Magnitude estimation of fat amounts in product.

d. Assessment/comments: Fat is the only nutrient considered.

3. American Meat Institute/Roper Study (Ref. 96)

a. Design: Multistage, stratified national probability sample of households, in home interviews.

b. Subjects: N=2,000, males who shared food shopping responsibility equally with other people in the household were selected when possible, otherwise any food shopper available from household was selected.

c. Relevant format topics: Attitudes and behavior regarding food labels, understanding of "RDA" and "DRV."

d. Assessment/comments: A comprehensive survey on food labeling issues.

4. Kellogg Study (Ref. 97)

a. Design: Not a probability sample, subjects call toll-free number for some product-specific reason.

b. Subjects: N=272, unknown characteristics.

c. Relevant format topics: Understanding of DRV, knowledge of how to adjust DRV for varying calorie needs, rated helpfulness of DRV information.

d. Assessment/comments: Sample characteristics are unknown.

5. GMA/NFPA Industry Study (Ref. 71)

a. Design: Central location test (see description above). Questions that were asked before subjects saw any food label formats or questions that did not involve use of formats are considered survey questions.

b. Subjects: See description above.

c. Relevant format topics: Frequency of reading food labels, frequency of various uses of food label information, understanding of DRV concept.

d. Assessment/comments: Large sample, detailed questions about possible label uses, DRV questions are asked after respondents have been exposed to particular food label formats, subjects exposed to Control format are not asked DRV questions, only 4,790 respondents are asked the DRV questions.

6. National Consumers League (Ref. 98)

a. Design: National probability sample of telephone households.

b. Subjects: N=1,139, 1,007 who read nutrition labels at least sometimes completed full questionnaire.

c. Relevant format topics: Frequency of reading food labels, reasons for reading food labels.

d. Assessment/comments: Most of the survey is devoted to issues related to use of the word "healthy" on food labels.

C. Focus Group Studies Submitted

1. FDA Study 1 (Ref. 85).
2. FDA Study 2 (Ref. 86)
3. Geiger (Ref. 72).

4. AHA Study 1 (Ref. 87).
5. AHA Study 2 (Ref. 87).

D. Informal Preference Polls

1. COSTCO Newsletter (Ref. 88).
2. Washington Post (Ref. 89).
3. Nutrition Action Newsletter (Ref. 90).
4. USA Today (Ref. 91).
5. Daily Herald (Ref. 92).
6. Atlanta Constitution (Ref. 92).
7. New York Times (Ref. 94).

The studies vary greatly in the issues addressed, methodology, sampling, types of nutrition formats studied, types of evaluation measures used to assess formats, and degree of control used in the research. Many of the consumer studies submitted or referenced in comments about nutrition label formats were based on recently conducted research studies and on interpretations that had not yet appeared in the scientific literature.

FDA considers the findings of research studies submitted in comments to constitute an important separate class of comments for purposes of evaluating various nutrition label formats. Research findings based on specific measures need to be considered as distinct from conclusions based on combining findings across several different measures. Research findings also need to be considered in the context of a body of similar research to evaluate consistency in the pattern of effects across studies (e.g., reliability) and consistency in the identification of important controlling factors (e.g., validity). Comments offering conclusions based on research findings are discussed below in the relevant sections. In this section, the research findings themselves are discussed in terms of methodologies used, types of evaluation measures, consistency of effects across studies, the strength of effects, and implications for the design of the nutrition label format. The agency believes that to clarify its reasons for decisions about the nutrition label format that rely on research findings, it is necessary to articulate its understanding of the relevance, reliability, and relative significance of the various research findings.

To facilitate discussion of research findings, FDA considers it useful to distinguish among three primary types of evaluation measures used to assess nutrition label formats: Performance measures based on label use tasks, consumer preference judgments of various formats, and questions about consumer understanding of selected elements of possible nutrition labels, such as Daily Values (DV's) (called in the format proposal DRV's). Each type of evaluation measure has a different relevance to the selection of an improved format for the nutrition label.

2. Performance Measures Based on Specific Label Use Tasks

As a rule, different tasks and performance measures have been used to evaluate how well a format meets the different primary performance objectives specified in the 1990 amendments. These objectives as discussed in section V.B. of this document are: (1) To enable consumers to readily observe the nutrition information, (2) to enable consumers to comprehend the nutrition content of the particular product, and (3) to enable consumers to understand the relative significance of product nutrition information in the context of a total daily diet. (Objectives (1) and (2) are closely linked for testing purposes and will be frequently discussed together in this document). In the research reviewed by FDA, measures to evaluate formats in relation to these objectives have appeared only in experimental studies, probably because this type of measure requires a substantial degree of control over the conditions under which such measurements are taken.

For performance measures based on specific label use tasks, respondents are asked to perform a task using the information from a nutrition label. The task is constructed so that a performance measure can be defined (e.g., speed, accuracy, likelihood of giving appropriate response), indicating the degree to which the respondent can readily observe and comprehend product label nutrition information or "understand its relative significance in the context of a total daily diet."

a. *Product comparison tasks.* The type of tasks most commonly used to evaluate formats with respect to the objective of enabling consumers to readily observe and comprehend product nutrition information were product comparison tasks. These tasks presented respondents with two or more product labels simultaneously and asked them to engage in a relatively simple information search (e.g., find differences between the products, identify which product is higher or lower in a certain nutrient) where answers were scored correct/ incorrect and timed.

104. The product comparison type of task was employed by the two FDA format studies (Refs. 69 and 70) and by three other studies submitted in comments to the format proposal (Refs. 71, 72, and 73). One study (Ref. 72) simply asked respondents to read certain information from a product label and scored whether they gave the correct answer.

Performance levels on product comparison tasks were high, with most of these studies finding accuracy levels of 70–90 percent correct.

The product comparison type of task tended to produce consistent format effects. The most consistent finding, replicated in all studies, was that simple formats that have clean, nonredundant displays of nutrient information per serving worked best in this kind of task. Because it has the least amount of information, the current format performed well on product comparison tasks. But several studies (Refs. 70, 72, and 73) found that other ways to display nutrient information per serving, using either g/mg amounts or percent DV declarations, were equally effective when the format was executed with a clean and uncluttered appearance.

Multiple column nutrient information per serving displays were much more difficult than single column displays for consumers to use for product comparisons. Several studies (Refs. 69, 70, and 71) found that product comparison performance dropped sharply for labels using the "as packaged/as prepared" dual declaration format. Both the major industry format study and FDA's first experimental format study found that declaring nutrient amounts per serving in adjacent columns of g/mg amounts and percent DV led consumers to make more mistakes and to take longer on the product comparison type of task. FDA's second experimental study, however, showed that when g/mg nutrient amount information was placed immediately next to the nutrient name in an unordered array, and percents were placed in a column array, the adverse effects on product comparison performance disappeared.

Most studies found that the addition to the label of a listing of the DV's for some or all nutrients did not greatly affect the ability of consumers to use the nutrition label for product comparison purposes. Similarly, the use of a highlighting or grouping scheme on the nutrition label neither impaired or improved respondents' performance of product comparison tasks.

The use of adjectives on the nutrition label did appear to cause respondents to miss nutrient differences between products when the adjectives used to describe the nutrient for each product were the same. Several studies (Refs. 69, 71, and 73) found that formats using adjectives did not perform as well as formats without adjectives on product comparison tasks.

FDA considers this product comparison type of performance measure to be a valid and reliable indicator of how well a given format's information can be readily observed and comprehended. The major conclusions that FDA drew from this research are that: (1) Clean, uncluttered nutrition label formats work best, (2) dual column declarations of nutrition information per serving make it harder for consumers to readily observe and comprehend nutrition information, and (3) adjective formats lead consumers to miss quantitative differences between products when different nutrient levels are characterized by the same adjective. The formats that FDA tested (Refs. 69 and 70) that were effective on product comparison tasks included the CONTROL, CONTROL/DRV, PERCENT, PERCENT/DRV, GROUPING, and HIGHLIGHTING.

b. *Dietary judgment tasks.* A different type of task was used to evaluate formats with respect to the second performance criterion, enabling consumers to understand the relative significance of product nutrition information in the context of a total daily diet. Most of the dietary judgment tasks presented respondents with one product label at a time and asked them to make a dietary judgment about the product (e.g., how likely they would be to eat the product if they were trying to limit/increase a specific nutrient in their diet; what nutrients they should try to cut back on/get more of in other foods they eat that day after eating three servings of the product; whether they consider a high/low nutrient claim for the product to be correct/incorrect). Respondent dietary judgments were then scored as correct/incorrect or appropriate/ inappropriate.

105. This type of dietary judgment task was used in the second FDA format study (Ref. 70) and two industry studies (Refs. 71 and 74). Measures based on dietary judgment tasks produced consistent format effects. The most consistent finding, replicated by all these studies, was that providing adjectives to describe nutrient levels per serving or declaring nutrient levels per serving as percentages of the nutrient DV helped respondents to make correct and appropriate dietary judgments relative to formats where nutrient levels were declared in g/mg amounts. These studies found that other nutrition label format design elements, such as inclusion of a listing of DV's, highlighting, or grouping nutrients on the label, did not improve performance on these types of dietary judgment tasks.

A consistent finding across two studies (Refs. 70 and 71) was that percent DV declaration had a moderating effect on dietary judgments relative to formats without percent DV declaration. Respondents were less likely to consider a given nutrient level unacceptably high or to say that they would avoid the food entirely because of its nutrient levels when the amount per serving information was presented as percent DV.

Performance levels on this type of dietary judgment task ranged from 45 to 80 percent correct across studies.

FDA considers that how well consumers are able to judge the magnitude of specific nutrient levels as measured by this type of dietary judgment task is a valid and reliable indicator of how effectively a given format helps consumers to understand the significance of product nutrition information in the context of a total daily diet. The major conclusions that FDA drew from this research are that: (1) The declaration of nutrient amount information as percentages of DV or the placement of adjectival descriptors next to the nutrient amount information are both effective ways to help consumers understand the significance of product nutrition information in the context of a total daily diet, (2) percent DV declarations moderate dietary judgments about a food, and (3) other format elements, such as a list of DRV's for important macronutrients, highlighting, or grouping nutrients according to dietary guidelines, do not help consumers make better dietary judgments. The formats that FDA tested that were effective on this kind of task were the PERCENT DV, PERCENT DV/ DRV, and ADJECTIVE.

106. Several comments on the format proposal recognized that the ADJECTIVE and PERCENT DV formats have benefits to consumers for dietary judgment types of tasks. They argued that both of these format design elements correct a common tendency to misjudge the magnitude of specific nutrient levels when they are given in g/mg amounts. The comments asserted that consumers make such errors because they tend to use a single numeric standard to estimate magnitude.

The comments stated that when nutrient amounts per serving are declared in g/mg amounts, the numbers appearing on the label cannot be used as guides to estimate the relative magnitude of nutrient levels in the product. These comments continued: A reasonable reference standard for one nutrient is quite different from the reasonable reference standard for another nutrient. For example, 5 g is a high level for saturated fat, but 100 mg is a low level for sodium. Because the nutrients on the label vary greatly in terms of reference standards, the common tendency of consumers to use a single numeric standard when nutrient amounts are declared in g/mg units leads to flawed dietary judgments.

Percent DV declarations, by contrast, display nutrient amounts per serving in comparable units, and this type of display facilitates the appropriate use of a common numeric reference standard for all nutrients. Adjectival descriptors also serve to translate nutrient levels into comparable units by describing disparate nutrient amounts per serving in easily understood ordinary language terms.

FDA agrees that this reasoning provides a plausible explanation of the research finding that percent DV declarations and adjectives help consumers make more appropriate magnitude estimates of nutrient levels in a product.

c. *Number-of-servings calculation tasks.* Some studies employed a one-product task where respondents were asked to estimate how many servings of the product were needed to meet a daily requirement for a certain nutrient. FDA considers this number-of-servings type task to be relevant to consumers' abilities to use product information for meal planning and quantitative dietary management purposes that are properly considered part of placing the product in the context of a total daily diet.

107. This type of performance measure was used in the second FDA format study (Ref. 70) and in four other studies submitted in comments to the format proposal (Refs. 71, 72, 73, and 75). The number-of-servings type of performance measure did not show consistent format effects across studies, possibly because of variations in stimuli and procedures between studies.

One well controlled study (Ref. 70) found that the current nutrition label format was the worst format on this type of performance task, but a less well-controlled study (Ref. 72) found that the current nutrition label was among the best formats on the number-of-servings type of task. One study (Ref. 70) that asked for a numerical answer found that PERCENT DV formats performed almost as well as the best formats on this measure, but another study (Ref. 71) that asked the respondent to articulate the computation process found that PERCENT DV formats were much worse than the best performing formats.

In all studies, performance levels on the number-of-servings calculation task were noticeably lower than for the kinds of tasks discussed above. Performance levels ranged from 10 to 50 percent

correct across studies. All studies found that this type of task was highly sensitive to respondents' education levels and arithmetic sophistication.

FDA considers this type of performance measure to be relevant to how well a given format serves to place product information into the context of the total daily diet, particularly with respect to the role played by including a listing of the DV's on the label. However, a lack of consistent results across studies and low levels of consumer competence to perform the required computations suggests that this measure be considered of secondary importance for evaluating nutrition label formats.

d. *Single product rating tasks.* Some studies showed respondents a product label in a given format and asked them to rate the product on healthfulness or to rate purchase intentions toward the product. The measure compared ratings made after seeing front panel information consisting of nutrient or health claims and ratings made after being exposed to product information on the nutrition label.

108. This type of measure was used in the second FDA format study (Ref. 70) and in one other study submitted as a comment (Ref. 75). Both studies showed a consistent effect: Consumers relied more heavily on back panel than front panel nutrition information when making general judgments about a product. They become more negative toward the product after seeing the back panel nutrition information relative to an initial impression based on front panel information alone. Neither study found that the format of the nutrition label had much effect on this type of measure.

Because it appeared insensitive to format effects, FDA does not consider this type of single product rating comparison to be an important consideration for evaluating how well a format meets the criteria specified by the 1990 amendments.

e. *Measures based on two or more types of tasks.* Some studies defined scales that combined more than one type of performance measure, such as product comparison questions and number-of-servings questions. Where possible, FDA considered these scales to represent only one of the composite measures, the one they most resembled, so that they could be discussed in the appropriate sections above. Such measures were evaluated by comparing results with other measures from the same study and with measures from other studies which utilized similar elements.

109. One study (Ref. 73) submitted as a comment to the format proposal reported results for a scale based on product comparison questions and number-of-servings questions (discussed in section V.D.2.a. and V.D.2.c. of this document). In this instance, the results showed that format effects on the scale were quite different from format effects on a different scale in the same study which was clearly made up of product comparison questions. Therefore, FDA considered this scale to be an example of the number-of-servings type of performance measure.

110. Another study (Ref. 74) reported results for a scale based both on number-of-servings type questions and dietary judgment type questions. Examination of the results for this scale showed that the performance findings most resembled findings from other studies based on dietary judgment questions. Therefore, FDA considered this scale to be an example of a dietary judgment performance measure.

3. Preference Judgment Measures

In the research reviewed by FDA, consumer preference judgments of various formats were primarily choice measures based on a direct or implied question to respondents about which of some given set of possible examples of nutrition label formats would be most helpful, most useful, or would work best for consumers. Measures of this type occurred in all research modalities and were often the principal measures in focus group and informal preference poll research. Because respondents were typically asked to express a relative preference, the set of choices presented to respondents influenced the selection process and thereby constitutes an important limitation on the validity of this type of measure.

Preference measures are not of the same order as behavioral measures, which address how well a given format performs in a given label use situation. Stated preferences for formats reflect a respondent's implicit theory about what kind of format generally works best. Judgment in these instances is abstracted from any particular product or any particular label use situation.

An extensive scientific literature review suggests that untested theories about the amount and type of information that are most useful to consumers are sometimes wrong (Refs. 76, 77, 78, 79, and 80). In particular, studies of preference for nutrition information have generally shown that consumers prefer the largest amount of information offered (Refs. 81, 82, and 83) but perform best with limited amounts of information specifically related to the task (Ref. 84).

a. *Experimental studies.* 111. Both FDA format studies and three other studies submitted as comments on the format proposal employed relative choice measures of format preference based on choosing a most preferred or least preferred format from the set of formats being evaluated in the study (Refs. 69, 70, 72, 73, and 75). Direct comparisons between studies are difficult because no two studies used exactly the same choice set of formats.

Despite differences between studies, there were basic consistencies in the pattern of preference results across studies. In every case, respondents tended to prefer the format with the most information in the choice set and tended to dislike formats with the least information in the choice set. The addition of a listing of DV's to the nutrition label for some or all of the nutrients was seen as more informative, and was always highly preferred, over alternatives lacking a listing of DV's. All of the studies that asked respondents to give reasons for their selection of a certain format (Refs. 69, 70, and 73) found that providing more information was one of the most common reasons given.

Other format features in addition to a DV list that were viewed positively relative to formats without such features were adjectives, bar graphs, highlighting, and, to a lesser extent, grouping and declaring nutrient amount per serving as percent of a DV.

All studies that included both performance and relative preference measures (Refs. 69, 70, 72, 73, and 75) found little or no consistency in the pattern of format results across performance and preference measures. For studies that included performance measures of the product comparison type (Refs. 69, 70, 72, and 73), the common finding was an inverse ordering between formats that were preferred and formats that performed well on this type of task.

Two experimental studies (Refs. 71 and 74) varied formats between subjects such that each subject saw a single format and rated only that format. One study (Ref. 74) asked respondents to rate the helpfulness, ease of use, and adequacy of information of the single format. The other study (Ref. 71) asked respondents to rate ease of use and adequacy of information. Neither study found that respondents gave the highest ratings to the format with the most information. A format similar to the current format that did not include a listing of DV's for some nutrients was

among the highest rated formats in both studies.

In one study, respondents expressed suspicion toward formats using adjectives (which provided relatively more information), apparently because they felt the company was deciding how and when the adjectives were used. In the other study, respondents were more negative toward formats using percent DV declarations. However, in the latter study, the PERCENT DV formats were executed with extra columns of information, so that a single nutrition label had as many as four numeric columns. Respondents in this study considered the PERCENT DV with DV list format to provide more information than was desirable.

FDA is convinced by these results that consumer preferences for various nutrition label formats were very sensitive both to the set of formats the respondent was asked to compare and to the particular methodology used to measure preference. Moreover, preferences did not correspond to objective measures of format performance. This lack of correspondence raises serious questions about the underlying validity of such measures, even though respondents were asked to base preferences on which formats they thought would work best. Given these methodological problems and the apparent lack of validity, FDA considers preference measures to be of secondary importance for decisions about the nutrition label format.

b. *Focus group studies.* Research using focus group discussions about nutrition label issues elicited preferences for various kinds of format design elements by showing the group examples of different formats and asking them to discuss their reactions.

112. The two FDA focus group studies and three other focus group studies submitted as comments on the format proposal discussed the groups' reactions to various format elements (Refs. 72, 85, 86, and 87). In every study, respondents indicated strongly that they would like more information on the nutrition label, particularly with respect to helping them understand whether given nutrient levels could be considered high or low. A listing of DV's for some or all nutrients was always among the most preferred additions to the nutrition label. Other format design features favorably mentioned in some or all of the focus group studies were bar graphs, percent DV declarations, and percent of calorie declaration for macronutrients. Other features, such as adjectives or pie charts, received some favorable mentions, but fewer than the above features.

Respondents in focus group discussions often stated they would like to see a simpler and easier to use label than the current nutrition label. One focus group study (Ref. 85) asked respondents to consider in detail how they might use certain format features and found that pie charts and bar graphs were seen to be hard to use. Formats using adjectives were sometimes criticized because of suspicion about who decided how and when the adjectives were to be used.

FDA considers the focus group preference results to be consistent with the preference results of experimental studies.

c. *Informal preference polls.* Many comments from the general public were generated by articles in newspapers and newsletters that solicited consumer opinions in the form of informal polls based on examples of possible nutrition label formats. FDA considers such articles to be informal preference polls and therefore a form of research. FDA recognizes limitations on the validity of such research: respondents are highly self selected, no background information about respondents is available, responses are influenced by the accompanying news article, and responses depend on the choice set of formats given in the article. FDA has tried to identify the actual articles and the choice sets of formats presented to readers in interpreting these comments.

113. FDA identified seven informal preference polls that generated comments on the format proposal (Refs. 88, 89, 90, 91, 92, 93, and 94). One informal preference poll conducted by a consumer buying club in its newsletter (Ref. 88) asked consumers to rate their preferences toward three formats taken from FDA's research formats: ADJECTIVE, HIGHLIGHTING, and GROUPING. Over 400 responses were received. Seventy percent of the responses favored the ADJECTIVE format.

A midwest newspaper (Ref. 92) published examples of all seven formats used in FDA's format study 2 and asked readers to indicate which one they preferred. Approximately 100 responses were received. Sixty-five percent of the responses favored the ADJECTIVE format.

A consumer group newsletter (Ref. 90) published an example of a recommended format that included adjectives and a listing of DV's for macronutrients and asked readers to respond to FDA in support of the recommended format. Approximately 130 responses were received in support of such a format.

A nationally distributed newspaper and a regional newspaper (Refs. 91 and 93) published an example of a graphically enhanced PERCENT DV with DRV format (Appendix C from the format proposal). Approximately 40 responses were received. Sixty-five percent of the responses disapproved of the published format.

A major eastern newspaper (Ref. 89) published examples of four formats taken from the format proposal; PERCENT DV with DRV (Appendix C), CONTROL with DRV Ranges (Appendix E), CONTROL with Sex-Specific DRV (Appendix E), and CONTROL with Dietary Guidance (Appendix F). It asked readers to respond to FDA with their preferences, and approximately 450 responses were received. Two formats (CONTROL with DRV ranges and CONTROL with Sex-Specific DRV) were most preferred overall, each by approximately 35 percent of respondents.

FDA considers the results of informal opinion polls to be consistent with the preference results observed in experimental studies and focus groups. Most consumers say they prefer the format with the most information out of the set of formats they are asked to evaluate. However, FDA is not convinced that formats that have more information are necessarily the formats that best meet the criteria specified in section 2(b)(1)(A) of the 1990 amendments.

4. *Measures of consumer understanding.* Some of the research submitted or referenced in comments to the nutrition label format proposal consisted of survey questions about consumer understanding of various elements of proposed nutrition labels (Refs. 71, 87, 95, 96, 97, and 98). Some of these questions addressed topics such as whether consumers use nutrition labels and, if so, for what purposes. Other questions addressed the concept of a DV: how consumers understand it, whether they can use it, how they might use it, or whether they are aware of it. A third type of question about consumer use of format elements was how consumers assign magnitude estimates to nutrient levels.

FDA considers this kind of research about format elements to provide an important context for the decision about an improved nutrition label format. Although it does not directly address the format objectives specified by the 1990 amendments, this research does provide some insight on how consumers understand and use the nutrition label.

a. *Survey questions about consumer use of nutrition labels.* 114. Four surveys submitted as comments on the format proposal (Refs. 71, 87, 96, and 98) asked questions about how often respondents read nutrition labels and ingredient information on food packages. These studies consistently found that approximately 70 to 80 percent of consumers report that they read this information almost always, often, or sometimes. These figures are consistent with a number of other surveys (Refs. 99 and 100) that asked similar questions.

In several studies submitted as comments, consumers were asked about specific purposes for reading nutrition labels. One study (Ref. 71), which asked 5,600 respondents detailed questions about possible label uses, found that the most common purposes for reading nutrition labels were: To calculate how high or low the product is in certain nutrients, to get a general idea of nutritional content, to compare different types of food products, and to help determine brand choices. The least common purposes for reading nutrition labels were to help in meal planning or to figure out how much of the product you should eat.

Other submitted studies reported results consistent with these findings. Specifically, one study (Ref. 96) found that only 7 percent of those who read nutrition labels did so "to help in planning a specific meal." Another study (Ref. 87) found that 83 percent of respondents would be very or somewhat likely to use information on the food label to help reduce fat intake.

FDA considers the results of these questions about consumer uses of nutrition labels to show that consumers are already using nutrition labels for purposes that are consistent with the format objectives of the 1990 amendments. Indeed, the two most common types of reported uses: (1) To evaluate nutrition characteristics of single products and (2) to assist in making choices between products, correspond well to the two primary criteria specified for formats in the 1990 amendments. The agency believes that the introduction of a revised nutrition label and accompanying educational activities will have a significant impact on use of the nutrition label for these purposes in the future.

b. *Questions about Daily Values.* 115. FDA received a number of studies as comments on the format proposal that asked questions related to consumer understanding of the concept of DV's. One study (Ref. 96) reported that 22 percent of respondents said that they were familiar with the term "Daily Reference Value" or "DRV" compared with 65 percent who said they were familiar with the term "Recommended Daily Allowance" or "RDA". Two studies (Refs. 87 and 97) found that only about half of respondents could correctly identify (i.e., read from the label) the DRV for a specific nutrient.

One study (Ref. 71) found that approximately two-thirds of all respondents considered the DRV to be appropriate for "everyone" or "most people." The same study found that 71 percent of respondents considered the DRV to apply to them personally. However, two other studies (Refs. 87 and 97) found that approximately two-thirds of all respondents stated that they understood that a DRV based on 2,350 calories would be high for a person who ate less than a 2,350 calorie diet.

One study (Ref. 87) showed respondents a label with a listing of DRV information and a footnote stating that DRV's were based on a 2,350 calorie diet. It found that more than half of all respondents could not correctly answer a question about the number of calories on which the DRV was based.

FDA considers results of questions about consumer use and understanding of DRV's to be tentative and likely to change because the public's exposure to the concept has been very limited, and educational activities to explain the concept have not been undertaken. The experimental format research (see section V.D.2. of this document) did not find that listing the DRV's on the nutrition label had much effect in a positive or negative direction on label uses that required evaluation or comparison of specific products, although it did improve calculation of number of servings needed to meet a daily requirement. None of this research, however, evaluated the impact of listing the DRV's on the food label on consumers' overall dietary management behavior, either alone or in conjunction with possible education initiatives.

FDA concludes that in the absence of reliable guidance from research findings, it has to rely on other comments to evaluate the potential value of listing the DRV's on the food label as a guide to better overall dietary management behavior.

c. *Magnitude estimation of specific nutrient amounts.* 116. Two studies submitted as comments addressed the issue of consumers' ability to make correct magnitude judgments about the level of a nutrient when told the amount. One study (Ref. 87) found that over one-half of all respondents considered 13 g of fat to be a large amount of fat.

A more detailed study (Ref. 95) asked respondents to estimate whether a given amount of fat in a product would be considered a low, medium, or high amount of fat. The amount of fat was systematically manipulated to determine how respondents assigned magnitudes across a range of values (7, 13, 20, and 33 g of fat). At the lowest level (7 g of fat per serving), approximately 20 percent of respondents considered the product to be high in fat. At the highest level (33 g of fat per serving), approximately 50 percent of respondents considered the product to be high in fat. The same magnitude estimation results were found when the amount of fat was expressed as a percentage of the DRV for fat. When amount of fat was expressed as a percentage of the DRV for fat, however, respondents were slightly less likely to give a "don't know/can't tell" answer than they were when fat amounts were expressed in g. Also, respondents were more likely to give a "medium" answer when the level of fat was expressed as 50 percent of the DRV instead of 33 g.

FDA considers these findings to show that consumers estimate nutrient level magnitudes of fat in a reasonable manner. However, the agency also concludes that a tendency exists for some consumers to see low fat levels as too high and other consumers to see high fat levels as less than high. More research is necessary to determine whether these results might be due to response biases inherent in the particular kinds of questions being used, or whether they reflect the different attitudes toward fat in the general population. FDA considers these findings to be consistent with the results of magnitude estimation measures used in experimental studies (see section V.D.2. of this document). FDA is convinced that an important consideration for decisions about the nutrition label format is whether the format helps consumers make appropriate magnitude estimations of nutrient levels in the product.

E. Criteria to Use in Judging Nutrition Labeling Format

Section 2(b)(1)(A) of the 1990 amendments specifies the requirements that an appropriate nutrition label format must meet (see Section V.C. of this document), but it does not specify how to weight these requirements with respect to various possible label uses or how to weight the various measures intended to evaluate alternate formats against the requirements. The 1990 amendments also do not specify how to balance the benefits of a revised

nutrition label against the practical limitations of small package sizes and the interests of many consumers, particularly older and less educated consumers, to have a highly legible label. In the format proposal, FDA requested comment on the criteria to use in judging nutrition label formats.

117. Most comments strongly supported the view expressed in the format proposal that a simple, uncluttered nutrition label is highly desirable. Comments from consumer groups and health professional organizations emphasized the benefits of a simple and uncluttered label for older and less educated consumers. Comments from food manufacturers and industry associations emphasized in addition that a simple, uncluttered format would allow greater flexibility to accommodate packaging constraints. Consumer research conducted by industry and by FDA demonstrated that simpler, less cluttered label formats help consumers to make comparisons between products.

FDA is convinced by the research results and these comments that a simple and uncluttered format is the best way for information on the nutrition label to be "readily observed and comprehended," as called for by the 1990 amendments. Accordingly, FDA is taking the steps discussed below to minimize the amount of information and the number of columns used on the nutrition label.

118. A number of comments from food manufacturers, consumer groups and health professional groups called for consistent label formats for both FDA and USDA regulated food products. The comments identified many benefits of having a uniform format for all food products including: (1) Making it easier for consumers to compare different kinds of products, (2) making it easier for consumers to become familiar with, and to learn how to use, the new labels, and (3) reducing the likelihood of consumer confusion because of apparent inconsistencies between different food labels.

FDA agrees that consistency between FDA and USDA regulated food labels should be an important consideration in decisions about the nutrition label format.

119. A number of comments from food manufacturers, consumer groups, and health professional groups argued that decisions about the nutrition label format should be informed by consumer testing, and that the agency should not propose formats that have not been tested. For the most part, these comments were directed at three label formats included in the format proposal that presented more elaborate listings of DRV's and more extensive educational footnotes than any of the formats included in FDA's previous nutrition label format research.

The agency agrees with the comments that emphasized the importance of consumer research in informing decisions about the nutrition label format. However, the agency is satisfied that most of the format elements that have been suggested for a revised nutrition label format have been sufficiently tested to permit research-based conclusions about their effects on consumer comprehension and label use behavior. The agency's view is that format elements that were less well tested, such as those suggested by the three formats described above, do not introduce sufficiently novel elements to the nutrition label to require independent testing. Information about the performance characteristics of more cluttered labels, listings of DV's, and elaborate footnotes is already available from extant research and can be extrapolated to estimate the performance characteristics of these particular formats as well.

120. The agency received a number of comments about the relative importance that should be assigned to product comparison versus dietary judgment measures of format performance in making decisions about nutrition label format. Many comments, primarily from food manufacturers and trade associations, argued that enabling consumers to compare the nutritional characteristics of food products is the fundamental use for the nutrition label and concluded that label formats should be evaluated mainly on this basis. Other comments, primarily from consumer groups and health professional organizations, gave more emphasis to the importance of the food label for helping consumers to make dietary judgments about the nutritional value of the food product that involve placing the product in the context of a total daily diet. These comments concluded that decisions about a nutrition label format need to take account of both product comparison measures and dietary judgment measures. The research on the reported frequency of different kinds of nutrition label uses showed that comparing products and assessing nutritional value are the two most important consumer uses of the nutrition label and are considered about equally important by consumers.

FDA is convinced by the research and by these comments that decisions about a nutrition label format should consider both types of label uses and evaluation measures rather than only one. Use of the nutrition label to compare products is dependent on the consumer's ability to comprehend the nutrition information, and use of the nutrition label to assess nutritional value is dependent on the consumer's ability both to comprehend the information and to understand its significance in the context of the total daily diet. Accordingly, FDA has considered these primary nutrition label uses in making decisions about the nutrition label format.

121. One comment from a health professional argued that consumer preferences for nutrition label formats should be considered as important as the ability of a format to achieve the format objectives specified in the 1990 amendments because a format that is more preferred will be more likely to be used by consumers.

FDA is not aware of any data that support the assertion that a more preferred label format will be more likely to be read. The agency's view is that people read the nutrition label because they are interested in what it says, not because they have an impulse to read the label based on its appearance. Actual ease of use, that is, the ease with which a consumer can extract needed information from the nutrition label, rather than preference for a format, is likely to influence the probability of reading a nutrition label. The consumer research shows that consumer preference for different label formats is, if anything, negatively related to actual ease of use (see sections V.D.2. and V.D.3. of this document). Therefore, FDA does not agree that preference should be considered as important as performance criteria for decisions about nutrition label formats.

122. One comment from a consumer organization argued that label uses should be weighted according to the likelihood that consumers engage in such uses. The comment recommended that less importance be given to label uses that assume that consumers will add up their daily totals of fat, saturated fat, or other nutrients because relatively few consumers are likely to engage in such difficult and burdensome monitoring. The comment suggested that many more people are interested in making qualitative judgments about individual foods, such as "is this food high or low in fat?" and recommended that dietary judgment measures assessing this aspect of label use be given the most weight in decisions about the nutrition label format.

Consistent with the comment, the consumer research did not show quantitative monitoring of dietary intake to be a common label use behavior.

However, it also did not show that making qualitative judgments about a food is the only important use of the nutrition label (see comment 114 of this document). FDA is convinced by the research that helping consumers to make qualitative judgments should be an important, but not overriding, consideration in making a decision about the nutrition label format. Other evidence shows that consumers use the nutrition label to compare products and to assess a product's nutritional value. Accordingly, FDA has considered facilitating qualitative judgments as one of the dietary judgment factors important for evaluating the various proposed formats.

F. FDA's Tentative View

In the format proposal, FDA presented its tentative conclusions about the elements that it will include in the final nutrition format and requested comments about them. The agency listed the following four elements as those that were likely to be included in the final nutrition format:

(1) The information must be presented in a manner that is simple and minimizes clutter.

(2) The information must be presented in tabular fashion, although perhaps enhanced by other graphic devices to provide rapid access to, and greater visibility of, key nutrition information.

(3) The nutrition information display must include either a listing of the quantitative amount of each nutrient, in absolute terms (e.g., g), or a listing of the amount as a percent of the proposed RDI or DRV, or both.

(4) Nutrient information must be linked to the dietary guidance that is considered important to public health.

123. Comments mentioning the first three elements were unanimously supportive. Comments mentioning the fourth element were generally supportive, although a number of comments argued either that the nutrition label cannot or should not be the primary vehicle for providing general dietary recommendations, or that educational materials should not appear on the food label at all.

The agency disagrees with statements that the nutrition label should not play a role in educating consumers. FDA is convinced that the nutrition label is an important source of basic information for consumers, and that the 1990 amendments require that the label facilitate consumer education. The agency's view of the educational role of the nutrition label is elaborated in section V.B. of this document.

However, the agency does agree that the nutrition label cannot be the primary vehicle for providing general dietary recommendations. Accordingly, as discussed later in this document, FDA, USDA, health professional organizations, and the food industry are developing a comprehensive consumer education program that will ease the transition to the revised nutrition label and help consumers to use the label to make well-informed dietary choices.

FDA points out that under the act, the requirement that nutrition information be linked to dietary recommendations need not require presentation of dietary guidance on the label. The House report that accompanied the 1990 amendments states, "While the bill does not mandate any particular approach, it does require the Secretary to specify requirements that would permit the consumer to understand the nutrition information pertaining to a particular food in relation to recommended dietary information" (Ref. 16). The declaration of nutrient amounts as percent DV provides such information. For the nutrient in the food for which a DV has been established, the percent DV advises the consumer how much of the recommended intake of that nutrient is provided by the food. Seen in this way, a requirement that nutrition information be linked to dietary guidance plays a greater role in describing the food than in presenting educational material.

G. The Format and Format Elements

FDA received approximately 1,000 responses to the format proposal and to a public meeting, notice of which was given in the *Federal Register* of July 23, 1992. Responses were received from consumers, health professionals, trade and retail associations, State and local governments, foreign governments, professional societies, consumer advocacy organizations, industry, and universities. Many of the comments selectively responded to issues of particular concern to the individual or organization commenting, but a large number included a reference to the specific formats favored or opposed.

1. Titles and Terminology

a. *Title for the nutrition label.* 124. A number of comments addressed the issue of the title for the nutrition label. The majority of comments supported retaining the current label heading "Nutrition Information per Serving." Comments suggested that consumers are familiar with this heading, and that the title is descriptive of the information that follows. One comment opposed the introduction of any new title because new terms are confusing. Another comment expressed concern that new titles have not been proposed or tested. Other comments suggested such terms as "Nutrition Information," "Nutrient Information," and "Nutrient Facts."

FDA acknowledges that the current title is descriptive and familiar to consumers. However, the agency also notes that the current title requires more space than several alternatives that are equally descriptive. The agency has concluded that modifying one of the suggested alternatives to "Nutrition Facts" yields a term that will clearly describe the information declared on the nutrition label. This more succinct term also allows the title of the nutrition label to use a larger typeface in the same space so that the nutrition label will be more readily noticed, and thus, more readily observed by consumers. Accordingly, in § 101.9(d), the agency is requiring that the term "Nutrition Facts" instead of "Nutrition Information per Serving," be presented as the heading of the nutrition information.

b. *Terminology for subcomponents of nutrients.* In its format proposal (57 FR 32070 at 32071), FDA solicited comment on certain format elements not addressed by research studies. The agency requested comment on what terminology and graphic elements would most effectively distinguish subcomponents of nutrients from the declaration of the total amount of the nutrient and improve their visibility in the nutrition label display.

i. Subcomponents of fat and of carbohydrate. 125. The majority of comments supported the use of the terms "total fat" and "total carbohydrate." Many comments suggested using indentation of subcomponents as a graphic means to further distinguish subcomponents because it is a commonly used technique that would be easily understood by most consumers. A few comments suggested bolding and highlighting of the broader classification to further distinguish subcomponents of fat and carbohydrate. Other comments suggested using such terms as "includes," "including," "of which," and "which includes" before the subcomponent to further establish that the subcomponent is a part of a broader classification.

Section 403(q)(1) of the act specifies that nutrition labeling shall include information on several nutrients, including total fat and total carbohydrates. In order to be consistent with the terminology used in the 1990 amendments, the supplementary proposal (56 FR 60366 at 60387 and 60388) included provision for listing "total fat" and "total carbohydrate" as mandatory elements of the nutrition label. Given the statutory derivation of

this terminology, the support for its use in the comments, the fact that the terminology reflects the broad category of nutrient, and the lack of opposition to the use of this terminology, the agency is retaining the provisions for the declaration of total fat and total carbohydrate based in § 101.9(c)(2) and (c)(6) and, by reference, in § 101.9(d)(7).

The agency agrees that indentation of subcomponents along with the use of the term "total" before the major classification provides effective means of establishing separate and recognizable subcomponent status. The agency is not providing for the use of terms such as "including" and "of which." While these terms may add clarity, they will also introduce additional words to the label, contributing to label clutter. The agency is persuaded by the comments that the use of indentation of subcomponents is sufficient to clearly distinguish the subcomponents of total fat and total carbohydrate because it is a commonly used and well understood graphic device. Therefore, the agency is requiring the indentation of saturated, polyunsaturated, and monounsaturated fatty acids in § 101.9(c)(2)(i) through (c)(2)(iii), respectively, and the indentation of dietary fiber, sugars, sugar alcohol, and other carbohydrates in § 101.9(c)(6)(i) through (c)(6)(iv), respectively, when such nutrients are declared. In addition, as explained in section V.H.1. of this preamble, the broader classifications must be highlighted by boldface print as provided in § 101.9(d)(1)(iv).

ii. Calories and calories from fat. 126. The plurality of comments supported using the term "total" preceding or following "calories" to denote that it includes the calories from fat (i.e., "total calories" or "calories, total"). Some comments suggested that a potential for confusion exists because "calories from fat" must be declared on the nutrition label, and consumers may be unaware that they are included in the larger category "calories." These comments expressed concern that consumers would mistakenly add calories from fat to the larger classification declared simply as "calories." Additionally, several comments suggested indenting "calories from fat" to further distinguish it from "total calories."

The agency is persuaded by the comments that the term "total" preceding or following "calories" will better enable consumers to understand that it is the larger classification of which the subcategory "calories from fat" is a part. The agency notes that it is requiring the term "total" for the other larger classifications, total fat and total carbohydrate. A label that has the term "total" preceding two of the three larger classifications may have the potential to confuse consumers with regard to the third. However, the agency also notes that the term "calories" has fewer words, and therefore requires less space and minimizes clutter. Furthermore, consumers have been seeing the term "calories" on labels to designate total calories, and, unlike the other nutrient subcomponents, the subcomponent "calories from fat" designates subcomponent status by its structure. Therefore, in § 101.9(c)(1), FDA is providing for the use of the terms "total calories;" "calories, total;" or "calories." In addition, in § 101.9(c)(1)(ii), the agency is requiring that the subcategory "calories from fat" be indented for consistency with other nutrient subcomponents when it is listed in a column under the total calorie information.

c. *Terminology for Daily Reference Value.* In its mandatory nutrition labeling proposal (55 FR 29487) FDA asked for comments concerning an appropriate single new term to be used to refer to all the reference values in the nutrition label. On its own, FDA arrived at "Daily Value (DV)" as a possibility for use as this single term. FDA used this term in the research that it conducted on formats. Most consumers correctly interpreted the general meaning of the term. However, during probing in focus group discussions conducted by the agency, several consumers commented that the word "value" may connote something of worth and suggested that another term might be appropriate for food labeling purposes. In its supplementary proposal published November 27, 1991 (56 FR 60366 at 60371), the agency reiterated its request for comment on, and suggestions for, appropriate terminology to be used to refer to the entire set of reference values.

127. A number of comments responded to the issue of terminology for a single term to denote all label reference values. Two comments stated that the word "value" may give the impression that these levels are goals to be achieved rather than points of reference. A wide range of alternative terms were offered, including "Human Daily Need," "Recommended Daily Standard," "Reference Value," "Daily Amount," "Reference Daily Intake," and "Recommended Daily Intake." However, no general agreement emerged from the comments, and no research data were submitted in support of suggested alternatives for the term "Daily Value."

One comment stated that the term "reference" has little meaning for most consumers, while a few others said that the use of the term precludes persons assuming that the value is a goal. Another comment stated that the term "standard" avoids the confusion of having to differentiate between minimum and maximum intakes. One comment suggested that the term "U.S. RDA" be retained to denote all label reference values. Many other comments requested retention of the U.S. RDA's; however, those comments appeared to be referring to retention of the current numerical values for the U.S. RDA, not the terminology to be used on the label.

FDA disagrees that the term "U.S. RDA" should be retained. The term was developed in 1972 when label reference values for all nutrients listed on the label were derived from the Recommended Dietary Allowances (Ref. 23). The term was developed to suggest the link between the Recommended Dietary Allowance and the label reference values developed by the agency. However, the reference values for a number of the nutrients that are to be included in the nutrition label, under the final rule on DRV's and RDI's, published elsewhere in this issue of the **Federal Register**, are not based on a Recommended Dietary Allowance value because the National Academy of Sciences has not established Recommended Dietary Allowances for these nutrients. It therefore would be inaccurate and misleading to retain the term "U.S. RDA."

Further, the agency believes that terms that use the words "recommended," "requirement," or "need" would be misleading to consumers and would complicate nutrition education efforts. Some of the reference values that FDA is adopting are intended to guide consumers relative to maximum intakes (for example, saturated fat), while others are intended to serve as a basis for planning general diets to meet nutrient requirements (for example, vitamin C) or as minimum intakes (for example, potassium). It would be incorrect to imply that FDA "recommends" that consumers consume the maximum intake level for total fats, or that such levels are "required" or "needed." Also, FDA cannot agree that the term "standard" is appropriate. While the comment argued that this term does not suggest a minimum or a maximum, the agency believes that it commonly implies a level to be achieved or surpassed, and for which it is undesirable to fall below. Thus, it may connote a minimum level for many consumers.

Moreover, the term "daily intake" suggests a requirement or prescriptive

need for individuals, rather than a general reference point. Furthermore, the agency is concerned that if the term were used, it could become a source of confusion in information and educational materials on nutrition because "daily intake" for nutrients is used to mean current consumption levels, rather than reference intakes based on dietary recommendations. For example, the current daily intake of fat is estimated to be 95 g per day based on food consumption surveys. However, the agency's DRV for fat is 65 g for a 2,000 calorie diet and is based on dietary guidance.

After reviewing the comments carefully, the agency concludes that it is appropriate to retain the proposed term "Daily Value." FDA research has shown that the term is generally understood by consumers as a point of reference, and no appropriate or well-supported alternatives have been suggested to the agency. FDA acknowledges that two comments suggested that the word "value" may be indicative of a goal. However, no data were submitted to support this suggestion, and no other comments objected to the term on these grounds. Therefore, FDA will use "Daily Value" as the single term to refer to all reference values on the nutrition label and is providing for its inclusion in § 101.9(d)(6).

To preclude any confusion, the agency points out that the Daily Values are a specific, regulatorily established set of reference values that have been derived based on dietary guidance and, for certain nutrients, on the assumption of a 2,000 calorie per day diet (see the document on RDI's and DRV's published elsewhere in this issue of the **Federal Register**). FDA recognizes that alternate daily caloric requirements (e.g., 2,500 calories) produce alternate recommended values for those nutrients with dietary recommendations that are based on calorie requirements, and that these alternate values can be considered "daily values" for people consuming the given calorie level. However, the recommended values for various calorie intake levels other than 2,000 calories per day should not be confused with the Daily Values, specifically the DRV's that FDA is establishing by regulation (see § 101.9(c)(7)(iii)) and that are referenced in several of the regulations that FDA is adopting today (see, e.g., § 101.13).

2. PERCENT DV Format

The majority of comments that supported the PERCENT DV or PERCENT DV with DRV format were from consumer groups and health promotion organizations, although several industry and other types of organizations also supported the proposed format. The majority of comments that opposed the PERCENT DV format were from industry.

128. The major argument given in support of the PERCENT DV format was that the percent formats are easy to use and provide clear information about how a food fits into a total daily diet. FDA's research showing that the percent formats have superior performance characteristics, particularly with regard to label tasks related to dietary judgments, was sometimes cited. Some comments argued that consumers are mainly interested in using the nutrition label to make qualitative judgments about specific foods, such as whether the food is low or high in a nutrient of interest. Many fewer people, it was argued, keep running lists of nutrient amounts throughout the day. The comments argued that the percent format facilitates this type of qualitative judgment.

Many of the comments opposed to the PERCENT DV format also addressed the issue of consumers' ability to use the PERCENT DV information, arguing that consumers would not be able to use percent displays effectively. Specific arguments included that the percent formats did not perform well in the Grocery Manufacturers of America and the National Food Processors Association (GMA/NFPA) industry study (Ref. 71), and that consumers do not understand percents.

FDA has carefully considered the arguments regarding percent displays but finds no basis not to conclude that consumers will be able to use PERCENT DV declarations more effectively than they would any other format tested. The consumer research (see section V.D.2. of this document) supports the assertion that the PERCENT DV format, with or without a listing of the seven macronutrient reference DV's, improves consumers' abilities to make correct dietary judgments about a food in the context of a total daily diet. This result was replicated in three separate studies (Refs. 70, 71, and 74), two of them industry-sponsored, and on three different dietary judgment tasks: judging the correctness of nutrient claims about the product, identifying the nutrients in the product that needed to be counterbalanced by changes in the daily diet, and judging how much to eat of the given food if you want to reduce intake of certain nutrients. In one industry-sponsored study (Ref. 71), the PERCENT DV format helped consumers judge how much to eat of a given food despite the fact that PERCENT DV formats were executed with extra columns of nutrient information per serving.

As noted in section V.D.2. of this document, the percent DV format element is one of only two format elements that have been shown to improve consumer performance on dietary judgment tasks (the other format element is the use of adjectives). In addition, the PERCENT DV format, when executed without additional columns, scored as well or better than any other format on all of the other tasks measured in FDA's study. No evidence was submitted to FDA showing that consumers cannot effectively use a PERCENT DV format when it is appropriately executed.

FDA studies (Refs. 69 and 70) found that for label use tasks involving simple comparisons between products, PERCENT DV declaration formats were best executed as single column displays with g/mg amounts next to the nutrient name and not in a column. Executed in this manner, no difference was found between PERCENT DV formats and the CONTROL format on product comparison tasks.

The GMA/NFPA industry study (Ref. 71) found that when the format was executed as two adjacent columns of numbers with different units (g/mg amounts and percent DV declarations), performance on simple comparison tasks was adversely affected. This result is likely attributable to the additional columns added to the format, particularly since the units differed, and is not an inherent weakness of the PERCENT DV declaration formats (see section V.D.2. of this document). FDA considers the placement of g/mg amounts in an unordered array next to nutrient names to be a necessary feature of the PERCENT DV format because it improves consumers' abilities to readily observe and comprehend the percent information on the nutrition label as demonstrated by FDA format studies. Thus, use of this format is consistent with section 2(b)(1)(A) of the 1990 amendments.

The argument that people have difficulty in understanding percents is not borne out by the consumer research. In the nutrition label situation, a consistent system of percents is used such that virtually all the nutrients on the label can be declared in equivalent units, in this instance percent DV. A list of nutrients declared in equivalent units has the unique property that the list of values is self-anchoring, that is, values in the list can serve as references for each other. A low value on the list is likely to be a "true" low value, a high value on the list is likely to be a "true" high value. This consistency is not possible when the list contains nutrients declared in very different units. Five g

of saturated fat may be a "true" high value and 115 mg of sodium may be a "true" low value, but few consumers see the number 5 as high and the number 115 as low according to FDA research. Percent DV declarations help consumers because they overcome the problems associated with declaring nutrients in nonequivalent units (see comment 106 of this document).

Gram/milligram formats with a list of DV's give consumers the numbers they would need to calculate percentages and thus to transform the amounts to equivalent numbers. However, research, including FDA's format research, has consistently shown that most consumers are unwilling or unable to transform data provided on labels (Refs. 70 and 101). Available evidence shows that providing consumers with raw data is not effective. Providing them with data in the form needed to make judgments, e.g., in consistent percentages, is effective.

Consumers have been seeing vitamin and mineral levels expressed as percent of U.S. RDA on food products for about 20 years. Few know what the U.S. RDA's are for specific nutrients or even know what units the U.S. RDA's are in. No arguments have been raised that percents in this context are difficult to use or hard to understand. The presentation of macronutrient data in percents is a logical extension of the system that consumers have been using with apparent success for years.

Therefore, FDA is requiring in § 101.9(d)(7)(ii) that nutrition information per serving be declared as percent of the DV in the primary columnar display on the nutrition label.

129. Many of the industry supporters of the PERCENT DV format cited the relatively small space requirements for the format, particularly if the DV listing is not required.

FDA agrees that the PERCENT DV format without a DV listing requires little additional space relative to the CONTROL format. A strength of the PERCENT DV format not shared by any other format except ADJECTIVE is that consumers can use it equally well for most label use tasks with or without the reference DV listing. For this reason, the agency is not requiring that the reference DV list be displayed as such. Rather, it is displayed as part of an example of recommended nutrient amounts for different calorie intake levels, and the normal placement is not beside the Percent DV information but beneath it.

In addition, the calorie-specific daily value list may be omitted in simplified formats and on small and intermediate sized packages (§ 101.9(f)(5) and (j)(13), respectively). In contrast, labels declaring amounts of nutrients only in g/mg units require consumers to compare the reference DV list with the amount declarations in order to make dietary judgments. Thus, for such labels, the presentation of the reference DV list adjacent to the declaration of amounts is necessary for most label use tasks.

Accordingly, § 101.9(d)(9) provides that daily values for 2,000 and 2,500 calorie diets be placed in columns beneath the vitamin and mineral information. However, if space is not adequate beneath the vitamin and mineral information, § 101.9(d)(11) provides that the calorie-specific daily value information may be placed to the right of the Percent DV information. In addition, § 101.9(f)(5) allows the calorie specific daily value information to be omitted from labels of products that qualify for the simplified format, and § 101.9(j)(13)(ii)(C) allows it to be omitted from packages with 40 or less square inches of label surface available to bear labeling.

130. A number of comments argued against the PERCENT DV format because of poor legibility of the basic format. They argued that legibility will be lower because the absolute amount declarations are hidden and are likely to be hard for consumers to find and because two numbers are required for each nutrient.

FDA disagrees that the basic format has poor legibility. The agency's research showed that consumers are easily able to use the PERCENT DV format displayed with amounts by weight in parentheses next to the nutrient name (see section V.D.2. of this document). Most consumers will not need to use the amounts by weight. The format prominently and clearly displays the one piece of nutrient information that will be most easily used and understood by the general population. The amounts by weight are provided for consumers who find it easier to use them, such as individuals who manage their diets using g/mg amounts.

131. Other comments argued that consumers will be confused because they will have to learn a new type of declaration, and those consumers used to the amount by weight declarations may mistakenly use the percentages as absolute amounts.

FDA disagrees with this argument. Evidence from consumer research shows that consumers generally are not able to effectively use the current format for some important label uses, such as placing a food in the context of their total daily diet (see section V.D.2.b. of this document). In contrast, research shows that consumers are able to use percent displays for all of the label uses tested, including those tasks related to dietary judgments, such as placing the food in the context of the total daily diet. As consumer education reaches more people, and as consumers become more familiar with the percent display format, its effective use will increase. In addition, under § 101.9(d)(7)(ii), as explained in section V.H.1. of this document, the symbol for percent (i.e., "%") must be used after each number. Therefore, consumers are not likely to use the percentages as absolute weight amounts.

Many of the comments opposed to the use of the PERCENT DV formats did not acknowledge that these formats provide g/mg amount information on the nutrition label. FDA included amounts by weight to meet the needs of consumers who had come to rely on such information. An appropriate balance must be achieved between how much and how prominently information can be presented on the label. The relative numbers of people likely to use different information is an important consideration in achieving this balance. Few people currently engage in the kind of dietary management that requires keeping daily running sums of particular nutrients, such as assumed by some of the comments opposed to PERCENT DV formats.

132. Several comments stated that PERCENT DV formats are misleading because they provide inappropriate dietary guidance or offer no guidance to those consumers whose daily requirements differ from the DV. Concern was expressed that consumers will believe the numbers apply to them personally.

The agency disagrees that PERCENT DV declarations are misleading because they provide inappropriate dietary guidance. A major advantage of a percent unit is that it communicates the relative magnitude of the nutrient level in a food without the consumer having to be concerned about the absolute level or units of the underlying scale being used. Knowledge of quantitative dietary goals for specific nutrients is not inherent in, or necessary for, accurate magnitude assessments of the nutrient levels in the food. The DV base of the percent does not have to exactly fit each individual's needs in order for the percent to accurately reflect the relative magnitude of the nutrient level in the product.

FDA considers estimation of the relative magnitude of nutrient levels in the food to be central to the placement of a food in the context of the total daily diet. FDA's research and other research submitted as comments to the format

proposal showed that consumers were able to use PERCENT DV formats to assess high/low levels of nutrients more effectively than any other format (see section V.D.2.b. of this document). Therefore, for purposes of placing the food in the context of a total daily diet, a label use for which consumers have no need to adjust the scale for individual variations, the declaration of nutrient amounts as percent DV cannot be considered misleading or inappropriate dietary guidance.

Although, for the reasons described above, detailed knowledge of the DV's and their relation to an individual's diet is not necessary for using a PERCENT DV format to make product comparisons or dietary judgments about the product, it is useful for other dietary management purposes. Information about how daily values vary by calorie needs will help those people who so desire to estimate their own personal daily values and will help them to differentiate the concept of a reference Daily Value used for labeling and regulatory purposed from personally appropriate dietary guidance.

Therefore, to decrease the likelihood of consumer misunderstanding, the agency is requiring in § 101.9(d)(9)(i) that a footnote accompany the percent DV declarations stating that these declarations are based on a 2,000 calorie diet, and that personal needs vary depending on an individual's calorie intake. In addition, to assist consumers in estimating their own quantitative dietary needs relative to the reference DV's, the footnote will display daily values of total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber based on 2,000 calories and 2,500 calories. By providing a concrete example of how individual dietary needs may vary depending on calorie intake level, the footnote will help people to place their personal dietary needs with respect to the reference Daily Values and to avoid any misunderstanding as to whether the reference DV's are dietary guidance meant for them.

133. Several comments argued that PERCENT DV formats are mathematically misleading because they are calculated against an implied range if the terms "or less" and "or more" are used, or because consumers will not be able to reconstruct the percents from the absolute amounts and the DV numbers because of the rounding rules for percents of macronutrients.

FDA disagrees that consumers will see qualifying terms such as "or less" and "or more" as constituting a range from which a percent cannot be calculated. These terms were included on the PERCENT DV/DRV format in the second FDA label format study, and no subject expressed confusion resulting from their presence (Ref. 70).

FDA agrees that the rounding rules for percents for macronutrients and sodium in proposed § 101.9(c)(12) (56 FR 60366 at 60390) have the potential to cause consumer confusion when used with the PERCENT DV format. The agency notes that the amount by weight declarations for these nutrients have already been rounded, and that additional rounding of the percents may lead to an undesirable degree of inaccuracy, depending on the specific percent.

Therefore, the agency is requiring in § 101.9(d)(7)(ii) that percent declarations for macronutrients, sodium, and potassium in the PERCENT DV/DV format be calculated by using as the numerator the actual amount of the specified nutrient before rounding for label declaration. The resulting proportion will be transformed to a percentage and rounded to the nearest whole percent.

134. Some comments argued that the PERCENT DV format should not be selected because the lack of DRV's for some nutrients will result in blanks in the principal numeric column. The comments argued that such blanks will leave consumers with no information about the level of some nutrients and will be confusing to them. However, none of the comments that supported the PERCENT DV format suggested that the lack of DV values for some nutrients was a disadvantage of the format.

Several of the comments that discussed the lack of reference values in the context of whether the DV list should be required on the label provided arguments that apply to all uses of the DV information and thus also apply to the PERCENT DV format. These comments argued that it is more beneficial for consumers to have the values for some nutrients than to have the values for no nutrients.

The agency disagrees that blanks in the principal numeric column resulting from the lack of DV's for some nutrients is sufficient reason to reject the PERCENT DV format. The g/mg amounts will be listed for nutrients that have no DV, so that some information will be presented for these nutrients. Since a reference value has not been set for these nutrients, none of the alternative formats would give additional information to help the consumer evaluate the food with respect to nutrients that lack a DV. For example, no value will appear in the DV listing for the nutrients, so comparison of the amount in the product with the DV, as might be done with the CONTROL/DV format, would not be possible. No scheme for assigning adjectives or for highlighting would be able to include nutrients without a DV, so that formats using these elements would not present more information about such nutrients than the PERCENT DV format. Since no other format overcomes the gap in information that results from lack of DV's for some nutrients, the lack of DV's for specific nutrients cannot be seen a reason to reject the PERCENT DV format. The agency agrees with the comments that argued that presenting DV-related information for some nutrients is more beneficial to consumers than withholding such information about all nutrients.

135. Some comments argued that PERCENT DV formats are calculated against a base that will change as scientific knowledge about nutrition changes, just as dietary guidance changes as knowledge increases, and that, therefore, a PERCENT DV declaration should not be required.

These comments address the issue of putting on the label dietary information that will change over time with increasing knowledge. The underlying assumption of these comments is that percent DV declarations will communicate quantitative dietary goals for specific nutrients, but, as discussed above (see comment 132 of this document), FDA's view is that percent DV's are not likely to be used for this purpose. U.S. RDA's have been subject to change in the same sense, but this fact has not prevented their successful use on nutrition labels as a basis for declaring nutrient amounts as percentages. Therefore, the agency disagrees that the possibility of change is a substantial reason to avoid percent declarations on the nutrition label.

136. A number of comments argued that PERCENT DV formats encourage good/bad food judgments.

The agency does not agree with this argument. Both FDA and industry research found that PERCENT DV declarations tend to produce the most accurate judgments about whether products are high or low in various nutrients. The g/mg formats were more likely to lead to extreme and inappropriate dietary judgments than PERCENT DV declarations (section V.D.2.b. of this document and Ref. 102)

137. One comment expressed the view that FDA does not have the legal authority to require percentages, since the 1990 amendments only require the declaration of amounts. Others argued that the 1990 amendments do not mandate that FDA change the current format.

FDA disagrees with these comments. As discussed above, section 2(b)(1)(A) of the 1990 amendments requires that the nutrition information be conveyed in a manner that enables the public to understand the relative significance of the nutrition information in the context of the total daily diet. Moreover, the legislative history states that this provision requires the Secretary to specify requirements that permit the consumer to understand the nutrition information about a particular food in relation to recommended dietary information (Ref. 16, p. 18). Expressing the level of a nutrient in the food as a percent of a reference amount (the DV) is the simplest and most straightforward way of permitting the consumer to understand the amount of a nutrient in the context of the total daily diet. Thus, the 1990 amendments provide clear authority to require percentages. Moreover, given the requirements of the 1990 amendments, and particularly the requirement in section 2(b)(1)(A) of the 1990 amendments, revision of the current format is unavoidable and necessary.

138. A comment from a foreign government stated that PERCENT DV information is country-specific because the DRV information on which it is based varies by country, and mandatory inclusion of percent DV information on a label would make it difficult to achieve equivalence in nutrition labeling requirements between the United States and other countries. The comment noted that their free trade agreement with the United States requires that the two countries work toward equivalent requirements on nutrition labeling. The comment pointed out that Codex guidelines provide for supplementary nutrition information only on a voluntary basis.

The agency supports efforts toward international harmonization of food labeling. However, the 1990 amendments direct FDA to require a number of format elements that are not in harmony with international food labeling. The agency believes that it has been directed to require a format that will enable consumers to choose appropriate foods and to place the food within the context of their total daily diet, without the constraints of meeting international guidelines.

3. The DV List on the Label

a. *Including the DV list on the label.* A number of comments from industry, consumer groups, and health promotion organizations addressed the issue of whether the DV list should be required, optional, or not permitted on the nutrition label.

139. The major arguments supporting mandatory inclusion of the DV list on the label, made primarily by consumer groups and health professional organizations, were: (1) That the DV's must be listed for people to estimate how their needs may vary from those represented on the label, particularly if the individual is on a more restrictive diet than represented in the DV's, (2) that consumers need the DV information on the label because they have to become comfortable and familiar with the DV concept in order for them to use the new nutrition label to place the food in the context of their daily diet, to put nutrient content information in perspective, or to provide a frame of reference for decision making, and (3) that consumers need the information because quantitative dietary goals are necessary in order to encourage and help consumers understand proper dietary practices.

The major argument against inclusion of the DV list on the label, made primarily by food manufacturers and food industry associations, was that consumers will misinterpret the DV's as dietary recommendations for their personal dietary needs, which will lead to the DV's providing inappropriate dietary guidance. Comments argued that DV's are unacceptable for dietary guidance because they are population based reference values for an "average" consumer that do not take account of individual differences such as sex, weight, activity level, and other factors influencing personal dietary needs.

Many comments opposed to requiring DV's argued that a listing of DV's on the nutrition label provides no product-specific information to consumers, and that mandating the listing on all labels requires repeating the same information on millions of food labels. One comment likened the requirement of placing the list of DV's on food labels to a requirement that banks provide addition and subtraction tables to their customers in each and every monthly statement. Many of these comments argued that inclusion of a list of DV's on the nutrition label will significantly increase the space requirements of the nutrition label, and that the increased space needs will make it extremely difficult for small packages to comply with nutrition labeling requirements.

Many comments opposed the mandatory inclusion of the DV's on the nutrition label because it will clutter the label and thereby decrease consumers' ability to readily observe and comprehend the nutrition information on the label. A number of comments, particularly from industry, supported optional inclusion of the DV list. The arguments for making the listing of DV's optional were similar to those for opposing it.

The agency finds merit in the argument that presenting the DV list on the label may potentially mislead consumers by giving undue prominence to values intended as references only and not as dietary guidance for individuals. The consumer research (see section V.D.4.b. of this document) showed that consumers were likely to interpret a single list of values labeled as "Daily Values" as personally applicable. At the same time, the agency agrees with the comments that argued that consumers should be able to assess how their personal dietary needs, which vary by factors such as age, sex, and activity level, may differ from the reference DV's used on the label. After extensive consideration, the agency is convinced that the best solution to these conflicting requirements is not to list the reference DV's identified as such as part of the primary information, but to provide a footnote as specified in § 101.9(d)(9)(i) that gives individualized daily values of total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber based on 2,000 calories and 2,500 calories.

Without a prominent display of the list of reference DV's for macronutrients on the label, the likelihood that consumers will misunderstand the reference DV's as personally relevant dietary guidance is greatly reduced. At the same time, a concrete example of how recommended nutrient amounts vary depending on an individual's needs will help consumers to understand how their own dietary needs stand with respect to the reference Daily Values.

The agency believes that the information in the footnote will accomplish virtually all the benefits that comments identified would follow from including the list of reference DV's on the label. By enabling consumers to evaluate the appropriateness of the percent DV's for their personal needs, the information in the footnote will serve to increase consumer confidence in the nutrition label and lead to more effective use. For consumers who want to practice quantitative dietary regulation that involves setting intake targets for certain nutrients and keeping a running tally of intake of these nutrients, the information in the footnote will provide maximum flexibility in the use of the nutrition label. The percent DV's on the label can be adjusted for different personal needs or an individual's caloric intake either by working with the percentages (such as having a target value of 120 percent

for 2,400 calorie diet and a target of 90 percent for an 1,800 calorie diet) or by working from absolute values derived from the calorie-based daily values in the footnote. The footnote will yield these benefits without implying that a specific reference DV is the appropriate target for every consumer.

However, FDA also agrees with comments that point out that inclusion of DV-related information on the nutrition label, such as that in the required footnote, imposes significant costs in terms of label space without providing product-specific information. Considering the appropriate balance, FDA is convinced that the agency should be flexible in requiring the footnote on product labels, particularly since the benefits of having such a listing are not relative to the specific food that carries the information, and that the information will be available to consumers if it appears on a significant percentage of food labels.

Therefore, the information specified in § 101.9 (d)(9) and (d)(10) may be omitted from small and intermediate sized packages as provided for by § 101.9(j)(13), and from products that qualify for a simplified format as provided for in § 101.9(f)(5).

140. Comments also addressed the placement on the label of information intended as context to help people more effectively use the nutrition information of the label. In the proposal, this information was a listing of the reference DV's. The agency has considered these comments in deciding the issue of the placement of the information in the footnote that FDA is requiring instead of a listing of the reference DV's. Several comments suggested that the daily value information should be required to be listed in a column beside the percent DV information, not in a footnote. Some comments agreed that placement in a footnote is sometimes necessary and suggested that FDA require a listing on separate lines rather than in a string. Others also recommended that placement in tabular form be required. Many of the industry comments stated that, in order to accommodate daily value information on many packages, flexibility in placement is essential.

Because the PERCENT DV formats do not require consumers to use information about the reference DV values to perform product-related dietary management tasks, the agency believes that allowing some flexibility in placement of the calorie-specific daily value information and excluding small and intermediate sized packages and products with simplified labels from the requirement to provide the footnote information will not compromise the effectiveness of the format (see comment 128 of this document). As long as the information appears on a substantial percentage of food packages, it will be readily available to consumers. FDA recognizes that the added information requires increased label space and agrees that manufacturers should have flexibility to place it so that they can use available label space efficiently. Thus, in § 101.9(d)(11), FDA is providing that the footnote information may be placed to the right of the percent DV information when there is not adequate space to place it beneath that information.

b. *Lack of reference values.* In its final rule on RDI's and DRV's published elsewhere in this issue of the Federal Register, FDA has established DRV's for total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, potassium, and protein. However, the agency has not established DRV's for polyunsaturated fat, monounsaturated fat, other carbohydrates, sugars, sugar alcohol, soluble fiber, and insoluble fiber. Formats that include these nutrients will show missing values under the percent DV and the DV columns. In the format proposal (57 FR 32059 at 32070), FDA requested comment as to whether the missing values will cause consumer confusion and, if so, whether it would be helpful to place an entry in the column stating that a reference value is not available.

141. The comments were divided on whether the lack of reference values for some nutrients would be confusing to consumers. Several comments stated that appropriate educational efforts would reduce consumer confusion, and that the potential confusion possibly caused by missing values does not outweigh the usefulness of providing the percent DV and DV information for nutrients for which such values exist. Several comments suggested that it was most appropriate to merely leave the entry blank, citing concerns about label clutter and the need to keep the label simple. Other comments suggested that the format include an entry of some type to indicate that a reference value has not been established. One comment pointed out that it is current practice for some food and supplement labels to state that a U.S. RDA has not been established for some nutrients.

As noted in comment 134, the agency agrees that presenting DV information for some nutrients is more beneficial to consumers than withholding such information about all nutrients. The agency is concerned about space limitations on food labels and label clutter. The label format presented in this final rule contains considerably more information than is required by the existing label, and comparisons to the current practice of stating that U.S. RDA's have not been established for some nutrients may overlook the increased information required on the nutrition label. Given the fact that nutrition labeling has been extended to virtually all foods regulated by the agency and the concern that too much information on the nutrition label may overwhelm consumers, FDA finds no basis to conclude that statements that a reference value is not available for the particular component will add clarity to the label. Therefore, FDA is not providing for the use of statements regarding the lack of established reference values.

c. *Use of qualifying terms in presentation of calorie-specific recommended nutrient amounts.* The agency proposed (57 FR 32058 at 32070) to require the use of the qualifying terms "or less" and "or more" in conjunction with the proposed DRV list. Comments about qualifying terms are relevant to the presentation of calorie-specific daily values, as provided for by § 101.9(d)(8). While the agency did not specifically discuss the nutrients for which each of these qualifying terms were appropriate in the proposal, the examples presented in the appendices made it clear that the agency's intent was to use these terms in conjunction with those nutrients for which current dietary guidance specifies an "open-ended" decrease or increase in consumption. Therefore, because recommendations for total fat, saturated fat, cholesterol, and sodium intake are stated in specific amounts or less (Refs. 2, 3, and 4), the agency used the qualifying term "or less" with these nutrients. On the other hand, the recommendation for carbohydrate is stated as 55 percent or more (Ref. 3). Thus the agency used the qualifier "or more" with this nutrient. FDA included such qualifiers in its research.

142. A few comments opposed the use of the qualifying terms because of the interest in reducing label clutter or because their use conveys a message that a food should be avoided if it contains high amounts of a nutrient qualified by "or less." Several comments opposed the use of the qualifying terms if a range of values was used rather than a single value. One comment considered the qualifying terms unnecessary if FDA adopts a 2,000 calorie base.

The majority of comments supported the use of qualifying terms and suggested that such terms convey to consumers the notion of a variable target intake rather than a prescriptive intake.

Some comments supported "or less" and "or more." Others stated that "less than" was preferable to "or less," and one stated that "no more than" and "no less than" were preferable to "or less" and "or more." These comments argued that the recommendation for saturated fat intake was less than 10 percent of calories from saturated fat, and therefore the use of "less than"as a qualifier in general was more appropriate. No comment presented data concerning consumer use and interpretation of qualifier terms. A comment suggested dropping "or more" for carbohydrate, regardless of calorie base, as it is in conflict with the Dietary Guidelines for Americans (Ref. 4), which recommend the use of sugars only in moderation.

FDA agrees that the use of qualifying terms assists consumers in appropriate interpretation of the daily value information and may help to preclude too literal an interpretation of the values. Moreover, since no single caloric level can be specific for all individuals, the agency concludes that qualifying terms are appropriate regardless of the caloric level used. Furthermore, the agency is convinced that regardless of which term is selected, the qualifiers should be used consistently to avoid consumer confusion.

FDA acknowledges that, while Diet and Health (Ref. 3) recommends that 55 percent or more of calories be consumed as carbohydrate, the Dietary Guidelines (Ref. 4) recommend the use of sugars only in moderation. The label format will list sugars as a subset of carbohydrate. The agency is persuaded that the use of the qualifying term "or more" or "more than" with carbohydrate has the potential to be misleading to consumers given that carbohydrate includes sugars. The use of this term may be particularly confusing to consumers when the source of carbohydrate in a food is primarily sugars. Therefore, FDA will not provide for the use on the label of the qualifier "more than" or "or more" with carbohydrate.

FDA finds merit in the term "or less" because this term is presented after the quantitative value and thus does not interfere with the consumer's ability to locate the quantitative values (especially when the daily values are presented in a column). However, the agency believes that the term "less than" conveys a less specific target and thus meets the concerns of many comments that asserted that consumers need to be alerted to the fact that recommended amounts vary greatly from individual to individual. The agency also acknowledges that the qualifying term "less than" is more consistent with the recommendation for saturated fat.

Therefore, FDA is persuaded that qualifying terms should be included when daily values are presented, and that the qualifying term should be "less than." The agency has included this requirement in § 101.9(d)(9)(i). For consistency and to avoid consumer confusion, FDA will not provide for the use of the term "or less."

143. One comment stated that the agency should allow the use of the term "or more" with dietary fiber because such a qualifier is consistent with current dietary guidance.

FDA disagrees that it is appropriate to use the qualifying term "or more" with dietary fiber. While there is relatively little evidence that high fiber intake impedes mineral absorption and bioavailability (Ref. 3), concerns about excessive fiber consumption have led to specific recommended ranges for dietary fiber intake rather than open-ended recommendations. The report from the Life Sciences Research Organization (Ref. 103), which provides the basis for the DV for dietary fiber, specifically provides a range for recommended dietary fiber intake (10 to 13 g per 1,000 calories, or approximately 20 to 35 g per day) and is not stated as 25 g or more. Therefore, the use of "or more" with fiber is not consistent with dietary recommendations, and FDA will not provide for its use on the label to qualify dietary fiber.

d. *Clarifying footnote for daily value caloric intake level.* In the format proposal (57 FR 32058 at 32071), FDA asked for comment on the effectiveness of a footnote to convey to consumers the need to modify the DV amounts to meet their nutritional needs and for suggestions for alternative footnote statements. The proposal included the following explanatory footnote in the PERCENT DV with DRV graphic format: "For a 2,350 calorie diet. Your Daily Value may be higher or lower depending on your calorie intake."

Comment was requested on the following three alternative footnotes listed in the proposal (57 FR 32058 at 32071):

(1) Based on a 2,300 calorie diet. Fewer calories are recommended for women and young children.

(2) As part of a 2,400 calorie diet. Many young children and women over 50 need 2,000 calories or less. For a 2,000 calorie diet the Daily Value would be less than 65 g Fat, less than 20 g Saturated Fat, less than 275 g Carbohydrate, and 25 g Fiber (Sodium and Cholesterol do not change).

(3) A 2,000 calorie diet is for women over 50 and young children. Most teenagers, sedentary men, active and very active persons, and pregnant and breastfeeding women need more calories.

144. Comments were received from manufacturers, health promotion organizations, State governments, trade associations, universities, and consumer advocate organizations. The majority of comments supported the requirement of a footnote to clarify the calorie base for the daily value listing.

The explanatory footnote in the PERCENT DV with DRV graphic format was specifically supported by five of the comments. This footnote stated "For a 2,350 calorie diet. Your Daily Value may be higher or lower, depending on your calorie intake." However, one manufacturer objected to this footnote on the basis that it was ambiguous and ineffective and did not provide the necessary information.

Most comments stated that it is important for the consumer to understand that the DV may need to be adjusted because it is based on the number of calories consumed, and recommended calorie consumption depends on various factors, such as physical activity level, age, sex, weight, height, and metabolism. Two comments, although opposing inclusion of the DV, argued that an explanatory footnote should be included if the DV is included.

Two comments objected to all of the alternatives. One comment, from a consumer advocacy organization, asserted that the third alternative listed above would create more confusion by attempting to identify every segment of the population.

Two comments, one from a health professional organization and the other from a food manufacturer, stated a preference for using the footnote in the format shown in appendix F (57 FR 32058 at 32089) as the footnote clarifying the DV list. This footnote summarizes the Dietary Guidelines and includes statements such as "Eat a wide variety of foods." However, it does not include a reference to the DV's or the caloric level on which they are based because the format that the footnote appears on does not list DV's. (The format in appendix F of the format proposal is discussed in section V.G.11 of this document). One of the comments recommending this footnote stated that the footnote should be prefaced with statement about DV's varying with calorie needs. The following was suggested: "Your calorie, fat, carbohydrate, fiber, and protein intake will vary based on age, height, weight, metabolism and activity level."

A trade association opposed the footnote included in appendix F of the format proposal as the clarifying footnote for the DV list, stating that it added to the clutter, and that it did not provide any relevant information to the consumer because too many calculations would be required to use the information in the footnote. Two comments suggested that the statement in the footnote of appendix F, "choose a diet low in fat (30% or less)," be clarified to reference the total caloric intake for the day. One comment requested that footnote information be consistent with dietary guidance and the nutrition label by changing "Use sugar * * * in moderation" to "Use sugars * * * in moderation."

Various other suggestions were made for the appropriate wording of a footnote. Some comments were concerned with brevity in the interest of space. Other comments emphasized clarity, offering longer footnotes. Several comments were concerned with conciseness. Some variations arose from the preference for a range rather than a single number for the DV.

The various footnotes offered in the comments stated that an individual's DV depends on calorie needs, listed individual characteristics that affect calorie needs, or simply provided the calorie base of the DV on the label.

Three comments from manufacturers suggested that footnotes should be optional. Another comment suggested a voluntary program of explanatory information provided in footnotes, with a stipulation that the footnote become mandatory if 70 percent of packages were not including it by 1996. Two comments objected to inclusion of a footnote on the basis that the label cannot be a source of dietary guidance. Others were concerned about the space used by the footnote.

Two comments addressed other possible footnotes to the nutrition information. Inclusion of dietary guidance for special dietary needs was suggested by a manufacturer. A consumer advocacy organization suggested the use of footnotes to explain the use of adjectives such as "high" on the basis that FDA is wrong in assuming that people will relate "high" to the idea of limiting consumption elsewhere. The following statement was suggested: "People eating this food may need to limit the fat (or other nutrient) that they consume from other foods."

The agency notes that the consumer research suggests that many consumers do not notice footnotes. One survey asked respondents how many calories the DRV's were based on, while the respondents viewed a label with a footnote providing the information. Over half of the respondents could not give the answer (Ref. 87). Another study provided subjects with a nutrition label that had a footnote stating the caloric level base (2,350 calories) of the DRV list. Over 70 percent of the subjects stated that the DRV's applied to them (Ref. 71), even though, according to this report, this caloric base should apply to only 10 percent of the population. However, in other surveys, when respondents were asked directly whether DRV's based on a specific calorie level applied to them, most recognized that adjustment would be needed and were able to give the correct direction of adjustment (Refs. 87 and 97). These results show that although most consumers do not notice footnotes, those who are given the information (and by inference, those who do read the footnote) are able to interpret it appropriately.

FDA, in section V.B. of this document, has addressed comments regarding whether the nutrition label is subject to a requirement to provide general dietary guidance to consumers. The agency concluded that the first consideration for the nutrition label must be to help consumers make informed food choices by enabling them to both comprehend the nutritional value of the food and to understand its relative significance in the context of the total daily diet. Thus, general dietary guidance is not to be provided as part of the nutrition label. If a particular label has space, however, general dietary guidance may be included outside of the nutrition label, as discussed further below.

The agency does not agree that a footnote should be placed on the label urging people, after eating the food, to limit nutrients in which the food is high. Such information depends on the use of adjectives with the PERCENT DV format, which the agency is not allowing, as discussed in section H.4. of this document.

FDA agrees with the majority of comments that a footnote is necessary to help consumers determine how their individual dietary needs compare with the reference DV's used on the label and to prevent the possible misunderstanding of the applicability of the reference DV's (see comment 132 of this document). At a minimum, an acceptable footnote must specify the calorie level used for the reference DV's so that consumers have some basis to evaluate possible differences between their dietary needs and the reference DV's used on the label. Also, a statement that an individual's daily values vary according to calorie needs is essential when calorie-specific daily values are presented. FDA has provided for a footnote that includes this information in § 101.9(d)(9)(i).

The agency believes that many other pieces of information mentioned in comments, such as the information presented in Appendices E and F ... the format proposal, may be appropriately included on the food label to give useful context to the nutrition information. However, this information may not be included within the nutrition label itself because such additional information would require significant additional space to present and therefore would detract from the readily identifiable image of the nutrition label. Specifically, it would be appropriate to list typical calorie intakes for men, women, and children and to summarize dietary guidance on the food label. Furthermore, if the manufacturer is willing to supply copies of the Dietary Guidelines for Americans upon request, a statement of the availability of such information would be appropriate. Examples include the following:

(1) Typical intakes for women are 1,600 to 2,200 calories, for men 2,000 to 3,000 calories, and for children (ages 4 to 14) 1,800 to 2,500 calories.

(2) Use this nutrition information to help you plan your total daily diet. The Dietary Guidelines recommend that Americans:

- Eat a wide variety of foods
- Choose a diet with plenty of vegetables, fruits, and grain products
- Choose a diet low in fat (30 percent of calories or less), saturated fat (less than 10 percent of calories), and cholesterol
- Use sugars, salt, and sodium in moderation

(3) For more complete information, a copy of the "Dietary Guidelines for Americans" may be obtained from (manufacturer's name and address).

e. *Footnote listing the caloric conversion factors.* 145. A number of comments addressed the inclusion of caloric conversion factors for fat, carbohydrate, and protein on the label to help consumers use the nutrition information to apply the recommended Dietary Guidelines for Americans. Several comments agreed that stating the caloric value per gram of fat, carbohydrate, and protein would help consumers better understand and use the nutrition information on the label. Many other comments objected to the inclusion of caloric conversion factors because of space considerations and because of reservations about how many people would be able and likely to use such information.

The agency is persuaded by comments from nutrition education experts that the public will benefit from having the caloric conversion factors on the label. FDA recognizes, as discussed above, that 9, 4, and 4 calories per gram for fat, carbohydrate, and protein, respectively, are general factors that may not apply to all foods. However, they are applicable to the majority of foods, and therefore, inclusion of these factors will be useful as a general guide. Moreover, FDA finds that any concerns about space are eliminated by its providing for intermediate size labels in § 101.9(j)(13). Accordingly, § 101.9(d)(9) requires that this information be included on the label.

4. CONTROL Format; Expression of Absolute Amounts in Grams/Milligrams

The majority of comments that opposed the PERCENT DV formats supported the CONTROL format. A few comments supported the current format, rejecting the revised list of nutrients, the new order in which nutrients are declared, and the PERCENT DV display. FDA has responded to the comments opposing the revision in the required list of nutrients and the order of nutrients earlier in this document (section III.A.2. of this document). A majority of the industry comments supported the CONTROL format without the DRV list. Some consumer groups and health organizations also supported the CONTROL format; however, they recommended that the DRV list be included.

146. Most comments in favor of the CONTROL format stated that research has not consistently shown that any other format has better performance characteristics on label use tasks than the CONTROL format.

The agency disagrees with this argument. Both FDA's and industry's research found that the simplest label formats with the smallest amount of information and the least number of columns had the best performance for label use tasks that require only simple comparisons or identifying differences between products. Because it has the least amount of information, the CONTROL format performs well on this kind of task. FDA's research suggests that with certain placement of the information, some other formats, including the percent formats, that provide more information can perform as well as the CONTROL format on these tasks. The industry study demonstrates that these other formats can also be designed in ways that lead to poorer performance on simple comparison tasks (e.g., by adding more columns to the display).

Both FDA's and industry's research also shows that for label use tasks that require consumers to make dietary judgments about the product, such as whether the food is high or low in certain nutrients or how the food fits into a daily diet, the best performing formats are those that include either the PERCENT DV declaration or adjectives. Other design elements such as listing reference DV's, grouping nutrients, or highlighting nutrients do not appear to improve performance on these types of dietary judgment tasks. The CONTROL format is among the poorest performers on tasks that require dietary judgment.

Being able to comprehend the nutrition information and to understand its relative significance in the context of a total daily diet means, at least in part, that consumers must be able to make accurate high/low judgments about the food. PERCENT DV and ADJECTIVE displays present high/low information directly. The g/mg formats (such as the CONTROL format) require that the consumer calculate percentages to get the information. The CONTROL format requires, in addition, that the consumer know the recommended amount for each nutrient. Research results show that consumers do not know the recommended amounts for nutrients, that many are not able to make such calculations, and that many are not willing to make the large number of calculations that would be required to include all of the listed nutrients in the judgment (see comments 105, 106, and 107 of this document).

147. Other comments supported the CONTROL format because it is uncluttered, because consumers are used to it, and because it is more consistent with dietary guidance, which is given in terms of g/mg amounts, than is the PERCENT DV format.

The agency agrees that simplicity and lack of clutter are important criteria in selecting a format. However, enough effective information must be presented to make the nutrition label useful. Therefore, the selection of a required nutrition label cannot be based simply on which one has the least amount of information.

Some of the arguments about consumer familiarity with a format were addressed in section V.G. 2 above. The agency noted that evidence from consumer research shows that consumers are not able to effectively use the current format for some important label uses. Therefore, consumers' greater familiarity with it does not have important benefits. In contrast, research shows that consumers are able to effectively use the PERCENT DV format, even though the format is new to them. The agency also noted above that g/mg amounts will continue to appear on the nutrition label for use by consumers who have come to rely on nutrition information presented this way.

148. A large number of comments were opposed to the CONTROL format because it does not meet the criterion in the 1990 amendments of enabling consumers to understand the significance of the nutrition information in the context of a total daily diet. This argument was sometimes stated in conjunction with FDA's research finding that the CONTROL format had poor performance characteristics, particularly with regard to the dietary judgment tasks.

FDA agrees with this argument. A summary of research findings related to the CONTROL format appears in section V.D.2. of this document. For all the reasons discussed in this section, FDA concludes that the CONTROL format is not adequate to meet the criteria of the 1990 amendments.

5. HIGHLIGHTING Format

Highlighting was discussed in the format proposal both as a separate format and as a format enhancement. Most comments regarding the use of HIGHLIGHTING dealt with it as a format enhancement, and these comments are discussed in a later section.

149. The comments that discussed HIGHLIGHTING as a format were from industry health professional organizations, and consumer advocacy organizations. Most comments were opposed to the format. Many of these comments discussed the HIGHLIGHTING, ADJECTIVE, and GROUPING formats together The comments argued that the HIGHLIGHTING format is inadequate and misleading because it gives undue emphasis to desirable components, thus tending to obscure the levels of undesirable components. In addition the comments stated that the HIGHLIGHTING, ADJECTIVE, and GROUPING formats have no satisfactory means of communicating the level of components that do not have a DV, such as complex carbohydrates and sugars. Some comments argued that a modified HIGHLIGHTING format that flagged both desirable and undesirable components of a product should not be selected because extensive consumer testing would have to be conducted to determine whether people are able to distinguish between the two types of flags. Other comments argued that the HIGHLIGHTING, ADJECTIVE, and GROUPING formats foster good-bad food messages.

Several comments from professional organizations argued that the HIGHLIGHTING format is redundant because nutrient content claims can be made on the front of the package. These comments stated that if anything is highlighted, it should be undesirable components to balance the front panel. Other comments argued that this format did not score well in consumer research and did not improve consumer comprehension of the label. One comment noted that international harmonization is problematic with HIGHLIGHTING, ADJECTIVE, and GROUPING formats because in Canada, such information is generally required to be grouped together and given equal prominence, whereas these formats include some form of emphasis in one or more parts of the nutrition label.

A supporting comment argued that the HIGHLIGHTING format is best because it is straightforward, easy to understand, and information can be quickly gleaned from it. The agency is persuaded by the comments and the research that the HIGHLIGHTING format should not be selected. FDA notes that this format has most of the disadvantages of the CONTROL/DV format (of which it is a variant), and it has several additional limitations. The format did not score well in consumer research on measures that involved putting the food into the context of a total daily diet. In addition, it emphasizes desirable features of products, which may already be emphasized by front panel statements and which may tend to obscure the levels of less desirable components. Therefore, FDA is not requiring the use of the HIGHLIGHTING format.

6. ADJECTIVE Format

Issues regarding the use of adjectives to describe nutrient levels arose in three contexts: support or opposition to the ADJECTIVE format itself; mandatory use of adjectives with another format, particularly the PERCENT DV with DRV format; and voluntary use of adjectives as a format enhancement. Adjectives as a format enhancement are discussed in section V.H.2. of this document.

150. Some comments argued that adjectives are inherently value-laden and would communicate a good-bad food perception.

The agency does not agree with this argument. As noted above in the discussion of this argument for the PERCENT DV format (section V.G.2. of this document), both FDA and industry research found that the ADJECTIVE and the PERCENT DV declarations tended to produce the most accurate judgments about whether products are high or low in various nutrients (Refs. 70 and 71). The g/mg formats were more likely than ADJECTIVE formats to lead to extreme and inappropriate dietary judgments, such as responses that a food was high in a nutrient in which it was actually low, or that a food should be avoided altogether because of a particular nutrient level. The agency is not requiring the ADJECTIVE format for other reasons.

151. Several comments argued that a complete scheme for assigning adjectives to all nutrients required to be listed on the label does not exist. They argued that because DRV's have not been established for all nutrients, including sugars and polyunsaturated fats, an acceptable scheme would be time consuming to develop.

The agency agrees that a complete scheme for assigning adjectives to all nutrients does not currently exist, and that the lack of DV's for some nutrients would complicate the development of such a scheme. However, as explained in Comment 134, all of the alternative formats except the CONTROL format share the limitation that DV's have not been set for some nutrients. Because the limitation is constant for almost all formats, it cannot be seen as a disadvantage unique to one format. The agency believes that providing DV information for the nutrients that have DV's is more beneficial than withholding it for all nutrients because it is unavailable for some. Nonetheless, the agency is not requiring the ADJECTIVE format for reasons stated in comment 152 of this document. Therefore, the issue raised by these comments need not be addressed further.

152. Several comments opposed the ADJECTIVE format because it would be confusing to consumers. One comment argued that the format provides information on whether a nutrient is high, medium, or low, but not whether it is a desirable or undesirable nutrient. Some comments argued that the format is too cluttered and directive. Some comments noted that the ADJECTIVE format showed a number of weaknesses in the consumer research, particularly a tendency for consumers to fail to differentiate between products when different nutrient levels were described by the same adjective. The comments noted that wide ranges, as proposed for the category "medium," would be misleading to consumers who did not attend to the nutrient values.

Several comments supported the ADJECTIVE format, arguing that the format is easy to read and does not require math calculations or working with numbers at all. One stated that it would be easier for the elderly and visually impaired to use. Other comments supported it because it was preferred by consumers in the research.

FDA is not requiring the ADJECTIVE format for the following reasons. The agency agrees that the ADJECTIVE format showed weakness on an important label use task, the product comparison task that required detecting differences between nutrients. The agency also agrees with the comments that argued that the wide range for some of the adjective categories may be misleading to consumers who use the label in certain ways. The agency acknowledges that the ADJECTIVE format was the most preferred in some studies but notes that preference measures must be interpreted cautiously and cannot be used as a definitive criterion, for the reasons discussed in section V.D.3. of this document. The agency further notes that none of the studies provided evidence that the ADJECTIVE format is easier for elderly consumers to use.

7. GROUPING Format

Grouping by whether dietary guidelines recommend choosing a diet high or low in specific nutrients was tested in FDA's Study 2 (Ref. 70). This format element did not generate many comments, and the comments about it were frequently included in statements about the HIGHLIGHTING or ADJECTIVE format. Most of the comments were opposed to GROUPING.

153. One argument against the GROUPING format was that it is too value-laden, lending itself to a good–bad food message. Another comment argued that the GROUPING format does not provide meaningful information related to the particular product. Other related comments argued that the GROUPING format did not have good performance characteristics in research, and that subjects reported that they found it too prescriptive. Some comments argued that it would be confusing to consumers in general, and one comment argued that it would be especially confusing to consumers with diabetes.

The agency agrees with these comments. FDA's research showed that the GROUPING format did not perform well on the dietary management tasks and did not offer any significant advantages over other formats (Ref. 70). In addition, although the format was not strongly disliked, many subjects who disliked it reported that they found it too prescriptive. This complaint is consistent with the complaints of many of the comments.

The agency has decided not to require that nutrients be listed under the

GROUPING format headings for the reasons discussed in the paragraphs above and below.

154. A few comments argued that the GROUPING format would be a challenge to implement because adequate consensus does not exist on where to place some subcomponents, such as polyunsaturated fats. In addition, comments challenged the format because its recommendations are not entirely consistent with those of the dietary guidelines. For example, the dietary guidelines recommend moderate intake of some nutrients, such as sodium, but the GROUPING format recommends low intake.

The agency agrees that the placement of some nutrients and nutrient subcomponents is problematic under the GROUPING format. This problem in placing all nutrients is one of the reasons the agency has decided against the GROUPING format.

155. Several comments in support of the GROUPING format argued that it provides nutrition education by stating which nutrients should be eaten in greater and lesser amounts. A few comments argued that the proposed order of nutrients on the label tends to group them into those targeted for lower and higher intakes, so that the GROUPING format is unnecessary with the new nutrient order.

FDA agrees that the intent of the grouping format is to provide general dietary guidance. However, the fact that the format did not offer significant advantages over other formats on any performance measure considered in the consumer research shows that dietary guidance as offered in this format did not benefit consumers. The proposed new order of nutrients uses the widely accepted design of placing first the elements of greatest importance and is intended to accomplish some of the goals of the GROUPING format. The GROUPING format's failure to convey the intended dietary guidance, as measured in the consumer research (Ref. 70), is one of the reasons the agency has decided against this format.

8. Modified Grouping Format

A few comments mentioned the Modified Grouping format in which the order of the nutrients changed according to the amount in the product.

156. Almost all comments were opposed to the Modified Grouping format. The major argument against it was that it would reduce consistency and increase confusion among consumers. Comments stated that using this type of format is especially difficult for older people, who have a particular need for nutrition information. As the population ages, larger numbers of consumers will have difficulty with such a format.

The agency agrees with this argument and notes further that available research shows that with advancing age, consumers have increasing difficulty extracting relevant information from displays in which the order of nutrients vary (Ref. 104).

The agency is not requiring the Modified Grouping format because it has no reason to believe that this format would meet the requirements of the 1990 amendments for the reasons stated above. The agency further notes that consistency of placement of nutrition information is a principle that has guided the development of the new format because such consistency has been shown to help consumers, as noted above.

9. CONTROL Format With DV Ranges

In its format proposal (57 FR 32058 at 32072), the agency discussed several alternative formats to those tested by the agency. For those reference values based on caloric intake, one alternative was the use of a range of DV's based on a caloric intake range instead of a single caloric intake value (Appendix E in the format proposal). The agency requested comment on this alternative.

157. Comments were evenly divided concerning the use of ranges for DV's. A number of comments, primarily from food industry representatives, supported the use of a range for the DV's because a range could assist consumers in realizing that nutritional needs vary with individuals, and ranges are easier for consumers to work with than single DV values. Others supported the use of a range because the use of a specific reference value would cause consumers to conclude that the values applied directly to them as individuals. Several comments suggested specific caloric ranges to be used (including 1600 to 2800, 1600 to 2400, and 1500 to 2800).

A number of comments from a variety of groups, including consumer advocates and the food industry, argued against the use of ranges. Reasons for opposing the use of ranges included concerns that ranges would be confusing to consumers, that they would overwhelm consumers, that they are too broad to be meaningful, that they use more label space than single values, that consumers would not be able to calculate their reference value from a range, and that they have not been evaluated in appropriately designed studies to determine if they would be more effective and less misleading than a single value. One comment cited research conducted for the purposes of developing a dietary guidance graphic (Ref. 105) that showed that consumers experienced difficulties using a range of values relative to dietary guidance.

FDA has carefully considered these comments and concludes that there is not sufficient support, nor a substantial rationale, for providing reference values as a range. The agency notes that no comment contained research or other data to substantiate the utility or appropriateness of ranges. No evidence shows that consumers do in fact find ranges easier to work with, and no data suggest that ranges are less likely than single values to confuse or mislead consumers. In fact, the agency has reviewed the literature on how people assign magnitude to numbers (e.g., Ref. 120). This literature concludes that in order to estimate magnitude, people generally have to answer the question, "compared with what?" usually invoking a norm or reference standard as a context for comparison. The DV is intended to be such a reference standard. When expressed as a range, the value of the DV as a norm against which the level of the nutrient can be understood is compromised because the norm cannot be easily identified without additional assumptions and computations. Thus, the use of ranges is inconsistent with the 1990 amendments, which require that nutrition information be conveyed in a manner that allows consumers to comprehend the nutrition information (section 2(b)(1)(A) of the 1990 amendments). Ranges apparently have the opposite effect.

The agency is also concerned that the use of ranges would mislead some consumers to believe that the consumption of a nutrient at any level within the declared range is appropriate for them. For consumers whose calorie intake is at the middle or low end of the range, however, the label could induce consumption of nutrients such as fat or saturated fat in excess of the dietary guidelines, which would adversely affect public health.

For these reasons, FDA has rejected the presentation of reference values as ranges. The argument that consumers need assistance to realize that nutritional needs vary with individuals has been addressed by requiring daily value information for 2,000 and 2,500 calorie diets.

10. CONTROL Format With Sex-specific Daily Values

158. A few comments supported reference values based on gender (Appendix E in the format proposal). One comment suggested that gender specific reference values were appropriate because women have

different nutritional requirements than men. Other comments opposed the use of separate reference values for men and women. The primary concerns were the issues of space, readability, and clutter on the label. One comment suggested that the format presented too much information for the consumer to process. The same comment opposed gender-based reference values because their use did not recognize that some active women are more like men in terms of their calorie need, while some older men have calorie needs more like those suggested for women. Several comments argued that gender is only one factor to consider in determining an individuals's dietary intake, and therefore its presentation on the label has the potential of inappropriately emphasizing one factor.

While the agency acknowledges that women in general have different nutritional needs than men, FDA notes that such comparisons can be made for a variety of groups comprised of persons 4 or more years of age. Thus, the agency agrees that the use of gender specific reference values may inappropriately emphasize only one factor in evaluating dietary intake. However, the agency agrees that examples of recommended nutrient amounts for different calorie level intakes may help consumers to estimate their personal daily recommendations. Therefore, as discussed in comment 139 of this document, FDA is requiring the inclusion of recommended nutrient amount information for 2,000 calorie and for 2,500 calorie diets in the nutrition information.

11. CONTROL Format With dietary guidance

159. A number of comments, primarily from industry, supported the CONTROL Format with Dietary Guidance (Appendix F in the format proposal). Several comments supported this format on the basis that it was most like the current format and therefore familiar to consumers. Two comments argued that FDA should select the CONTROL Format with Dietary Guidance because USDA prefers it, and harmonization between the two agencies is important. Supporting comments argued that this format helps consumers to put the food in the context of a total daily diet, reinforces the dietary guidelines, and is simple and uncluttered. One comment suggested that the caloric equivalents of the macronutrients may enable consumers to better utilize the information provided.

The major arguments against CONTROL with Dietary Guidance were that the information is too vague to be effective and adds clutter to the label. Some of these comments noted that the footnote discusses foods when the information on the label is about nutrients, so that, except for vague information about fat, no relevant information about recommended nutrient amounts is available on this label. Several comments argued that it would not be clear to consumers that the dietary guidance information applied to total diet and not to individual foods. Other comments noted that because this format has not been tested, the agency has no basis to assume that consumers will be able to relate the dietary guidance to the nutrition information. Comments also pointed out that many calculation steps and further instruction would be required to apply the dietary guidance to the consumer's daily diet.

Some comments noted that the dietary guidance footnote would be problematic for meat products because it recommends a diet high in vegetables, fruits, and grain products, which might imply to consumers that they should not eat meat.

The agency does not agree that CONTROL with Dietary Guidance format as shown in the format proposal is consistent with the requirements, or effective for meeting the objectives, of the 1990 amendments. The addition of the dietary guideline and calorie conversion information does not serve to put the levels of nutrients in the food into the context of a daily diet. However, the format includes information that helps consumers to understand the significance of the nutrient levels in the food.

Therefore, the agency is incorporating one of the elements from this proposed format as a mandatory requirement of the nutrition label format. Specifically, FDA recognizes that it will be useful to some consumers to have the caloric conversion factors on the label. The placement beside the nutrient names as shown in Appendix F of the format proposal is not acceptable, however, because the g/mg amounts will be placed beside the nutrient names in the required format. Both pieces of information on the same line would decrease or eliminate the spacing that helps to make the format comprehensible. Therefore, the agency is requiring that the caloric conversion factors be included on the nutrition label as a footnote, as described in § 101.9(d)(10).

12. New Formats Submitted as Comments

160. One comment suggested a format for the nutrition label quite different from any other format suggested and quite different from any format that had been previously tested. Called a graphical profile, the format expressed quantitative nutrition information in terms of distance along a spoke radiating from a central point, where each spoke represented a mandatory nutrient component. The points on each spoke were connected with each other to form a pattern that distinctively identified the nutrient profile for the product. The comment claimed that the format has a number of advantages, including: (1) Providing consumers with easily remembered mental "shapes" of the products that they wish to consume or avoid and (2) helping consumers to place the food in the context of a total daily diet by allowing for easy comparison between the shape of the nutrient profile for the product and an ideal shape based on dietary recommendations.

FDA is impressed by the ingenuity of this format but is convinced that such an innovative format for the nutrition label cannot be required without extensive consumer testing. No consumer research to support use of this format to accomplish the requirements specified in the 1990 amendments was submitted. Furthermore, FDA notes that the format encourages a comparison between the specific food and the dietary guidelines, whereas the recommended comparison is between the total daily diet and the dietary guidelines. Therefore, FDA is not adopting the graphical profile format. The agency is prepared to work with interested persons to develop consumer research that would show the usefulness and validity of this format.

H. Graphic Enhancements and Format Elements

The agency received numerous comments concerning the various format elements and graphic enhancements discussed and illustrated in the format proposal.

1. Format Legibility

161. Many comments, particularly from older and vision-impaired consumers and from organizations and health care professionals serving their needs, suggested that the legibility of nutrition information should be improved through regulations specifying larger sized or boldface type, easier to read type styles, use of upper and lower case letters, minimum type

spacing, and greater color contrast between print material and background, such as black lettering on white background. An alternative suggestion was for FDA to specify minimum print size and color contrast.

A number of comments from package designers and from individual food companies pointed to the problems in requiring graphic elements that add to the space requirements for the nutrition label, given the limited size of many packages and the competition for label space from other required or desirable information (e.g., UPC information, storage and preparation instructions, recipes). Other comments urged the agency to set minimal and flexible standards for graphic requirements related to readability that would allow manufacturers to accommodate the wide variation in package sizes, package shapes, and current graphic elements on packages.

The agency recognizes that mandating graphic elements to assure a desirable level of readability for the required nutrition information has both advantages and disadvantages, particularly when these elements may require more space. The agency agrees that some flexibility in the mandated graphical elements is necessary in order to accommodate the wide range of packages on which the information will appear. However, FDA also agrees with the comments that stated that the readability of the nutrition label needs to be improved to help older and vision-impaired consumers who otherwise would be effectively denied access to nutrition information of food packages. The agency points out that, as stated in the format proposal (section V.B.), certain graphic techniques go directly to the requirements in the 1990 amendments (section 2(b)(1)(A)) that the information be presented in a way that enables consumers to readily observe the information.

With the aim of achieving minimal readability standards for the required nutrition information, FDA has developed for use in this document, and in the presentation of the new label, a format design that incorporates many of the graphic elements suggested by the comments to produce a more readable label. FDA agrees with comments that argue that a consistent "look" to the required nutrition information on food packages will help consumers to find the information on the package and to recognize the information for what it is—a profile of the nutrient content of the food. Although FDA is providing for some flexibility in label execution, companies are encouraged to use this label as a model for designing labels for their packages (see section 101.9(d)). The specifications for this presentation of the graphical elements are included in the Code of Federal Regulations as appendix B to part 101.

FDA understands that some flexibility in execution of the nutrition label is necessary to accommodate various package sizes and shapes and current graphic features that serve as brand identifiers. For these reasons, a number of graphic alternatives to the model label are permitted. For example, § 101.9(d)(11) allows the footnote to be moved to the right of the percent DV information if space is not adequate beneath the vitamin and mineral information, and § 101.9(d)(8) allows for a vertical display of vitamin and mineral information when more than four vitamins and minerals are declared.

In addition, although the model label calls for dark or one color type on a white or neutral color background, flexibility in background and type color is allowed § 101.9(d)(1)(i). FDA is aware that some products traditionally use color as a brand identifier and print nutrition information in white or neutral color type on a darker color background. This type of graphic technique, called "reverse type," is known to have poorer readability characteristics than regular type. FDA is not prohibiting the use of reverse type. However, FDA expects that unless impractical, the nutrition information will be presented in dark type on a light color background. Impracticability is presented by situations like those described above, in those situations in which reverse type will be significantly less expensive than the FDA preferred alternative, or in other similar appropriate circumstances. If reverse type is used, FDA expects that the impairment in readability resulting from such a technique will be compensated for by the use of other graphic techniques to improve readability, such as increased type size. It will not be acceptable to reduce the contrast between print and background, whether by light letters on a light background or dark letters on a dark background, to the point where readability of the label is significantly degraded.

Although the agency is committed to the flexible application of graphic techniques to achieve an acceptable level of readability for the required nutrition information, FDA considers it necessary in order to ensure that the nutrition information is conveyed in a manner that enables the public to readily observe and comprehend such information to set minimal standards and requirements for certain key graphic elements of the nutrition label. Such requirements will prevent confusion about the minimal level of readability that is necessary for the nutrition information. The key graphic elements that are specifically required on all packages are set forth in §§ 101.9(d)(1)(ii), 101.9(d)(1)(iii), and 101.9(d)(1)(iv). They consist principally of type size and type style requirements, namely that a consistent upper and lower case type style be used, that a single, easy-to-read type style be used, that product information be in at least 8 point type (the lower case "o" no smaller than 1/16th inch) with at least 2 points leading (i.e., space above and below letters) and kerned (space between letters) no tighter than −4 setting, and that headings, certain nutrient names, and percentage amounts be highlighted by bolding or other form of highlighting.

In addition, to preserve a readily identifiable image or "look" for the label, a number of other graphic elements are required, as discussed in § 101.9(d)(1)(i), (d)(1)(v), (d)(2), and (d)(7)(ii). These sections require a hairline box to set off the nutrition information, hairline rules in certain places within the nutrition label, larger print size for the title, "Nutrition Facts," and display of the percent sign (%) after the numerical value of the percent DV for each nutrient.

FDA has been persuaded by comments and careful consideration of alternatives that these requirements will benefit a substantial number of consumers who currently have difficulty reading nutrition information on food packages. FDA considers this benefit to be worth the cost of the small increase in space allotted to nutrition information that may be required for some food packages. The agency notes that the previous regulations on type size also mandated a minimum type size for the lower case "o" of 1/16th inch but applied the same minimum type size requirement to the upper case "o" as well, which resulted in most manufacturers using all upper case type styles. The practical effect of requiring upper and lower case type styles and keeping the same minimum type size requirement will be to increase the minimum size of upper case letters by approximately 30 percent. To further compensate for the increased demands on label space, FDA will allow the information in the footnote, which unlike the product specific information is the same for all products, to meet or exceed a 6 point type minimum type size requirement. FDA considers that the requirements for upper and lower case type styles, leading, and kerning will enhance the readability of 6 point

type enough that it will not present problems for most consumers.

2. Other Graphic Enhancements

162. Several comments from retailers, manufacturers, graphics designers, universities, and a nutrition professional group were directed specifically at reverse printing as used in the graphic adaptations of appendix C of the proposal. Two comments stated that reverse printing would be helpful to consumers and should be permitted on a voluntary basis. However, the remaining comments addressed technical or legibility problems. Several comments stated that the format examples were not readable, that the reverse printing overwhelmed the smaller type, and that "stacked" titles (i.e., with components arranged vertically, e.g., placing "servings" on one line and "per container" on the next line) were confusing. The principal technical problem mentioned was that reverse printing tends to fill in and become unreadable, depending on the printing process used and available label area.

One manufacturer of many products stated that only two out of four printing processes used by the firm would be able to implement the graphic adaptations of appendix C. Another manufacturer stated that it would be able to print reverse graphics only for large containers. A graphics design firm stated that reverse printing adds significant costs. Another design firm cited two technical barriers to reverse printing: Multi-screen labels are difficult to hold in alignment and retain clarity, and reverse printing cannot be applied to packages with light backgrounds because the background must be dark for light, reverse print, to show through. The comments stated that many brand identification colors are light, and manufacturers object to having to change them, arguing that brand identification would be lost.

FDA agrees that reverse printing should not be required, given the difficulties mentioned in the comments. The agency finds convincing the arguments against the legibility of reverse print discussed in the professional literature (Ref. 107).

Because of the need for flexibility to place the nutrition panel in variously sized panels, the agency does not object to stacked titles.

163. The majority of comments stated that other kinds of graphic enhancement of nutrition information, such as underlining, bolding, and using larger type size or contrasting color, would encourage and assist consumers in using the information. However, opinions were divided as to whether the combination of enhancements illustrated in appendix C of the proposal would be helpful. A number of comments criticized the graphic adaptations as cluttered, jumbled, obtrusive, or distracting from or overwhelming the smaller type. However, except for a few suggestions that graphic enhancements be entirely at the discretion of the manufacturer, the comments favored some degree of standardization through FDA regulations. Comments frequently stressed the need for uniformity of appearance of labels across the food supply to facilitate education efforts and consumer access to and use of the nutrition information.

Several comments from consumers, a graphics designer, and a nutrition professional group stated that the number of different font sizes on a label should be minimized to ensure legibility. One comment cited a book in support of this view (Ref. 108). Several comments urged FDA to keep the label uncluttered. Other comments provided specific guidelines for maximizing the label's usefulness. These guidelines generally involved removing as much print as possible, keeping titles linear rather than stacking them, and including only essential information.

Several comments from industry and health education organizations endorsed voluntary, judicious use of other graphic enhancements such as spacing, indentation, use of upper and lower case letters, and selection of type face and size. These comments generally opposed making such enhancements mandatory until consumer research is conducted to ensure that they effectively aid consumer comprehension. Other comments from groups representing older readers and the vision impaired provided research demonstrating the importance of type size, type style, type spacing, the use of upper and lower case letters, and contrast between type and background to these readers. A consumer organization suggested that FDA establish an advisory committee of experts to provide guidance for the selection of graphic devices for further consideration. Two manufacturers opposed graphic enhancements altogether as contrary to the requirements of 1990 amendments for consistency in presentation of information. One comment characterized the combination of extreme bolding and close proximity of columns in the graphic adaptation of the PERCENT DV with DRV format as diverting attention from the quantitative values and stated that, with respect to the objectives of the 1990 amendments, the format constitutes near misbranding.

Based on the research submitted in comments, the agency is convinced that it can proceed to require certain graphic enhancements. While some comments questioned the appropriateness of requiring such enhancements at this time, other comments submitted research that demonstrated that these enhancements are effective and appropriate for creating a nutrition label that is readily observable and comprehensible, as required by the 1990 amendments. The agency agrees that keeping the format uncluttered is important and therefore has minimized clutter in the model format. The agency has carefully considered which format enhancements to combine, based on the comments and the research presented.

FDA is convinced that the specific elements mandated provide a visually integrated image that will give the nutrition label a uniformity of appearance across the various types of packages in the market and will enhance consumer use of the information. For example, an important element in the appearance of the nutrition label is its pattern of bolding. In § 101.9(d)(1)(iv), the agency is requiring bolding of the heading "Nutrition Facts" which is being employed as an identifying title, like a logo or trademark, to distinguish the nutrition label from other information on the package, as well as bolding of headings of certain nutrient names and percentage amounts. The agency is convinced that this and the other measures that it is requiring will serve to establish the readily identifiable "look" that it is seeking and finds to be necessary to achieve the relevant goals of the 1990 amendments.

164. Comments were received from a consumer, a health care provider, a State government agency, and two manufacturers suggesting that industry be permitted to use graphical devices, such as pie charts, to illustrate nutrient content claims. Comments suggested that uniformity of labeling could be maintained by requiring that any supplementary graphics be placed outside the nutrition label area. Other suggestions were that FDA permit the voluntary inclusion on the label of information from authoritative sources, such as the Dietary Guidelines for Americans (Ref. 4) or Diet and Health (Ref. 3), to aid consumer understanding of nutrition information in the broader context of current dietary advice to the public.

FDA has no objections to the use of graphic devices to amplify or explain nutrition information, provided that the

illustrations are presented in a manner that is truthful and not misleading, and that the devices are not placed within the label area in which the nutrition information appears. The agency also agrees that supplementary information outside the nutrition label can help consumers better understand the characteristics of individual foods in relation to the total diet. However, such supplementary information must be consistent with the requirements for nutrient content or health claims that are established in companion documents published elsewhere in this issue of the **Federal Register**. Manufacturers are also encouraged to utilize other means to disseminate dietary guidance information, such as incorporation of such materials in promotional and print advertising materials or by means of shelf talkers and placards at point-of-sale.

165. Several industry comments requested that manufacturers be given flexibility, either in the case of small packages or in general, to declare vitamins and minerals and DRV's in either tabular or linear arrangement for both full and simplified formats. A manufacturer suggested permitting a linear array for micronutrients present at levels of at least 2 percent of the DV.

The agency agrees that manufacturers need flexibility in accommodating the required nutrition information, particularly for small packages and printable surface areas that are oddly shaped or narrow. Consequently, FDA is providing options in the display of a number of the types of information required. For example, in § 101.9(d)(ii), the agency is providing that the information about calorie-specific daily values and caloric conversion information may be placed beneath the vitamin and mineral declarations or to right of the Percent DV column. In § 101.9(d)(8), the agency is providing that the vitamin and mineral declarations may be presented vertically in the Percent DV column when more than four vitamins and minerals are declared or horizontally beneath the macronutrients. In § 101.9(f), the agency is providing for optional use of a simplified format under certain circumstances. In § 101.9(j)(13)(i), the agency is providing exemptions to the requirement to bear nutrition labeling for small packages, and in § 101.9(j)(13)(ii), the agency is providing options for intermediate sized packages to minimize the amount of label space that must be used for nutrition labeling. For small or intermediate sized packages, manufacturers may list nutrition information in a linear fashion, use certain abbreviations, omit the calorie-specific recommended nutrient amounts, or present the nutrition information on other label panels (see sections V.G.3., V.H.1., and V.J. of this document).

3. Highlighting

In the format proposal, the agency requested comments on the feasibility of allowing highlighting as a voluntary graphic enhancement of the principal format. Specifically, the agency requested comments related to whether the use of voluntary highlighting would confuse or assist consumers to observe and comprehend label information. Many different possible schemes for highlighting could be applied to the nutrition label. Many comments addressed noncontingent highlighting, in which certain material is highlighted regardless of any product characteristics, such as highlighting certain nutrient names (e.g., fat, sodium, cholesterol) or titles (e.g., Percent DV, Amount per serving) on the nutrition panel. Other comments addressed contingent highlighting, in which certain material is highlighted only if the product has certain characteristics, such as highlighting the nutrition information for fat on the label of a product that meets FDA's criterion for low fat. In it's research, the agency tested a contingent highlighting scheme that highlighted nutrients whose levels in the food qualified for adjectival descriptors (high or low depending on the nutrient) that were consistent with dietary guidelines.

Many different possible techniques of highlighting exist, including boldface print, all capital letters, italic print, larger print, reverse print, different colored print, and color banding. In the format examples published in the format proposal, only boldface print was used for highlighting.

166. Many of the comments that discussed noncontingent highlighting suggested that highlighting should be considered as a format enhancement and should be used for column headings and names of nutrients. Other comments argued that the agency should require the highlighting of certain nutrients because of their health significance regardless of the level in the product. The nutrients most frequently mentioned in the comments in this regard were those associated with chronic disease, such as sodium, fat, and cholesterol. Most of these comments suggested that boldface type and all capital letters are adequate to achieve such highlighting.

Several comments addressed the issue of whether noncontingent nutrition label highlighting should be mandatory or voluntary. Some manufacturers objected to any required highlighting because of the increased cost and increased label space required. Other comments argued that if highlighting is allowed at all, it should be mandatory so that the benefits of highlighting would be universally available to consumers, and so that labels would be uniform. Some of these comments argued that uniformity of labels is important to reduce consumer confusion.

The agency agrees than mandatory highlighting imposes some burden on manufacturers and needs to be justified on the basis of obvious benefits to consumers. The agency also agrees that the use of highlighting to enhance column headings and nutrient names can increase the visual interest of the label and make it more legible for some consumers.

However, the agency is concerned that allowing too many optional highlighting schemes will lead to less consistency between labels, and that highlighting has the potential to increase label clutter and consumer confusion. Therefore, in § 101.9(d)(i)(iv) the agency is requiring mandatory highlighting of the title of the nutrition panel, "Nutrition Facts", headings ("Amount per serving" and "% Daily Value"), nutrient names ("Calories", "Total Fat" "Cholesterol," "sodium," "total Carbohydrate," and "Protein") and percentage amounts for certain nutrients. The agency concludes that these requirements, by establishing a specific "look," strike an appropriate balance between establishing a nutrition label that is readily observable and one that only increases clutter and confusion.

The agency does not agree that nutrients associated with chronic disease should be highlighted. The agency notes that the revised order of the nutrients already calls attention to the nutrients of major public health significance.

167. Several comments supported or opposed the voluntary highlighting of certain nutrients based on their level in the product (contingent highlighting). Supporting comments, primarily from food manufacturers or trade associations, argued that allowing such highlighting would provide useful information to consumers. Opposing comments, primarily from health professionals, professional associations, and consumer advocate or health promotion organizations, argued that allowing contingent highlighting on a voluntary basis would likely lead to inconsistent and possibly self-serv-

highlighting that would be more likely to misinform than inform consumers.

Several comments supported contingent highlighting but recommended that it be subject to the definitions used in FDA's research studies or to the requirements for nutrient content claims, because highlighting is a nutrient content claim. Related comments supported a link between a nutrient content claim on the front panel and highlighting the relevant information on the nutrition panel. For example, if a low fat claim is made on the front panel, the nutrition information for fat would be highlighted.

Some comments recommended that highlighting of undesirable rather than desirable aspects of foods be required because manufacturers will emphasize the good qualities, and such highlighting will provide a balance. In contrast, a trade association commented that the highlighting of "bad" nutrients should not be required because it would be misleading. Another comment suggested that highlighting be allowed only on a case-by-case basis so that both FDA and food manufacturers have maximum flexibility.

Some comments opposed highlighting and argued that attention should be drawn to specific nutrient levels by nutrient content claims rather than by highlighting. Other comments argued that the highlighting of positive information only will accentuate benefits without including information about risks and will lead consumers to ignore vital information on negative aspects of certain products. Several comments from industry were opposed to contingent highlighting because it would communicate a good food/bad food message. Several comments stated that highlighting will imply an educational message which is more appropriately addressed in educational materials.

Other comments opposed highlighting because, they claimed, FDA will not have adequate enforcement resources. Permitting voluntary highlighting will open the door for inappropriate use of highlighting, which will then require additional regulatory intervention. Another comment, consistent with comments about other forms of dietary guidance on the label, argued that selective highlighting based on current dietary recommendations will change over time, and that it is unwise to include shifting format elements on the label.

FDA is not persuaded by the comments that contingent highlighting on the nutrition label will benefit consumers. Consumer research did not find that contingent highlighting increases effective use of the nutrition label for product comparison or dietary judgment uses (see section V.D.2.a. and V.D.2.b. of this document). There is no consensus among the comments, and the consumer research does not support that requiring a particular contingent highlighting scheme is appropriate. FDA is persuaded by comments that voluntary contingent highlighting can be applied inconsistently in a way that would be potentially misleading to consumers. Among products with similar nutrition profiles, some would highlight certain nutrients and others would not. Consumers who read nutrition labels could not depend on the fact that all labels of similar products would look the same, and the differences could undermine the credibility of the information on the nutrition label and lead to consumer confusion.

The inconsistency of labels that would result also leads the agency to disagree that highlighting should be allowed on a case-by-case basis. Consistent treatment of similar information is important for effective use of the nutrition label by consumers. FDA agrees that attention can be drawn to the levels of specific nutrients in a food by nutrient content claims rather than by highlighting information on the nutrition label. Because of problems of inconsistent treatment of similar information and the lack of demonstrated benefits in the research, FDA is not allowing the use of contingent highlighting on the nutrition label.

4. Adjectives

168. A majority of the comments that addressed the issue of adjectives were in favor of their use in some context. Several consumer groups recommended that the PERCENT DV with DRV format be enhanced by a footnote providing FDA's definition of high and low for nutrients. The comments argued that adjectives help consumers to make qualitative judgments about the food without having to make calculations or evaluate percentages. Some comments noted that the ADJECTIVE format was the most preferred in FDA's research.

In contrast, comments opposed to adjectives in the nutrition label argued that they clutter the format and would be redundant with PERCENT DV formats. Comments also expressed the concern that the wide range of values that will fall in the medium category may mislead consumers.

The agency does not agree that there is a need to include adjectives on the PERCENT DV with DRV format. The agency's research showed that consumers are able to make accurate high/low judgments using percents alone, and that when consumers relied on adjectives (see section V.D.2.a. above), they tended to overlook nutrient differences if the nutrients were described by the same adjective. The additional words would add clutter to the label without benefit to consumers. Therefore, FDA is not providing for the addition of adjectives to the PERCENT DV with DV format.

I. Dual Declarations

A few comments raised format issues with respect to foods that use dual declaration displays on the nutrition label (i.e., nutrition information declared both on as packaged/as prepared or per serving/per 100 g bases) A number of issues related to the topic of dual declarations are discussed in detail in the companion document on serving sizes published elsewhere in this issue of the Federal Register. FDA recognizes that such displays raise special format issues, and these are discussed here.

169. One trade association comment urged that FDA consider the label space requirements of dual declaration formats before deciding to require a change in the current nutrition label format. Several comments stated that the PERCENT DV with DRV format would not leave room enough for both "as packaged" and "as prepared" columns on nutrition labels. One industry comment stated that industry sponsored research has shown that the PERCENT DV with DRV format becomes particularly complex and cumbersome when used on food labels using dual declaration displays.

FDA agrees that dual declaration displays have much greater space requirements than the single base display required for most food products. FDA notes, however, that dual declaration displays are voluntary, not mandatory. For this reason, FDA does not agree that the requirements of dual declaration displays should be a determining factor in the decision about the nutrition label format. However, FDA does agree that the unique requirements of dual declaration displays should be accommodated as much as possible within the constraints of the format that is required for all nutrition labels, and the agency therefore has created a new section, § 101.9(e), to specifically address the format of the nutrition label when dual columns are utilized.

FDA notes that several studies submitted as comments or listed in the format proposal found that dual

declaration displays of any kind made the product nutrition label significantly harder for consumers to use and understand (see section V.D.2. of this document). The execution of dual declaration displays for the PERCENT DV with DV format in the GMA/NFPA industry study (Ref. 71) demonstrated the problem with multiple column displays on the nutrition label. In that study, a number of the dual declaration displays placed both g/mg and PERCENT DV declarations in separate columns on the nutrition label, resulting in as many as five columns of information when DV's were listed. The display was complex and cumbersome, but it is not the only, and certainly not the best, way to execute the PERCENT DV format with dual declarations.

FDA's execution of the PERCENT DV format in Study 2 (Ref. 70) purposely arranged the percent declarations in two columns and presented a single g/mg declaration per nutrient in a noncolumn array next to the nutrient name so as not to intrude visually on the columns of percents. With this execution, the PERCENT DV with DRV format performed as well as other formats on labels using dual declaration displays. The agency is convinced that dual declaration executions of the PERCENT DV with DV format should follow the pattern of minimizing the number of columns displaying nutrient amount per serving information. Accordingly, in § 101.9(e) the declaration of the required g/mg nutrient amounts on dual declaration nutrition labels is required to follow the same requirements as for single declaration nutrition labels, which is to be in an unordered array next to the nutrient name. Placement of optional g/mg amounts is discussed in comment 170 of this document.

170. A comment argued that declaring two g/mg amounts in parentheses next to the nutrient name as proposed in the dual declaration format example included in the format proposal looks like "matrix coordinates" and is likely to be confusing to many consumers. One comment suggested an alternative for presenting dual declaration g amounts. The comment suggested that only the g/mg amounts of the product as packaged be in the table, and that a footnote provide the additional amounts in the second declaration for the food.

FDA agrees that even when presented in a noncolumn array, the declaration of two g/mg amounts for each nutrient on the nutrition label (e.g., one each for as packaged/as prepared or per serving/per 100 g) in addition to two columns of percent DV amounts for nutrients having DV's is likely to be cumbersome and confusing to some consumers. Based on the research findings (see section V.D.2. of this document), FDA is confident that a single g/mg amount declared in a noncolumn array does not have a detrimental effect on consumers' abilities to understand and use the nutrition information on the label, but FDA did not test a format with two g/mg amounts for each nutrient. FDA is convinced by this comment that only a single g/mg amount (as packaged and according to the label serving size based on reference amounts in § 101.12(b)) for each nutrient should be required in dual declaration labels. The second set of g/mg amounts may be presented optionally next to the required g/mg values, differentiated from them by a comma or other means. Alternatively, the second set of g/mg amounts may be presented in a footnote. When the second set of g/mg amounts is presented in a footnote, either the total amounts or the additional amounts may be declared. When the additional amounts are declared, only those nutrients that are present in different amounts than the amounts declared in the required g/mg information may be listed. The footnote must clearly state which amount is declared. The agency has included this provision in § 101.9(e)(3)(i).

Examples of nutrition label formats for products using a dual declaration display that conforms to the new regulations are presented in appendix E.

J. Simplified Format

Most comments from consumers, industry, and professional organizations supported the concept of using a simplified format stating that it is easier for consumers to understand, cuts down on label clutter, and gives manufacturers flexibility in preparation of labels. The comments and FDA's response to concerns raised by the comments are summarized below.

1. Terminology

171. A few comments commended FDA and USDA for attempting to bring consistency to nutrition labeling regulations by allowing for similar types of simplified formats but requested that the two agencies use the same term rather than "simplified" format in FDA regulations and "abbreviated" format in USDA regulations.

Both FDA and USDA are in agreement with these comments. In accordance with the language in the 1990 amendments, they will use the term "simplified" format. However, because the foods regulated by each agency are different, the specific regulations pertaining to the simplified format will differ somewhat by agency.

2. Required Use and Criteria

172. Several comments disagreed with FDA's interpretation of that part of section 403(q)(5)(C) of the act which states "the Secretary *shall require* the amounts of such nutrients to be stated in a simplified form * * *" (emphasis added) to mean that foods that qualify for the simplified format must use that format, i.e., they may not choose to use the full nutrition labeling format. These comments urged that use of the simplified format be optional as, in some instances, consumers may be better served by one uniform nutrition label, and manufacturers should be given the flexibility to meet consumer preferences. In support of such labeling being voluntary, the comment cited the following legislative history:

> However, the bill provides that the Secretary *may permit* the information to be included on the label or labeling in a simplified form if a food contains insignificant amounts of more than one-half of the nutrients required to be on the label. (emphasis added)

(Ref. 16)

FDA advises that the draft legislation was revised by the Senate subsequent to the above House report to replace the word "may" with "shall" and to add that the form of the simplified format was to be "prescribed by the Secretary" (136 Congressional Record, S. 16607 (Oct. 24, 1990)). The changes were not explained in legislative history, so that the intent of Congress is not clear. The agency acknowledges that it is possible that Congress was merely trying to require that the final regulations provide for a simplified format rather than requiring that the format be used whenever a food met the qualifying criteria. In fact, inasmuch as the intent of the 1990 amendments was to increase the amount of nutrient information provided to consumers, it is not entirely consistent that the act would require less information on certain foods.

Based on reassessment of the statute and its legislative history in response to the comments, FDA concludes that use of the simplified format should be at the manufacturer's discretion, whenever a food product meets the criteria of containing insignificant amounts of half of the required nutrients. Accordingly, FDA has modified § 101.9(f)(1) by changing the word "shall" to "may."

173. A comment from a consumer group suggested that FDA require a different base than one-half of all 15 required nutrients for determining if a product qualifies for the simplified format because using all 15 nutrients results in "double-dipping." The comment suggested that calories from

fat should not be included because total fat represents the same nutrient, and that total carbohydrate should also not be included because complex carbohydrate and sugars comprise total carbohydrate. The comment stated that this procedure would result in a base of 13 different nutrients, of which seven must be present in insignificant amounts to qualify to use the simplified format.

FDA agrees that counting both "total fat" and "calories from fat" for the purpose of determining whether a food qualifies for use of the simplified format results in a double count being given to the fat content of a product. The agency, therefore, has deleted calories from fat from the qualifying criteria. However, in the case of "total carbohydrate," the agency notes that § 101.9(c)(6) is revised to delete "complex carbohydrate" as an element of nutrition labeling. Although "other carbohydrate" replaced "complex carbohydrate," the declaration of "other carbohydrate" is not mandatory. Therefore, the required subcomponents in § 101.9(f) no longer comprise the total amount of the component "total carbohydrate." Accordingly, "total carbohydrate" must continue to be included among the nutrients used as a base for determining whether a food qualifies for use of the simplified format.

The deletion of "calories from fat" and "complex carbohydrate" results in a base of only 13 nutrients. According to section 403(q)(5)(C) of the act, the simplified format is to be allowed if a food contains insignificant amounts of "more than one-half the nutrients required * * *." Therefore, it follows that the simplified format may be used when a food contains insignificant amounts of seven or more of the base nutrients.

As a result, and in accordance with the reordering of nutrients in § 101.9(c), FDA has modified § 101.9(f) to state that the nutrition information may be presented in a simplified format "when a food product contains insignificant amounts of seven or more of the following: Calories, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron."

Although FDA has deleted "calories from fat" from the list of nutrients in § 101.9(f) used to determine when a product may use the simplified format, "calories from fat" continues to be a nutrient that must be declared under section 403(a) of the act in nutrition labeling when present in more than insignificant amounts. Therefore, FDA has modified § 101.9(f)(3)(ii), redesignated as § 101.9(f)(2)(ii), to require declaration of calories from fat in addition to any other nutrients identified in § 101.9(f) that are present in more than insignificant amounts. For the same reason, the agency has modified § 101.9(f)(4) to require calories from fat to be included in the statement "not a significant source of _____" if it is present in insignificant amounts.

174. One comment requested that FDA confirm that eligibility for use of the simplified format is not limited to those foods listed in the supplementary proposal as examples of foods that would use the simplified format (56 FR 60421 at 60474), but that the use of a simplified format is determined on a product-by-product basis.

FDA advises that the interpretation in the comment is correct. The determination that a food qualifies for the simplified format is dependent on the amount of nutrients in that food.

175. Some industry comments requested that FDA provide guidance on how the simplified format applies to foods for children under two years of age as these products are exempted by proposed § 101.9(j)(4) from labeling of calories from fat, saturated fat, and cholesterol, all of which are included in the list in proposed § 101.9(f)(1) of the 15 "required nutrients." Comments questioned whether the stipulation of insignificant amounts of eight or more required nutrients for the simplified format applies to such foods and if it does apply, whether calories from fat, saturated fat, and cholesterol are included in the eight insignificant nutrients, even though they are not required to be labeled.

In developing the proposed rules, FDA did not consider the application of regulations governing the use of the simplified format to foods for children less than 2 years of age. Since these foods have a required base of only 11 nutrients (i.e., calories, total fat, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron), it is appropriate that they be allowed to use a simplified format when more than one-half (i.e., 6) of these 11 nutrients are present in insignificant amounts. Section 101.9(f) has been modified to include this provision for foods for children less than 2 years of age.

3. Definition of "insignificant amount"

176. A few comments recommended changes in FDA's proposed definition of "insignificant amount" of a nutrient as that amount that allows a declaration of zero in nutrition labeling. The term "insignificant amount" was used in section 403(q)(5)(C) of the act in reference to when a food would be exempt from nutrition labeling (proposed § 101.9(a)) and to when a food would qualify for the simplified format (proposed § 101.9(f)(1)). Comments on both uses of the term are discussed in this section to ensure consistent use of the term.

A few comments stated that the use of a mathematical base for determining "insignificant amounts" does not consider the actual need for the nutrients in the maintenance of good health, and that because FDA proposed to define "source" as from 10 to 19 percent of the RDI or DRV, anything less than 10 percent should be "insignificant." Other comments recommended the level of insignificance be changed to 0.5, 2, 5, or 8 percent of the RDI or DRV for particular nutrients. Another comment noted that defining "insignificant amount" as an amount less than 0.1 g of carbohydrate and protein is in conflict with the definition of "insignificant amount" for calories as less than 5 calories, given that 1 g of carbohydrate and protein furnishes only 4 calories. A comment also stated that, as a practical matter, consumers cannot reasonably be expected to differentiate between 0.5 g amounts.

FDA did take maintenance of health into consideration when it based its proposed definition of "insignificant amount" for calories (including calories from fat), total fat, cholesterol, sugars, and sodium on the amount defined as "free" under the proposed nutrient content claims rule (see final rule entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms" published elsewhere in this issue of the **Federal Register**). (In addition, in the final rule on nutrient content claims, FDA defined "saturated fat free" as less than 0.5 g of saturated fat per serving.) For most nutrients, FDA has determined the level that is dietetically trivial or physiologically inconsequential (56 FR 60421 at 60433) and has established those levels as the "free" levels. Therefore, for those nutrients for which a level of "free" has been defined, FDA is denying the request to change the definition of "insignificant amount."

For those macronutrients that are required to be included in nutrition labeling but that do not have definitions of "free" levels (i.e., total carbohydrate, dietary fiber, and protein), FDA has reconsidered the proposed amounts and, in accordance with the comments, it is specifying in § 101.9 (f)(1) and (j)(4) that an insignificant amount of these nutrients is "an amount that allows a declaration of less than 1 g." Because 1 g of each of these food components

yields 4 calories, this amount is closer to the amount that will yield an "insignificant" amount of calories. By doing this, differentiation of amounts of 0.5 g will no longer be necessary.

In the case of vitamins and minerals, which also do not have definitions of "free" levels, FDA is not persuaded that amounts less than the amount defined as a source of a nutrient (i.e., less than 10 percent of the RDI) in § 101.54(c)(1) in the document on nutrient content claims published elsewhere in this issue of the Federal Register can be considered "insignificant." In fact, assuming that as many as 20 foods are consumed in a day (Ref. 109), levels of 5 percent or more of the RDI per food would be sufficient to assure that a person's daily requirements were met. Therefore, FDA rejects the suggestions that amounts greater than 2 percent but less than 10 percent of the RDI be considered insignificant.

177. One comment expressed concern about a potential compliance problem with § 101.9(f)(1) for firms who elect to "round down" Class II nutrients under § 101.9(g)(4)(ii) and to "round up" calories, sugars, total fat, saturated fat, cholesterol, or sodium under § 101.9(g)(5). The comment stated that by defining "insignificant" based on analytical capabilities while at the same time requiring that the simplified format be used, a firm could find itself in violation of § 101.9(f)(1) by either claiming that it is required to use the simplified format, or by asserting that it must use the complete nutrition format.

FDA does not believe its proposed definition of "insignificant" has any bearing on this concern because the concern could exist at any defined level. However, the amendment of § 101.9(f)(1) discussed above, whereby the simplified format is allowed, not required, on foods that meet the qualifying criteria, resolves the comment's concerns for Class II nutrients. For other nutrients, FDA advises that firms should determine label values to be in compliance with § 101.9(g) and then determine, based on those values, whether or not a food qualifies to use the simplified format.

4. Nutrients To Be Declared

178. While most comments supported the required declaration of "core" nutrients (i.e., calories, total fat, total carbohydrate, protein, and sodium) in the simplified format, a few comments requested that the proposed mandatory declaration of the "core" nutrients be deleted. Comments from firms manufacturing honey, chewing gum, and spices requested that FDA adopt a more simplified format for foods that have very limited nutritional value. These comments requested that only those nutrients that are present at more than insignificant levels be required to be declared. For example, chewing gum would declare only calories and carbohydrates, and seasoned salt only sodium.

FDA is not persuaded that it should drop the requirement for declaration of the core nutrients. This core information is essential to aid consumers in learning about the relative nutritional qualities of all foods, and it allows them to judge the consequences of the food selections they make. Most comments supported this position. Also, as discussed above in this section on format, consistency in presentation is a principle that has guided the agency in developing the new format because such consistency has been shown to help consumers. Therefore, FDA is not making the requested change.

179. A few comments from the soft drink industry expressed opposition to mandatory listing of sugars in the simplified format stating that it is not consistent with the intent of the law which is to enhance consumers' understanding of sound dietary practices. The comments contended that mandatory declaration of sugars places undue emphasis on a nutrient that does not warrant such emphasis in light of its physiological impact. One comment explained that the greatest concern posed by sugars is their potential carcinogenicity which, considering the rapid passage of soft drinks through the mouth, is significantly lower than other sugar-containing foods.

A comment from the honey industry also objected to required declaration of sugars on honey products on the basis that it "could mislead consumers into thinking that the honey had been manufactured from what consumers most likely regard as 'sugar'—table sugar."

As discussed in section III.F.3. of this document, the agency has concluded that the mandatory declaration of sugars content in nutrition labeling is consistent with the law. In regard to the simplified format, the 1990 amendments and its legislative history give no direction on the content of the simplified label, only that it be "in a simplified form prescribed by the Secretary." Based on the criteria Congress put on the use of the simplified format, it is possible to infer that its purpose is not to save space on the label nor to allow the declaration of otherwise mandatory nutrients to be omitted, but rather to modify the label by allowing nutrients not present in significant amounts to be omitted. FDA does not believe that the legislation allows it, or that there is any reason, to permit a nutrient that is required to be declared in complete nutrition labeling to be omitted from the simplified format when that nutrient is present in more than insignificant amounts.

In response to the comments from the honey industry, FDA acknowledges that consumers must be made aware of the different purposes of the ingredient statement and the nutrition label and be taught how to use the information in each. Developing this awareness will be a component of the consumer education program discussed in section IX. of this document.

The comment presented no data to show that consumers will be misled by a declaration of sugars in the nutrition label. As discussed in section III.F.3. of this document, FDA believes that sugars should be a mandatory component of nutrition labeling because it will assist consumers in planning diets that conform to current dietary guidelines and is of great interest to consumers. Therefore, FDA finds no basis not to require that sugars be treated in the nutrition label of honey as they would be in the nutrition label of any other product that is a natural source of sugars, such as fruits.

5. Use of statement "Not a Significant Source of"

A number of comments were received that addressed the requirement in § 101.9(f)(4) that the simplified format include the statement "Not a significant source of _____," with the blank filled in with the name of the missing nutrient, when additional nutrients are voluntarily added to the food or declared in the simplified format.

180. Many comments on this subject supported the proposal. However, a few comments from consumers, health professional associations, and industry suggested that all simplified labels should include a statement identifying those nutrients present in insignificant amounts, such as "Not a significant source of _____." One comment stated that consumers may be misled by the missing information unless the nutrients that are not present are identified. Two other statements that were suggested were: "This product does not provide you with any _____" where the blank is filled in with the names of nutrients present in insignificant amounts, or a statement that informs consumers that "This food contains less than ½ of the nutrients required for full nutrition labeling."

FDA is not persuaded that consumers will be confused by the absence of certain nutrients on simplified labels.

Most of the foods that will be able to use this format are basic commodities or simple foods (e.g., oil, butter, sugar, syrups, juices, drinks) for which it is reasonable to expect that consumers will know that the missing nutrients are not present in the food. Therefore, in response to the Congressional intent that the label be "simplified," the agency is not making the suggested change.

181. Other industry comments generally opposed requiring such a statement when additional nutrients are voluntarily added to the food or declared in the simplified format on the grounds that it clutters the label with a long list of nutrients that are not present. One comment stated such a requirement is discriminatory, especially if the additional nutrient is declared because of a nutrient content claim. Another comment suggested that simplified labels that declare naturally occurring nutrients be treated differently from those that declare added nutrients. Several comments suggested that the statement "Not a significant source of other nutrients" be used in lieu of the proposed statement as this would provide consumers information without cluttering the label.

FDA disagrees with the comments. When nutrients are voluntarily added to a food or voluntarily declared in the nutrition label, or when a nutrient content claim is made on the label, the food is being marketed as a significant source of nutrients. In such cases, the food label would be in violation of section 201(n) of the act unless consumers are advised about the full nutritional profile of the food.

FDA shares the concern about the space required by the list of nutrients not present. However, the statement "Not a significant source of other nutrients" is too broad and therefore could be misleading on a large proportion of foods. Even though the food may not contain significant amounts of the nutrients required in § 101.9(c), it may contain significant amounts of other essential nutrients that are not required to be declared in nutrition labeling. The language suggested by the comment, however, asserts that the food is not a source of any other nutrients. Thus, to determine whether such a statement is true, it would be necessary to analyze for all known essential nutrients. The agency believes that such a situation makes no sense and therefore is not making the suggested change.

182. One industry comment opposed the exemption of standardized enriched foods from the required statement "Not a significant source of _____," stating that there is no basis for treating different food products (i.e., nonstandardized enriched foods) discriminatorily. Another comment wanted FDA to state that the addition of a nutrient such as vitamin C to a food, if required by a standard of identity or another government standard (i.e., a purchase specification to qualify for use in the Special Supplemental Food Program for Women, Infants, and Children (WIC)) would not require the statement "Not a significant source of _____."

FDA is persuaded that foods containing added vitamins and minerals, whether under a food standard or not and whether required by purchase specifications or not, should be treated similarly. Therefore, FDA has modified proposed § 101.9(f)(4) to require that if any vitamins or minerals are declared as part of the simplified format for any reason, the statement "not a significant source of _____" shall be included at the bottom of the nutrition label. This statement is also required if any additional naturally occurring nutrients are voluntarily declared in the simplified format. To clarify the regulation, the requirement that any added vitamins and minerals must be declared as part of the simplified format is removed from proposed § 101.9(f)(4) to become new § 101.9(f)(2)(iv). Additionally, § 101.9(f)(4) is subdivided into § 101.9 (f)(3) and (f)(4).

6. Format for the Simplified Label

183. Many comments from industry responding to the supplementary proposal were opposed to requiring the DRV list in the simplified format, arguing that such a required list would considerably expand the simplified format and therefore defeat its purpose.

A few comments responding to the format proposal argued that examples of simplified formats illustrated at appendix D of the proposed rule were merely abbreviated versions of the nutrition label format and not simplified formats as called for by the 1990 amendments. These comments were particularly critical of the inclusion of the listing of DRV's in the simplified format because they argued that an abbreviated list of DRV's would communicate incomplete, and therefore misleading, information about a total daily diet. Other comments supported the examples of simplified formats in the proposed rule on the grounds that they eliminated unnecessary information but retained a consistent appearance with the regular format.

FDA agrees that an important consideration for the simplified format is that it retain common elements with the regular format to facilitate consumer understanding and use of the nutrition information. FDA does not agree that section 403(q)(5)(C) of the act requires a simplified format that is simpler in other respects than being an abbreviated version of the regular format. As discussed in comment 179 of this document, the 1990 amendments and their legislative history give no direction on the content of the simplified format. However, FDA agrees with the concern expressed about the value of an abbreviated list of DRV's. After careful consideration of the comments, the agency is convinced that by declaring quantitative amounts as percent of Daily Values, the simplified format will retain sufficient common elements with the regular format to facilitate consumer use and comprehension. The agency is also convinced that not requiring the full footnote and calorie conversion information required in § 101.9 (d)(8) and (d)(9) on the simplified format will not sacrifice important objectives of the legislation because the information is not specific to the particular food and is available on a significant portion of the food supply. Therefore, FDA is requiring in § 101.9(f)(5) that a simplified format contain only quantitative and Percent of Daily Value information in the same format as required for full or dual nutrition labeling in § 101.9 (d) and (e), respectively.

184. Comments to the format proposal addressing the use of the simplified PERCENT DV formats generally preferred the use of columns rather than the in-line presentation. Comments stated that the in-line presentations appear significantly more difficult to use and make it difficult to distinguish the actual quantitative amounts from the DRV's. One comment was received from a consumer interest group opposing the line concept on the grounds that it is difficult to read, confusing, and will allow a company to hide the content of fat, sodium, or other undesirable nutrients in the product. The comment maintained that if a line format is allowed, it should only be permitted when no additional voluntary disclosures are made. The comment stated that such additions would make the nutrition information comparable in length to the required format, and FDA has already determined that the required format would not be legible in a line format. However, several industry comments were received in support of allowing the abbreviated nutrition information to be presented in either vertical columns or lines because of the

flexibility and saving in space provided in this option.

FDA agrees that, where label space is adequate, the simplified label is best understood when the information is presented in columns, particularly when additional nutrients are voluntarily disclosed. However, as discussed in section VI.K. of this document, the agency is aware that special allowances are necessary on labels of small or intermediate sized packages. Therefore, in § 101.9(f)(5) the agency is requiring that nutrition labels on products qualifying for the simplified format present the required information in the same format as is required in § 101.9 (d) and (e) for other packaged foods, except that foods in small and intermediate sized packages that come under § 101.9(j)(13) are allowed by that section to present the information in a linear fashion. Examples of simplified formats are seen in appendix F.

185. One industry comment said that while it supported the simplified nutrition label format for sugar, this format, as depicted in the proposal, may be confusing on labels of soft drinks because consumers may conclude that the soft drink has 36 g carbohydrate and 36 g sugars. If sugars are required to be listed, the format should provide for indentation that would clarify that sugars are a subcategory of total carbohydrates.

FDA agrees that the format must allow for subcomponents to be indented under the primary component. Accordingly, § 101.9(c)(8)(ii) specifies that sugars are to be indented under total carbohydrate. A similar requirement is specified for each subcomponent. In addition, § 101.9(d)(1)(iv) requires the primary component to be highlighted to further differentiate it from its subcomponents.

VI. Exemptions and Special Conditions

A. Small Business

The 1990 amendments granted an exemption from mandatory nutrition labeling for small businesses. Under section 403(q)(5)(D) of the act, a small business is defined as a business with less than $500,000 annual gross sales of food or any commodity, or a business with annual gross sales of more than $500,000 but less than $50,000 in food sales. The exemption does not apply to those products that make nutrition claims or provide nutrition information.

186. Many comments from industry, trade associations, and international organizations have stressed that the dollar exemption limits in proposed § 101.9(j)(1) that implement the 1990 amendments are too low. The comments note that the sum of analytical, printing, and other costs of nutrition labeling are prohibitively expensive for low volume products. Many small food producers that exceed the $500,000/$50,000 sales limit report that they will suffer a severe economic hardship if forced to comply with the nutrition labeling rules. One comment stated that without an increased exemption, 25 percent of food businesses in Kansas would close. Retail bakery and confectionery trade groups stated that the nature of their business dictates that they offer hundreds of different products throughout the year, and that limiting and standardizing product lines would cause a retail operation to lose its character and appeal. Yet, the need to nutrition label products would force such standardization. Other consequences for small businesses that would not qualify for the exemption that were identified in the comments included the loss of a substantial portion of annual profits, loss of low volume product lines, and small business failure.

FDA has considered these comments and believes that there is merit in many of the contentions they raise. To gain adequate information on what to recommend as a reasonable and appropriate adjustment to the 1990 amendments' standard, FDA participated in a series of public forums that had been scheduled by USDA to discuss the small business issue. These forums were held in May, 1992, in Kansas City, MO; Atlanta, GA; and San Francisco, CA. In a notice of the public forums (57 FR 19410, May 6, 1992), FDA announced its participation in the forums and requested comment on a number of issues, such as which option should be used to amend the current statutory exemption—increasing the gross annual sales exemption, providing an exemption based on the number of units sold of a particular product line, basing the exemption on the number of employees, or any combination of such options. Comments were also requested on the feasibility of compliance with various limits and the effect on the percent of the diet bearing nutrition labeling.

The agency has compiled the information it received. However, at the current time the agency is constrained by the requirements of section 403(q)(5)(D) of the act. Therefore, § 101.9(j)(1)(i) has not been changed. If Congress amends the statute, FDA will implement the change as soon as possible thereafter.

187. Comments have questioned FDA's interpretation of that part of section 403(q)(5)(D) of the act that states "If a person offers food for sale * * * or has business done in sales to consumers" to mean that foods produced by small businesses that are exempt would have to bear nutrition labeling if they were sold by a larger retailer who was not exempt. The comments stated that this interpretation would have a devastating impact on many small entrepreneurs who primarily sell their products through larger retailers or department stores.

In § 101.9(j)(1)(ii), FDA proposed that this exemption applied to any "person who manufactures, packs, or distributes food for ultimate sale to consumers at the retail level as well as any person directly involved in the retail sale of foods to consumers." The legislative history was not specific as to whether the term "retailer" applied only to the small business retailer/producer or to a larger retailer acting as a middle-man in handling the sale of the items to the ultimate consumer (Ref. 16). The agency is convinced by the comments that its interpretation would have unintended consequences on small businesses and, therefore, is removing "as well as any person directly involved in the retail sale of foods to consumers" from § 101.9(j)(1)(ii). To further clarify which foods are covered by the small business exemption and to streamline the regulations, FDA is also deleting the remaining portion of § 101.9(j)(1)(ii) and revising § 101.9(j)(1)(i) to state that "Food offered for sale by a manufacturer, packer, or distributor who has annual gross sales made or business done in sales to consumers that is not more than * * *." The agency's intent with this change is that the exemption will apply to persons whose name appears on the label as the manufacturer, packer, or distributor of the product, regardless of who ultimately sells the product to the consumer. As a consequence, § 101.9(j)(1)(iii) is redesignated as § 101.9(j)(1)(ii).

B. Ready-to-Eat Foods

188. Comments stated that proposed § 101.9 (j)(2) and (j)(3) did not adequately track section 403(q)(5)(A)(i) and (q)(5)(A)(ii) of the act, which both pertain to foods ready for consumption but differ in that section 403(q)(5)(A)(i) of the act addresses foods served for immediate human consumption and section 403(q)(5)(A)(ii) addresses similar types of foods that are sold ready for human consumption but not for immediate human consumption and that are processed and prepared primarily on the premises.

The agency is persuaded that proposed § 101.9 (j)(2) and (j)(3) in its supplementary mandatory nutrition

labeling proposal (56 FR 60366) (which were based on proposed § 101.9 (h)(2) and (h)(3) in FDA's July 19, 1990, mandatory nutrition labeling proposal) did not adequately implement the 1990 amendments. FDA is therefore revising these two sections as discussed below in accordance with the 1990 amendments and in response to comments.

1. Foods for Immediate Human Consumption

In proposed § 101.9(j)(2) of its supplementary proposal (56 FR 60366), FDA proposed to exempt "food products provided by restaurants or other food service facilities offering restaurant-type services (e.g., delicatessens, bakeries, feeding facilities in organizations such as schools, colleges, hospitals, and transportation carriers (such as trains and airplanes))." While this list was not all-inclusive, it was intended to respond to section 403(q)(5)(A)(i) of the act which directed the agency to exempt food "which is served in restaurants or other establishments in which food is served for immediate human consumption * * *." Examples of congressional intent concerning the types of facilities covered by section 403(q)(5)(A)(i) of the act are limited in the legislative history to cafeterias and hospitals (Ref. 16).

189. While many comments supported the exemption in § 101.9(j)(2) for restaurants, several comments requested clarification about the coverage of the proposed section. For example, comments asked whether it covers retail confectioners, ready-to-eat food carryouts, vending machines, and food delivery systems such as meals-on-wheels programs or establishments such as pizza-delivery companies. Comments also pointed out the great diversity in the types of establishments in which food is served for immediate human consumption in the United States. For instance, comments stated that in addition to full-service restaurants, many establishments such as delicatessens, bakeries, candy stores, and convenience stores provide customers with tables and chairs to sit and immediately consume foods purchased. Others, whether for lack of space or for other reasons, do not provide such facilities. For example, frequently food franchises in shopping malls sell cookies or other snack foods expecting customers to eat the foods while walking in the mall or while sitting on benches located throughout the mall.

Comments from a company producing sandwich and salad items in a commissary for sale in vending machines requested to be included under this exemption because the subject foods are sold for immediate consumption, not for "take-home" use, and because the foods are prepared in a commissary kitchen similar to a restaurant/cafeteria kitchen, where foods are assembled by hand and subject to individual product variations. The comment argued that mandatory nutrition labeling would require standardization of menu items, thereby prohibiting common day-to-day variations in the food items produced, and would require larger labels or smaller type-size, both of which would be difficult or impossible to read through the small glass door of a refrigerated vending machine.

Similarly, one comment pointed out that some foods sold in convenience stores are intended for immediate human consumption and compete directly with foods served by restaurants and delicatessens. It stated that many stores have seating areas for customers to use while eating foods purchased on-site, and that in some states, such convenience stores must have restaurant licenses. Foods sold range from self-service beverages to prewrapped sandwiches, prepared off-site by vendors and offered for sale in store display cases.

FDA notes that section 403(q)(5)(A)(i) of the act addresses restaurants and "other establishments in which food is served for immediate human consumption." To respond to the comments stating the proposed rules did not adequately track the 1990 amendments, the agency is revising proposed § 101.9(j)(2) to include a new paragraph (ii) that states that the exemption is to include food products served in "other establishments in which food is served for immediate human consumption." In addition, in response to comments seeking clarification of the coverage of such "other establishments," and in recognition of the diversity of food service operations in the United States, the agency advises that while some enforcement decisions will need to be made on a case-by-case basis, for efficient enforcement of the act, it is providing in § 101.9(j)(2)(ii) that, in addition to food service in hospitals and cafeterias, the agency considers that this exemption applies to establishments such as bakeries, delicatessens, and retail confectionery stores where there are facilities for "immediate consumption" on the premises (i.e., tables or counters with chairs); to food service vendors such as lunch wagons, mall cookie counters, vending machines, and sidewalk carts where foods are generally consumed immediately where purchased or while walking away (including similar foods sold from convenience stores); and to food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices for immediate consumption.

FDA recognizes that some persons might consider that it is inconsistent for the agency to exempt packaged foods sold in vending machines from nutrition labeling but not from ingredient labeling. However, the agency is convinced that such foods are exempted from nutrition labeling by section 403(q)(5)(A)(i) of the act because vending machines serve food for immediate consumption, and there is no similar statutory exemption from ingredient labeling.

Regarding convenience stores, FDA agrees that some foods sold in such stores bear many similarities to foods sold at restaurants and delicatessens and should qualify for similar exemptions. Because circumstances will vary greatly according to the services a particular convenience store offers, it is not possible to state precisely which foods do or do not have to provide nutrition labeling. Rather, determinations will have to be made on a case-by-case basis. However, § 101.9(j)(2) generally provides an exemption for foods of the type served in restaurants or other establishments in which food is served for immediate human consumption. Such foods might include beverages (both self-service and those served by store personnel), frankfurters in a roll, cold sandwiches, pizzas, and hand-packed ice cream cones.

190. Many comments requested that proposed § 101.9(j)(2) be amended to clearly exempt foods "sold for sale or use" in restaurants or other establishments in which food is served for immediate human consumption as specified in section 403(q)(5)(A)(i) of the act. They argued that the statutory language indicates that food intended for use in restaurants is exempt from mandatory nutrition labeling in the absence of nutrient content or health claims. The comments pointed out that proposed § 101.9(j)(2) merely provided an exemption for foods provided by restaurants and did not cover foods intended for sale or use in restaurants.

The agency agrees that the proposed regulations did not fully implement section 403(q)(5)(A)(i) of the act that covers foods sold for sale or use in restaurants or other such establishments. As directed in the statute, this exemption applies to all foods sold in restaurants, including packaged products such as a specialty

house dressings made by the restaurant, or used in restaurants, such as portion controlled packages (e.g., individual catsup or coffee whitener packages) for use only in restaurants. If a manufacturer makes a product for sale only in restaurants (e.g., a package of candy), that product need not be nutrition labeled. However, if there is a reasonable possibility that the product will be purchased directly by consumers in a setting other than a restaurant or other establishment in which it is served for immediate consumption, it must be nutrition labeled (see Ref. 25). Accordingly, FDA has modified proposed § 101.9(j)(2) to add a new paragraph (iii) that exempts foods sold for sale or use only in restaurants or other establishments in which food is served for immediate human consumption.

191. A few comments requested that the second sentence of proposed § 101.9(j)(2) be revised to adequately implement section 403(q)(5)(F) of the act that exempts food "which is sold by a food distributor if the food distributor principally sells food to restaurants or other establishments in which food is served for immediate human consumption and does not manufacture, process, or repackage the food it sells." The comments pointed out that the second sentence in proposed § 101.9(j)(2) would only exempt "foods sold to restaurants by distributors * * *" which is duplicative of that part of 403(q)(5)(A)(i) of the act that stipulates an exemption for foods sold for sale or use in restaurants and fails to include the broader exemption in 403(q)(5)(F) of the act for all foods sold by distributors who principally sell food to restaurants or other establishments in which food is served for immediate human consumption and who do not manufacture, process, or repackage the food they sell.

The agency is persuaded that there is a need to revise the second sentence of proposed § 101.9(j)(2). As discussed in the legislative history (Ref. 25), the food distributor that sells principally to restaurants and other food service establishments is exempted from mandatory nutrition labeling requirements as long as the food distributor does not manufacture the product sold to the consumer. However, the legislative history states:

> The manufacturer of such products would be responsible for providing the nutrition information on the products if there is a reasonable possibility that the product will be purchased directly by consumers, even if the principal customers are restaurants and other wholesale purchasers. * * * [T]he distributor is not liable as long as the distributor does not manufacture the product sold to the consumer.
> (Ref. 25)

In essence, this legislative history makes clear that section 403(q)(5)(F) of the act is intended to direct the agency to do for foods sold to restaurants what it does for foods sold to consumers; that is, to hold the manufacturer, not the seller, responsible for nutrition labeling of foods. (The only exception to this approach is the voluntary nutrition labeling program for raw fruits, vegetables, and fish in which the retailer is to provide the nutrition information.) This exemption would apply to an independent distributor who principally distributes institutional foods directly to restaurants and similar establishments and does not manufacture, process, or repackage the food it sells.

Thus, under this exemption, such a distributor is not responsible for nutrition labeling a product, even if it sells the product in a so-called "cash and carry" store, unless it manufactures, processes, or repackages the food for sale to consumers. On the other hand, a manufacturer of institutional size food products is responsible for nutritionally labeling those products if there is a reasonable possibility that they will be sold to consumers, for example, through such a mechanism as a cash and carry store.

Therefore, proposed § 101.9(j)(2) is modified by adding § 101.9(j)(2)(iv) to fully implement this exemption.

192. One comment recommended that statements such as "for food service use" or "not labeled for retail sale" be used as one means of qualifying for the exemption or that such foods be identified by the size of the package. The comment suggested that such a rule would be of particular help for foods imported for the food service trade.

The legislative history quoted in the preceding comment makes clear that nutrition labeling is required "if there is a reasonable possibility that the product will be purchased directly by consumers * * *." Therefore, the agency does not believe that a label statement can be used as the basis for this exemption. The agency is concerned that, if permitted, a label statement such as "for food-service use" would be used to claim exemption for products that Congress intended to be nutrition labeled. Therefore, rather than create the possibility for potentially misleading labeling, FDA is denying this request.

Imported foods that are in large packages that are obviously not intended or packaged for sale to consumers would be considered exempt under § 101.9(j)(9) which deals with foods shipped in bulk form that are to be processed, labeled, or repacked at a subsequent site.

193. Several comments opposed proposed § 101.9(j)(2) because it would exempt restaurants from mandatory nutrition labeling. These comments urged that restaurants, particularly the regional and national chain restaurants, be required to have nutrition information available to consumers. Some comments suggested that the required information could be: (1) limited to calories, fat, saturated fat, cholesterol, and sodium; (2) based on computer analysis of nutrient databases; and (3) presented in alternative ways such as brochures, menu boards, posters, or tray liners. A few large fast food restaurant chains requested guidelines for voluntary nutrition labeling with flexibility in format and content. They requested that restaurants be allowed to use their own serving sizes, present information on an as-served basis, and update information annually.

In response to comments requesting that restaurants be required to provide nutrition information, the agency points out that section 403(q)(5)(A)(i) of the act specifically exempts restaurants and other establishments in which food is served for immediate human consumption from mandatory nutrition labeling, unless a nutrient content claim or a health claim is made. The requirements that pertain when claims are made are discussed extensively in the final rules on the general requirements for nutrient content claims and health claims that are published elsewhere in this issue of the **Federal Register**.

FDA is aware, however, of the consumer interest in knowing the nutrient content of foods eaten away from home. In response to that interest and to the comments from fast food chains, the agency intends to work closely with all interested parties, particularly those in the food-service sector, to develop guidelines for presenting nutrition content information in a restaurant setting in such a way that it will not inhibit the flow of useful nutrition information (e.g., claims) to the consumer, while at the same time providing assurance of the reasonable accuracy of the information, thus furthering the goal of the 1990 amendments to aid consumers in maintaining healthy dietary practices.

194. One comment agreed that the 1990 amendments exempt restaurants from mandatory nutrition labeling but requested that they be regulated under sections 201 and 403(a) of the act. The comment also requested that FDA clarify that the 1990 amendments have

no preemptive effect on state or local regulation of the nutritional disclosures by restaurants.

FDA advises that the exemptions in § 101.9(j) in no way exempt any foods from regulations promulgated under sections 201 and 403(a) of the act. In regard to State and local preemption, the legislative history states that "Because food sold in restaurants is exempt from the nutrition labeling requirements of section 403(q)(1) through (q)(4) of the act, the bill does not preempt any State nutrition labeling requirements for restaurants. If States do require such labeling in restaurants, it is important that they make every effort to make those requirements consistent with the requirements of the bill." (Ref. 110).

2. *Foods Not for Immediate Consumption.* 195. Many comments objected to proposed § 101.9(j)(3) that allowed an exemption for in-store delicatessen and bakery foods only when they were sold from behind service counters. Comments pointed out that the 1990 amendments made no distinction for such foods when sold from behind the counter rather than from a self-service display. They stated that such a rule would be totally unworkable and would adversely affect the bakery and deli departments. Such a rule, according to the comments, would make it impossible to sell foods that are sold from behind the service counter during the day, at night, when no service clerks are available, or to assemble sandwiches and salads for fast pickup during the lunch hour from self-service counters, without nutrition labeling those foods. A trade association reported that 21 percent of in-store bakeries' sales come from bulk self-service units and 42 percent from prepackaged self-service cases, and that, if compelled to standardize and label their products, such bakeries would be unable to continue in competition with wholesale bakery items.

The comments argued that in-store delicatessens and bakeries should be able to adhere to the same regulations as their independent counterparts, with whom they compete for business. They stated that in-store delicatessens and bakeries operate as independent bakeries in that their accountability is separate from the rest of the store.

Other comments stated that the intent of Congress was that foods similar to restaurant foods that are ready for immediate consumption, and that are produced by retailers that offer variable and nonstandardized products, should be exempt from nutrition labeling to eliminate the substantial burdens that would otherwise be imposed if such labeling were mandatory. Many comments have pointed out that the average baker or confectioner produces hundreds of different products each year, and that the average sales per product are relatively low. Comments stated that the precise selection of foods produced is frequently modified according to changing preferences of customers, seasons, holidays, ingredient availability, and the individuality of the baker/confectioner. Comments argued that it is this ability of the retailer to vary and customize food products that gives the establishment its character and appeal, and that forced standardization to allow for nutrition labeling would eliminate product competitiveness by disallowing innovation and creativity. This loss of competitiveness, in turn, would create a major economic burden and thereby lessen consumer choice.

The agency is persuaded that proposed § 101.9(j)(3) did not adequately implement section 403(q)(5)(A)(ii) of the act, could result in economic harm to in-store delicatessens and bakeries, and created an artificial demarcation between foods sold from service versus self-service areas of the delicatessen or bakery. Therefore, FDA believes that it is necessary to revise § 101.9(j)(3) to more closely reflect the language of the act.

As stated above, section 403(q)(5)(A)(ii) of the act applies to foods that are: (1) Similar to the type addressed in section 403(q)(5)(A)(i) of the act, (2) ready for human consumption, and (3) offered for sale to consumers but not for immediate human consumption. Accordingly, FDA is modifying § 101.9(j)(3) by adding paragraphs (i) through (iii) to reflect these three statutory requirements. There were no specific concerns presented in comments that suggest any problems with these requirements.

Section 403(q)(5)(A)(ii) of the act also requires that the foods to which it applies be processed and prepared primarily in the retail establishment. The agency is codifying this requirement in § 101.9(j)(3)(iv). Comments were very divided on this issue, particularly for bakery items. Some comments argued that breads shipped to a retail store in a semi-finished condition and baked-off just before retail sale would not meet the criteria of "prepared and processed primarily" at the retail store and should not be exempt. However, other comments disagreed with this position, stating that frozen dough products are further processed at the bakery by being proofed, shaped, molded, filled, decorated, cut, assembled, customized, or otherwise completed or further processed and should be exempt.

The legislative history discusses this situation stating that for bakeries "simply thawing frozen bread would not be sufficient; the bread would have to be baked on the premise" (Ref. 16). While this statement appears to indicate that baking (i.e., cooking at a high temperature in an oven) is sufficient to qualify a food for this exemption, comments have argued that "baking" is not equivalent to heating but includes a number of steps, such as "selecting, weighing, and mixing ingredients, fermentation, and shaping and forming the dough prior to actual heating the product."

This example with bread illustrates the difficulty in applying the criterion of "processed and prepared primarily in a retail establishment." Because of the wide variety of foods sold in delicatessens, bakeries, retail confectionery stores, and other stores of this type that may not qualify for exemption under § 101.9(j)(2), it becomes administratively impossible to identify for each type of food sold the exact amount of processing or preparation that would be needed to say that that food was "processed and prepared primarily" on-site.

In many establishments, foods such as bakery items or salads, may be prepared entirely on-site; however, in other similar establishments, much less of the processing and preparation of these foods is actually done on the premises. Similar variations are encountered with other foods, such as cheeses, which may only need to be sliced and portioned, or puddings, which may be purchased in cans and only need to be put in trays in the display case for portioning. The characteristics that all of these foods have in common is that they are ready-to-eat, they are the same type of foods sold in restaurants, and they are portioned and packaged on-site.

Legislative guidance to assist the agency in defining what is meant by "processed and prepared primarily in a retail establishment" in addition to that cited above is scant. However during Senate debate, one of the sponsors of the bill that became the 1990 amendments stated that:

> This exemption recognizes that when food is processed and prepared primarily on the premises and sold there, as in the prepared food sections of supermarkets, nutrition labeling is not appropriate. On the other hand, if the preparation or processing of food is standardized and is accomplished primarily at another establishment and the same food is then shipped to a retail food store in a form that requires minimal or no further processing, nutrition labeling can be easily accomplished and is required.

(Ref. 110).

The agency interprets this legislative history to mean that if the food arrives at a store in a form to be sold directly to the consumer (i.e., it is "standardized"), then nutrition labeling must be required. However, if the food is not standardized, i.e., it has to undergo processing or preparation, including portioning, before being sold to the consumer, then nutrition labeling is inappropriate and should not be required. In the case of the examples cited above, FDA finds that nutrition labeling would therefore not be required on bread that is shaped; filled, decorated, assembled, or customized and baked (i.e., cooked at a high temperature) in the retail establishment. Cheese that is sliced and portioned according to directions given by the consumer, and pudding that is portioned according to directions given by the consumer, also need not be nutrition labeled. In these examples, the food is not "standardized" in the form that it is to be sold to consumers when it arrives at the store. Similarly, candies sold in retail confectionery stores that are selected by consumers to be part of a packaged assortment are not "standardized."

However, because of the great diversity of situations in which foods are sold, it must be recognized that a decision regarding exactly what foods do or do not require nutrition labeling cannot be fully resolved by regulation. Circumstances at the retail location must be the deciding factor.

196. A few comments from the retail baking and confectionery industries and from grocery stores requested that the exemption for single-unit bakeries, delicatessens, and confectioneries apply equally to multi-unit establishments that do most or all of their preparation at a central facility or shop. Each type of respondent attempted to limit such an exemption by describing what it would encompass. For example, a comment from the retail baking industry described multi-unit bakeries as being owned, controlled, and operated by the same entity and stated that finished products would be delivered unwrapped or in bulk delivery boxes to each store or outlet. The confectionery industry requested that the exemption cover satellite operations operated by the same businesses, selling the same products, and using the same packaging. A small retail grocery chain suggested limiting the exemption to foods prepared in central kitchens for use in the retailer's own stores. Reasons given for using central facilities included ensuring quality control through a controlled environment that promotes food safety and integrity and allowing for economies of scale. Comments stated that the average number of bakeries operated by a multi-unit retail bakery was 2.4 in 1988, and that many small independent confectioneries only operate one additional outlet.

FDA does not believe that the 1990 amendments allow for exemptions beyond those discussed in the preceding comments. This position is based on the final criterion given in section 403(q)(5)(A)(ii) of the act, which states that foods to which the section applies shall not be offered for sale outside the retail establishment in which they are primarily processed and prepared. The agency is codifying this requirement in § 101.9(j)(3)(v). While foods that are fully prepared and portioned (i.e., "standardized") at the central facility are required to bear nutrition labeling, there may be some types of food products or circumstances in which the portioning or packaging is not standardized, and in which nutrition labeling would consequently not be required (e.g., salads that are portioned and packaged according to directions given by the consumer).

FDA notes that the problems presented in most of the comments on this aspect of this exemption have more to do with the size of the businesses than whether there are good reasons not to require nutrition labeling. FDA believes that the best way to deal with most of these comments is through a change in the small business exemption.

C. Foods of No Nutritional Significance

To reflect the first sentence in section 403(q)(5)(C) of the act, FDA proposed an exemption for foods of no nutritional significance in § 101.9(a). It proposed to include the other exemptions in § 101.9(j). To minimize any confusion that these differences in placement may cause, the agency has decided to group all exemptions in one place in this final rule. Accordingly, that part of proposed § 101.9(a) that exempted foods of no nutritional significance is redesignated as § 101.9(j)(4).

197. Comments from the coffee industry noted that, unlike FDA's mandatory nutrition labeling proposal, the supplementary proposal did not explicitly identify coffee as being nutritionally insignificant. Thus, the comment requested clarification in the final rule. The comments pointed out that coffee is always consumed as a brew. An analogy was drawn to § 101.45(b)(4) in the guidelines for voluntary nutrition labeling of raw fruit, vegetables, and fish, which states that nutrition information is to be based on the edible portion of the food. Comments stated that the available nutrients in brewed or plain instant coffee would meet the criteria for being nutritionally insignificant.

The agency agrees that only the edible portion of coffee should be considered in determining the nutritional significance of the product. Therefore, based on a review of available nutritional data on a serving of coffee and on the revisions in the levels that are significant, discussed in comment 176 of this document, FDA has concluded that coffee beans, roasted ground coffee, or dry plain (i.e., unsweetened) instant coffees contain no nutrients at other than nutritionally insignificant levels. As a result, these foods are exempt from mandatory nutrition labeling. Unsweetened plain tea powders or tea leaves likewise would be exempt.

In response to comments requesting clarification of the exempt status of coffee and tea, FDA has included in § 101.9(j)(4) a listing of coffee beans (whole or ground), tea leaves, and unsweetened plain instant coffee and tea as examples of foods that are exempt from nutrition labeling because of their lack of nutrients. The agency reiterates, however, that this exemption is available only when there are no nutrient content or health claims on the label or in labeling or in advertising of the coffee or tea.

198. The spice industry commented that FDA did not establish a reference amount for spices, thereby implying that spices are exempt from mandatory nutrition labeling. Comments requested that the agency provide an explicit statement in the final rule regarding the exemption of spices, spice blends (e.g., curry powder), and condiment-type dehydrated vegetables (e.g., dried garlic) as well as flavor extracts and food colors, from the nutrition labeling requirements.

As discussed in the final rule on serving size published elsewhere in this issue of the **Federal Register**, FDA has set a reference amount of ¼ teaspoon for most spices and condiment-type dehydrated vegetables. In reviewing the nutritional data in Agriculture Handbook No. 8–2 and 8–11 (Refs. 111 and 112), the agency has found that, under FDA's criteria for determining nutritional insignificance, the vast majority of spices, spice blends, and condiment-type vegetables are exempt from mandatory nutrition labeling. FDA found, however, that one spice (paprika) and one spice blend (chili powder), exceed the cutoff levels for one or two nutrients. Using the appropriate rounding procedures, paprika is over

the cutoff for vitamin A (6 percent of the RDI), and chili powder is over the cutoff for both vitamin A (4 percent of the RDI) and sodium (5 mg) per ¼ teaspoon serving. The levels at which these nutrients are nutritionally insignificant (i.e., the amounts that can be rounded to zero) are less than 2 percent of the RDI for vitamin A and less than 5 mg for sodium. Therefore, under the act, paprika and chili powder will have to be nutrition labeled (see Ref. 16, p. 16: "Foods such as certain spices, which have insignificant amounts of most but not all nutrients, are covered by the nutrition labeling requirements."). Because not all spices and spice blends are nutritionally insignificant, they are not included as a category under § 101.9(j)(4).

Condiment-type dehydrated vegetables, flavor extracts, and food colors do meet the criteria for foods of no nutritional significance and, therefore, are exempt from mandatory nutrition labeling. As with unsweetened coffee and tea, § 101.9(j)(4) will include these examples of nutritionally insignificant foods.

199. One comment suggested that "fun foods" defined as foods with empty calories (i.e., those with no nutrients other than calories), such as plain sugar candies, gum, and carbonated beverages, should be exempt from mandatory nutrition labeling except for a declaration of calories and the statement "no other significant sources of nutrients." The comment argued that the statement "Contains less than 2 percent of the RDI" for such foods is deceptive and miseducates consumers.

FDA advises that these types of foods would qualify under § 101.9(f) for the simplified label and would only be required to list the core nutrients, not the statement "Contains less than 2 percent of * * *." Moreover, Congress did not provide for an exemption of such a category of foods in the statute. Therefore, the agency is taking no action on this comment.

200. The pickle industry commented that, as a cost-saving measure, only sodium content (as is permitted under current regulations) should be required to be labeled on dill pickle products, rather than the full simplified format. The comment argued that, even though a serving of dill pickles also contains 1 g of carbohydrate, sodium is the only nutrient of any concern to consumers.

FDA rejects this comment. Section 403(q)(5)(C) of the act exempts from nutrition labeling foods that contain insignificant amounts of all of the nutrients required within nutrition labeling. The same section also provides for a simplified form of nutrition labeling if a food contains insignificant amounts of more than one-half the mandatory nutrients. No provisions of the 1990 amendments would allow for declaration of only a single nutrient in nutrition labeling. Accordingly, FDA is not making the suggested changes in the regulations.

201. One trade association commented that bottled water products have little or no nutritional value, and that such products should be exempt from mandatory nutrition labeling. The comment asserted that the following industry practices should be permitted without triggering nutrition labeling obligations: (1) Bottlers should be allowed to add back minerals as flavor enhancers that are removed during purification and declare "minerals added" on the principal display panel; (2) bottlers should be allowed to describe bottled water with natural or added fluoride as "fluoridated water;" (3) bottlers should be allowed to add sodium fluoride or add back trace minerals that may contain sodium as an incidental additive and still be permitted to claim "sodium free" on the label; (4) "essence" bottled water products (i.e., those containing 1 percent or less of juice or flavors) should be considered nutritionally insignificant; and (5) bottled mineral water products should be permitted to have a listing on the label of certain minerals, e.g., sodium, bicarbonate, calcium, magnesium, and other trace minerals in mg per liter in addition to a declaration of total dissolved solids content (which some state laws currently require). The comment argued that the EC Directive on Nutrition Labeling expressly exempts mineral water and other waters from nutrition labeling, and, for the sake of harmonization, FDA should do likewise.

FDA points out that, separate from this rulemaking on nutrition labeling to implement the 1990 amendments, the agency is in the process of amending its regulations on bottled water, partly in response to a petition from the trade association that submitted the comment. The bottled water regulations will address certain aspects of labeling apart from nutrition labeling, e.g., definitions, information about mineral content, and required label statements. Under the 1990 amendments, Federal regulations will preempt any State standards of identity that are not identical to it (section 403(a)(1) of the act).

A recent IOM report, "Food Labeling: Toward National Uniformity" (Ref. 113), noted that many States have expressed concern about the heightened potential for consumer confusion because of the increased number of bottled water products on the market and the aggressive marketing and advertising claims of superiority made for them. Thus, FDA maintains its position that nutrition information relating to food must be provided for all products, including bottled and mineral water, that contain more than insignificant amounts of any of the nutrients or food components that are required to be listed, or whose label, labeling, or advertising contains a nutrient content claim or any other nutrition information in any context. For products that qualify for the simplified format, if manufacturers voluntarily declare nutrients allowable under § 101.9(c) that are not among the 14 required nutrients (e.g., potassium), the required statement "Not a significant source of _____," must be used, with the blank filled in with the name of any of the 14 required nutrients or food components that are not present or are present in insignificant amounts. Moreover, if a product is voluntarily enriched or fortified with added vitamins or minerals, any such nutrients must be declared using the simplified format and followed by the above statement. Thus, a product labeled as "bottled water, minerals added" will have to bear nutrition labeling.

The agency considers the identity statement "fluoridated water" misleading if the product is derived from a source naturally containing fluoride. Use of the term "fluoridated" represents that fluoride has been added in the processing. Thus, the term "fluoridated water" should be used to describe only products to which fluoride has been added in the manufacturing process, and such products would be required to bear nutrition labeling that complies with the simplified format.

Bottled water products containing juice or other flavors are subject to the same nutrition labeling requirements as any other food. If a product meets the criteria for no nutritional significance, and no claims are made, then nutrition labeling is not required. A "sodium free" declaration on bottled water or on any other food label will trigger nutrition labeling, because such a claim promotes the nutritional properties of the product.

202. One comment stated that, to avoid varying interpretation, FDA should clarify what it means by the term "implicit" as it applies to nutrient content claims or information that will bar a food from an exemption from nutrition labeling under the "no nutritional significance" provisions.

A thorough discussion of implicit claims may be found in the companion documents on nutrient content claims and health claims, found elsewhere in this issue of the Federal Register.

D. Foods for Infants and Children Less Than 2 Years of Age

In the mandatory nutrition labeling proposal (§ 101.9(k)(4)) and in the supplementary proposal (§ 101.9(j)(4)), the agency proposed to require that foods, other than infant formula, that are represented or that purport to be specifically for infants and toddlers less than 2 years of age bear nutrition labeling, except that such labeling shall not include information on the number of calories from fat or the amount of saturated fat and cholesterol present in the food.

203. The comments supported this proposal. One comment, noting that proposed § 101.9(j)(4) refers to "toddlers less than 2 years of age" and other references in § 101.9 refer to toddlers as children less than 4 years of age, recommended that "children less than 4 years of age" be used, or that the term "toddler" be clarified. Another comment pointed out the practical fact that some foods used in the 1 to 2 year age bracket are also used by some children up to 4 years of age as well as by adults who have problems chewing food.

FDA does not agree that these special labeling requirements proposed for foods for infants (other than infant formula) and toddlers less than 2 years of age should be extended to children less than 4 years of age despite the fact that no other nutrition labeling requirements use 2 years of age as a cutoff. The agency does not believe there is scientific support to change the cutoff to 4 years because dietary recommendations for very young children are specific in citing 2 years of age as the age under which dietary modifications are not appropriate. For instance, the "Report of the Expert Panel on Blood Cholesterol Levels in Children and Adolescents" of the National Cholesterol Education Program (NCEP) states:

> The fast growth of infants requires an energy-dense diet with a higher percentage of calories from fat than is needed by older children. Based on current knowledge, it is inappropriate to apply nutrient guidelines for fats, cholesterol, and calories to children under 2 years of age.

(Ref. 114.)

and:

> As toddlers over 2 years of age begin to eat with the family, they may safely make the transition to this (recommended) eating pattern.

(Ref. 114.)

However, FDA believes that some clarification is needed as to the types of foods addressed in § 101.9(j)(4) (which is redesignated as § 101.9(j)(5)(i)). The agency advises that the infant and toddler foods to which the special labeling requirements are intended to apply are the types of foods represented in § 101.12(b), Table 1 entitled "Reference Amounts Customarily Consumed: Infant and Toddler Foods" in the rule entitled "Food Labeling; Serving Sizes" published elsewhere in this issue of the Federal Register. FDA notes, however, that in its serving size reproposal (November 27, 1991, 56 FR 60394 at 60397), "toddlers" was interpreted to mean children 1 through 3 years of age. Therefore, the agency advises that no special significance should be given to the word "toddler;" rather it is the age category that is important. To reduce the possibility of confusion, FDA is replacing the word "toddler" with "children." The distinguishing characteristic of foods to which the special labeling requirements in § 101.9(j)(5)(i) apply is that they are specifically represented or purported to be "for use by infants and children less than 2 years of age." Foods represented or purported to be for use by "children less than 4 years of age" or by "children 3 or more years of age" are not subject to the special labeling requirements of § 101.9(j)(5)(i) but should fully declare required information on fats and cholesterol.

With regard to the comment that these foods are sometimes used by older children or adults, FDA acknowledges that this occurs. The agency believes, however, that the represented use of the product must be the deciding factor. Inasmuch as the foods to which § 101.9(j)(5)(i) applies are represented to be for use by infants and children less than 2 years of age, the agency considers the use of these types of foods by children over 2 years of age or by older persons to be not particularly relevant in determining how these foods should be labeled. Accordingly, FDA has not made any change to § 101.9(j)(5)(i) in response to this comment.

204. One comment stated that the word "or" was used ambiguously in the proposed version of § 101.9(j)(5)(i) so that it was not clear whether "calories from saturated fat" or "saturated fat content" was prohibited. The comment also suggested that information on calories from saturated and unsaturated fat and the amount of unsaturated fat also should be prohibited, and that § 101.9(j)(5)(i) should be clarified by enumerating those parts of § 101.9(c) that are affected.

FDA agrees that all information relating to fatty acids should be prohibited on foods represented or purported to be for use by infants and toddlers (i.e., children) less than 2 years of age. In the proposed version of § 101.9(j)(5)(i), FDA only specified the fatty acid component that is required in nutrition labeling.

Therefore, to make the suggested change and to clear up any confusion, § 101.9(j)(5)(i) is modified to state: "* * * such labeling shall not include calories from fat ((c)(1)(ii) of this section), calories from saturated fat ((c)(1)(iii)), saturated fat ((c)(2)(i)), polyunsaturated fat (c)(2)(ii)), monounsaturated fat ((c)(2)(iii)), and cholesterol ((c)(3))."

205. One comment suggested the additional exclusion of fiber on labels of foods for infants, citing a statement made by the American Academy of Pediatrics that fiber probably is not needed in infants less that 1 year old.

FDA, in reviewing the reference cited by the comment (Ref. 115), noted that on the same page as this cited statement is the additional statement that more work needs to be done before any firm recommendations can be made on dietary fiber in pediatric nutrition.

FDA is thus not convinced that dietary fiber should be excluded from nutrition labels for foods intended for infants and children less than 2 years of age. Most foods included in Table 1 of § 101.12(b) in the final rule entitled "Food Labeling; Serving Sizes," published elsewhere in this issue of the Federal Register, contain less than 1 g of fiber per 100 g of edible portion (Ref. 116). Under usual circumstances, these levels would seem to preclude the consumption of high-fiber, low-calorie diets by infants or children under 2 years of age who consume such foods. Also, because dietary fiber has a natural laxative effect, the label declaration of fiber content may be useful information to the purchasers of these foods.

206. A comment to the format proposal objected to the inclusion of DRV's on foods for infants and toddlers because DRV's were not proposed for infants or children less than 4 years of age, and labels on jars of baby food are too small to allow for the additional information. The comment argued that DRV's for adults and children 4 or more years of age are not appropriate for infants and toddlers, and that there could be serious health consequences if a parent tried to adapt an infant's diet to the proposed DRV's.

FDA agrees with the comment for the reasons presented therein. In addition,

the agency believes that it is inappropriate and unnecessary to include the caloric conversion information required by § 101.9(d)(10) on foods intended for children less than 4 years of age because DRV's for this group have not been established and calculation related to such values may be misleading. Accordingly, for foods for infants and children less than 4 years of age, the agency is adding an exemption in § 101.9(j)(5)(ii) that excludes the declaration of Percent Daily Values for nutrients other than vitamins and minerals for which there are RDI's specifically established for infants and children less than 4 years of age. The exemption also applies to the footnote and caloric conversion information. Except for the omission of this information, which is otherwise required in § 101.9(d)(2)(ii), and the footnote and caloric conversion information required in (d)(9) and (d)(10), the format of the nutrition labels on such products should comply with the requirements of § 101.9 (d), (e), or (f), as appropriate. Examples of labels for foods for children less than 4 years of age and less than 2 years of age are given in appendix G.

E. Medical Foods

207. All comments received supported this exemption. In addition, several comments expressed support for the agency's intention, stated in the supplementary proposal (56 FR 60366 at 60377), to develop specific regulations for medical foods in the near future. Some comments suggested that nutrition labeling, intended for use by the general population, does not provide the kind of information needed by health care professionals or patients selecting or using medical foods. The comments noted that, in light of this exemption, there is little guidance for labeling of medical foods, other than general food labeling regulations, citing the need for labeling of nutrient content and purported uses and adequate and appropriate directions for use. In addition to the need for specific labeling requirements, some comments identified the need for quality control and good manufacturing practices specific for medical foods.

Section 403(q)(5)(iv) of the act exempts medical foods from nutrition labeling requirements. The agency agrees with the comments that the exemption for medical foods from nutrition labeling is appropriate considering that these products are not intended for use by the general population but rather are intended for use under the supervision of a physician for specific dietary management of a disease or condition. However, the agency also recognizes that the exemption creates a void in terms of specific labeling regulations suitable for these products. FDA believes, as noted in some comments, that the proper labeling of the nutrient content and purported uses of medical foods, perhaps in a different manner or in more detail than is required for other, more traditional foods, and adequate and appropriate directions for use, as well as assurances of the quality of medical food products, are all of vital public health interest. While these issues are beyond the scope of this rulemaking, the agency intends to develop regulations covering these aspects of medical foods in a future **Federal Register** document.

208. The comments support incorporation into the nutrition labeling regulations the definition of medical foods from section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)). Section 403(q)(5)(iv) of the act incorporated this definition by reference into the statute, and FDA in proposed § 101.9(j)(7) to incorporate the statutory definition of "medical food" into the nutrition labeling regulations. Some clarification of this definition was included in the preamble and codified sections of the proposal, providing some guidance in regard to the intended use of a medical food. However, several comments cited particular products and asked whether the products would be regulated as medical foods.

FDA considers the statutory definition of medical foods, from section 5(b) of the Orphan Drug Act, to delineate the principal characteristics of medical foods. Additional clarification of this definition, contained in the preamble of the proposal, gives guidance on some of the types of products that the term "medical foods" pertains to by identifying a variety of foods that the agency regards as medical foods and some that are not presently regarded as medical foods. Criteria that product must meet to be considered a medical food are stated in the preamble of the proposal, as well as in proposed § 101.9(j)(7), redesignated as § 101.9(j)(8) in the final rule. FDA believes that this definition and the information clarifying the definition in the proposal are reasonable guides for use by industry in determining the characteristics of a medical food at present.

However, following review of the comments generated by this proposal, FDA acknowledges that further clarification of the types of products that are considered to be medical foods by the agency would be helpful to manufacturers. While these comments go beyond the scope of this rulemaking, the agency intends to address this issue in a future **Federal Register** document.

209. One comment suggested that in proposed § 101.9(j)(7)(v), the words "* * * provided only to a patient receiving active and ongoing medical supervision * * *" be changed to read "* * * intended only for a patient receiving active and ongoing medical supervision * * *." The comment stated that manufacturers can label products in a manner that gives a clear indication of the intended level of supervision, but that the word "provided" in this section might require a distribution system beyond the control of the manufacturer, restricting availability of medical foods to prescription status or distribution through an institution.

The agency agrees with this recommended change for the reasons stated in the comment and has modified new § 101.9(j)(8)(v) accordingly.

210. One comment suggested that the word "seeks" in proposed § 101.9(j)(7)(v) be changed to "require." The comment noted that while some patients receiving a medical food under the supervision of a physician are capable of seeking "medical care on a recurring basis," others receiving a medical food under the supervision of a physician are not able to actually "seek medical care" on their own (e.g., a comatose patient).

FDA agrees with the suggested change. The agency acknowledges that a medical food, under the supervision of a physician, may be consumed by, or be administered enterally to, some patients capable of seeking medical care and may be administered enterally to other patients who may be too ill to actively seek medical care. In both instances, the patient may require a medical food 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. FDA has modified § 101.9(j)(8)(v) accordingly.

F. Foods Shipped in Bulk Form

211. FDA received many comments that supported proposed § 101.9(j)(8) that exempts foods shipped in bulk form. A few comments sought clarification of this exemption, requesting that new § 101.9(j)(8) include a statement that flavors and other food ingredients (as opposed to processed foods) shipped in bulk form from one manufacturer to another for use in the manufacture of other foods are exempt.

FDA intended the term "processed" in § 101.9(j)(8) (redesignated as

§ 101.9(j)(9)) to indicate that food ingredients used in the manufacture of other foods were exempt, maintaining the scope of current § 101.9(h)(8). However, for further clarification, FDA is modifying § 101.9(j)(9) as requested to state:

> Food products shipped in bulk form that are not for distribution to consumers in such form and that are *for use solely in the manufacture of other foods or that are* to be processed, labeled, or repacked at a site other than where originally processed or packed. (Emphasis added).

G. Foods for Institutional Food Service Use

212. Several comments objected to proposed § 101.9(j)(9) that would require manufacturers or distributors of foods for institutional food service use (i.e., for use by hospitals, schools, prisons) to provide nutrition information required by this section directly to the institutions on a current basis. The comments stated that this requirement was in conflict with section 403(q)(5)(A)(i) of the act, which exempts food that is sold for sale or use in restaurants or other establishments in which food is served for immediate human consumption. The act does not differentiate between food served in institutional and noninstitutional settings. In fact, the comments pointed out that the legislative history specifies that similar food service establishments include cafeterias and hospitals.

FDA agrees with the comments and has deleted proposed § 101.9(j)(9) to bring the final rule into compliance with the 1990 amendments. To clarify that institutional food service establishments are included under the exemption for restaurants and other establishments, FDA has added them as examples in § 101.9(j)(2)(ii).

However, the agency finds merit in other comments that supported nutrition labeling of foods sold to restaurants and other food service establishments in order to enable food service operators to become more aware of the nutritional content of foods they serve, to offer more healthful menu options, and to use more accurate descriptors on their menus. The agency, therefore, encourages manufacturers, packers, and distributors to make nutrition information available to food service operators whenever possible.

H. Single-Ingredient Packaged Fish Products

213. Comments received from the fish industry objected to the inconsistencies between the voluntary nutrition labeling program for raw fish and the mandatory nutrition labeling program. They pointed to the potential for confusion when raw fish under the voluntary program are labeled on an "as consumed" (i.e., "as proposed") basis, and the same fish, when frozen and packaged by a manufacturer, are labeled on an "as packaged" basis. They also pointed to the inconsistency with the USDA proposal that allows single-ingredient raw meat and poultry items, whether frozen or unfrozen, to be under a voluntary program with nutrition information reported on either an "as packaged" or "as consumed" basis.

FDA agrees that consumers may be confused to find inconsistent nutrition labeling on two packages of the identical fish (e.g., fillet of flounder) when one is under the voluntary program for raw fish, and the other is under the mandatory program for frozen packaged fish. According to the final rule for the voluntary program (November 27, 1991 56 FR 60880; corrected at, March 6, 1992, 57 FR 8174), nutrition information for raw fish is to be reported for a 3 ounce, cooked edible portion (see appendix B, 57 FR 8174 at 8175). The final rule on serving size, published elsewhere in this issue of the **Federal Register**, provides that under the mandatory nutrition labeling program, nutrition information for frozen packaged fish is to be reported for that amount required to prepare 85 g (approximately 3 ounces) of cooked fish (§ 101.12 (b) and (c)) but is to be based on the product "as packaged" (§ 101.9(b)(9)).

To reduce the inconsistencies in nutrition labeling between raw versus frozen packaged single-ingredient fish, and between single-ingredient fish versus single-ingredient meat and poultry, FDA is adding a special labeling provision for fish in § 101.9(j)(11) that allows single-ingredient fish to be labeled on a cooked (i.e., "as prepared") basis consistent with the voluntary program for fish and with USDA's rules for single-ingredient meat and poultry products. Packaged fish that contain added ingredients such as water, salt, or additives such as sodium tripolyphosphate are considered multi-ingredient processed packaged fish products and must continue to be labeled on an "as packaged" basis.

However, in the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register**, claims such as "lean," "extra lean," and "low fat" are based on as packaged values. Therefore, single ingredient packaged fish products that make such claims must provide nutrition information on an "as packaged" basis.

I. Raw Fish in Voluntary Nutrition Labeling Program

214. One comment objected to the manner in which FDA defined "raw" for the purpose of determining what fish products are covered by the exemption in proposed § 101.9(j)(10) that subjects the food to the voluntary nutrition labeling program. The comment stated that "absent a definition in the NLEA, the term "raw" means "uncooked" regardless of whether or not the product is frozen and, therefore, packaged frozen raw fish should not be subject to mandatory nutrition labeling.

FDA discussed its interpretation of the word "raw" as it pertains to fish in its proposed rule (July 2, 1991, 56 FR 30468 at 30470) and final rule (56 FR 60880 at 60886) implementing the voluntary nutrition labeling program for raw fruit, vegetables, and fish. Lacking legislative guidance, the agency chose to draw a practical line in terms of retail selling practices and program implementation rather than one based on a strict definition of the term "raw." While the agency included in the voluntary program those fish that are generally sold raw (i.e., not heat treated), it also included thermally processed shelled or unshelled lobster, crab, and shrimp. The intent was to allow for voluntary nutrition labeling of fish that are generally sold refrigerated, or on ice, or are alive at purchase in fish stores or in the fresh fish section of grocery stores and that are not packaged or are packaged by the retailer or by a packer. These are the types of products for which mandatory nutrition labeling is most impractical. In contrast, providing nutrition labeling for raw, frozen fish that are packaged by a manufacturer (usually in a box with a printed label and brand name) and sold in the frozen food case of a grocery store is no more difficult for a manufacturer than providing nutrition labeling of other packaged foods. Thus, these products appropriately come under the mandatory nutrition labeling program.

The agency has made a similar distinction with frozen packaged raw fruit and vegetables and has received no comment on it. It is likely that the greater concern on the part of the fish industry was a result of the inconsistency between nutrient values to be declared in the voluntary versus mandatory programs (i.e., nutrient values based on "as prepared" versus "as packaged" levels, respectively). The agency believes the exemption in new § 101.9(j)(11) should eliminate this concern. Accordingly, FDA sees no need to amend its interpretation of the term "raw."

The agency would like to clarify, however, a misinterpretation of the above definition of raw fish that appeared in comments. FDA considers raw shellfish in or out of the shell to be under the voluntary program, whether they are sold bagged in plastic containers or displayed loosely in trays or bowls. In addition, pasteurized crab meat that is not shelf-stable and is sold on ice or refrigerated would be included under the voluntary program, whereas canned pasteurized crab meat that is shelf-stable would be subject to mandatory nutrition labeling regulations. As discussed above, the agency considers nutrition labeling of the refrigerated product that may not have gone through a manufacturing plant impractical. However, the processing of the canned product is standardized, and nutrition labeling can be easily accomplished and is required.

J. Meat Products Regulated by FDA

215. Several comments recommended that nutrition labeling of game meat should be on a voluntary rather than mandatory basis. One game meat association stated that because buffalo is a red meat, it should be exempt from FDA regulations and should be allowed the option of voluntary labeling under USDA guidelines. The comment also requested that any required nutrition information should be allowed to be displayed at the point of purchase to reduce costs associated with nutrition labeling.

A number of comments expressed concern that the cost of analytical testing and nutrition labeling would be prohibitive for the small game meat producer. A request was made that an economic impact study be conducted of the effect of the proposed regulations on the buffalo industry before any final rule is issued. Comments suggested small business exemptions for producers marketing less than from 100,000 to 150,000 pounds per year per each product label. A few comments also requested that introductory test market, seasonal, short run, and experimental products should be exempt from nutrition labeling.

FDA is responsible for the regulation of all meats not covered by USDA under the Federal Meat Inspection Act and the Poultry Products Inspection Act (e.g., deer, bison, rabbit, wild turkey, or ostrich, hereinafter identified as "game meats"). Therefore, the law does not provide an option for such products to be covered by USDA guidelines. However, FDA appreciates the fact that game meat producers have had little, if any, experience with nutrition labeling, and that analytical data base information is scarce. Accordingly, the agency will give game meats as much latitude as possible under the 1990 amendments.

Because many game meat producers are small enterprises, it is possible that some will fall under the current small business exemption. Many of those that do not may do so in the future if a legislative amendment is passed to increase the exemption. However, if an amendment is not forthcoming, all nonexempt producers must provide the required nutrition information when the regulations become effective.

While the statute does not allow FDA to include raw game meats under the voluntary nutrition labeling program for raw fruit, vegetables, or fish, for consistency among all animal flesh products, single-ingredient game meat products (frozen or unfrozen, packaged or unpackaged) will also be included in § 101.9(j)(11) that permits the information to be declared on either an "as purchased" or "as prepared" basis (see comment 213 of this document).

Also, in response to a comment, FDA is adding § 101.9(j)(12) to the final regulations to allow nutrition information to be provided in accordance with paragraph (a)(2) of this section which allows the required information to be placed on labeling, that is on signs, posters, tags, or in binders or booklets displayed at the point-of-purchase. FDA believes that this action will allow game meat producers to give first priority to nutrient analyses and data collection and to update nutrient declarations more frequently than would be possible if the information were printed on food labels.

216. One comment requested the use of a data base to reduce the cost of nutrition labeling for game meat. It was noted that the nutrient composition of buffalo meat varies widely according to whether the animal was grain fed or range fed and according to age at slaughter. Another comment recommended that nutrient information for buffalo meat come from actual sample testing and not computer composites. The comment requested that FDA/USDA "do the same complete nutritional study for the buffalo industry as it does for other industries enveloped by the proposal."

FDA acknowledges that there is limited nutrient data available on game meats. The agency advises that it does not conduct nutrient analyses for any commodities; however, it is willing to work cooperatively with game meat producers to produce a valid nutrient data base. To this end, the Agriculture Research Service of USDA has experience in working collaboratively with industry in developing food composition data (Ref. 117).

217. Many game meat processors requested exemption from nutrition labeling for custom services. Custom processed meat includes wild game or domestic stock that is butchered to the specifications of the customer. The meat may have been sold to the customer or brought in by the customer for butchering. Comments stated that because the customer owns the animal at the time of butchering, the nutritional aspect of the meat product is the responsibility of the customer.

Consistent with similar regulations being issued simultaneously by USDA for nutrition labeling of meat and poultry products, FDA is exempting custom processed fish and game meats from mandatory nutrition labeling. This exemption is found in new § 101.9(j)(11)(ii). Legal authority for this is that what is being sold is not the food but the processing. Thus, the food is not subject to section 403(q) of the act.

K. Small Packages

218. A number of comments supported the small package exemption proposed in § 101.9(j)(11). While a few comments supported the provision that nutrition labeling be provided for foods in small packages at the point of purchase in accordance with paragraph § 101.9(a)(2), many other comments objected to this requirement. Several of these comments objected on the grounds that the 1990 amendments did not include a requirement for point of purchase disclosure for small packages, or that point of purchase displays of nutrition information would create "unnecessary clutter" and "place an undue burden on retailers" to find space for the information. One comment stressed the economic impact the proposal would have on supermarkets, especially those with front-end operations and checkout lanes where a wide variety of small package items are offered for sale. The comment stated that such areas would have to be reconfigured with fewer items available because of space lost to signage and fewer inventory changes made throughout the year. A comment raised a question about who would be held responsible if the information was not available at the point of purchase. Comments recommended that manufacturers, not retailers, should be responsible for nutrition information on all packaged foods. A suggestion was also made that interested consumers could refer to larger retail packages of the same product or could write or call the manufacturer for the nutrition

information by using an address or telephone number given on the package label.

FDA is persuaded by the comments that it is impracticable to require point of purchase display of nutrition information for small packages. However, because section 403 (q)(5)(B) of the act states only that the nutrition labeling requirements shall not apply to the label of the food, not the labeling as is included in section 403(q)(5)(C) and (q)(5)(D), the agency concludes that nutrition information about food in small packages must be provided to consumers through alternative means. The agency agrees with the comments that manufacturers should bear the responsibility for nutrition labeling of packaged foods and finds merit in the suggestion that manufacturers provide an address or telephone number on the package for consumers to write or call for nutrition information. FDA believes that almost all small packages should be able to add a short phrase, such as "For nutrition information, call 1-800-123-4567" to the label. In fact, many packages currently give an address or telephone number for consumer use in obtaining additional information about the product.

Therefore, FDA has modified § 101.9(j)(11), redesignated as § 101.9(j)(13)(i), to delete the requirement that foods in small packages that bear no nutrition claims or other nutrition information provide the required nutrition labeling in accordance with § 101.9(a)(2). The agency replaced it with a requirement that the manufacturer clearly state on the package label where a consumer may write or call to obtain the required nutrition information. If a manufacturer finds that it is impracticable to comply with even this requirement on a particular product, the manufacturer should write to the agency in accordance with § 101.9(g)(9) (see section VI.P.3. of this document).

219. A few comments from health professional organizations expressed the belief that the 12 square inch standard for "small packages" was too large, and that consumers should have as much information as possible about what they purchase and consume. One comment stated that "with the increase in fabricated foods and single serving size packaging, [they were] convinced that nutrition information can and should go on less space," adding that by using an abbreviated format, nutrition labeling is possible on smaller packages, down to 8 square inches.

However, several other comments objected to the 12 square inch definition for small packages, stating that it would not allow enough space for all the required information on the label, especially on a product with a lengthy ingredient list. The comments stated that the 12 square inch standard for exempting small packages was established years ago when much less information was required on food labels (i.e., before mandatory nutrition labeling). The comments also expressed concern that attempting to include all of the required information in 12 square inches would result in a label that would not be legible, making it difficult for sight-impaired or elderly persons to read. Comments also said that such a presentation would discourage use of the nutrition information, thereby undermining the purposes of the 1990 amendments.

Two manufacturers commented on the unique space problems arising when more than one language is used on small packages inasmuch as § 101.15(c)(2) requires that if a language other than English is used, all information on the label must be printed in both English and the other language. One comment pointed to the fact that the United States has become an increasingly bilingual nation, making Spanish-language labeling a "necessity in many parts of the country."

Several comments requested a more flexible rule based on "practically available space" or "usable surface space" on labels. One comment stated that the term "surface area available to bear labeling" is newly coined and unfamiliar and likely to be confusing. The comment recommended that the exemption be couched in terms of "total square inches on the information and alternate panels," which are familiar terms to manufacturers.

Other suggestions included: (1) Using a 20 square inch surface area, (2) excluding the principal display panel from the 12 square inch requirement, (3) excluding odd shaped parts of packages from the total surface area available for nutritional labeling, (4) allowing a linear (i.e., string) format for the nutrition information, (5) making the nutrition profile optional, (6) allowing for abbreviations of nutrients, (7) deleting the requirement for declaration of "Servings per container" on single-serving containers, and (8) allowing required nutrition information to appear anywhere on the package expected to be read by consumers rather than just on the information panel as required by § 101.2. In regard to the latter comment, one comment suggested that § 101.2 be modified to allow required information to be placed on other label panels adjoining the principal display panel or the information panel when there was insufficient space on a single panel.

A few comments stated that no manufacturer should be required to change its existing label style or container size to accommodate nutrition labeling. The comments urged that areas of a package not traditionally used for labeling should be excluded from the total surface area (e.g., many companies do not use lids of jars, necks of bottles, or bottoms of cans for labels). One comment recommended that current company practices be grandfathered until the company changes its packaging or container.

The agency received additional comments regarding small package limitations in response to the format proposal. Several comments from manufacturers of smaller size products such as candy rolls and bars, chewing gum, canned fish, and cookies stated that such labels could accommodate only the CONTROL format. Two comments suggested raising the minimum 12 square inch requirement for "small packages" to 13 square inches.

A number of comments addressed the inclusion of the DRV's on the labels of small packages. These comments apply to inclusion of the footnote providing calorie-specific recommended nutrient amount information specified in § 101.9(d)(8)(i).

The majority of comments asserted that it would be difficult to accommodate the DRV's without a relaxation of the minimum requirement of 12 square inches of printable label space. Most of those seeking relief suggested the option of listing DRV's in linear rather than column array over an intermediate range of printable package area. Alternate upper limits suggested were 20 and 26 square inches or no more than 30 percent of printable package area devoted to the nutrition label. One manufacturer provided support for 20 square inches as a minimum area below which DRV's could not be accommodated without violating minimum type size or principal display panel size requirements. It submitted executions of the proposed and alternate formats for several existing products. One comment suggested several principles to be followed by FDA in establishing a range within which the DRV listing could be modified or deleted while preserving legibility and remaining in conformance with existing labeling requirements concerning type size and area devoted to the principal display panel.

FDA acknowledges the need to give consumers as much information as possible. The agency is persuaded,

however, that with requirements for more nutrition-related information, it may be difficult to get all of the required information on packages that just meet or slightly exceed 12 square inches of surface area available to bear labeling, particularly for products that do not qualify for the simplified format. However, in light of the exemption from nutrition labeling on the package label for products with less than this amount of usable surface space, provided that no nutrition claim is made (see preceding comment), the agency believes that exempting a larger number of foods by increasing the definition of "small package" size would undermine the intent of the 1990 amendments.

However, based on the comments, FDA has concluded that justification exists for developing a graduated system that would allow added flexibility for foods in an intermediate package size group. To select the dimensions of such an intermediate sized package, FDA reviewed comment suggestions, examined the space requirements of the required label with the calorie-specific daily values, and reviewed data on available label area for a sample of packaged foods (Ref. 117a). The agency is rejecting suggestions such as the use of only "practically available space" or "usable surface space" or the exclusion of "oddly shaped parts of packages" because there is a significant potential for differences of opinion about what is "practically available," "usable," or "oddly shaped." The remaining suggestions are to exclude the principal display panel, to use an upper limit of 20 or 26 square inches of surface area available to bear labeling, or to require that no more than 30 percent of the surface area available to bear labeling be devoted to the information panel.

The agency believes that the suggestion to apply the 30 percent criterion to space requirements necessary to comply with FDA regulations has merit. Based on current requirements (see § 101.1(b) and (c)), the principal display panel can be considered to cover 40 percent of the total surface area available to bear labeling. On the assumption that no more than half of the remaining 60 percent of the label should be required to be devoted to FDA-required information (i.e., the nutrition label and ingredient list), 30 percent of the total surface area would be used for such information. This is consistent with the comment.

Based on the data examined, FDA believes an upper limit of 40 square inches of surface available to bear labeling is appropriate to define an intermediate sized package. The smallest legal sized execution of the format required under § 101.9(d) is approximately 7 square inches. For many processed foods, the addition of the ingredient list could bring the space needed for presenting this FDA-required information to 11 square inches. Using the 30 percent factor, this information could be accommodated on packages with 37 square inches available to bear labeling. In order to provide incentive to allow sufficient space to make the label readily observable and easily comprehensible, the agency has decided to round this number up to 40 square inches. The agency is providing for this upper limit in § 101.9(j)(13)(ii).

The agency does not agree with the comment that the term "surface area available to bear labeling" is newly coined and unfamiliar, inasmuch as it has been used in § 101.2(c)(3)(i) for 17 years.

FDA looked to the comments for suggestions of added flexibility for the labeling of foods in intermediate sized packages available to bear labeling. Suggestions in the comments included: Allowing a linear (i.e., string) format for nutrition information (including the DRV listing), making DRV's optional, allowing for abbreviations, deleting the requirement for declaration of "Servings per container" on single-serving containers, and allowing required nutrition information to appear in other places than those required by § 101.2 (i.e., the information panel). Dependent upon the circumstances of a particular package size and shape, the agency is not opposed to the use of any of these suggested methods. In addition, as provided for in § 101.9(g)(9), manufacturers may request special allowances for provision of the required information on tags affixed to the product according to § 101.9(a)(2) as discussed in section VI.P.3. of this document, Foods For Which Labeling Is Impracticable.

In regard to the request to delete the requirement for declaration of "Servings per container" on single serving containers, FDA finds that inasmuch as the declaration of "Serving size" on such products will specify that the serving is the entire unit (e.g., 1 can or 1 bar), it would be needlessly repetitive to state that there is one serving per container. Therefore, FDA has modified § 101.9(d)(3)(ii) that pertains to all container sizes to state that "Servings per container" is not required on single serving containers as defined in § 101.9(b)(6).

While the provisions being made to increase flexibility are for the purpose of making it easier for manufacturers to place mandatory nutrition labeling on packages of an intermediate size, they may also be used on "small packages" (i.e., packages with less than 12 square inches of surface area available to bear labeling) whose labels are exempt under § 101.9(j)(13)(i) when manufacturers elect to provide a nutrition label on those foods.

FDA is providing in § 101.9(j)(13)(ii)(A) that the required nutrition information may be presented in a tabular fashion when the package shape or size cannot accommodate a column display on any label panel. This form of presentation is currently used on many foods in long rectangular or round packages, such as candy bars and is shown in Appendix H. In addition, to facilitate the provision of information on small packages, § 101.9(j)(13)(ii)(A) provides for the use of a tabular presentation on all products with less than 12 square inches of surface area available to bear labeling, regardless of the package shape. Further, if the label will not accommodate a tabular display, § 101.9(j)(13)(ii)(A) also provides that the required nutrition information may be presented in a linear (i.e., string) fashion.

In regard to abbreviations, one comment stated that the design limits of their company's printers for labels to be affixed to foods packaged in retail stores limited the description of nutrients to 10 characters. While the agency is concerned about the use of abbreviations and any possible consumer confusion they may cause, FDA believes their use under limited and controlled conditions may be preferable to overcrowding within the nutrition label. Therefore, based on this comment, the agency is providing the following abbreviations in § 101.9(j)(13)(ii)(B) for those mandatory nutrients whose names exceed 10 characters.

Serving size: Serv. size
Servings per container: Servings
Calories from fat: Fat cal
Saturated fat: Sat fat
Cholesterol: Cholest
Total carbohydrate: Total carb
Dietary fiber: Fiber

Section 101.9(d)(9)(iv) allows these abbreviations to also be used in a footnote within the nutrition label.

As discussed above in section V. of this document on the format of the nutrition label, FDA is providing in § 101.9(j)(13)(ii)(C) that the footnote and caloric conversion information required in § 101.9(d)(9) and (d)(10) may be omitted on intermediate sized packages. When the footnote required by § 101.9(d)(8) is omitted, an alternate footnote must be used that states:

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

The agency believes that concerns expressed in comments requesting that the nutrition information be allowed to appear elsewhere on the package rather than just on the information panel as required by § 101.2 (see § 101.9(i)) are generally addressed by § 101.2(a)(1). This section states that if the information panel is too small to accommodate the necessary information or is otherwise unusable label space, e.g., folded flaps or can ends, the panel adjoining to the right may be used. However, in recognition of the increased need for this flexibility in packages with less than 40 square inches available to bear labeling, FDA is providing in § 101.9(j)(13)(ii)(D) that nutrition labeling on intermediate sized packages may appear on any label panel.

As a conforming change, § 101.9(c), (d), and (i) have been modified to reflect the provisions of § 101.9(j)(13).

In regard to the comments requesting an exemption or postponement based on current company labeling practices, FDA advises that Congress did not provide in the 1990 amendments for any such actions. The agency recognizes the possible economic burdens associated with changing labeling practices and has tried to incorporate sufficient flexibility to minimize the need for such changes but has no authority to prevent them. FDA advises that in § 101.1 the agency stated that, in determining the area of the principal display panel, tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles and jars were to be excluded. Therefore, it is reasonable to conclude that the agency will not include these areas in determining the "surface area available to bear labeling."

220. A comment requested clarification as to whether manufacturers of products that are sold in small packages that qualify for the small package exemption are required to omit nutrition information from the label and then present it through other means as required in proposed § 101.9(a)(2), or whether they may attempt to provide the nutrition labeling.

While comment 218 of this document addressed the underlying concern in this comment about the mandatory inclusion of required nutrition information in labeling at the point of purchase, FDA does not view this or any other exemption under § 101.9(j) (except for infant formula which is subject to other labeling requirements) as prohibiting a manufacturer from including nutrition labeling on the label of a food product. The agency encourages the inclusion of nutrition information on the label of exempted products whenever possible. To clarify the situation, § 101.9(j)(13)(i) has been modified to state that the new requirement for an address or telephone number for consumer use in obtaining nutrition information is to apply to products that qualify and use this exemption.

L. Shell Eggs

221. One manufacturer commented on the labeling of egg cartons, stating that proposed § 101.9(j)(12) allowing for the presentation of the required nutrition information immediately beneath the carton lid is as impractical for many egg cartons as requiring its display on the upper surface of the lid because both surfaces conform to the shape of the eggs. The comment suggested that packaging of this kind may not be readily imprinted at all. The comment further stated that eggs are a largely homogeneous agricultural commodity, and eggs sold at retail in their shells should all be treated alike with respect to nutrition labeling, whether the eggs are in bulk, on trays without cartons, or in cartons. The comment requested that eggs be exempt under 21 U.S.C. 343(q)(3) that allows the Secretary to provide that nutrition labeling be displayed at the point of purchase for foods received in bulk containers.

FDA is persuaded by the comment that it may be impractical for egg cartons that conform to the shape of the eggs to bear nutrition labeling. Accordingly, FDA is modifying § 101.9(j)(12) (redesignated as § 101.9(j)(14)) to allow the required nutrition information to appear on the inside or the outside of the carton, or on an insert that can be clearly seen when the carton is opened. By doing this, FDA is greatly expanding the total surface area available to bear labeling.

FDA rejects the suggestion that, because some eggs are sold in bulk, all eggs should be allowed to be labeled at the point of purchase according to the exemption for bulk foods (§ 101.9(j)(9)). As discussed above, nutrition labeling for eggs may appear on the egg carton or on a package insert. FDA concludes that there is no need to modify § 101.9(j)(14) to allow for further special conditions for shell eggs packed in cartons. If, in fact, a manufacturer finds it impossible to label a particular egg carton or to include a package insert, it may request a special allowance from the agency, as discussed in comment 223 of this document.

M. Multi Unit Packages

222. A few comments disagreed with the requirement in proposed § 101.9(j)(13)(iii) that each unit within a multipack state "this unit not labeled for retail sale." Comments stated that this requirement is redundant because § 101.9(j)(13)(i) and (j)(13)(ii) adequately prevent the product from being sold without nutrition labeling.

The agency does not agree that the requirement is redundant. Although multiunit containers may be enclosed and are not intended to be separated from the retail package under normal conditions of sale, occasionally the individual units are separated from the multiunit container and purchased separately. Proposed §§ 101.9(j)(13)(i) and (j)(13)(ii), redesignated as §§ 101.9(j)(15)(i) and (j)(15)(ii), state: "The multiunit retail food package labeling contains all nutrition information in accordance with this section;" and "The unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale." These sections cannot guarantee that the units in a multiunit package will not be separated; e.g., frozen juice bars, soft drink bottles, and sticks of butter are sometimes separated from an enclosed multiunit package by consumers prior to purchase at the retail level. Therefore, FDA is not modifying the regulation.

223. A soft drink trade association requested a provision in the final rule to exempt from nutrition labeling glass bottles with lithographed labeling that are marketed in multi-unit packages. These bottles, the comment pointed out, are often loosely packed rather than securely enclosed. The comment made reference to the technical limitations of labeling glass by the lithograph method, and the impracticality of placing nutrition labeling on the individual bottles or "unit containers." The comment requested that the agency clarify the proposal to ensure the continued availability of lithographed bottle multiunit packages and suggested that the nutrition labeling information appear on the information panels of the multiunit retail package.

The agency acknowledges that there will be some circumstances in which strict adherence to the regulations (in this case the requirement that units be securely enclosed in the retail package) is not technologically feasible, or some other circumstance makes it impracticable. Proposed § 101.9(g)(8) would have allowed for alternative means of compliance or additional exemptions to deal with the situation when firms were unable to develop

adequate nutrient profiles. The agency concludes based on this comment that this latitude should be available for additional circumstances. Accordingly, FDA is modifying § 101.9(g)(8), redesignated as § 101.9(g)(9), to broaden its scope by stating "When it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of this section (e.g., to develop adequate nutrient profiles to comply with paragraph (c)), * * *."

Additionally, FDA believes that actions taken to address technological or other problems on a case-by-case basis do not need to be established by regulation in response to a petition to initiate rulemaking. Therefore, the agency is replacing "establish by regulation" with "permit" in § 101.9(g)(9) and is deleting the reference to a petition, stating instead that firms in need of such special allowances shall make their request in writing to the Food and Drug Administration, Office of Nutrition and Food Sciences (HFF-200), 200 C St., SW., Washington, DC 20204. However, FDA concludes that no change is necessary in § 101.9(j)(15) in response to this comment.

N. Foods Sold from Bulk Containers

224. A food retailer wrote in support of the requirement in proposed § 101.9(j)(14) that nutrition labeling information for bulk foods be provided at the point of purchase. However, the comment took exception to the agency's intention to include within the requirement individually wrapped bulk food items such as candies, arguing that the exemption for small packages should apply to small individually wrapped food items that are sold in bulk.

FDA disagrees with this comment. The labels of individually wrapped small food items, such as bite size pieces of candy, are exempt from nutrition labeling under the small package exemption (§ 101.9(j)(13)) because of the lack of space needed to print the required information. However, under section 403(q) of the act, foods sold from bulk containers must be nutrition labeled whether or not they are individually wrapped. Nutrition labeling can, and should, be presented on the labeling of the bulk container or on a counter card, sign, or other appropriate device as identified in § 101.100(a)(2). Moreover, as discussed above, the exemption for small packages only applies to the label and not to a product's labeling. The agency reiterates its position as stated in the **Federal Register** of July 19, 1990 55 FR 29487 at 29505, and 56 FR 60366 at 60379:

> * * * Many foods, such as candies, cookies, and pasta, are offered for sale from large containers such as barrels or bins. FDA has traditionally required that these foods be labeled in accordance with section 403(i)(2) of the act through the use of a counter sign or card on the labeling of the bulk container [21 CFR 101.100(a)(2)]. The agency believes that nutrition labeling can be provided in a similar manner. Therefore, the agency will require nutrition information for such foods.

Accordingly, no changes are being made to § 101.9(j)(14), redesignated as § 101.9(j)(16).

225. Several other comments were received in support of the requirement in the proposed version of § 101.9(j)(16) that nutrition labeling information for bulk foods be provided at the point of purchase. Two comments recommended that nutrition information be provided in the form of brochures or "tear-off" sheets at the point of purchase, so that consumers can have the information available at home.

FDA agrees that tear-off sheets or brochures with the required nutrition information would be useful to consumers and encourages manufacturers to provide retailers with the required nutrition information in such form. Section 403(q)(3) of the act states: "For food that is received in bulk containers at a retail establishment, the Secretary may, by regulation, provide that the nutrition information required * * * be displayed at the point of sale." Thus, the statute does not specify the form in which this information is to be provided. Accordingly, FDA has not made the recommended change.

226. A retail ice cream manufacturer requested that the proposed version of § 101.9(j)(16) be clarified so that scoops of ice cream that are dispensed by store employees from bulk ice cream containers are clearly not subject to the "sold from bulk containers" requirement.

FDA advises that it is not necessary to exempt ice cream from the requirements of § 101.9(j)(16). Ice cream that is dispensed by store employees from bulk ice cream containers at an ice cream store is for immediate human consumption and would therefore be exempt from mandatory nutrition labeling under revised § 101.9(j)(2)(ii).

227. A retail grocery chain stated that popular bulk food items sold from bins and barrels but packaged by clerks for customer convenience should not be required to have nutrition labeling on each package.

FDA advises that § 101.9(j)(16) allows food products sold from bulk food containers to display the required nutrition information "either on the labeling of the bulk container plainly in view or in accordance with provisions of paragraph (a)(2) of this section." Section 101.9(a)(2) allows use of counter cards, signs, tags affixed to the product, or other appropriate devices. Accordingly, the containers such foods are put into when sold to the consumer need not bear nutrition labeling as long as the required nutrition information is plainly in view, regardless of whether it is the consumer or a store employee that packages the product. However, if the foods are packaged in an area that is off-limits to customers, and the information is not plainly in view, the required nutrition information must be available on the package label or in labeling adjacent to the packages accordingly to the provisions of § 101.9(a)(2).

O. Foods Used as the Sole Item of the Diet

228. One professional organization and one consumer interest group wrote in support of FDA's tentative decision to delete the exemption in current § 101.9(h)(3) for foods promoted as the sole item in a diet (such as formulated weight-loss products) and to have the same labeling requirements for those products as all other foods. The consumer interest group stated that "considering the minimal long-term benefit from these products and the potential for harm from the unsupervised use of these products, FDA should consider greater labeling requirements for these products."

FDA intends to monitor the use and labeling of foods used as the sole item of the diet and, as discussed in the supplementary proposal (56 FR 60366 at 60378), will consider at a later date whether there should be additional or different requirements for the nutrition labeling of these products.

P. Other Requests for Exemption

1. Donated Foods

229. Two comments from food banks requested an exemption from mandatory nutrition labeling, citing that food banks are nonprofit charitable organizations, and as such, it would be "unreasonably costly and unduly burdensome for (food banks) to be required to apply complete nutrition labeling to repacked food products." The comments stated that the exemption is necessary to ensure that mandatory nutrition labeling rules do not hamper the ability of charitable organizations to receive and distribute foods to needy individuals.

Section 403(q)(1) of the act requires nutrition labeling on food that "is intended for human consumption and is

offered for sale." Accordingly, donated foods that are given without charge to the ultimate consumer are not subject to mandatory nutrition labeling. This provision of the 1990 amendments was not included in the proposed implementing regulations. To correct this omission, the agency is modifying § 101.9(a) to state that "Nutrition information relating to food shall be provided for all products intended for human consumption and offered for sale * * *."

230. A second request from these foods banks was that food companies having inventories of foods not in compliance with new labeling rules after the effective date of section 403(q) of the act be permitted to donate those products to charitable organizations.

Section 10(a)(2) of the 1990 amendments states that the new nutrition labeling requirements shall not apply to foods labeled before the effective date. Therefore, companies will be able to continue to sell all foods that are labeled in compliance with current regulations before the effective date of section 403(q) of the act, May 8, 1993. As a result, there should be no inventories of labeled food that cannot be sold to consumers. The agency wishes to state, however, that it has long been the agency's policy that misbranded foods, such as those that have been the subject of a seizure or recall, can be donated to charitable organizations rather than being destroyed if they do not present a safety concern, and the recipient is fully informed as to the problem with the food (e.g., short weight).

231. Two comments expressed concern that if donated foods are exempted from nutrition labeling, the goals of nutrition labeling will not be met for individuals who rely on such foods.

In passing the 1990 amendments, Congress intended to require that consumers have the necessary information at their disposal to select diets that are consistent with dietary recommendations aimed at improving the health status of Americans. However, by requiring nutrition labeling only on foods offered for sale, Congress limited the coverage of the nutrition labeling requirements. Therefore, while the agency would encourage nutrition labeling on any foods repackaged or relabeled by charitable organizations, the statute does not require such labeling.

The agency is pleased to note, however, that in conversations with the Food and Nutrition Service, USDA, which administers the Food Distribution Program, the Food and Nutrition Service has stated that it plans to incorporate nutrition labeling on all foods that it distributes to individuals. The Food Distribution Program purchases surplus foods from American markets and distributes them to State agencies for further distribution to individuals and eligible local outlets.

2. Exported Foods

232. Comments from a trade association and a manufacturer requested that products intended for export be exempt from U.S. nutrition labeling regulations because they will necessarily be required to comply with the importing country's labeling criteria.

FDA advises that under section 801(e) of the act, foods intended for export will not be deemed misbranded under section 403 of the act under certain circumstances. Section 801(e) states that:

> A food, drug, device or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it:
>
> (A) Accords to the specifications of the foreign purchaser,
>
> (B) Is not in conflict with the laws of the country to which it is intended for export,
>
> (C) Is labeled on the outside of the shipping package that it is intended for export, and
>
> (D) Is not sold or offered for sale in domestic commerce.

Thus, if a company complies with the requirements of section 801(e) of the act, it need not be concerned about misbranding the food by failing to comply with section 403(q) of the act.

3. Foods for Which Labeling Is Impracticable

233. Two dairy companies requested that returnable glass milk bottles be exempt from nutrition labeling because the total surface area available for labeling is much less than 12 square inches. The labeling surface is the closure on the top of the bottle. If the label were placed on the side of the bottle it would be impossible to recycle the bottle for milk use because of problems with washing and disinfecting the bottle after each use. The comments stated that the returnable glass bottle is important for the environment, and that many of their customers purchase it for that reason. They suggested the nutrition labeling for milk in returnable glass bottles be placed on placards at the point of purchase.

Other comments requested special allowances for uniquely shaped package containers (such as containers of honey in the shape of a bear, individual juice containers in the shape of a hand grenade, or cheese balls) or packaging materials that do not allow for fine printing (e.g., styrofoam ice cream cups).

FDA is willing to consider allowing the required nutrition information for returnable glass milk bottles to be available in labeling, as provided for in § 101.9(a)(2). As discussed in comment 223 of this document, § 101.9(g)(9) of this final rule allows that when it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of nutrition labeling, FDA may permit alternative means of compliance or additional exemptions to deal with the situation.

4. Foods Purchased Under Government Contract

234. One trade association and one manufacturer requested exemptions for products produced for Government contracts (e.g., the National School Lunch Program, military feeding operations), using the reasoning that any products sold would be offered to the final consumer as part of a total meal/diet, and nutrition information on the meal must be supplied by the facility offering the meal.

FDA advises that products of the type discussed in the comment that are sold for use in restaurants and institutional food service operations are exempt under § 101.9(j)(2)(iii). As long as it is not reasonably possible that they will be sold directly to consumers, they need not be nutrition labeled. Therefore, no further exemption is necessary.

VII. Other Issues

A. Assortments of Food

235. A few comments requested clarification on whether assortments of foods, such as a box of assorted chocolates or nuts, would have to bear nutrient information on each type of chocolate (or nuts), or whether an average nutrient value would suffice.

The agency advises that in the preamble to the mandatory nutrition labeling proposal (55 FR 29487 at 29505), it stated that "where assortments of food are packaged, firms will be required to express nutrient content based on the package as a whole (e.g., the entire product contents may be combined for a nutrient analysis)." FDA recognizes that the terms "will be required" and "may be combined" appear inconsistent. Therefore, to clarify the regulation and in accordance with the agency's intent to offer flexibility in the labeling of assortments of foods, FDA has modified § 101.9(e)(1), recodified as § 101.9(h)(1), by deleting "of the total product" and adding a new sentence that states that when

separately packaged ingredients or assortments of the same type of foods are intended to be eaten at the same time, the nutrition information may be specified for each component or as a composite value. In developing a composite nutrient value, the entire product contents would be combined for a nutrient analysis.

In addition, to clarify the term "assortments of food" FDA has modified § 101.9(h)(1) by adding "assortments of the same type of food" and including the example of assorted nuts.

236. A few comments addressed the labeling of variety packs containing an assortment of individually packaged products (e.g., assorted ready-to-eat breakfast cereals or snack foods such as corn chips, cheese puffs, and potato chips). A food manufacturer marketing variety packages stated that they currently label each of the single-serving packages placed in a multi-serving container separately. The comment stated that the outer wrapping is generally transparent, making extensive labeling on the outer wrapping infeasible. Another comment suggested that the outer label contain the statement "Individual inner units carry nutrition information" where each of the single-serving packages in the variety pack bears nutrition labeling. The comment also stated that larger sizes of the individual packages of foods in the variety pack are invariably available to consumers at the same location, and the nutrition labels on those larger packages may be reviewed if desired.

FDA points out that a primary purpose of the 1990 amendments is to allow consumers to maintain healthy dietary practices. To do this, consumers must have access to nutrition information at the point of purchase. In many situations, consumers can look at the nutrition labels of larger packages of the individual foods for nutrition information. However, the agency does not agree that it is always possible to do so.

With respect to the transparent nature of the outer wrapping, FDA does not believe this makes labeling on that wrapping infeasible. Many bakery products are packaged in transparent wrappers and these products provide nutrition and other label information.

Inasmuch as many variety packs are currently printing the required nutrition information for each of the products contained in the variety pack in a table on the outer package, and because the outer packages are generally large, the agency concludes that a special allowance is not required for variety packs. Accordingly, FDA rejects the suggestion that the outer label merely state that the individual units within the package provide nutrition information.

However, the agency has no objection to manufacturers labeling only the individual inner packages if the information is provided in such a way that consumers can clearly see it at the time of purchase. Examples of this type of packaging can be found currently in the marketplace where nutrition labeling is provided on the tops of single-serving packages of breakfast cereals. Accordingly, FDA is adding a new paragraph § 101.9(h)(2) to specify that nutrition labeling of single-serving packages within variety packs must be clearly visible at the point of purchase. Proposed § 101.9(e)(2) is redesignated as § 101.9(h)(4).

237. FDA received comments from companies that sell food products by mail order, particularly varieties of foods and food assortments that are marketed as gifts. The comments requested special provisions in the regulations to provide some flexibility for packaged gift assortments because these packages are assembled from several thousand separately labeled food items, many of which are similar, differing only in size or flavor, and which are used in many different assortments. Because of the unique characteristics of the mail order gift food industry, caused, in part, by rapidly changing selections of gift packages offered, the comments contended that nutrition labeling would have a devastating effect on the industry, unless alternative means of compliance are allowed.

The comments requested that a new paragraph be added under proposed § 101.9(e) for assortments of foods intended to be used as gifts, allowing for nutrition information on such foods to: (1) Be included on labeling, (2) be based on uniform serving sizes, (3) omit reference to "servings per container," (4) be calculated as averages for categories of foods having similar dietary uses or similar significant nutritional characteristics for characterizing nutrients, (5) be based on calculations from nutrient data bases, and (6) omit foods meeting the definition of "small package" in § 101.9(j)(13) from determinations of nutrient content. A subsequent comment on behalf of the mail order gift food companies modified the last provision to state that foods in small packages only be omitted if they are not listed in promotional catalogues and are "optical garnishes" used to enhance the appearance of the gift package, or bonus items included as a free gift or promotional item.

FDA is persuaded that special allowances are justified for gift packages containing a variety of foods (e.g., cheese, jams, and crackers packed together in one gift box) or of food assortments (e.g., several different types of jam in one box). Accordingly, the agency is adding a new paragraph § 101.9(h)(3) to address gift packages.

New § 101.9(h)(3)(i) allows the required nutrition information to appear on the label or in labeling that is within or attached to the outer gift package. This provision allows the information to be consolidated in a single document that could accompany several different gift food packages that contain the same assortment of foods, although not necessarily in consistent size packages, as are identified in the document. This action is in recognition of the fact that the person who buys the gift package is generally not the person who will use the information. According to the comments, on average, 65 percent of company sales are shipped to recipients other than the purchaser. Moreover, many packages shipped to purchasers are subsequently offered as gifts to other persons.

The "outer package" is intended to mean the container directly within which component items are packed. It does not mean the shipping carton, unless component items are packed directly within the shipping carton instead of being packed in a separate inner container.

Comments also have persuaded the agency that standardizing the serving sizes for foods included in gift packages will simplify the simultaneous presentation of information on a variety of different types of foods by putting the information for all products on a comparable weight basis and, thereby, increase the likelihood that consumers will use and understand the information. The comments requested that, where there is no uniform household measure that is either a common multiple or fraction of the quantity of an individual food in an assortment, one ounce (fluid or solid as appropriate) be used as the standard serving size. Rather than leaving open the possibility of the use of any "uniform household measure," however, FDA believes that an allowable exemption from the serving size requirements would be permissible only when all of the foods in a particular gift package are not subject to the same reference amount customarily consumed, as specified in § 101.12(b).

FDA has no objection to the suggestion of a one ounce serving size

for solid foods in such circumstances. The selection of one ounce is acceptable based on the fact that it is the simplest value for use in calculations, many of the foods are packaged in multiples of one ounce, and it is the same as the reference amounts customarily consumed for many of the types of foods used in gift packages (e.g., many cheeses, crackers, and nuts) specified in § 101.12 in the companion document on serving sizes published elsewhere in this issue of the Federal Register.

In the case of liquids, the agency believes a larger serving size is needed because of the extra weight of water, and because there are no reference amounts specified in § 101.12 for liquids at only one fluid ounce. Based on the reference amounts in § 101.12, FDA believes a serving size of 2 fluid ounces is more appropriate for nonbeverage liquids such as syrups, and 8 fluid ounces is appropriate for beverages. These are the reference amounts in § 101.12(b) for maple syrup and for all beverages, respectively. The agency does not believe that it is reasonable to collapse the number of categories of foods any further than these three groups for the purpose of nutrition labeling of gift packages. Therefore, in response to the comments and in an effort to minimize the number of different serving sizes required in the nutrition labeling of gift packages, § 101.9(h)(3)(ii) allows for a serving size of 1 ounce for all solid foods, 2 fluid ounces for nonbeverage liquids, and 8 fluid ounces for beverages where there is no uniform reference amount customarily consumed for each individual food used in an assortment or variety of foods within a gift package.

However, the agency believes it would be misleading to allow nutrient content or health claims based on these serving sizes for foods packaged in gift packs where they differ from reference amounts specified in § 101.12(b) that are used as criteria for the claims. Therefore, § 101.9(h)(3)(ii) states that the reference amounts customarily consumed that are listed in § 101.12 must continue to be used for purposes of evaluating whether individual foods in a gift package qualify for nutrient content claims or health claims.

Inasmuch as section 403(q)(1)(B) of the act requires that the number of servings per container be included on the nutrition label, FDA does not believe that it has the authority to permit this information to be deleted. However in § 101.9(h)(3)(iii), FDA is allowing for the number of servings per container to be stated in the nutrition label as "varied" in recognition of the fact that each type of gift package will furnish a different number of servings. This action is consistent with § 101.9(b)(8) in the companion document on serving size published elsewhere in this issue of the Federal Register, which allows a manufacturer to declare "varied" for the number of servings per container for random weight products. The assembling of gift packs has a random quality. FDA is persuaded that requiring more specific information on labeling would necessitate a unique label or labeling for each package, negating the usefulness of these special provisions.

Section 101.9(h)(3)(iv) provides that average, composite nutrient values may be declared in nutrition labeling for reasonable categories of foods having similar dietary uses and similar significant nutritional characteristics. While the comments requested that composite values be allowed for reasonable categories of foods having similar dietary uses or similar significant nutritional characteristics, FDA believes that both criteria are necessary. Many forms of cheese and peanut butter have similar dietary uses in that they are used to make sandwiches or are eaten on crackers, yet they have far different nutritional characteristics and should not be composited.

The comments suggested, and FDA concurs, that companies should submit to FDA their determinations of "reasonable categories" for review and acceptance. FDA's decision on the companies' determinations will be based, in large part, on whether the values of the characterizing nutrients for foods in the category meet the compliance criteria set forth in § 101.9(g)(3) through (g)(6). To that end, companies should also submit a list of proposed characterizing nutrients for each "reasonable category" of foods.

For example, assuming total calories, total fat, saturated fat, and cholesterol are the categorizing nutrients for a group of cheeses, each cheese's content of these 4 nutrients would have to be no greater than 20 percent in excess of the declared values in the nutrition label, in accordance with § 101.9(g)(5), or reasonably less than the declared values, in accordance with § 101.9(g)(6). Nutrients other than the characterizing nutrients could be stated as an average, or composite, for the category, without having to meet the standards of § 101.9(g)(3) through (g)(6).

While the comments requested that FDA specifically permit the use of data bases for calculating the nutrition information for foods in gift packages, the agency does not believe a separate policy from that which the agency is establishing for other packaged foods (see section VII.B.2. of this document) is necessary or appropriate.

Section 101.9(h)(3)(v) allows foods that meet the definition for small packages under § 101.9(j)(13)(i) that are included in a gift package to be omitted in determining the nutrition information if they are not specifically listed in a promotional catalogue, and they are used in small quantities as "optical garnishes" to enhance the appearance of the gift package or are included as a free gift or promotional item. According to the comment, these items are used in very small quantities and may vary greatly from package to package. On the understanding that the "optical garnishes" are generally small plain candies wrapped in bright colored paper, the agency believes that the small amount used will make an insignificant nutrient contribution to the total package. Free gifts or promotional items, by definition, are not "offered for sale" and are therefore exempt under § 101.9(a).

B. Compliance (§ 101.9(g))

1. Compliance Procedures

In discussing the agency's rationale for requiring a single nutrient value on the label in lieu of permitting ranges of values, FDA tentatively concluded that its current compliance policy with respect to nutrient variability satisfied the requirements of the 1990 amendments (56 FR 60366 at 60373).

The compliance policy in current § 101.9(e) (proposed § 101.9(g)) requires that the nutrient content of the composite of 12 subsamples be at least equal to the labeled value for Class I nutrients (i.e., added nutrients in fortified and fabricated foods) and at least 80 percent of the labeled value for Class II nutrients (naturally occurring or indigenous nutrients). Proposed § 101.9(g)(4) specified that these requirements are applicable for vitamins, minerals, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat, and potassium content. Likewise, in proposed § 101.9(g)(5), the nutrient content of the composite is required to be no more than 20 percent above the labeled value for calories, sugars, total fat, saturated fat, cholesterol, and sodium.

238. The agency received a number of comments regarding its compliance policy as stated in proposed in § 101.9(g) (56 FR 60366 at 60391). A few comments agreed with allowing an 80 to 120 percent leeway in the compliance of foods. One comment noted that while the nutrient values may not be absolute,

they are more consistent for the consumer. Also, the present system makes it easier for manufacturers to obtain compliance. However, the majority of comments disagreed with FDA's compliance policy, requesting that either a tighter or looser standard be used.

Consumers were strongly opposed to the so-called "80-120 rule." They felt the range was too lenient and stated that they would like to see a tighter standard adopted, especially for calories. Fat, carbohydrate, and cholesterol were also identified as nutrients that should have very accurate or exact label declarations. Some suggested other limits of acceptance, such as a plus or minus 5 to 10 percent range. Several comments supported a more accurate declaration of nutrients in consideration of the needs of persons with medical conditions requiring adherence to specialized or restricted diets. Other consumers considered the 20 percent margin of error as being inaccurate and misleading. Some comments considered that with today's available technology, food manufacturers could and should more accurately declare nutrients, notably calories, on the labels and meet more stringent standards.

Several comments included suggestions as how to better declare nutrient content on the label. Suggestions included the declaration of a tolerance standard on all product labels and an example of what the tolerance could mean. For example, the label of a product having a 10 percent tolerance for calories would state the declaration as "100 calories--could be 90 or 110 calories." One comment suggested that a statement be required adjacent to the calorie value declaring that it is "only an approximate figure." Another suggested that all food labels carry a warning of the 20 percent margin of error permitted for calories.

Comments from industry and trade associations considered the 80/120 percent range unduly restrictive. They supported more flexible compliance standards that would provide "representative values" of a product's nutrient content. Representative data in one comment was defined as the mean or the mean plus or minus one standard deviation. Their contention was that, because of the natural variation of foods, application of FDA's compliance procedures result in gross under-representation of some nutrients, such as vitamin A in carrots, and gross over-representation of other nutrients, such as sodium in soft drinks (because of variability in water sources). The comments took exception to FDA's assertion in the discussion on fresh produce and seafood, in the mandatory nutrition labeling proposal (55 FR 29487 at 29506) that nutrient content can largely be controlled in most manufactured foods. In fact, they stated there is greater variability in processed foods because of the complexity of prepared foods, the further processing that is required, the need to total the variability for each ingredient for prepared foods, the flexibility needed for obtaining ingredients from various sources or suppliers, and the analytical variability for required nutrients. One comment recommended that an 80 to 120 percent compliance range be used for nutrients with a low degree of natural or analytical variability. For nutrients with a high degree of natural or analytical variability, a less stringent 65 to 135 percent compliance range was suggested.

Another comment endorsed a more flexible compliance standard whereby micronutrient levels need only be present at a minimum level of 80 percent of declared levels. They recommended that no maximum compliance level be set. This comment was particularly in reference to the difficulty of achieving compliance for a product that has a standard of identity, such as pasta, where maximum and minimum levels of enrichment are specified by the standard. The comment stated that levels of added nutrients may vary depending upon the method of enrichment, indigenous nutrient levels in the wheat, analytical error, rounding of values declared on the label, and loss of nutrients during the drying process.

The agency disagrees with establishing more stringent requirements for label values. FDA shares concerns about individuals with very specific health problems where diets must be closely monitored and controlled. However, no data have been presented, and FDA is not aware of any such data, to suggest that health problems have been created because of the allowable variances. Therefore, the agency considers health management under professional guidance satisfactory using the nutrient values on the labels based on current regulations. In addition, it should be noted that the natural variability of foods may lead to both under- and over-reporting within the allowable variances for individual foods. These variances will tend to balance out over the entire day's diet.

While it is highly desirable to have a precise nutrient value on the label, it is impractical. The natural variability of a food is dependent upon a number of factors. Among them are the season of the year, soil type, variety (cultivar), and weather conditions. The processing that a food undergoes also alters its nutrient content. In addition to these variables, the agency places restrictions on the label declarations in regard to the rounding of nutrient values. These rounding rules are to avoid the impression of unwarranted accuracy as well as to make a label easier for a consumer to review and understand. To declare nutrient values more accurately or precisely than is presently required would place an onerous burden on the manufacturer. The costs associated with the excessive controls to provide more exact label declarations are unreasonable and would not be commensurate with any possible additional health benefit.

The agency rejects the suggestions that declared values be qualified by statements that they reflect tolerance levels or margins of error. Such statements on the label informing consumers of the possible variation between labeled and analytical values would cause great confusion with no real benefit.

Similarly, FDA disagrees with the comments that suggested establishing less stringent requirements for determining compliance with declared label values. As seen in comments, consumers rely on the declared values, and the accuracy of those values is important. FDA does not believe larger suggested ranges, such as 65 to 135, would give consumers the information that they need to adequately evaluate their nutrition intake. Therefore, the agency is not making requested changes in § 101.9(g).

FDA advises that it has not set maximum compliance levels in § 101.9(g) for Class I and Class II nutrients, nor has it set minimum compliance levels for nutrients specified in § 101.9(g)(5) (i.e., calories, sugars, total fat, saturated fat, cholesterol, and sodium). The 20 percent variability permitted is not a range but rather a lower or upper limit, depending on the nutrient. The only regulatory limit on overages of Class I and II nutrients is given in § 101.9(g)(6), which states that "reasonable excesses" are acceptable within current good manufacturing practice. Likewise, § 101.9(g)(6) also states that "reasonable deficiencies" of calories, sugars, total fat, saturated fat, cholesterol, and sodium under labeled amounts are acceptable within current good manufacturing practice. FDA anticipates that manufacturers will be diligent in their own behalf in not underdeclaring Class I and II nutrients, such as vitamins and minerals, and in not overdeclaring nutrients such as calories and fat.

Regarding maximum levels of micronutrients in standardized enriched pasta products, regulatory relief cannot be achieved through modifications of § 101.9 but require changes in the standards of identity of such products.

239. Several comments suggested that the 80 and 120 percent criteria should only be a guideline or screening tool. A few comments expressed the position that FDA should not declare a product misbranded until the manufacturer has had an opportunity to establish that the variations are reasonable under the circumstances.

Other comments suggested that the 80 and 120 percent criteria be waived when there are small quantities. (The quantity limits suggested were 10 and 20 or fewer "units." "Units" were interpreted to be units of measurements, such as 10 or 20 calories or 10 or 20 mg of sodium.) The comments noted that small numbers combined with rounding rules and analytical variability result in inequities for label compliance (i.e., the analytical variance for some low levels of nutrients is greater than the allowed regulatory variance). For example, the comment stated that if a mean value of 1.3 units was rounded for label declaration to the nearest whole unit (i.e., 1 unit), then the acceptable range would be 0.8 to 1.2 units when applying the 80 and 120 percent criteria. The range would be below the true mean value which could result in many products being found out of compliance. Furthermore, these small differences of 0.2 units may not be within the accuracy of many methods, so that the analytical variance could be greater than the allowed regulatory variance. For these small quantities of 20 or fewer units, the comments recommended that a 50 to 150 percent rule be applied. One comment recommended that FDA clarify in the final rule that the rounding of nutrient values, as required by the proposal, would not disadvantage a manufacturer when making nutrient content claims to meet compliance criteria as well as standards of identity.

An alternative suggestion in another comment to avoid an extreme over- or under-declaration when the value is small is to declare the nutrient content to the nearest whole unit with compliance based on a fixed percentage (e.g., within 80 percent) or a fixed unit amount (e.g., one unit or 2 percent U.S. RDA, the basic increment of rounding). The regulation would then require that declared amounts be within 80 percent or one unit (such as a g) for Class II nutrients or within 120 percent or one unit for nutrients such as calories, fat, or sodium.

The agency is not persuaded that the current or proposed acceptance criteria for compliance evaluation should be changed. The compliance criteria permit reasonable excesses over labeled amounts or deficiencies under labeled amounts, dependent upon the nutrient being evaluated, (current § 101.9(e)(6), redesignated as § 101.9(g)(6)) within current good manufacturing practices. As discussed in section IV.A. of this document, the level of "reasonable" is not specified.

It is the manufacturer's responsibility to target labeled values to correspond to actual nutrient levels so that products will meet compliance requirements. This responsibility includes taking into consideration the effects of rounding. Any effect caused by the rounding of labeled values to meet the agency's requirements in § 101.9(c) should be accounted for by the manufacturer in developing a label value and would be included in the evaluation of a "reasonable" level by the agency. Analytical variance is also one of the factors in determining compliance acceptance. This fact is stated in § 101.9(g) (4) and (5) in this final rule.

Manufacturers should perform shelf-life stability studies to substantiate the declared nutrient levels of the product and to demonstrate that a product can meet label claims over the shelf life of the product. FDA does not believe that incorporation into the regulations of any additional explicit provision or compliance position for low level nutrients or small labeling increments would provide added protection for manufacturers.

240. One comment strongly recommended that FDA address sampling issues. It suggested that the current procedure in § 101.9(e)(2) (and in proposed § 101.9(g)(2)) of preparing a composite of 12 subsamples taken from a single lot be changed. Instead, it was suggested that a sample composite for analysis represent 12 different lots.

The agency disagrees with the suggested change in sampling procedures. The comment's suggestion reflects a sampling objective that appears to focus on estimating the nutrient content of product for a specified quantity (e.g., a company's production). FDA's sampling objective is to determine whether the average, within a given lot (a quantity that is defined in current § 101.9(e)(1)), meets label claims. From a compliance evaluation standpoint, the suggested sampling scheme is not a feasible alternative because the results obtained would not be traceable to a specific lot should an overage or deficiency be encountered. Instead of a compliance action against a smaller quantity (a single lot), it might be necessary to take a compliance action against a larger quantity (e.g., a company's production for a larger specified point in time). Therefore, FDA is making no change in § 101.9(g)(2) in response to this comment.

241. Several comments that disagreed with the agency's compliance policy provided suggestions to clarify the codified language. One comment recommended the elimination of total carbohydrate, complex carbohydrate, and unsaturated fat from the Class I category of nutrients at § 101.9(g)(4)(i). It maintained that these three nutrients are unlikely to be "added" but are the result of having used ingredients that inherently have these nutrients.

FDA agrees with the recommendation Therefore, the agency is amending § 101.9(g)(4)(i) to delete total carbohydrate, complex carbohydrate, and unsaturated fat from the Class I category. This deletion should allay the concerns of having the cited nutrients meet Class I nutrition labeling requirements. These nutrients remain in the Class II category (§ 101.9(g)(4)(ii)), although in accordance with the changes made in section III. of this document, complex carbohydrate is changed to other carbohydrate and unsaturated fat to poly- and monounsaturated fat.

To clarify the compliance policy concerning variability because of analytical methodology for Class I and Class II nutrients, FDA is modifying § 101.9(g)(4) by making a new paragraph out of the last sentence which begins with the word "Provided." This change should make clear that the proviso information regarding consideration of regulatory action is applicable to both Class I and Class II nutrients. This qualifying information was inadvertently moved under the paragraph on Class II nutrients in the July 19, 1990 mandatory nutrition labeling proposal, and the error was carried forward in the supplementary proposal.

242. One comment stated that manufacturers should be able to use mean values in all cases, except that statistical outliers should be ignored. The comment also urged the agency to codify its compliance policy to the extent that if a nutrient is found out of the 80 to 120 range of the labeled amount, the product would not be deemed out of compliance as long as the manufacturer can demonstrate that the label declarations represent mean values based on reasonable and adequate sampling and analyses.

FDA disagrees with the comment. The agency's position on the use of mean values is summarized in the preamble of the supplementary proposal (56 FR 60366 at 60373). This position is discussed in more detail in the "FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases" and in section VII.B. of this document. In short, FDA will allow the use of mean values derived from satisfactory data bases if the coefficient of variation is equal to or less than the maximum coefficient of variation specified in the above manual. The coefficient of variation is the standard of deviation (a measure of variability) expressed as a percentage of the mean.

243. A recommendation was made in one comment to amend § 101.9(g)(5) by adding: "Provided, that no regulatory action will be based on a determination of a nutrient value which falls above this level by a factor less than the variability generally recognized for the analytical method used in that product at the level involved." The comment noted this addition would extend the allowance for analytical variability permitted for vitamins, minerals, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat, and potassium, as given in proposed § 101.9(g)(4) to the nutrient declarations for calories, sugars, total fat, saturated fat, cholesterol, and sodium.

The agency agrees that analytical variance is a valid consideration when contemplating regulatory action for all nutrients. Accordingly, the proviso stated in § 101.9(g)(4), which is applicable for Class I and Class II nutrients, is added to § 101.9(g)(5).

244. One comment recommended a two-stage enforcement procedure. The first stage would involve analysis of a single 12-sample composite to determine whether the product passes the compliance standard of 80 to 120. If it passed, the agency would have no enforcement issue. If it did not pass, the agency would collect and measure the nutrient content in three other lots. The average of all four lots tested would be evaluated for compliance purposes.

The agency is not making the change in its procedures that was suggested by this comment. As recognized in several comments from manufacturers, it is the manufacturer's responsibility to accurately declare the nutrient content of a product. As discussed above, the interpretation of results obtained from more than one lot (same ingredients, same processing conditions) cannot be translated to other lots. Factors that could have altered the nutrient content of one lot may not be present for subsequent lots. Through quality control programs and careful consideration of declared nutrient amounts according to the guidelines in "FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases," manufacturers can help to ensure that each lot meets compliance standards. The suggestion made in this comment or in comment 240 of this document in regard to evaluating results representing the analysis of a composite from 12 different lots or an average of results from four composites could be implemented in a manufacturer's quality control procedures to assure compliance with § 101.9(g).

It should be noted that the analyzed nutrient content is not the sole factor in determining whether the agency will bring a particular enforcement action. Other factors that it considers include the effect of matrix upon the analyte, the level of the analyte in the food, information obtained during an establishment inspection of a firm, consumer complaints, past compliance history of the firm, and the firm's demonstrated ability to adequately perform the analysis for a nutrient.

245. A comment recommended that a new section be added to the codified language to the effect that "The metric declaration of the serving size shall be used to determine compliance under this section." The comment said that this change would eliminate any confusion about which of the dual declarations required for serving size would be the determining factor for nutrient declaration.

FDA agrees with the comment. In its serving size proposal (56 FR 60394 at 60410), the agency stated that in addition to the more approximate household measure, it needed a precise weight statement for serving size for compliance purposes. Accordingly, the agency proposed in § 101.9(b)(7) that the serving size in common household measures must be followed by the equivalent metric quantity. However, FDA did not specifically state that this metric measure would be used for compliance purposes. Therefore, for purposes of clarity, the agency is adding a new section, § 101.9(g)(7), to correct this oversight. Consequently, the remaining paragraphs in § 101.9(g) are redesignated.

246. One comment expressed concern that net weight regulations must be considered when evaluating a product against the 80 to 120 rule for compliance. The comment stated that manufacturers are required to sell products at levels above the declared label weight. The comment concluded that this resulted in a discrepancy between labeled nutrition information and actual nutrition values.

The agency does not consider this issue to be a valid concern. Because of the economic considerations of manufacturing, most products are close to label claims for net weight. Additionally, while an overage or underage of the net weight may slightly alter the nutrient content of the container (and particularly if the container is a single serving size), the serving size is the factor by which the nutrients are evaluated. As discussed in the preceding comment, FDA will composite samples and then use the metric weight declared as the label serving size to evaluate the accuracy of declared nutrient values.

2. Data Bases

247. FDA received a large number of comments regarding the use of data bases as sources of nutrient information for nutrition labeling. Most comments supported the use of data bases, giving as reasons that the use of data bases would reduce costs to industry (especially to small businesses), moderate food cost increases to be passed on to consumers, promote fair competition, save time, reduce the use of laboratory chemicals, provide sufficient accuracy, and ease compliance verification procedures. Comments requested the opportunity to use nutrient composition data in commercially available or published data bases directly or through calculation of ingredient values to yield the final composition of formulated products.

FDA appreciates the important role data bases can play in nutrition labeling. Industry-wide data bases were first suggested in 1979 as a possible means of reducing the cost of developing nutrition labeling for individual companies. FDA, USDA, and the Federal Trade Commission encouraged this concept in a notice of proposed rulemaking published in the Federal Register of December 21, 1979 (44 FR 75990) describing the agencies' policies and intentions with respect to numerous food labeling issues. In that notice, FDA, while not agreeing to approve data bases, stated that it would work with industry to resolve any compliance problems that might arise for food labeled on the basis of a data base that the agency had accepted.

FDA is concerned about the reliability of data bases to meet compliance requirements for nutrition labeling. Nutrient data may be valid for some purposes and not for others. For example, data bases that were developed largely for determining

average daily dietary intakes generally serve that purpose well. However, such data bases are usually not adequate to determine natural variability of a particular food or to develop labeling values that are in compliance with FDA nutrition labeling regulations.

Despite these concerns, FDA continues to acknowledge the potential usefulness of data bases to reduce costs associated with nutrition labeling. The agency set out its general policy on the use of data bases most recently in the proposed and final rules on the voluntary nutrition labeling program for raw produce and fish (56 FR 30468 at 30474, July 2, 1991 and 56 FR 60880 at 60884, November 27, 1991, respectively) and the supplementary nutrition labeling proposal (56 FR 60366 at 60373). In addition, the agency announced in the **Federal Register** of July 23, 1992 (57 FR 32796) the availability of a draft manual entitled "FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases." The manual, which replaces the former guide "Compliance Procedures for Nutrition Labeling," is intended to aid companies and trade organizations in developing and using a data base for nutrition labeling that would meet the regulations proposed as a result of the 1990 amendments. It also discusses the conditions under which the mean value derived from a satisfactory data base may be used for nutrition labeling. Comments were requested on the draft manual. These comments have been considered, and the agency is hereby announcing the availability of the final manual. The manual may be obtained from the Division of Nutrition (HFF-260), Office of Nutrition and Food Sciences, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

FDA anticipates that this manual will be of assistance in identifying a data base that is of a quality to provide an adequate basis for nutrition labeling. The use of such a data base to calculate the final composition of a product formulated from several ingredients presents additional problems, however, in that there are no allowances or determinations of the loss of nutrients that may occur during further processing. Depending on the type and amount of processing, significant amounts of nutrients may be lost. The agency is willing to work with manufacturers and trade associations to determine if successful models can be developed showing the relationship between ingredient composition and final product composition that account for losses during processing. While extensive analyses of ingredients and final products would be required to develop and validate a successful model, such action could lead to an acceptable data base.

If a manufacturer wishes to use a data base for nutrition labeling, it is advantageous to follow the statistical procedures outlined in the manual and have the data base accepted by FDA. If the agency finds that the nutrition label of a product which is based on a data base that has been accepted by FDA is not in compliance with § 101.9, FDA will not take immediate action against the product, provided that the company has followed good manufacturing practices in producing the food. Instead, the agency would work with the manufacturer to resolve the compliance issue. Action would be taken only if noncompliance was the result of failure to follow good manufacturing practices.

It must be noted that submission of a data base to FDA for review and acceptance is voluntary. The agency has not prescribed how an individual company is to determine nutrient content for labeling purposes. The choice of a data source is the prerogative of the manufacturer. The manufacturer needs to be judicious in this selection, however, to ensure that the product labeling is in compliance with the regulations. The compliance policy of the agency remains unchanged from current § 101.9(e). An FDA investigator/inspector will collect random units of food (e.g., consumer packages, items of product) from each of 12 different randomly chosen shipping cases of the same code/lot, and an FDA laboratory will prepare a single composite from the 12 units of food. Analysis of the composite will be performed using methods of the AOAC or other reliable and appropriate methods. FDA will then compare the values declared in the nutrition label and labeling with the results from the laboratory analyses. Section 101.9(g)(8) provides for the use of an approved data base.

248. Many comments were received expressing support for use of data bases because they can be used by a company one time, and there would be only a one time cost to determine the nutritional values for the label without regard to future changes in the product.

The agency is concerned that there is a misunderstanding regarding the use of data bases. Data bases are not static but dynamic because of changes in products. Those data bases submitted to the agency or used by companies are expected to reflect the nutritional content of products being offered for sale. Changes in variety, supplier, recipe, or manner of processing could lead to very different nutritional values for the product than those in the original data base. The agency, in monitoring products for compliance, will also review the maintenance of these data bases to ensure that the information in the data bases reflects the nutritional content of the products being offered for sale. Maintenance of a data base means that laboratory analyses of the product are done on a periodic basis to ensure that the nutritional values of the product are within the limits of the data base values. Proper maintenance of the data base is left to the originators of the data base. Frequency and type of maintenance are determined by the data base holders based on their knowledge of the changes in the products. Satisfactory data bases could be useful for periods of up to 10 years based on the size of the data base, plan for maintenance, and the complexity of the product. FDA reviews will be based on the amount of supplementation of the data bases with additional laboratory data (maintenance) during the period of use and the changes in the products covered by the data base.

3. "Nutrition Labeling Manual: A Guide for Developing and Using Data Bases"

FDA announced in the **Federal Register** (57 FR 32796) on July 23, 1992, the availability of a draft manual entitled "Nutrition Labeling Manual: A Guide for Developing and Using Data Bases" (the manual). This manual is intended to aid companies and trade organizations in developing and using a data base for nutrition labeling that meets the regulations resulting from the 1990 amendments. Comments on the manual were accepted until September 8, 1992. This manual provides generic instructions on how to develop and use a data base in preparing nutrition labeling for a food product. Eighteen comments were received from companies or trade associations. The following summarizes the comments and provides the agency response to those comments.

249. Almost all of the comments were opposed to the limit of 80 percent of the label claim for Class II (indigenous) nutrients and 120 percent for calories, sugars, total fat, saturated fat, cholesterol or sodium. The comments argued that these limits were overly restrictive and should be widened or average values should be used with no consideration of limits.

The use of 80 percent or 120 percent as limits for regulatory purposes is established in § 101.9(g) and has been addressed above in section VI. of this document. The manual was developed to aid in the calculation and

construction of data or data bases to meet the regulatory requirements of the agency. Should the agency change its regulations, it will reflect those changes in the manual. Until such changes are made, however, the manual must reflect the applicable regulatory limits.

250. All but one of the comments addressed the use of recipe data bases to calculate final composition of mixed products. The comments cited the savings in money to small businesses, the constant changes in recipes that make it too costly to do analytical testing of products, and the cost of analyzing a large number of products for which the volume is low. The expressed belief was that calculated values better represent the nutrient content over time. Several comments suggested criteria for a good recipe data base. One comment offered the following four proposed principles of good ingredient composition data bases:

(1) Confidence in the quality of data, supported by documentation of data sources. Companies maintaining or using ingredient composition data bases must be able to demonstrate the data source used for each type of product and each nutrient for which ingredient composition data bases are utilized.

(2) Proper maintenance of the data base. Companies developing or using ingredient composition data bases must have procedures in place to ensure that the values in the ingredient composition data bases are reviewed and updated as needed and on a regular basis.

(3) Specificity with respect to ingredients, product formulations, and processes. Companies using ingredient composition data bases must have procedures in place to ensure that the nutrient values are used only for specific applications. For example, a company should have a procedure to ensure that nutrient data specific for one product formulation or process are not used to prepare nutrient declarations for similar product formulations or processes, without assurance that the data are applicable to those products or processes.

(4) Validation of the data base. Companies developing or using ingredient composition databases must have procedures in place to ensure that nutrient values receive reviews, audits, and confirmation through nutrient analyses as often as necessary.

Other comments suggested that manufacturers should be required to substantiate any nutrient content or health claims with analytical data.

The agency agrees that the principles suggested by the comment are worthwhile and necessary for construction of a proper ingredient composition data base. This was the intent of the statement in the manual that calculation of the final composition of a mixed product using data bases of the nutrient composition of ingredients might be acceptable if properly modelled. The agency wanted to assure itself that the ingredient composition information was adequate, and that the calculation of the final nutrient value of the finished product reflected any possible loss of nutrients during processing. In addition, a successful mathematical model used for this purpose should be augmented over time with a review of its applicability by laboratory analysis of the nutrient content of both ingredients and final products. Models constructed with the features described above, and applied to a limited range of appropriate products, would receive serious consideration from the agency. The above features of an appropriate data base will be included in the manual.

The agency believes that in time the calculation of the final composition of mixed products from ingredient data bases may be acceptable for a range of food products. At this time, however, the agency believes that the data that make up ingredient data bases are of mixed quality and, therefore, of limited value. Companies that wish to use ingredient data bases must look at the individual analytical values of each ingredient to evaluate the data to assure themselves that the data are sufficient, meet the requirements expressed in the manual for representativeness, are valid from an analytical standard, and are sufficient to account for any variation in the ingredient.

The agency has stated that the company bears the final responsibility for the accuracy of the label. This principle has not changed and was repeated and supported by several of the comments.

251. Comments were received on changing various aspects of the agency's regulatory policy such as larger number of lots sampled and the average taken, composite samples consisting of several lots, exemption from compliance procedures when data bases are used regardless of whether the agency has accepted them or not, exemption from compliance procedures for nutrients that have a low concentration, and exemption from compliance procedures for companies/associations that have submitted basic data and a plan for data base development over time.

The manual is intended to aid manufacturers/associations in meeting the compliance regulations of the agency. The manual does not set compliance policy but rather offers some explanation for the compliance policy and provide different means of complying with the nutrition labeling regulations. Should the compliance policy of the agency change, the manual will also be changed to reflect those changes.

252. Many comments were received regarding the confidentiality of the submitted data bases. Developers of data bases did not want to see the information gained through analyses of products and ingredients released through freedom of information requests or used in unacceptable ways or for inappropriate products. In addition, development of data bases is a program with costs shared among the participating companies. The comments sought assurance that the data would not be available at no cost to companies that did not participate in its development. Formulations that are used to produce mixed products are also regarded as confidential company information, and the comments sought assurance that they would not be available to anyone who requests the information.

The agency is aware that the development of a data base is costly, and that it may contain information that is of a confidential nature. The agency agrees that release of a data base could vitiate substantial proprietary interests in valuable documents submitted to the agency. Furthermore, it has never been the agency's intent, nor does it have the resources, to maintain and manage data bases that are developed by manufacturers or associations. The agency believes that the availability of a data base is therefore the primary responsibility of the developer. The agency will continue with the policy of assisting the developers of data bases, providing guidance to those who ask for it, and accepting adequate data bases for the products submitted for review. Only those data sufficient to support the agency's decision to accept or not accept a data base will be retained. Confidentiality of such data will be determined and maintained in accord with regulations in part 20 (21 CFR part 20).

Those data base developers who choose to do so are encouraged to make their information available through such compilations as the USDA Handbook No. 8 so that all may benefit from the additional analytical information.

C. Proposed § 101.9(h)

253. A few comments objected to the requirement in proposed § 101.9(h) that nutrition information provided by manufacturers or distributors directly to professionals (e.g., physicians,

dietitians, educators) must contain or have attached to it the nutrition information exactly as required by § 101.9. The comments stated that it was inappropriate for a Federal agency to regulate the transfer of information in this manner.

FDA notes that this section of the regulation has been carried unchanged since 1973 (49 FR 6961, March 14, 1973). At that time, the agency stated that it did not want to restrict the flow of information from food manufacturers to professionals (such as more precise amounts rather than the increments used in nutrition labeling) but rather wanted nutrition information included or attached to it in the form it would be provided to consumers. Inasmuch as nutrition labeling is now mandatory, so that consumers will have the required information available to them on food product labels, FDA has decided to delete this requirement and is doing so in this final rule.

D. Section 101.9(k)

254. Many comments objected to proposed 21 CFR 101.9(k) which details types of nutrition-related claims that cause a food to be misbranded. Most of these comments asserted that the provisions of § 101.9(k) are contrary to the intent of the 1990 amendments and contrary to the will of Congress.

Many comments offered specific objection to proposed § 101.9(k) (3) and (4) and asserted that manufacturers should be allowed to provide information about the effects of soil, storage, transportation, or cooking on the nutrient content of foods. Some comments maintained that the restriction of such information is unconstitutional. A number of comments felt that labels should be required to provide information as to the exact identity of the contents (including substances of no nutritional value), the source of the contents, the amounts of all ingredients, and the techniques and dates of processing. One comment proposed that manufacturers should be required to put toll-free telephone numbers on all of their products so that consumers could call for information about those products.

Many comments asserted that proposed § 101.9(k)(5) is arbitrary and restrictive and expressed a belief that certain naturally-occurring food constituents will be rendered unavailable by this provision. A number of comments maintained that there is no legitimate reason for prohibiting substances found in nature from being incorporated into nutritional products and listed on the label. Some comments suggested amending proposed § 101.9(k) to allow the use of naturally-occurring constituents of foods and herbs, unless there is sufficient evidence that any specific such substance is harmful to human health.

Some comments also objected to proposed § 101.9(k)(6), maintaining that vitamins that are naturally present are better than added synthetic vitamins. These comments expressed a strong desire to know whether vitamins contained in any specific product are naturally-occurring or synthetic.

FDA regrets that its publication of § 101.9(k)(2) through (6) in the November 27, 1991 (56 FR 60393) proposal has created confusion. The publication of § 101.9(k)(2) through (k)(6) did not constitute a proposal of new regulations. It merely represented a proposed redesignation and republication of existing regulations for clarity and completeness.

The provisions embodied in current § 101.9(i)(2) through (i)(6), redesignated in the November 27, 1991, supplementary proposal as § 101.9(k)(2) through (k)(6), to which the comments directed their objections, were first proposed in the Federal Register of March 30, 1972 (37 FR 6493), and were promulgated and published in the Federal Register of January 19, 1973 (38 FR 2125), as § 1.17(i)(2) through (i)(6). Following an appropriate comment period, these regulations were modified and published as final regulations in the Federal Register of March 14, 1973 (38 FR 6961). The regulations were subsequently applied, with certain exemptions, to all food labeling ordered after December 31, 1973, and all labeling used for food products shipped in interstate commerce after June 30, 1975. In the reorganization and republication of section 21 of the Code of Federal Regulations that appeared in the Federal Register of March 15, 1977 (42 FR 14308), § 1.17(i) was renumbered as § 101.9(i). No changes were made to the original codified language of the subject paragraphs during any of these renumberings, and those regulations remain as adopted in 1973.

The only change in § 101.9(k) in the supplementary proposal was in the document entitled "Labeling; General Requirements for Health Claims for Food" (56 FR 60537, November 27, 1991). This document proposed to amend current § 101.9(i)(1), redesignated as § 101.9(k)(1), by adding a second sentence that reads "Information about the relationship of a dietary property to a disease or health-related condition may only be provided in conformance with the requirements of § 101.14 and subpart E of part 101." No comments voiced specific objection to this proposed change.

FDA notes that the provisions of current § 101.9(i) had long been in effect at the time Congress drafted the 1990 amendments. While Congress did enact provisions under the 1990 amendments that allow for health claims on foods, nothing in the act or in the legislative history of the act suggests that Congress intended that current § 101.9(i) should be changed. The agency therefore finds no basis for the assertion that the provisions of current § 101.9(i), redesignated as § 101.9(k), are now contrary to the intent of the 1990 amendments.

FDA has reconsidered the requirements of § 101.9(k)(5), however, in light of the comments. The agency concludes that there is no reason to prohibit safe substances from being incorporated into conventional foods or dietary supplements of vitamins and minerals as long as their presence is noted in the ingredient list, and the product's label or labeling does not state or imply that the food has special dietary properties because of the presence of the substance when, in fact, its usefulness has not been established. Section 411(b)(2) of the act provides that vitamin and mineral products may contain substances that are not vitamins or minerals as long as the substances are only identified as a part of the ingredient list. Therefore, proposed § 101.9(k)(5) is amended by deleting the second and third sentences.

Questions have been raised as to whether the amounts of these substances that are not vitamins or minerals can be included on the food label. Such information can be included in the ingredient list if, in addition to listing the ingredients in order of predominance by weight, quantitative information on each of the ingredients in the food is presented. However, information about the ingredients that are not vitamins and minerals may not be presented in a way that suggests that the dietary usefulness of these substances has been established.

While the comments raised objections to the other provisions of proposed § 101.9(k) (i.e., (k)(3), (k)(4) and (k)(6)), none provided arguments that convinced the agency that deletion or revision of those provisions was either appropriate or necessary in fulfilling the mandates of the 1990 amendments. The objections that were raised, however, suggest that a clarification of the intent of those provisions would prove helpful to those who voiced the objections. Such a clarification was provided in the Federal Register of March 14, 1973 (38 FR 6961). In that document, the agency

noted that § 1.17 (i)(3) and (i)(4) (redesignated as § 101.9(k)(3) and (k)(4)) are aimed at prohibiting unsubstantiated generalizations about nutrient losses because of soil, transportation, or processing and do not preclude a producer, manufacturer, or vendor from indicating a higher nutrient retention in a particular product as compared to other similar products. Nor do they preclude an indication that such retention results from special handling of the product, provided that such indications are factual. Further, these provisions do not preclude a manufacturer from suggesting cooking or handling methods that would result in optimum nutrient retention. While the agency recognizes that such information may be useful to consumers, it does not believe that it would be appropriate to require manufacturers to provide such information, either on the labeling or through other media.

Current § 101.9(i)(6), redesignated in the supplementary proposal as § 101.9(k)(6), prohibits any suggestion that a naturally-occurring vitamin is superior to an added vitamin. The agency finds no basis for such an assertion, and the comment offered no data in support of such an assertion. As the agency clarified in the promulgation of March 14, 1973 (38 FR 6950 at 6958), this section (then § 1.17(i)(6)) "forbids any suggestion that a natural vitamin is superior to an added vitamin, but permits any truthful designation of any nutrient as natural in origin."

FDA acknowledges its inadvertent oversight in not including a reference to proposed § 101.36, Nutrition Labeling of Dietary Supplements of Vitamins and Minerals, in proposed § 101.9(k). The inclusion of this reference is a logical outgrowth of the agency's stated intention that "nutrition labeling of vitamin and mineral supplements appear as similar as possible to the nutrition labeling of other foods" (56 FR 60366 at 60382). Section 101.9(k) applies to all foods, including dietary supplements of vitamins and minerals, and the agency did not intend to narrow its scope. Therefore, FDA tentatively concluded that it should correct this oversight by including an appropriate cross reference to § 101.36 in the final rule. However, the agency will propose its position on this issue following the DS Act. For completeness, FDA is inserting the word "label" in the first paragraph of § 101.9(k) to clarify that this section pertains to food labels as well as labeling.

255. One comment asserted that the phrase "represents, suggests, or implies" in the opening sentence of § 101.9(k) is unconstitutionally vague.

FDA disagrees with the comment's assertion that the phrase "represents, suggests, or implies" is unconstitutionally vague. The agency notes that the vagueness doctrine is generally applied to strike down prohibitions on speech that leave individuals without clear guidance on the type of speech that is prohibited. See, e.g., *Village of Hoffman Estates* v. *Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498-99 (1982); *Grayned* v. *City of Rockford*, 408 U.S. 104, 108 (1972). The provisions of § 101.9(k) are narrowly tailored and clearly delineate the types of statements about nutrients that will render a food misbranded. Thus, § 101.9(k) provides clear and precise guidance on the type of speech that is prohibited.

E. Conforming Amendments

256. A trade association wrote in support of the multiunit retail exemption in § 101.9(j)(15) and requested that § 1.24(a)(14) be amended to reflect the change by including a reference to section 403(q) and (r) of the act. The comment stated "we submit that this amendment is fully consistent with the requirements of the 1990 amendments and the provisions of the proposed § 101.9(j)(13) in that nutrition labeling will be provided on the outer carton together with the other information required under the referenced sections."

The agency agrees that § 1.24(a)(14) of the General Enforcement Regulations should be amended to reference 403(q) of the act, as amended by the 1990 amendments. This change merely conforms § 1.24(a)(14) to the rule that FDA is adopting in § 101.9(j)(15). Accordingly, the agency is amending § 1.24(a)(14) to read as follows: "The unit containers in a multiunit or multicomponent retail food package shall be exempt from regulations of section 403(e)(1), (g)(2), (i)(2), (k), and (q) of the act with respect to the requirements for label declaration of the name and place of business of the manufacturer, packer, or distributor; label declaration of ingredients; and nutrition information when * * *."

However, FDA cannot grant the comment's request with respect to section 403(r) of the act. Any container that bears a nutrient content claim or a health claim must comply fully with the requirements of that section of the act and of the regulations that implement it.

257. A food trade association requested that FDA amend § 101.100(d) to include section 403(q) and (r) of the act to provide that products shipped in bulk for further processing, labeling, or repacking in substantial quantities at an establishment other than where originally processed or packed, are exempt during the time of introduction into, and movement in, interstate commerce and during the time of holding in such establishment.

FDA agrees that § 101.100(d), Exemptions From Food Labeling Requirements, should be amended to include 403(q) of the act. Again, this modification merely reflects the rule that FDA is adopting in § 101.9(j)(9). However, for the reason explained in response to the previous comment, FDA is not granting the request with respect to section 403(r) of the act. Accordingly, FDA is amending 21 CFR § 101.100(d) to read as follows:

> Except as provided by paragraphs (e) and (f) of this section, a shipment or other delivery of food which is, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of section 403 (c), (e), (g), (h), (i), (k), and (q) of the act if: * * *."

Nutrition Labeling of Dietary Supplements of Vitamins and Minerals

258. Most comments, including those from supplement manufacturers and trade associations, supported the general concept of nutrition labeling for dietary supplements of vitamins and minerals. One comment, however, suggested that any decisions on nutrition labeling of vitamin and mineral supplements be deferred until the agency decides how it intends to regulate dietary supplements, in general. This comment is referring to FDA's Task Force on Dietary Supplements. The comment argued that the proposed labeling requirement would create a label with large amounts of information that is of little value to the consumer, particularly for single vitamin and mineral supplements.

As pointed out in the supplementary proposal (56 FR 60366 at 60381), section 403(q)(5)(E) of the act states that if a food to which section 411 of the act applies (i.e., dietary supplements of vitamins and minerals) contains one or more of the nutrients required to be listed in nutrition labeling, "the label or labeling of such food shall comply with the requirements of paragraphs (1) and (2) [of section 403(q) of the act] in a manner which is appropriate for such food and which is specified in regulations of the Secretary." In the supplementary proposal (56 FR 60366 at

60381 through 60382), the agency also stated that vitamin and mineral supplements are required to bear nutrition labeling under section 403(q)(5)(C) of the act even if they do not contain any of the nutrients required to be in nutrition labeling. Section 403(q)(5)(C) of the act provides that nutrition labeling is not required in such circumstances unless a claim is made about the nutritional value of the food. The statement of identity for supplements of vitamins or minerals, including single vitamins or minerals, may be a claim about the nutritional value of the supplement. However, because the DS Act imposes a moratorium on the implementation of the 1990 amendments, FDA is not taking any action to implement section 403(q)(5)(c) of the act at this time.

FDA's Task Force on Dietary Supplements is consequently irrelevant to this issue. Nothing in the Task Force's report would relieve the agency of the obligation to adopt regulations to implement the explicit requirements of the law.

Furthermore, the agency does not agree that nutrition information for vitamin and mineral supplements is of little value to the consumer. These products are represented and sold for their vitamin and mineral content. Thus, nutrition information about them will assist consumers in determining the role that the products can play in maintaining healthy dietary practices. Moreover, the agency notes that most vitamin and mineral supplements already bear nutrition information on their labels.

For the reasons stated, the agency tentatively concluded that it is not necessary to modify its requirement for mandatory nutrition labeling on labels of dietary supplements of vitamins and minerals. However, the agency will propose its position on this issue based on the provisions of the DS Act.

259. In testimony at one of the public meetings held by FDA, there was a comment suggesting that small packages of dietary supplements of vitamins and minerals be exempt from mandatory nutrition labeling.

Section 403(q)(5)(B) of the act provides for an exemption for foods in small packages "if the label of such foods does not contain any nutrition information." This provision is implemented in § 101.9(j)(13)(i). Thus, the question is raised as to whether the statement of identity for supplements of vitamins and minerals is a claim. FDA will address this question and the implementation of section 403(q)(5)(B) with respect to dietary supplements in accordance with the terms of the DS Act.

260. One comment recommended deleting proposed § 101.36(b)(1) that required the number of units recommended per day to be declared in the nutrition label on the basis that it is repetitious of information that is on the label in other places.

Likewise, a few comments were opposed to proposed § 101.36(b)(2) that required declaration of "Units per container" in the nutrition label. These comments asserted that such a requirement is redundant and unnecessary because the number of units per container is already listed on the principal display panel of dietary supplements as part of the net contents declaration.

FDA considered these comments and agrees that, for supplements in which the unit is a discretely defined unit (e.g., tablets or capsules), "Units per day" could be confusing. The agency is concerned that consumers could be confused by a statement that indicates that several units are to be taken per day (e.g. 3 tablets per day) when the nutrient information is given for one unit. If consumers do not look at the column legend that states that the nutrient information is "per unit," they might assume that the nutrient information is for the amount specified for consumption per day. To avoid the possibility for confusion, FDA tentatively concludes that the subheading "Each unit contains:" should be allowed for supplements in which the unit is a discretely defined unit (e.g., tablets or capsules). Directions concerning the number of units to be consumed per day should be given outside of the nutrition label.

The agency also agrees that, since § 101.105(a) requires the net quantity of content declaration to include a numerical count when appropriate, there is little benefit to be derived from information on the number of units per container appearing in two different places on the label. However, when the supplement is in a liquid or powdered form, FDA believes additional information similar to that on conventional foods best informs the consumer about the dosage unit. Therefore, FDA tentatively concludes that for dietary supplements of vitamins and minerals in liquid or powdered form, "Serving size" and "Servings per container" should be stated consistent with § 101.9(d). The agency will propose its position on these issues in the rulemaking required by the DS Act.

261. Several comments, mostly from the dietary supplement industry, opposed the dual labeling of nutrient content "per unit" and "per day" if more than one unit is specified for consumption per day. Comments argued that dual declaration is impractical and will result in overcrowding of already small labels, creating consumer confusion and obfuscating the label's message. Other arguments against dual declaration were that such a requirement may discriminate against supplements that are not in the one-per-day format, and that it would force the industry to reformulate products so that labels can accommodate all of the information. One comment pointed out that the proposed regulation does not address how required information should be presented when the recommended daily dose is a range, e.g., 1 to 3 tablets per day.

Among the comments opposing dual declaration, however, there was disagreement as to which declaration is preferable, "per unit" or "per day." Some comments stated that it was the total amount of nutrients that is important, and therefore, declaration should be on a "per day" basis. These comments pointed out that FDA regulations (§ 105.77) promulgated in 1973 specified that dietary supplements be labeled according to the quantity specified for consumption during one day. The comment stated that although these regulations were withdrawn in 1979, most companies still comply with them.

Other comments stated that consumers may deviate from the recommended dose and should be given credit for being able to multiply quantities of nutrients by the number of units consumed. Therefore, these comments stated that declaration should be on a "per unit" basis. Comments pointed out that the U.S. Pharmacopeia is developing quality standards for dietary supplements in which they propose that nutrient information be presented "per dosage unit."

Other comments suggested that as an alternative to just one form of declaration on the label, the label could reference other labeling such as package inserts that contain all of the required information, or could permit either "per unit" or "per day" listing as long as the label clearly states which type of information is provided. A few comments favored dual declaration. One comment stated that omitting either declaration might confuse people who think that the nutrition information for one unit applies to a day or vice versa.

The agency is persuaded that dual declaration of nutrition information "per unit" and "per day," when a daily dose of more than one unit is recommended, may create a readability

problem for consumers, given the limited label space available on most dietary supplement products. FDA also agrees that recommended daily consumption of other than well defined dosages (e.g., "consume 1 to 3 tablets per day") would pose a problem in terms of labeling on a "per day" basis.

FDA is concerned that consumers have nutrition information available at the point of purchase upon which to base purchase decisions. Therefore, the agency is not considering package inserts which could be viewed only after purchase of the product. Additionally, rather than allowing manufacturers to label on a "per day" or "per unit" basis, the agency favors one consistent method of labeling. A consistent method will allow consumer education programs to explain how nutrition labeling is to always appear and to teach consumers how to calculate their individual consumption levels if their intake differs from the amount specified within the nutrition label. The agency believes labeling "per unit" is more useful in that the product will always be consumed "per unit," however, consumers may not always follow a manufacturer's recommendation to consume a certain number of units per day and therefore may not actually consume the amount indicated "per day."

For these reasons, and to harmonize with the U.S. Pharmacopeia, the agency tentatively concludes that nutrition information should be declared on a "per unit" basis. FDA intends to propose its position in the rulemaking that is required under the DS Act.

262. In the supplementary proposal, FDA proposed that nutrition labels for dietary supplements of vitamins and minerals include a column of quantitative amounts by weight and a second column of percent of RDI's, expressed as "Percent Daily Value." Comments were requested on the usefulness of a list of DRV's and the percent of the DRV for fat, saturated fat, cholesterol, carbohydrate, dietary fiber, and sodium provided by the supplement when they are declared (i.e., when they are present in the supplement in more than insignificant amounts) (56 FR 60366 at 60383). In the format proposal, FDA stated that it anticipated modifying § 101.36, Nutrition Labeling of Dietary Supplements, to be as consistent as possible with the nutrition labeling of other foods and requested comment (57 FR 32058 at 32072).

Several comments to both the supplementary proposal and the format proposal addressed the format for declaring amounts of nutrients present. About half of the comments supported FDA's position. However, one comment argued that the unique characteristics of dietary supplements demand a different approach to their nutrition labeling. Characteristics identified included: (1) The vast majority of supplements are marketed in relatively small packages, (2) the nutrition profiles for these products typically reflect high levels of micronutrients and relatively insignificant amounts of macronutrients, (3) consumers look for and expect nutrition information on supplements that is different from that on conventional foods, and (4) consumers of supplements will already be asked to search through an array of nutrient names and units of measure to find the information they look for most: The percentage of their daily nutritional requirements that the supplement provides.

One comment from a manufacturer stated that there was no need to make significant changes in dietary supplement labels because current labels that have been used for many years are widely accepted and present the necessary data on vitamins and minerals in a logical and readily understandable form. A comment from another manufacturer opposed the required declaration in separate columns of quantitative amounts by weight of nutrients and by the percent RDI or percent DRV (expressed as "Percent of Daily Value"). The comment argued that only percent of daily value should be mandatory, and that listing of quantitative amounts by weight should be voluntary, because there is no congressional mandate to list quantitative amounts on two bases, no agency justification that two bases are useful to consumers, and a potential to confuse consumers with little understood terms, e.g., mg alpha-tocopherol. The comment also asserted that a requirement for too much information is discriminatory against products with larger numbers of nutrients and might discourage use of smaller packages that are less expensive to consumers. The comment also stated that a requirement for declaration of only percent of daily value would be consistent with the requirement for vitamins and minerals on conventional food labels.

A few comments objected to the required inclusion of a list of daily values in addition to the quantitative amounts by weight and the percent of daily value on the label. The comments stated that this additional information will produce an even more cluttered appearance and further contribute to the proliferation of numerical values on dietary supplement labels. One comment argued that "The goal of meeting the supplement consumer's need for relevant, comprehensible nutrition information should not be sacrificed out of a blind concern for consistency." The comment concluded that consumers of supplements are already familiar and comfortable with the concept of percent of daily value and their focus on this information should not be diverted by additional unnecessary and potentially confusing information.

While FDA continues to believe it is helpful to consumers to minimize inconsistencies in the label format between types of foods, the agency is persuaded that the unique characteristics of dietary supplements require a reevaluation of whether the format requirements for conventional foods should be carried over to dietary supplements. For example, the agency believes that the declaration of quantitative amounts on two bases (i.e., both by weight and by percent of daily value) needs to be considered for dietary supplements in terms of its usefulness to consumers. In that regard, the agency considers dietary supplement consumers to have special needs for quantitative nutrition information about the products they use by virtue of the way such products are formulated, marketed, and used. Dietary supplements are often formulated and marketed on the basis of offering specific amounts of certain nutrients to consumers. Dietary supplement product users are often trying to maintain a certain quantitative intake of specific nutrients in their diets and use the product to obtain this quantitative goal. Some of the nutrients contained in dietary supplements and declared on the nutrition label are not well known to many consumers. The quantitative goals that are importantly relevant to consumption of dietary supplement products may be stated in various units including units of weight or of percent of RDI's or DRV's. FDA intends to address this issue in the rulemaking that it will undertake in response to the DS Act.

In its reevaluation of format requirements for dietary supplements, the agency also looked at the requirement in nutrition labeling of conventional foods for a list of daily values for all nutrients declared on the label. After careful consideration of the comments, the agency tentatively concludes that it is not necessary or appropriate to require the inclusion of the DV list on dietary supplements. Because of the small size of most supplement packages and the

duplication of the more complex nomenclature of units for vitamins (e.g., mg alpha-tocopherol) that would be required in a DV list, the agency believes that the added complexity and proliferation of numerical values would interfere with consumers use of the quantitative information by weight and by percent of daily value. FDA will propose its position regarding the format of the nutrition label for dietary supplements based on the provisions of the DS Act.

263. A few comments opposed the requirement for declaration of the quantitative amount and the percent of the DRV of fat, saturated fat, cholesterol, carbohydrate, dietary fiber, sodium, and potassium when these nutrients are present in a supplement in more than insignificant amounts. One comment suggested that the declaration either be optional or be required only when these nutrients are present at levels greater than 10 percent of their respective DRV's. The comment stated that: (1) Excessive and useless information would detract from the importance of a product's vitamin and mineral content; (2) even though the vast majority of supplements lack these substances, all products would have to undergo extensive and expensive testing to determine whether listing of these components is necessary, thus burdening small companies with diverse supplement product lines; and (3) these requirements would hinder product development and increase the cost of bringing innovative products to market. Another comment stated that declaration of fat should be required only for fatty acid supplements of 1 g or more per unit since declaration of smaller amounts would clutter the label and be difficult to read.

As discussed in the preceding comment, FDA agrees that the declaration of the amount of the DRV's (i.e., the DV list) is not necessary on labels of dietary supplements of vitamins and minerals. However, FDA continues to believe that the quantitative amount and the percent of the DRV should be declared for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, sodium, and potassium when these nutrients are present in a supplement in more than insignificant amounts. Information about these food components, which are important to the maintenance of good health, is useful for consumers. This view was supported by comments from health professionals, consumer organizations, and the general public. Moreover, supplements are formulated products, and manufacturers should know from the ingredients that they use to make these products whether a supplement contains more than insignificant amounts of any of the nutrients for which DRV's have been established. When such ingredients are not used, laboratory analyses for such nutrients would be unnecessary. As discussed in comment 176 of this document, the definition of insignificant has been modified so that an "insignificant amount" of total carbohydrate, dietary fiber, and protein is an amount that allows a declaration of "less than 1 g" in the nutrition label. The agency will propose its position on this issue in the rulemaking that it does in response to the DS Act.

264. Several comments, predominantly from manufacturers and trade associations, disagreed with FDA's statement in the supplementary proposal that dietary supplements of selenium and chromium are not permitted because there are no regulations declaring these nutrients as approved food additives, GRAS, or prior-sanctioned ingredients. A trade association stated that nutrition labeling regulations are not the appropriate place to announce decisions about the GRAS status of nutrients. Comments argued that selenium and chromium are recognized as essential nutrients for humans. They pointed out that the National Research Council's Food and Nutrition Board has established a Recommended Dietary Allowance for selenium and an ESADDI for chromium (Ref. 23), and that FDA proposed RDI's for these nutrients. Moreover, comments stated that FDA has advised for many years that these trace minerals are "safe and suitable" for use in supplements. The comments argued that, therefore, FDA should adopt a general policy that trace minerals for which a Recommended Dietary Allowance or ESADDI has been established are GRAS, at least at levels not to exceed their respective Recommended Dietary Allowance/ESADDI.

The agency agrees that this rulemaking is not the appropriate place to announce decisions about the GRAS status of nutrients. Therefore, FDA reiterates that there are currently no sources of selenium or chromium that are either affirmed as GRAS or approved food additives for addition to human food. Any direct addition of these trace minerals to a food is based solely on the manufacturer's judgment that the nutrient sources are GRAS and is not sanctioned by the agency.

265. One comment advocated the parenthetical listing of the source of each vitamin or mineral immediately following its declaration on the nutrition information panel in lieu of a separate ingredient list. The comme· argued that this listing would avoid confusion by enabling consumers to readily identify the nutrient source and would save limited label space. Furthermore, the comment stated that it is already common practice in the supplement industry. The comment suggested that information about the source of the nutrient would allow the consumer to identify whether the source is the most physiologically desirable, e.g., beta-carotene versus vitamin A palmitate.

FDA advises that dietary supplements, like any food, are required to bear a complete list of ingredients under section 403(l)(2) of the act, and such list should not be confused with the nutrition label. Ingredient listing, moreover, is needed for substances other than vitamins or minerals, e.g., lactose, other fillers, artificial colors, flavors, binders, and excipients. Consumers desiring to know the source of a nutrient can merely look at the list of ingredients just as they would for a conventional food product. Therefore, in accordance with ingredient labeling regulations, the specific source of vitamin A must be shown in the ingredient list.

However, in response to this and another similar comment (see comment 81 of this document), the agency is allowing for the declaration of the percent of vitamin A present as beta-carotene in § 101.9(c)(8)(vi). The agency will propose its position regarding a similar provision in nutrition labeling regulations pertaining to dietary supplements of vitamins and minerals following provisions of the DS Act.

266. One comment objected to the listing of the quantitative amounts of vitamins and minerals to the nearest unit of the same level of significance at which the RDI's are specified in § 101.9(c)(8)(iv). The comment stated that it would be potentially confusing to consumers for thiamin, for example, to be declared to the first decimal place, e.g., 100.0 mg, and niacin to be declared to the nearest whole number, e.g., 100 mg. The comment suggested that decimal places be dropped, and that all nutrients be listed to the nearest whole number when nutrient levels are ten or more times the RDI.

While FDA intends to deal with this issue in its rulemaking that responds to the DS Act, the agency offers the following comments. FDA is not persuaded that consumers would be confused by decimals for some nutrients and not others. In addition, requiring only whole numbers would introduce a large amount of imprecision in the declarations of some nutrients. For

example, it would cause 1.5 mg of thiamin (i.e., 100 percent of the RDI) to be rounded up to 2 mg—a 33 percent increase.

However, when the decimal is followed by a zero, the agency generally has no objection to the zero being dropped. In fact, in the supplementary proposal, this was done in the declaration of the amount of vitamin B12 in the hypothetical sample label for "Daily Vitamins Plus Iron" (56 FR 60366 at 60383). Since RDI's in § 101.9(c)(8)(iv) are established only in whole numbers or in tenths of a unit, allowing zeros following decimals to be dropped, in effect, allows all nutrients to be declared to the nearest whole number when nutrient levels are ten times the RDI.

267. A couple of comments objected to FDA's proposal that compliance with the requirements for labeling of dietary supplements be determined in accordance with § 101.9(g), i.e., 100 percent of label claim for Class I nutrients. Comments argued that the 100 percent requirement is unreasonable in that it is more stringent than United States Pharmacopeia (USP) requirements for certain vitamin and mineral products, which generally allow lower limits of 90 percent to 95 percent of label claim.

FDA intends to deal with this issue in the rulemaking that responds to the DS Act. However, the agency notes that dietary supplements are fabricated products. Therefore, the question is raised why they should not be held to the same Class I nutrient standards as conventional foods that are fortified or enriched. Based on the agency's current compliance policy it has informed USP that anything less than 100 percent of the label claim for vitamin and mineral products is not acceptable to FDA, and that the only permissible deviation from this requirement would be the variability of the analytical method (Ref. 118).

The agency notes that, contrary to the statement in the comments, the General Notices of the USP state that a dosage should be formulated to provide 100 percent of the labeled amount (Ref. 119). The limits in the monographs allow for overages of ingredients known to decrease with time, for analytical error, for manufacturing and compounding variations, and for deterioration to an extent considered insignificant under practical conditions (Ref. 119).

268. One comment asserted that manufacturers should be prohibited from labeling a supplement in such a way as to confuse the weight of a unit of supplement with its nutrient content. For example, a calcium supplement that contains 250 mg of elemental calcium as calcium chloride should not be labeled as "calcium—625 mg" anywhere on the label.

FDA concurs that such labeling is potentially misleading to consumers. Section 403(a) of the act provides that a food will be deemed to be misbranded if its labeling is false or misleading in any particular. FDA concludes that existing statutory authority is sufficient for taking regulatory action if the weight of a product is specified on the label in a manner that is likely to mislead consumers into thinking that that is the weight of the nutrient contained in the product if those amounts are different.

IX. Consumer Education Program

Section 2(c) of the 1990 amendments directs the Secretary (and FDA, by delegation) to carry out activities that educate consumers about nutrition information on the food label and the importance of that information in maintaining healthy dietary practices. To achieve this purpose, FDA and USDA have jointly initiated a multi-year food labeling education campaign. The major goals of this campaign are to increase consumers' knowledge and effective use of the new food label to make accurate and sound dietary choices; to integrate food labeling education into existing and new nutrition and health education programs; and to build extensive partnerships capable of developing and evaluating labeling education targeted to the dietary needs of diverse populations, such as low literacy consumers, minorities, older Americans, children, and people with dietary restrictions.

As part of this effort, the agencies have established the National Exchange on Food Labeling Education which includes an information center housed in the Food and Nutrition Information Center at the National Agricultural Library. The National Exchange on Food Labeling Education provides the general public and professionals with access to information about food labeling research and educational activities (projects, programs, and materials) from both the public and private sector.

FDA and USDA have also worked to establish cooperative projects with diverse organizations and to facilitate the communication of information that targets various subpopulations as well as the general public. The agencies have thus developed extensive food label education networks that include consumers, health professionals and organizations, educators, trade associations, Federal and local government, and many others to assist in the dissemination and development of information and activities.

To ensure that consumers have accurate and adequate resource materials and information, the agencies have begun, and will continue, to conduct and report on existing and planned food labeling research; to develop education initiatives at the national and local level; to hold regularly-scheduled meetings to build labeling education exchanges; to produce videos; and to produce an array of public education materials, including a special edition of FDA Consumer magazine that summarizes the final food labeling regulations, and brochures (in English and other languages) on the new label and how to use it to meet the Dietary Guidelines for Americans (Ref. 4). These materials will be targeted to the general public, nutritionists, such special groups as ethnic minorities, and others. Organizations will also be able to use these resource materials to develop educational materials of their own.

X. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the Federal Register of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the Federal Register. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the Federal Register announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule

as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

XI. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in its nutrition labeling proposed rules published in the **Federal Register** of November 27, 1991 (56 FR 60366 et al.), the agency determined that under 21 CFR 25.24(a)(11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

In its November 1991 nutrition labeling proposed rules, the agency proposed that the final rules for these actions would become effective 6 months following their publication in the **Federal Register**. Several comments on the nutrition labeling proposed rules suggested that there would be significant adverse environmental effects from the final rules unless the agency allowed more time between the publication of the final rules and their effective dates. The concern in these comments was that, if the agency did not allow firms more time between the publication of the final rules and their effective dates to use up existing label inventories, large stocks of labels and labeled packaging would have to be discarded. These comments questioned whether the agency had sufficiently examined the impact of disposing of obsolete labels and labeled packaging on this country's solid waste disposal capabilities. Two comments estimated the amounts of labeling from their respective industries, i.e., dairy and confectionery, that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, these comments did not: (1) Provide details on how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to these two actions, or (3) describe what impact the discarded labels and packaging would have on the disposal of solid waste.

Based on its review of available data and comments received, the agency has decided to allow additional time for companies to use up their old labels. Thus, the nutrition labeling final rules will not be effective until May 8, 1994. FDA believes there will thus be ample time for food companies to use up most of the existing labeling and packaging stocks and to incorporate labeling language that complies with FDA's regulations into their food labels. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected and that an environmental impact statement is not required.

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List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1 and 101 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 403, 502, 512, 602, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, 352, 355, 360, 362, 371); sec. 215 of the Public Health Service Act (42 U.S.C. 216).

2. Section 1.24 is amended by revising paragraph (a)(14) to read as follows:

§ 1.24 Exemptions from required label statements.

* * * * *

(a) * * *

(14) The unit containers in a multiunit or multicomponent retail food package shall be exempt from regulations of section 403 (e)(1), (g)(2), (i)(2), (k), and (q) of the act with respect to the requirements for label declaration

of the name and place of business of the manufacturer, packer, or distributor; label declaration of ingredients; and nutrition information when:

(i) The multiunit or multicomponent retail food package labeling meets all the requirements of this part;

(ii) The unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale; and

(iii) Each unit container is labeled with the statement "This Unit Not Labeled For Retail Sale" in type size not less than one-sixteenth of an inch in height. The word "Individual" may be used in lieu of or immediately preceding the word "Retail" in the statement.

* * * * *

PART 101—FOOD LABELING

3. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

4. Section 101.9 is revised to read as follows:

§ 101.9 Nutrition labeling of food.

(a) Nutrition information relating to food shall be provided for all products intended for human consumption and offered for sale unless an exemption is provided for the product in paragraph (j) of this section. A nutrition claim or any other nutrition information on the label or in labeling or advertising in any context, and in any form of expression, implicit, as well as explicit, shall negate any exemption and subject a food to the provisions of this section.

(1) When food is in package form, the required nutrition labeling information shall appear on the label in the format specified in this section.

(2) When food is not in package form, the required nutrition labeling information shall be displayed clearly at the point of purchase (e.g., on a counter card, sign, tag affixed to the product, or some other appropriate device). Alternatively, the required information may be placed in a booklet, looseleaf binder, or other appropriate format that is available at the point of purchase.

(3) Solicitation of requests for nutrition information by a statement "For nutrition information write to _____" on the label or in the labeling or advertising for a food, or providing such information in a direct written reply to a solicited or unsolicited request, does not subject the label or the labeling of a food exempted under paragraph (j) of this section to the requirements of this section if the reply to the request conforms to the requirements of this section.

(4) If any vitamin or mineral is added to a food so that a single serving provides 50 percent or more of the Reference Daily Intake (RDI) for the age group for which the product is intended, as specified in paragraph (c)(8)(iv) of this section, of any one of the added vitamins or minerals, unless such addition is permitted or required in other regulations, e.g., a standard of identity or nutritional quality guideline, or is otherwise exempted by the Commissioner, the food shall be considered a food for special dietary use within the meaning of § 105.3(a)(1)(iii) of this chapter.

(b) [Reserved]

(c) The declaration of nutrition information on the label and in labeling of a food shall contain information about the level of the following nutrients, except for those nutrients whose inclusion, and the declaration of amounts, is voluntary as set forth in this paragraph. No nutrients or food components other than those listed in this paragraph as either mandatory or voluntary may be included within the nutrition label. Except as provided for in paragraphs (f) or (j) of this section, nutrient information shall be presented using the nutrient names specified and in the following order in the formats specified in paragraphs (d) or (e) of this section.

(1) "Calories, total," "Total calories," or "Calories": A statement of the caloric content per serving, expressed to the nearest 5-calorie increment up to and including 50 calories, and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. Energy content per serving may also be expressed in kilojoule units, added in parentheses immediately following the statement of the caloric content.

(i) Caloric content may be calculated by:

(A) Using specific Atwater factors (i.e., the Atwater method) given in Table 13, "Energy Value of Foods—Basis and Derivation," by A. L. Merrill and B. K. Watt, United States Department of Agriculture (USDA) Handbook No. 74 (slightly revised, 1973), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and is available from the Division of Nutrition, Center for Food Safety and Applied Nutrition (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be inspected at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.;

(B) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate, and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised 1973) pp. 9–11, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (the availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section);

(C) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate less the amount of insoluble dietary fiber, and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised 1973) pp. 9–11, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (the availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section);

(D) Using data for specific food factors for particular foods or ingredients approved by the Food and Drug Administration (FDA) and provided in parts 172 or 184 of this chapter, or by other means, as appropriate; or

(E) Using bomb calorimetry data and subtracting 1.25 calories per gram protein to correct for incomplete digestibility, as described in USDA Handbook No. 74 (slightly revised 1973) p. 10, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (the availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section).

(ii) "Calories from fat": A statement of the caloric content derived from total fat as defined in paragraph (c)(2) of this section in a serving, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that label declaration of "calories from fat" is not required on products that contain less than 0.5 gram of fat in a serving and amounts less than 5 calories may be expressed as zero. This statement shall be declared as provided in paragraph (d)(5) of this section. Except as provided for in paragraph (f) of this section, if "Calories from fat" is not required and, as a result, not declared, the statement "Not a significant source of calories from fat" shall be placed at the bottom of the table of nutrient values in the same type size.

(iii) "Calories from saturated fat" or "Calories from saturated" (VOLUNTARY): A statement of the caloric content derived from saturated fat as defined in paragraph (c)(2)(i) of this section in a serving may be declared voluntarily, expressed to the nearest 5-

calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. This statement shall be indented under the statement of calories from fat as provided in paragraph (d)(5) of this section.

(2) "Fat, total" or "Total fat": A statement of the number of grams of total fat in a serving defined as total lipid fatty acids and expressed as triglycerides. Amounts shall be expressed to the nearest 0.5 (½) gram increment below 3 grams and to the nearest gram increment above 3 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(i) "Saturated fat," or "Saturated": A statement of the number of grams of saturated fat in a serving defined as the sum of all fatty acids containing no double bonds, except that label declaration of saturated fat content information is not required for products that contain less than 0.5 gram of total fat in a serving if no claims are made about fat or cholesterol content, and if "calories from saturated fat" is not declared. Except as provided for in paragraph (f) of this section, if a statement of the saturated fat content is not required and, as a result, not declared, the statement "Not a significant source of saturated fat" shall be placed at the bottom of the table of nutrient values in the same type size. Saturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½) gram increment below 3 grams and to the nearest gram increment above 3 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(ii) "Polyunsaturated fat" or "Polyunsaturated" (VOLUNTARY): A statement of the number of grams of polyunsaturated fat in a serving defined as *cis,cis*-methylene-interrupted polyunsaturated fatty acids may be declared voluntarily, except that when monounsaturated fat is declared or when a claim is made on the label or in labeling about fatty acids or cholesterol, label declaration of polyunsaturated fat is required. Polyunsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½) gram increment below 3 grams and to the nearest gram increment above 3 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(iii) "Monounsaturated fat" or "Monounsaturated" (VOLUNTARY): A statement of the number of grams of monounsaturated fat in a serving defined as *cis*-monounsaturated fatty acids may be declared voluntarily except that when polyunsaturated fat is declared or when a claim is made on the label or in labeling about fatty acids or cholesterol, label declaration of monounsaturated fat is required. Monounsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½) gram increment below 3 grams and to the nearest gram increment above 3 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(3) "Cholesterol": A statement of the cholesterol content in a serving expressed in milligrams to the nearest 5-milligram increment, except that label declaration of cholesterol information is not required for products that contain less than 2 milligrams cholesterol in a serving and make no claim about fat, fatty acids, or cholesterol content, or such products may state the cholesterol content as zero. Except as provided for in paragraph (f) of this section, if cholesterol content is not required and, as a result, not declared, the statement "Not a significant source of cholesterol" shall be placed at the bottom of the table of nutrient values in the same type size. If the food contains 2 to 5 milligrams of cholesterol per serving, the content may be stated as "less than 5 milligrams."

(4) "Sodium": A statement of the number of milligrams of sodium in a specified serving of food expressed as zero when the serving contains less than 5 milligrams of sodium, to the nearest 5-milligram increment when the serving contains 5 to 140 milligrams of sodium, and to the nearest 10-milligram increment when the serving contains greater than 140 milligrams.

(5) "Potassium" (VOLUNTARY): A statement of the number of milligrams of potassium in a specified serving of food may be declared voluntarily, except that when a claim is made about potassium content, label declaration shall be required. Potassium content shall be expressed as zero when the serving contains less than 5 milligrams of potassium, to the nearest 5-milligram increment when the serving contains less than or equal to 140 milligrams of potassium, and to the nearest 10-milligram increment when the serving contains more than 140 milligrams.

(6) "Carbohydrate, total" or "Total carbohydrate": A statement of the number of grams of total carbohydrate in a serving expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, or if the serving contains less than 0.5 gram, the content may be expressed as zero. Total carbohydrate content shall be calculated by subtraction of the sum of the crude protein, total fat, moisture, and ash from the total weight of the food. This calculation method is described in A. L. Merrill and B. K. Watt, "Energy Value of Foods—Basis and Derivation," USDA Handbook 74 (slightly revised 1973) pp. 2 and 3, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (the availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section).

(i) "Dietary fiber": A statement of the number of grams of total dietary fiber in a serving, indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, declaration of dietary fiber is not required or, alternatively, the statement "Contains less than 1 gram" or "less than 1 gram" may be used, and if the serving contains less than 0.5 gram, the content may be expressed as zero. Except as provided for in paragraph (f) of this section, if dietary fiber content is not required and as a result, not declared, the statement "Not a significant source of dietary fiber" shall be placed at the bottom of the table of nutrient values in the same type size.

(A) "Soluble fiber" (VOLUNTARY): A statement of the number of grams of soluble dietary fiber in a serving may be declared voluntarily except when a claim is made on the label or in labeling about soluble fiber, label declaration shall be required. Soluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(B) "Insoluble fiber" (VOLUNTARY): A statement of the number of grams of insoluble dietary fiber in a serving may be declared voluntarily except that when a claim is made on the label or in labeling about insoluble fiber, label declaration shall be required. Insoluble fiber content shall be indented under dietary fiber and expressed to the nearest gram except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(ii) "Sugars": A statement of the number of grams of sugars in a serving, except that label declaration of sugars content is not required for products that contain less than 1 gram of sugars in a

serving if no claims are made about sweeteners, sugars, or sugar alcohol content. Except as provided for in paragraph (f) of this section, if a statement of the sugars content is not required and, as a result, not declared, the statement "Not a significant source of sugars" shall be placed at the bottom of the table of nutrient values in the same type size. Sugars shall be defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). Sugars content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less then 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iii) "Sugar alcohol" (VOLUNTARY): A statement of the number of grams of sugar alcohols in a serving may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about sugar alcohol or sugars when sugar alcohols are present in the food, sugar alcohol content shall be declared. For nutrition labeling purposes, sugar alcohols are defined as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA (e.g., mannitol) or is generally recognized as safe (e.g., xylitol, sorbitol). In lieu of the term "sugar alcohol," the name of the specific sugar alcohol (e.g., "xylitol") present in the food may be used in the nutrition label provided that only one sugar alcohol is present in the food. Sugar alcohol content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less then 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iv) "Other carbohydrate" (VOLUNTARY): A statement of the number of grams of other carbohydrates may be declared voluntarily. Other carbohydrates shall be defined as the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, except that if sugar alcohol is not declared (even if present), it shall be defined as the difference between total carbohydrate and the sum of dietary fiber and sugars. Other carbohydrate content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(7) "Protein": A statement of the number of grams of protein in a serving, expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When the protein in foods represented or purported to be for adults and children 4 or more years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 20 expressed as a percent, or when the protein in a food represented or purported to be for children greater than 1 but less than 4 years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 40 expressed as a percent, either of the following shall be placed adjacent to the declaration of protein content by weight: The statement "not a significant source of protein," or a listing aligned under the column headed "Percent Daily Value" of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the Daily Reference Value (DRV) or Reference Daily Intake (RDI), as appropriate, for protein and expressed as Percent of Daily Value. When the protein quality in a food as measured by the Protein Efficiency Ratio (PER) is less than 40 percent of the reference standard (casein) for a food represented or purported to be for infants, the statement "not a significant source of protein" shall be placed adjacent to the declaration of protein content. Protein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis as given in the "Official Methods of Analysis of the AOAC International" (formerly the Association of Official Analytical Chemists), 15th Ed. (1990), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, except when the official procedure for a specific food requires another factor. Copies may be obtained from AOAC, 2200 Wilson Blvd., suite 400, Arlington, VA 22201-3301, or may be inspected at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(i) A statement of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the RDI or DRV for protein, as appropriate, and expressed as Percent of Daily Value, may be placed on the label, except that such a statement shall be given if a protein claim is made for the product, or if the product is represented or purported to be for use by infants or children under 4 years of age. When such a declaration is provided, it shall be placed on the label adjacent to the statement of grams of protein and aligned under the column headed "Percent Daily Value," and expressed to the nearest whole percent. However, the percentage of the RDI for protein shall not be declared if the food is represented or purported to be for use by infants and the protein quality value is less than 40 percent of the reference standard.

(ii) The "corrected amount of protein (gram) per serving" for foods represented or purported for adults and children 1 or more years of age is equal to the actual amount of protein (gram) per serving multiplied by the amino acid score corrected for protein digestibility. If the corrected score is above 1.00, then it shall be set at 1.00. The protein digestibility-corrected amino acid score shall be determined by methods given in sections 5.4.1, 7.2.1, and 8.00 in "Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation," Rome, 1990, except that when official AOAC procedures described in section (c)(7) of this paragraph require a specific food factor other than 6.25, that specific factor shall be used. The "Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation" as published by the Food and Agriculture Organization of the United Nations/World Health Organization is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Nutrition, Center for Food Safety and Applied Nutrition (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be inspected at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. For foods represented or purported for infants, the corrected amount of protein (grams) per serving is equal to the actual amount of protein (grams) per serving multiplied by the relative protein quality value The relative protein quality value shall be determined by dividing the subject food protein PER value by the PER value for casein. If the relative protein value is above 1.00, it shall be set at 1.00.

(iii) [Reserved]

(8) Vitamins and minerals: A statement of the amount per serving of the vitamins and minerals as described in this paragraph, calculated as a

percent of the RDI and expressed as percent of Daily Value.

(i) For purposes of declaration of percent of Daily Value as provided for in paragraphs (d), (e), and (f) of this section, foods represented or purported to be for use by infants, children less than 4 years of age, pregnant women, or lactating women shall use the RDI's in paragraph (c)(8)(iv) of this section that are specified for the intended group. For foods represented or purported to be for use by both infants and children under 4 years of age, the percent of Daily Value shall be presented by separate declarations according to paragraph (e) of this section based on the RDI values for infants from birth to 12 months of age and for children under 4 years of age. Similarly, the percent of Daily Value based on both the RDI values for pregnant women and for lactating women shall be declared separately on foods represented or purported to be for use by both pregnant and lactating women. When such dual declaration is used on any label, it shall be included in all labeling, and equal prominence shall be given to both values in all such labeling. All other foods shall use the RDI for adults and children 4 or more years of age.

(ii) The declaration of vitamins and minerals as a percent of the RDI shall include vitamin A, vitamin C, calcium, and iron, in that order, and shall include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are added as a nutrient supplement, or when a claim is made about them. Other vitamins and minerals that are:

(A) Required or permitted in a standardized food (e.g., thiamin, riboflavin, and niacin in enriched flour) and that standardized food is included as an ingredient (i.e., component) in another food; or

(B) Included in a food solely for technological purposes and declared only in the ingredient statement need not be declared if neither the nutrient nor the component is otherwise referred to on the label or in labeling or advertising. The declaration may also include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are naturally occurring in the food. The additional vitamins and minerals shall be listed in the order established in paragraph (c)(8)(iv) of this section.

(iii) The percentages for vitamins and minerals shall be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level and the nearest 10-percent increment above the 50-percent level. Amounts of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared in nutrition labeling but may be declared by a zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)." Alternatively, except as provided for in paragraph (f) of this section, if vitamin A, vitamin C, calcium, or iron is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement "Not a significant source of _____ (listing the vitamins or minerals omitted)" is placed at the bottom of the table of nutrient values. Either statement shall be in the same type size as nutrients that are indented.

(iv) [Reserved]

(v) The following synonyms may be added in parentheses immediately following the name of the nutrient or dietary component:

Vitamin C—Ascorbic acid
Thiamin—Vitamin B_1
Riboflavin—Vitamin B_2
Folate—Folacin
Calories—Energy

(vi) The percent of vitamin A that is present as beta-carotene may be declared to the nearest 10-percent increment immediately adjacent to or beneath the nutrient name (e.g., "Vitamin A (90 percent as beta-carotene)").

(9) [Reserved]

(d)(1) Nutrient information specified in paragraph (c) of this section shall be presented on foods in the following format, as shown in paragraph (d)(12) of this section, except on foods on which dual columns of nutrition information are declared as provided for in paragraph (e) of this section, on those food products on which the simplified format is required to be used as provided for in paragraph (f) of this section, on foods for infants and children less than 4 years of age as provided for in paragraph (j)(5) of this section, and on foods in small or intermediate-sized packages as provided for in paragraph (j)(13) of this section. In the interest of uniformity of presentation, FDA urges that the nutrition information be presented using the graphic specifications set forth in Appendix B to Part 101.

(i) The nutrition information shall be set off in a box by use of hairlines and shall be all black or one color type, printed on a white or other neutral contrasting background whenever practical.

(ii) All information within the nutrition label shall utilize:

(A) A single easy-to-read type style,

(B) Upper and lower case letters,

(C) At least one point leading (i.e., space between two lines of text) except that at least four points leading shall be utilized for the information required by paragraphs (d)(7) and (d)(8) of this section as shown in paragraph (d)(12), and

(D) Type that is kerned (i.e., has proximity of placement) no tighter than −4 setting.

(iii) All information except for the information required in paragraphs (d)(4), (d)(6), (d)(9), and (d)(10) of this section shall be in type size no smaller than 8 point. The information required in paragraphs (d)(4), (d)(6), (d)(9), and (d)(10) of this section shall be in type size no smaller than 6 point.

(iv) The headings required by paragraphs (d)(2), (d)(4), and (d)(6) of this section (i.e., "Nutrition Facts," "Amount per Serving," and "% Daily Value*"), the names of all nutrients that are not indented according to requirements of paragraph (c) of this section (i.e., "Calories," "Total Fat," "Cholesterol," "Sodium," "Total Carbohydrate," and "Protein"), and the percentage amounts required by paragraph (d)(7)(ii) of this section shall be highlighted by bold or extra bold type or other highlighting (reverse printing is not permitted as a form of highlighting) that prominently distinguishes it from other information. No other information shall be highlighted.

(v) A hairline rule that is centered between the lines of text shall separate "Amount Per Serving" from the calorie statements required in paragraph (d)(5) of this section and shall separate each nutrient and its corresponding percent Daily Value required in paragraphs (d)(7)(i) and (d)(7)(ii) of this section from the nutrient and percent Daily Value above and below it, as shown in paragraph (d)(12) of this section.

(2) The information shall be presented under the identifying heading of "Nutrition Facts" which shall be set in a type size larger than all other print size in the nutrition label and, except for labels presented according to the format provided for in paragraph (d)(11) of this section, unless impractical, shall be set the full width of the information provided under paragraph (d)(7) of this section, as shown in paragraph (d)(12) of this section.

(3) Information on serving size shall immediately follow the heading as

shown in paragraph (d)(12) of this section. Such information shall include:

(i) "Serving Size": A statement of the serving size as specified in paragraph (b)(7) of this section.

(ii) "Servings Per Container": The number of servings per container, except that this statement is not required on single serving containers as defined in paragraph (b)(6) of this section.

(4) A subheading "Amount Per Serving" shall be separated from serving size information by a bar as shown in paragraph (d)(12) of this section.

(5) Information on calories shall immediately follow the heading "Amount Per Serving" and shall be declared in one line, leaving sufficient space between the declaration of "Calories" and "Calories from fat" to allow clear differentiation, or, if "Calories from saturated fat" is declared, in a column with total "Calories" at the top, followed by "Calories from fat" (indented), and "Calories from saturated fat" (indented).

(6) The column heading "% Daily Value," followed by an asterisk (e.g., "% Daily Value*"), shall be separated from information on calories by a bar as shown in paragraph (d)(12) of this section. The position of this column heading shall allow for a list of nutrient names and amounts as described in paragraph (d)(7) of this section to be to the left of, and below, this column heading. The column headings "Percent Daily Value," "Percent DV," or "% DV" may be substituted for "% Daily Value."

(7) Except as provided for in paragraph (j)(13) of this section, nutrient information for all nutrients required by paragraph (c) of this section, except vitamins and minerals, shall be declared as follows:

(i) The name of each nutrient specified in paragraph (c) of this section shall be given in a column and followed immediately by the quantitative amount by weight for that nutrient appended with a "g" for grams or "mg" for milligrams as shown in paragraph (d)(12) of this section.

(ii) A listing of the percent of the DRV as established in paragraphs (c)(7)(iii) and (c)(9) of this section shall be given in a column aligned under the heading "% Daily Value" established in paragraph (d)(6) of this section with the percent expressed to the nearest whole percent for each nutrient declared in the column described in paragraph (d)(7)(i) of this section for which a DRV has been established, except that the percent for protein may be omitted as provided in paragraph (c)(7) of this section. The percent shall be calculated by dividing the actual amount (i.e., before rounding) for each nutrient by the DRV for the nutrient, except that the percent for protein shall be calculated as specified in paragraph (c)(7)(ii) of this section. The numerical value shall be followed by the symbol for percent (i.e., %).

(8) Nutrient information for vitamins and minerals shall be separated from information on other nutrients by a bar and shall be arrayed horizontally (e.g., Vitamin A 4%, Vitamin C 2%, Calcium 15%, Iron 4%) as shown in paragraph (d)(12) of this section, except that when more than four vitamins and minerals are declared, they may be declared vertically with percentages listed under the column headed "% Daily Value."

(9) A footnote, preceded by an asterisk, shall be placed beneath the list of vitamins and minerals and shall be separated from that list by a hairline.

(i) The footnote shall state:

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

Your daily value may be higher or lower depending on your calorie needs.

	Calories:	2,000	2,500
Total fat	Less than	65 g	80 g
Saturated fat.	Less than	20 g	25 g
Cholesterol	Less than	300 mg	300 mg
Sodium	Less than	2,400 mg	2,400 mg
Total carbohydrate.	.....	300 g	375 g
Dietary fiber	.....	25 g	30 g

(ii) If the percent of Daily Value is given for protein in the Percent of Daily Value column as provided in paragraph (d)(5)(ii) of this section, protein shall be listed under dietary fiber, and the DRV established in paragraph (c)(7)(iii) of this section shall be inserted on the same line in the numeric columns.

(iii) If potassium is declared in the column described in paragraph (d)(5)(i) of this section, potassium shall be listed under sodium and the DRV established in paragraph (c)(9) of this section shall be inserted on the same line in the numeric columns.

(iv) The abbreviations established in paragraph (j)(13)(ii)(B) of this section may be used within the footnote.

(10) Caloric conversion information on a per gram basis for fat, carbohydrate, and protein shall be presented beneath the information required in paragraph (d)(9) and shall be separated from that information by a hairline. This information may be presented horizontally as shown in paragraph (d)(12) of this section (i.e., "Calories per gram: fat 9, carbohydrate 4, protein 4") or vertically in columns.

(11) If the space beneath the information on vitamins and minerals is not adequate to accommodate the information required in paragraphs (d)(9) and (d)(10) of this section, the information required in paragraph (d)(9) may be moved to the right of the column required in paragraph (d)(7)(ii) and set off by a line that distinguishes it and sets it apart from the percent daily value information. The caloric conversion information required in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(12) The following sample label illustrates the provisions of paragraph (d) of this section.

BILLING CODE 4160-01-m

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

(e) Nutrition information may be presented for two or more forms of the same food (e.g., both "as purchased" and "as prepared") or for common combinations of food as provided for in paragraph (h)(4) of this section, for different units (e.g., slices of bread or per 100 grams) as provided for in paragraph (b) of this section, or for two or more groups for which RDI's are established in paragraph (c)(8)(iv) of this section (e.g., both infants and children less than 4 years of age) as shown in paragraph (e)(5) of this section. When such dual labeling is provided, equal prominence shall be given to both sets of values. Information shall be presented in a format consistent with paragraph (d) of this section, except that:

(1) Following the subheading of "Amount Per Serving," there shall be two or more column headings accurately describing the forms of the same food (e.g., "Mix" and "Baked"), the combinations of food, the units, or the RDI groups that are being declared. The column representing the product as packaged and according to the label serving size based on the reference amount in § 101.12(b) shall be to the left of the numeric columns.

(2) When the dual labeling is presented for two or more forms of the same food, for combinations of food, or for different units, total calories and calories from fat (and calories from saturated fat, when declared) shall be listed in a column and indented as specified in paragraph (d)(5) of this section with quantitative amounts declared in columns aligned under the column headings set forth in paragraph (e)(1) of this section.

(3) Quantitative information by weight required in paragraph (d)(7)(i) of this section shall be specified for the form of the product as packaged and according to the label serving size based on the reference amount in § 101.12(b).

(i) Quantitative information by weight may be included for other forms of the product represented by the additional column(s) either immediately adjacent to the required quantitative information by weight for the product as packaged and according to the label serving size based on the reference amount in § 101.12(b) or as a footnote.

(A) If such additional quantitative information is given immediately adjacent to the required quantitative information, it shall be declared for all nutrients listed and placed immediately following and differentiated from the required quantitative information (e.g., separated by a comma). Such information shall not be put in a separate column.

(B) If such additional quantitative information is given in a footnote, it shall be declared in the same order as the nutrients are listed in the nutrition label. The additional quantitative information may state the total nutrient content of the product identified in the second column or the nutrient amounts added to the product as packaged for only those nutrients that are present in different amounts than the amounts declared in the required quantitative information. The footnote shall clearly identify which amounts are declared. Any subcomponents declared shall be listed parenthetically after principal components (e.g., 1/2 cup skim milk contributes an additional 40 calories, 65 mg sodium, 6 g total carbohydrate (6 g sugars), and 4 g protein).

(ii) Total fat and its quantitative amount by weight shall be followed by an asterisk (or other symbol) (e.g., "Total fat (2 g)*") referring to another asterisk (or symbol) at the bottom of the nutrition label identifying the form(s) of the product for which quantitative information is presented.

(4) Information required in paragraphs (d)(7)(ii) and (d)(8) of this section shall be presented under the subheading "% DAILY VALUE" and in columns directly under the column headings set forth in paragraph (e)(1) of this section.

(5) The following sample label illustrates the provisions of paragraph (e) of this section:

BILLING CODE 4160-01-M

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

(f) The declaration of nutrition information may be presented in the simplified format set forth herein when a food product contains insignificant amounts of seven or more of the following: Calories, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron; except that for foods intended for children less than 2 years of age to which § 101.9(j)(5)(i) applies, nutrition information may be presented in the simplified format when a food product contains insignificant amounts of six or more of the following: Calories, total fat, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron.

(1) An "insignificant amount" shall be defined as that amount that allows a declaration of zero in nutrition labeling, except that for total carbohydrate, dietary fiber, and protein, it shall be an amount that allows a declaration of "less than 1 gram."

(2) The simplified format shall include information on the following nutrients:

(i) Total calories, total fat, total carbohydrate, protein, and sodium;

(ii) Calories from fat and any other nutrients identified in paragraph (f)(1) of this section that are present in the food in more than insignificant amounts; and

(iii) Any vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are required to be added as a nutrient supplement to foods for which a standard of identity exists.

(iv) Any vitamins or minerals that are voluntarily added to the food as nutrient supplements.

(3) Other nutrients that are naturally present in the food in more than insignificant amounts may be voluntarily declared as part of the simplified format.

(4) If any nutrients are declared as provided in paragraphs (f)(2)(iii), (f)(2)(iv), or (f)(3) of this section as part of the simplified format, the statement "Not a significant source of _____" (with the blank filled in with the name(s) of any nutrient(s) identified in § 101.9(f) and calories from fat that are present in insignificant amounts) shall be included at the bottom of the nutrition label.

(5) Except as provided for in paragraphs (j)(5) and (j)(13) of this section, nutrient information declared in the simplified format shall be presented in the same manner as specified in paragraphs (d) or (e) of this section, except that the footnote and caloric conversion information required in paragraphs (d)(9) and (d)(10) of this section are not required. When the footnote and caloric conversion information are omitted, an asterisk shall be placed at the bottom of the label followed by the statement "Percent Daily Values are based on a 2,000 calorie diet" and, if the term "Daily Value" is not spelled out in the heading, a statement that "DV" represents "Daily Value."

(g) Compliance with this section shall be determined as follows:

(1) A collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, or in the absence of any common container code or marking, a day's production, constitutes a "lot."

(2) The sample for nutrient analysis shall consist of a composite of 12 subsamples (consumer units), taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot. Unless a particular method of analysis is specified in paragraph (c) of this section, composites shall be analyzed by appropriate methods as given in the "Official Methods of Analysis of the AOAC International," 15th Ed. (1990), which is incorporated by reference in accordance with 5 U.S.C. 552(a) or 1 CFR part 51 or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures. The availability of this incorporation by reference is given in paragraph (c)(7) of this section.

(3) Two classes of nutrients are defined for purposes of compliance:

(i) *Class I.* Added nutrients in fortified or fabricated foods; and

(ii) *Class II.* Naturally occurring (indigenous) nutrients. If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food, the total amount of such nutrient in the final food product is subject to class II requirements unless the same nutrient is also added.

(4) A food with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium shall be deemed to be misbranded under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act) unless it meets the following requirements:

(i) *Class I vitamin, mineral, protein, dietary fiber, or potassium.* The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

(ii) *Class II vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium.* The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label.

Provided, That no regulatory action will be based on a determination of a nutrient value that falls below this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

(5) A food with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. *Provided,* That no regulatory action will be based on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

(6) Reasonable excesses of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium over labeled amounts are acceptable within current good manufacturing practice. Reasonable deficiencies of calories, sugars, total fat, saturated fat, cholesterol, or sodium under labeled amounts are acceptable within current good manufacturing practice.

(7) Compliance will be based on the metric measure specified in the label statement of serving size.

(8) Compliance with the provisions set forth in paragraphs (g)(1) through (g)(6) of this section may be provided by use of an FDA approved data base that has been computed following FDA guideline procedures and where food samples have been handled in accordance with current good manufacturing practice to prevent nutrition loss. FDA approval of a data base shall not be considered granted until the Center for Food Safety and Applied Nutrition has agreed to all aspects of the data base in writing. The approval will be granted where a clear need is presented (e.g., raw produce and seafood). Approvals will be in effect for a limited time, e.g., 10 years, and will be eligible for renewal in the absence of significant changes in agricultural or industry practices. Approval requests shall be submitted in accordance with the provisions of § 10.30 of this chapter. Guidance in the use of data bases may be found in the "FDA Nutrition Labeling Manual—A Guide for Developing and Using Data Bases," available from the Division of Nutrition, Center for Food Safety and Applied

Nutrition (HFF-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(9) When it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of this section (e.g., to develop adequate nutrient profiles to comply with the requirements of paragraph (c) of this section), FDA may permit alternative means of compliance or additional exemptions to deal with the situation. Firms in need of such special allowances shall make their request in writing to the Office of Nutrition and Food Sciences (HFF-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(h) Products with separately packaged ingredients or foods, with assortments of food, or to which other ingredients are added by the user may be labeled as follows:

(1) If a product consists of two or more separately packaged ingredients enclosed in an outer container or of assortments of the same type of food (e.g., assorted nuts or candy mixtures) in the same retail package, nutrition labeling shall be located on the outer container or retail package (as the case may be) to provide information for the consumer at the point of purchase. However, when two or more food products are simply combined together in such a manner that no outer container is used, or no outer label is available, each product shall have its own nutrition information, e.g., two boxes taped together or two cans combined in a clear plastic overwrap. When separately packaged ingredients or assortments of the same type of food are intended to be eaten at the same time, the nutrition information may be specified per serving for each component or as a composite value.

(2) If a product consists of two or more separately packaged foods that are intended to be eaten individually and that are enclosed in an outer container (e.g., variety packs of cereals or snack foods), the nutrition information shall be specified per serving for each food in a location that is clearly visible to the consumer at the point of purchase.

(3) If a package contains a variety of foods, or an assortment of foods, and is in a form intended to be used as a gift, the nutrition labeling shall be in the form required by paragraphs (a) through (f) of this section, but it may be modified as follows:

(i) Nutrition information may be presented on the label of the outer package or in labeling within or attached to the outer package.

(ii) In the absence of a reference amount customarily consumed in § 101.12(b) that is appropriate for the variety or assortment of foods in a gift package, 1 ounce for solid foods, 2 fluid ounces for nonbeverage liquids (e.g., syrups), and 8 fluid ounces for beverages may be used as the standard serving size for purposes of nutrition labeling of foods subject to this paragraph. However, the reference amounts customarily consumed in § 101.12(b) shall be used for purposes of evaluating whether individual foods in a gift package qualify for nutrient content claims or health claims.

(iii) The number of servings per container may be stated as "varied."

(iv) Nutrition information may be provided per serving for individual foods in the package, or, alternatively, as a composite per serving for reasonable categories of foods in the package having similar dietary uses and similar significant nutritional characteristics. Reasonable categories of foods may be used only if accepted by FDA. In determining whether a proposed category is reasonable, FDA will consider whether the values of the characterizing nutrients in the foods proposed to be in the category meet the compliance criteria set forth in paragraphs (g)(3) through (g)(6) of this section. Proposals for such categories may be submitted in writing to the Office of Nutrition and Food Sciences (HFF-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(v) If a food subject to paragraph (j)(13) of this section because of its small size is contained in a gift package, the food need not be included in the determination of nutrition information under paragraph (h) of this section if it is not specifically listed in a promotional catalogue as being present in the gift package, and:

(A) It is used in small quantities primarily to enhance the appearance of the gift package; or

(B) It is included in the gift package as a free gift or promotional item.

(4) If a food is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare nutrition information on the basis of the food as consumed in the format required in paragraph (e) of this section (e.g., a dry ready-to-eat cereal may be described with one set of Percent Daily Values for the cereal as sold (e.g., per ounce), and another set for the cereal and milk as suggested in the label (e.g., per ounce of cereal and 1/2 cup of vitamin D fortified skim milk) and a cake mix may be labeled with one set of Percent Daily Values for the dry mix (per serving) and another set for the serving of the final cake when prepared): *Provided*, That, the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(i) Except as provided in paragraph (j)(13) of this section, the location of nutrition information on a label shall be in compliance with § 101.2.

(j) The following foods are exempt from this section or are subject to special labeling requirements:

(1)(i) Food offered for sale by a manufacturer, packer, or distributor who has annual gross sales made or business done in sales to consumers that is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers of not more than $50,000, *Provided*, That the food bears no nutrition claims or information on a label or labeling or in advertising.

(ii) For purposes of this paragraph, calculation of the amount of sales shall be based on the most recent 3-year average of business activity. Where firms have been in business less than 2 years, reasonable estimates must indicate that annual sales will not exceed the amounts specified. For foreign firms that ship foods into the United States, the business activities to be included shall be the total amount of food sales, as well as other sales to consumers, by the firm in the United States.

(2) Food products which are:

(i) Served in restaurants;

(ii) Served in other establishments in which food is served for immediate human consumption (e.g., institutional food service establishments, such as schools, hospitals, and cafeterias; transportation carriers, such as trains and airplanes; bakeries, delicatessens, and retail confectionery stores where there are facilities for immediate consumption on the premises; food service vendors, such as lunch wagons, ice cream shops, mall cookie counters, vending machines, and side-walk carts where foods are generally consumed immediately where purchased or while the consumer is walking away, including similar foods sold from convenience stores; and food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices);

(iii) Sold for sale or use only in such facilities; or

(iv) Sold by a distributor who principally sells food to such facilities: *Provided*, That:

(A) This exemption shall not be available for those foods that are manufactured, processed, or repackaged by that distributor for sale to any persons other than restaurants or other establishments that serve food for immediate human consumption, and

(B) The manufacturer of such products is responsible for providing the nutrition information on the products if there is a reasonable possibility that the product will be purchased directly by consumers.

(3) Food products that are:

(i) Of the type of food described in paragraphs (j)(2)(i) and (j)(2)(ii) of this section,

(ii) Ready for human consumption,

(iii) Offered for sale to consumers but not for immediate human consumption,

(iv) Processed and prepared primarily in a retail establishment, and

(v) Not offered for sale outside of that establishment (e.g., ready-to-eat foods that are portioned and packaged on-site and sold by independent delicatessens, bakeries, and retail confectionery stores where there are no facilities for immediate human consumption, by in-store delicatessen, bakery, or candy departments, or at self-service food bars such as salad bars).

(4) Foods that contain insignificant amounts of all of the nutrients and food components required to be included in the declaration of nutrition information under paragraph (c) of this section. An insignificant amount of a nutrient or food component shall be that amount that allows a declaration of zero in nutrition labeling, except that for total carbohydrate, dietary fiber, and protein, it shall be an amount that allows a declaration of "less than 1 gram." Foods that are exempt under this paragraph include coffee beans (whole or ground), tea leaves, plain unsweetened instant coffee and tea, condiment-type dehydrated vegetables, flavor extracts, and food colors.

(5)(i) Foods, other than infant formula, represented or purported to be specifically for infants and children less than 2 years of age shall bear nutrition labeling, except as provided in paragraph (j)(5)(ii) and except that such labeling shall not include calories from fat (paragraph (c)(1)(ii) of this section), calories from saturated fat ((c)(1)(iii)), saturated fat ((c)(2)(i)), polyunsaturated fat ((c)(2)(ii)), monounsaturated fat ((c)(2)(iii)), and cholesterol ((c)(3)).

(ii) Foods, other than infant formula, represented or purported to be specifically for infants and children less than 4 years or age shall bear nutrition labeling, except that such labeling shall not include listings of percent of Daily Value and the footnote required in paragraphs (d)(7), (d)(9), and (d)(10) of this section. Nutrient names and quantitative amounts by weight shall be presented in two separate columns.

(6) Dietary supplements of vitamins and minerals except that the labeling of a dietary supplement of vitamins and minerals in conventional food form, e.g., a breakfast cereal, shall conform to the labeling established in this section.

(7) Infant formula subject to section 412 of the act, as amended, except that such foods shall be labeled in compliance with part 107 of this chapter.

(8) Medical foods as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)). A medical food is 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. A food is subject to this exemption only if:

(i) It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube;

(ii) It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;

(iii) It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;

(iv) It is intended to be used under medical supervision; and

(v) It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

(9) Food products shipped in bulk form that are not for distribution to consumers in such form and that are for use solely in the manufacture of other foods or that are to be processed, labeled, or repacked at a site other than where originally processed or packed.

(10) Raw fruits, vegetables, and fish subject to section 403(q)(4) of the act, except that the labeling of such foods should adhere to guidelines in § 101.45. The term "fish" includes freshwater or marine fin fish, crustaceans, and mollusks, including shellfish, amphibians, and other forms of aquatic animal life.

(11) Packaged single-ingredient products that consist of fish or game meat (i.e., animal products not covered under the Federal Meat Inspection Act or the Poultry Products Inspection Act, such as flesh products from deer, bison, rabbit, quail, wild turkey, or ostrich) subject to this section may provide required nutrition information for a 3-ounce cooked edible portion (i.e., on an "as prepared" basis), except that:

(i) Such products that make claims that are based on values as packaged must provide nutrition information on an as packaged basis, and

(ii) Nutrition information is not required for custom processed fish or game meats.

(12) Game meats (i.e., animal products not covered under the Federal Meat Inspection Act or the Poultry Products Inspection Act, such as flesh products from deer, bison, rabbit, quail, wild turkey, or ostrich) may provide required nutrition information on labeling in accordance with the provisions of paragraph (a)(2) of this section.

(13)(i) Foods in small packages that have a total surface area available to bear labeling of less than 12 square inches, *Provided*, That the labels for these foods bear no nutrition claims or other nutrition information. The manufacturer, packer, or distributor shall provide on the label of packages that qualify for and use this exemption an address or telephone number that a consumer can use to obtain the required nutrition information (e.g., "For nutrition information, call 1–800–123–4567").

(ii) Foods in packages that have a total surface area available to bear labeling of 40 or less square inches may modify the requirements of paragraphs (c) through (f) and (i) of this section by one or more of the following means:

(A) Presenting the required nutrition information in a tabular or, as provided below, linear (i.e., string) fashion rather than in vertical columns if the product has a total surface area available to bear labeling of less than 12 square inches or if the package shape or size cannot accommodate a column display on any label panel. Nutrition information may be given in a linear fashion, only if the label will not accommodate a tabular display, and, in that case, any subcomponents declared shall be listed

parenthetically after principal components (e.g., saturated fat shall be declared in parentheses after total fat).

The following sample label illustrat tabular display.

BILLING CODE 4160-01-M

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%

BILLING CODE 4160-01-C

(B) Using any of the following abbreviations:
Serving size—Serv. size
Servings per container—Servings
Calories from fat—Fat cal
Saturated fat—Sat fat
Cholesterol—Cholest
Total carbohydrate—Total carb
Dietary fiber—Fiber

(C) Omitting the footnote and caloric conversion information required in paragraphs (d)(9) and (d)(10) of this section and placing another asterisk at the bottom of the label followed by the statement "Percent Daily Values are based on a 2,000 calorie diet" and, if the term "Daily Value" is not spelled out in the heading, a statement that "DV" represents "Daily Value."

(D) Presenting the required nutrition information on any label panel.

(14) Shell eggs packaged in a carton that has a top lid designed to conform to the shape of the eggs are exempt from outer carton label requirements where the required nutrition information is clearly presented in no less than 1/16-inch type size immediately beneath the carton lid or in an insert that can be clearly seen when the carton is opened.

(15) The unit containers in a multiunit retail food package where:

(i) The multiunit retail food package labeling contains all nutrition information in accordance with the requirements of this section;

(ii) The unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale; and

(iii) Each unit container is labeled with the statement "This Unit Not Labeled For Retail Sale" in type size not less than 1/16-inch in height. The word "individual" may be used in lieu of or immediately preceding the word "Retail" in the statement.

(16) Food products sold from bulk containers: *Provided,* That nutrition information required by this section be displayed to consumers either on the labeling of the bulk container plainly in view or in accordance with the provisions of paragraph (a)(2) of this section.

(k) A food labeled under the provisions of this section shall be deemed to be misbranded under sections 201(n) and 403(a) of the act if its label or labeling represents, suggests, or implies:

(1) [Reserved]

(2) That a balanced diet of ordinary foods cannot supply adequate amounts of nutrients.

(3) That the lack of optimum nutritive quality of a food, by reason of the soil on which that food was grown, is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(4) That the storage, transportation, processing, or cooking of a food is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(5) That the food has dietary properties when such properties are of no significant value or need in human nutrition.

(6) That a natural vitamin in a food is superior to an added or synthetic vitamin or to differentiate in any way between vitamins naturally present from those added.

5. Section 101.100 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 101.100 Food; exemptions from labeling.

* * * * *

(d) Except as provided by paragraphs (e) and (f) of this section, a shipment or other delivery of a food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of section 403 (c), (e), (g), (h), (i), (k), and (q) of the act if:

* * * * *

6. Appendix B to Part 101 is added to read as follows:

BILLING CODE 4160-01-M

Appendix B to Part 101

Graphic Enhancements used by the FDA

A.Overall

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

B. Typeface and size

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

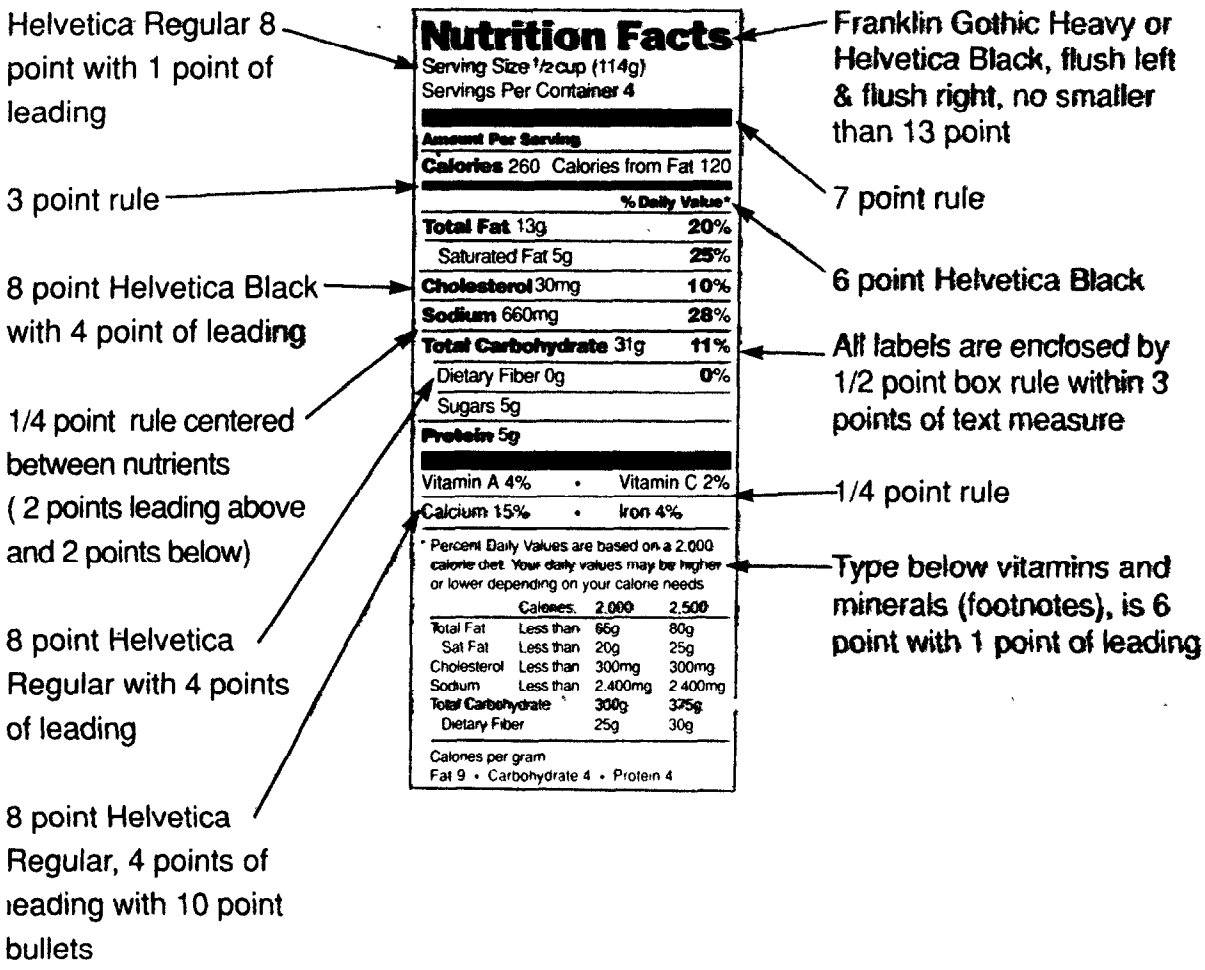
C. Rules

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

D. Box

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

Appendix B to Part 101



BILLING CODE 4160-01-C

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Editorial Note: The following appendixes will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-M

Appendix A:
Shortened Format (See comment 8)—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

BILLING CODE 4160-01-C

APPENDIX B.—TRUE PROTEIN DIGESTIBILITY VALUE OF COMMON FOODS

Major product group	Subgroup	Product	True digestibility	References
Cereals and Grains	Barley	Barley	90	1
	Corn and Corn Products	Corn, Extruded Cereal	62	2
		Corn, Corn Flake	70	2
		Corn, Degerminated Opaque 2	94	2
		Corn, Puffed Cereal	76	2
		Corn, Whole	89	2
		Corn, Whole Opaque 2	92	2
		Corn meal	84	2
	Millet	Millet	79	2
	Oats and Oat products	Oat, Sugared Flakes	67	2
		Oat Flakes	70	2
		Oat, Extruded Oat/Wheat	76	2
		Cereal	89	2
		Oat, Quick Oatmeal	82	2
		Oat, Oatmeal	90	3
		Oats, Rolled	....	...
	Rice and Rice Products	Rice	91	2
		Rice, Germ	87	4
		Rice, Brown, Cooked	72	5
		Rice, High Protein	85	2
		Rice, Milled, Cooked	86	6
		Rice, Polished	87	2, 5
		Rice, Crisped Rice Cereal	77	2
		Rice, Flakes	63	2
	Sorghum	Sorghum, Cooked	73	6
	Triticale	Triticale	90	2
	Wheat and Wheat Products	Bread	96	2
		Bread, Coarse, Brown	91	2
		Bread, White	89	2
		Bread, Whole Wheat	92	2
		Wheat, Bran	75	15
		Wheat, Brown, Cooked	93	6
		Wheat Endosperm (Farina)	98	2
		Wheat, Flour, 90% extracted	89	2
		White, Flour, 80% extracted	92	2
		Wheat Germ	81	2
	Wheat and Wheat Products	Wheat Gluten	98	2
		Wheat, Hard Spring	86	2
		Wheat, Meat Analogue	95	
		Wheat, Puffed Wheat	84	2
		Wheat, Shredded	73	2
		Wheat, Wheaties	80	2
		Wheat, White Flour	97	2
		Wheat, Whole	87	2
		Wheat, Whole, Hot Cereal	85	2
		Wheat, 40% Bran Flakes	69	2
Dairy Products	Casein	Acid-Casein	95	7
		Casein	96	8, 4
		Caseinate	95	7
		Rennet-Casein	94	7
	Cheese	Cheese, Cheddar	99	4
		Cottage, Cheese	99	2
	Lactalbumin	Lactalbumin	94	2
	Milk	Milk Retentate	97	7
		Milk, Skim	94	8
		Milk, Whole	94	2
		Milk, Whole, Powdered	95	2
	Whey	Whey Protein	95	4
Egg and Egg Products		Egg albumen	97	2
		Egg, Flakes	92	2
		Egg, Powdered, Dried	93	4
		Egg, Dried	98	2
		Egg, Powdered Defatted	100	2
		Egg, Scrambled	96	2
		Egg, Spray Dried	92	2
		Egg, Whole, Unprocessed	97	2, 9
Legumes and Oilseed Products	Beans (Mucunoa Spp.)	Beans, Velvet	68	4
	Beans (Phaseolus lunatus)	Beans, Butter	57	4
		Beans, Lima	78	4
	Beans (Phaseolus vulgaris)	Beans, Black	69	4, 10
		Beans, Brown, Cooked	79	11
		Beans, Common	82	4
		Beans, Haricot	71	4
		Beans, Kidney	81	8
		Beans, Natal round Yellow	80	4
		Beans, Pinto, Canned	73	8
		Beans, Red	78	4
		Beans, Seafarer	84	4
		Beans, Snap, Frozen	82	11
		Beans, Spotted Sugar	81	4

APPENDIX B.—TRUE PROTEIN DIGESTIBILITY VALUE OF COMMON FOODS—Continued

Major product group	Subgroup	Product	True digestibility	References
		Beans, Sugar	69	4
		Beans, Sugar, Speckled	78	4
		Beans, White Kidney	78	4
	Beans (Vicia Faba)	Beans, Broad	87	4
		Beans, Faba	86	10
	Cottonseed	Cottonseed	78	2
		Cottonseed Meal	80	4
		Cottonseed, Glandless flour	98	2
	Flaxseed	Flaxseed	85	4
	Lentils (Len culinaris)	Lentils	85	4, 8
	Lupins (Lupinus albus)	Lupine	76	4
	Peanut Products	Peanut Butter	95	2
		Peanut Flour	93	2
		Peanuts	87	4
		Peanut Meal	91	12
	Peas (Cajanus cajan)	Pigeon Peas	76	13
		Pigeon Peas, Raw	41	13
	Peas (Cicer Arietinum)	Chick peas, Canned	88	8
	Peas (Pisum sativum)	Pea Concentrate	94	3
		Peas	88	14
		Peas, Century, Autoclaved	83	10
		Peas, Green, Frozen	94	11
		Peas, Trapper, Autoclaved	84	10
		Peas, Yellow, Cooked	86	11
		Pea Flour	88	10
		Peas, Alaskan Field	88	2
	Peas (Vigna unguiculata)	Cowpeas	79	4
	Sesame	Sesame Seed, Dehulled	82	4
	Soy Products	Soybean	91	4
		Soy Concentrate	95	4
		Soy Flour	84	2
		Soy Flour, Defatted	87	2
		Soy Isolate	96	2
		Soy protein, spun	100	2
	Sunflower	Sunflower Seed	82	2
		Sunflower Seed-Flour	90	2
Meats and Meat Products	Beef	Beef	95	2
		Beef, Low Fat, Ground	91	2
		Beef, Powdered, Defatted	97	2
		Beef, Salami	98	8
		Beef, Stew	89	8
		Beefsteak	97	2
		Beef Tenderloin, Roasted	91	2
	Fish and Seafood	Haddock	100	4
		Sardine	95	4
		Shark	72	4
		Tuna, Canned	90	2
	Luncheon Meats	Canned Frankfurters	97	4
		Chicken, Frankfurters	97	8
		Sausage	94	8
	Pork	Pork Loin and Tenderloin	98	2
	Poultry	Chicken	100	4
		Chicken, Dark Meat	92	4
		Chicken, Light Meat	93	4
		Turkey Breast, Roasted	91	2
Miscellaneous Foods		Macaroni/Cheese, Canned	94	3
Nuts and Nut Products		Cashew	85	4
		Coconut, meal (defatted)	80	4
		Pecan	71	4
Starchy Roots, Tubes		Potato	89	4
Vegetables		Cabbage	88	4
		Kale	85	4
		Rape	85	4
		Mustard	82	4
		Turnip Leaves	86	4
		Mushrooms	90	4

Notes

True digestibility values obtained using adult subjects were considered first followed by data using the rat as the animal model. When more than one value was considered the values were averaged. Data sources:

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BILLING CODE 4160-01-M

Appendix C:
Sweet potatoes, Canned

Nutrition Facts

Serving Size 1/2 cup (95g)
Servings Per Container 4

Amount Per Serving	
Calories 90	Calories from Fat 0
	% Daily Value*
Total Fat 0g	**0%**
Saturated Fat 0g	**5%**
Cholesterol 0mg	**0%**
Sodium 55mg	**2%**
Total Carbohydrate 21g	**7%**
Dietary Fiber 2g	**8%**
Sugars 5g	
Protein 2g	

Vitamin A 160% (100% as Beta Carotene)

Vitamin C 40% • Calcium 2% • 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

Appendix D

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

Appendix D:
Footnote to 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

Appendix E:
Sample labels 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

Appendix E:
Dual declaration with footnote of nutrients added by combination of foods

Nutrition Facts

Serving Size 1 cup (35g)
Servings Per Container 10

Amount Per Serving	Cereal	Cereal with 1/2 cup Skim Milk
Calories	130	170
Calories from Fat	0	0
	% Daily Value**	
Total Fat 0g*	**0%**	**0%**
Saturated Fat 0g	**0%**	**0%**
Cholesterol 0mg	**0%**	**0%**
Sodium 200mg	**8%**	**11%**
Total Carbohydrate 30g	**10%**	**12%**
Dietary Fiber 4g	**16%**	**16%**
Sugars 18g		
Protein 3g		
Vitamin A	25%	25%
Vitamin C	25%	25%
Calcium	0%	15%
Iron	10%	10%

*Amount in Cereal. One half cup skim milk contributes an additional 40 calories, 65 mg sodium, 6g total carbohydrate (6 g sugars), and 4g protein.

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

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

Calories per gram
Fat 9 • Carbohydrate 4 • Protein 4

Appendix F:
Simplified 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.

Appendix F:
Simplified 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.

Appendix G:

Format for same food represented to be specifically for children less than 2 years of age (Fruit Dessert)

Nutrition Facts

Serving Size 1 jar (140g)
Servings Per Container 1

Amount Per Serving	
Calories 110	
	Amount
Total Fat	**0g**
Sodium	**10mg**
Total Carbohydrate	**27g**
Dietary Fiber	**4g**
Sugars	**18g**
Protein	**0g**

Vitamin A 6%	•	Vitamin C 45%
Calcium 2%	•	Iron 2%

Appendix G:

Format for foods for children less than 4 years of age (Fruit Dessert)

Nutrition Facts

Serving Size 1 jar (140g)
Servings Per Container 1

Amount Per Serving	
Calories 110	Calories from Fat 0

	Amount
Total Fat	**0g**
Saturated Fat	**0g**
Cholesterol	**0mg**
Sodium	**10mg**
Total Carbohydrate	**27g**
Dietary Fiber	**4g**
Sugars	**18g**
Protein	**0g**

Vitamin A 6%	•	Vitamin C 45%
Calcium 2%	•	Iron 2%

Appendix H:
Tabular Display

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%

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