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**Food Labeling; General Provisions;
Nutrition Labeling; Nutrient Content
Claims; Health Claims; Ingredient
Labeling; State and Local Requirements;
and Exemptions; Proposed Rules**

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration
21 CFR Part 101

[Docket Nos. 90N-0134 and 90N-0135]

RIN 0905-ADO8

**Food Labeling; Reference Daily
Intakes and Daily Reference Values;
Mandatory Status of Nutrition Labeling
and Nutrient Content Revision**

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this document to supplement, and to republish in modified form, its proposals entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" (55 FR 29487, July 19, 1990) and "Food Labeling; Reference Daily Intakes and Daily Reference Values" (55 FR 29476, July 19, 1990). In those documents, the agency proposed to amend its food labeling regulations to require nutrition labeling on most foods that are meaningful sources of nutrients, to revise the list of required nutrients and food components and the conditions for declaring them in nutrition labeling, and to establish up-to-date reference standards for those nutrients and food components. FDA is now modifying those proposals and responding to the recent enactment of the Nutrition Labeling and Education Act of 1990 by proposing: (1) To add sugars and complex carbohydrates to the list of required nutrients in nutrition labeling; (2) to prescribe a simplified form of nutrition labeling and the circumstances in which such simplified nutrition labeling must be used; (3) to allow specified products to be exempt from nutrition labeling; and (4) to establish regulations for the nutrition labeling of vitamin and mineral supplements. The agency is also responding to a citizen petition regarding methodologies for determining protein quality.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

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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.

In the same issue of the Federal Register, FDA published two technical supporting proposals. The first, entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values" (hereinafter identified as "the RDI/DRV proposal") (55 FR 29476), proposed: (1) To replace the current U.S. Recommended Daily Allowances (U.S. RDA's) with Reference Daily Intakes (RDI's); (2) to establish RDI's for protein and for 26 vitamins and minerals; (3) to establish RDI's for five groups: Adults and children 4 or more years of age, children less than 4 years of age, infants, pregnant women, and lactating women; and (4) to establish Daily Reference Values (DRV's) for adults and children 4 or more years of age for eight food components considered important to the maintenance of good health: Fat, saturated fatty acids, unsaturated fatty acids, cholesterol, carbohydrate, dietary fiber, sodium, and potassium. The second technical, supporting proposal, entitled "Food Labeling; Serving Sizes" (hereinafter identified as "the serving size proposal") (55 FR 29517), proposed: (1) To define serving and portion size on the basis of the amount of food commonly consumed per eating occasion by persons 4 years of age or older, by infants, or by children under 4 years of age (toddlers); (2) to require the use of both U.S. and metric measures to

declare serving size; (3) to permit the declaration of serving (portion) size in familiar household measures; (4) to permit the optional declaration of nutrient content per 100 grams (g) (or 100 milliliters (mL)); (5) to define a "single serving container" as that which contains 150 percent or less of the standard serving size for the food product; and (6) to establish standard serving sizes for 159 food product categories to ensure reasonable and uniform serving sizes upon which consumers can make nutrition comparisons among food products. Interested persons were given until November 16, 1990, to submit comments to the agency on these three proposed rules.

On September 26, 1990, the National Academy of Sciences' (NAS) Institute of Medicine (IOM) issued a report entitled "Nutrition Labeling, Issues and Directions for the 1990s." (the IOM Report) (Ref. 1). The IOM report, written under contract to the Public Health Service, U.S. Department of Health and Human Services and the Food Safety and Inspection Service, U.S. Department of Agriculture (USDA), makes recommendations for changes in food labeling that will assist consumers in implementing the recommendations of the Surgeon General's Report on Nutrition and Health (Ref. 2) and the National Research Council report, "Diet and Health. Implications for Reducing Chronic Disease Risk" (Ref. 3). On October 5, 1990, FDA published in the Federal Register (55 FR 40944) a notice announcing the availability of the IOM report and requested interested persons to comment on the implications of the report for the agency's July 19, 1990, proposals and for the other proposals that the agency has issued or will issue on food labeling.

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101-535). The 1990 amendments make the most significant changes in food labeling law since the passage of the Federal Food, Drug, and Cosmetic Act of 1938 (the act) and have a direct bearing on FDA's three July 19, 1990, proposals to revise nutrition labeling. The 1990 amendments add section 403(q) to the act 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) that certain nutrients and food components are to be included in nutrition labeling, although the Secretary can add or delete nutrients by regulation if he finds it necessary to assist consumers in maintaining healthy

dietary practices; (3) that 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) that a simplified nutrition label is to be used when the food contains insignificant amounts of most nutrients; and (5) that FDA is to develop regulations governing labeling of foods to which section 411 of the act applies. The 1990 amendments also require FDA to develop and implement specific consumer education activities.

While the requirements of the 1990 amendments that pertain to nutrition labeling are similar in many respects to FDA's three proposals of July 19, 1990, differences do exist that require the agency to issue this supplementary proposal to amend the July 19, 1990, mandatory nutrition labeling proposal and to request further comment. Those aspects of the July 19, 1990, proposal that are not addressed in the preamble of this supplementary proposal remain unchanged from the mandatory nutrition labeling proposal or the RDI/DRV proposal. FDA is incorporating herein those portions of the July 19, 1990, preambles that relate to aspects of the mandatory nutrition labeling and RDI/DRV proposals that remain unchanged.

The agency is aware from a preliminary review of comments that some further changes to the mandatory nutrition labeling proposal may be necessary. For example, the agency has received comments requesting a change in the definition of saturated fatty acids. However, there has been insufficient time for the agency to thoroughly review all of the comments and make all appropriate changes before issuing this supplementary proposal. The agency is proposing below some changes as a result of its preliminary review of the comments where it believes that such changes will help to clarify the requirements of the mandatory nutrition labeling and RDI/DRV proposals. FDA is also responding to a petition on protein quality issues that it received before the enactment of the 1990 amendments.

Persons who have already submitted comments on issues raised by the mandatory nutrition labeling and RDI/DRV proposals that are not addressed in this preamble need not do so again unless they would like to amend their comments based on the changes made in this supplementary proposal or to submit comments on those changes. However, FDA is providing this opportunity for interested persons to submit comments on any issues

addressed in the mandatory nutrition labeling proposal, the RDI/DRV proposal, or this supplementary proposal and on any and all aspects of these documents. FDA will consider and respond to all the comments that it receives on these documents in its final rule.

For clarity and completeness, the text of § 101.9 (21 CFR 101.9) set forth below includes the changes discussed in this supplementary proposal, the proposed provisions from the mandatory nutrition labeling proposal that have not been changed by this supplementary proposal, and the provisions of the current regulation to which the agency is either proposing no change or only minor nonsubstantive changes. To complete the section, the agency is also including the RDI and DRV values as proposed in the RDI/DRV proposal (55 FR 29476) (i.e., § 101.9 (c)(7)(iii), (c)(10)(iv), and (c)(11)(i), redesignated here as § 101.9 (c)(8)(iii), (c)(11)(iv), and (c)(12)(i)). There is nothing in the 1990 amendments that requires changes in the RDI/DRV proposal, and accordingly, the agency intends to analyze comments received on both the RDI/DRV proposal and this supplementary proposal and move toward a final regulation on these reference values with an effective date consistent with this rulemaking. Accordingly, the agency solicits any additional comments on the reference values and the groups for which RDI's are proposed.

Serving size, which is considered in proposed § 101.9(b), was addressed in the 1990 amendments but in a manner that is fully consistent with the agency's proposal (55 FR 29517). However, a preliminary review of the comments on the serving size proposal revealed significant disagreement. As a result, FDA is reconsidering its tentative position on serving size and intends to address this subject in a subsequent document. Therefore, FDA is not including proposed § 101.9(b) in the regulatory language at the end of this document.

Because the establishment and use of standard serving sizes is a new endeavor for the agency, FDA issued a notice on February 26, 1991 (56 FR 8084), announcing a public meeting to further discuss issues related to how serving size should be determined and presented as a part of nutrition labeling. The meeting was held on April 4, 1991, in Washington, DC. The agency was requested to hold an additional public meeting on the RDI/DRV proposal. However, FDA denied this request because it did not believe it could justify another public meeting given the

resources and time constraints under which it is working to meet the requirements of the 1990 amendments (Ref. 3a). Unlike the serving size issue, the establishment of reference values for nutrition labeling has been a practice of the agency for almost 20 years and is based on well-recognized scientific and dietary guideline documents.

II. Mandatory Nutrition Labeling—Legal Authority

Before the passage of the 1990 amendments, the act did not specifically mention nutrition labeling. In the mandatory nutrition labeling proposal, however, FDA tentatively concluded that it had authority to require nutrition labeling on virtually all foods that are a meaningful source of nutrition. The agency found this authority in section 403(a)(1) of the act, which states that a food is misbranded if its label or labeling is false or misleading in any particular, section 201(n) of the act, which states that the labeling of a food is misleading if it fails to reveal facts material with respect to consequences that may result from use of the food, and section 701(a) of the act, which authorizes FDA to adopt regulations for the efficient enforcement of the act. In the mandatory nutrition labeling proposal (55 FR 29487 at 29492), the agency stated that:

Given the history and use of nutrition labeling, the advances in nutrition science * * * and the public interest in healthful diets, FDA concludes that the nutritional content of a food is a material fact, and that a food label is misleading if it fails to bear nutrition information * * *.

The 1990 amendments confirmed the agency's authority to require nutrition labeling. Section 403(q) of the act states that a food shall be deemed to be misbranded if, with certain exceptions, it fails to bear nutrition labeling. Accordingly, FDA is proposing to revise § 101.9, as set forth below, to require nutrition labeling on all foods that are a meaningful source of nutrition under sections 201(n), 403(a)(1), 403(q), and 701(a) of the act.

III. Content of Nutrition Labeling

Section 403(q)(1) of the act, which was included in section 2(a) of the 1990 amendments, specifies that nutrition labeling shall include information on the total number of calories derived from any source; the number of calories derived from total fat; the amount of total fat, saturated fat (i.e., saturated fatty acids), cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, total protein, and any vitamin, mineral, or other nutrient

required to be placed on the label under the act before October 1, 1990, if the Secretary determines that information about the vitamin, mineral, or other nutrient will assist consumers in maintaining healthy dietary practices. Section 403(q)(2) of the act states that other nutrients may be required by regulation to be included in the nutrition label, or required nutrients may be removed, if the Secretary determines that their placement on the label would (or would not) assist consumers in maintaining healthy dietary practices.

In regard to section 403(q) of the act's reference to vitamins, minerals, and other nutrients that were required to be placed on the label before October 1, 1990 (section 403(q)(1)(E) of the act), FDA notes that this reference is somewhat confusing. No vitamins, minerals, or other nutrients were required to appear on the label and labeling of food before October 1, 1990. The apparent reference is to 21 CFR 101.9(c)(7)(iii), which provides that when nutrition labeling is required, it must include vitamin A, vitamin C, thiamin, riboflavin, niacin, calcium, and iron. FDA is proposing to require the inclusion of all of these nutrients in the nutrition label except for thiamin, riboflavin, and niacin, whose declaration the agency proposed to make voluntary in its mandatory nutrition labeling proposal (55 FR 29487). The agency tentatively concluded that "Public health concerns for deficient intakes of these nutrients (thiamin, riboflavin, and niacin) have lessened considerably in the last 20 years," and, accordingly, proposed to delete them as a mandatory part of nutrition labeling. The IOM report also stated that thiamin, riboflavin, and niacin are not current public health issues and did not recommend that the disclosure of their levels in food be required (Ref. 1). Thus, because the agency tentatively finds that inclusion of these three nutrients in the nutrition label is not necessary to assist consumers in maintaining healthy dietary practices, under section 403(q)(2)(B) of the act, FDA is proposing to delete them from the list of nutrients that are mandatory elements of nutrition labeling.

A. Sugars and Complex Carbohydrates

The principal change that the 1990 amendments would require in FDA's mandatory nutrition labeling proposal is the addition of sugars and complex carbohydrates to the list of nutrients and food components that must be declared in nutrition labeling. Accordingly, to comply with the 1990 amendments, FDA is modifying proposed § 101.9(c)(6)(i) and (c)(6)(ii)(A)

of the mandatory nutrition labeling proposal to make the declaration of complex carbohydrates and sugars mandatory.

In the mandatory nutrition labeling proposal, the agency proposed to make the declaration of these two food components voluntary. FDA set out the factors that it considered in deciding whether a nutrient or food component should be mandatory or voluntary in nutrition labeling:

The agency has proposed to make the declaration of a nutrient or food component mandatory in nutrition labeling when quantitative intake recommendations with respect to the nutrient or component are highlighted in the reports cited above (e.g., "Reduce total fat intake to 30% or less of calories." * * *), and the nutrient or component is of particular public health significance as defined in several recent consensus documents * * *. On the other hand, for those nutrients or food components for which quantitative intake recommendations are not highlighted but that do have some public health significance (e.g., " * * * increase intakes of starches * * * " * * *), or for which quantitative recommendations are available but that are not of pressing public health importance (e.g., the Recommended Dietary Allowances for several vitamins and minerals * * *), the agency is proposing to make declaration of the nutrient or component voluntary. (55 FR 29487 at 29493.)

Accordingly, while several recent dietary guidelines recommend that intakes of sugars and sugar-rich foods be limited (Refs. 2, 3, and 4), FDA did not propose to require the mandatory declaration of sugars content because specific quantitative recommendations have not been provided. Similarly, dietary guidelines have recommended increased consumption of complex carbohydrates but have not clearly defined the term "complex carbohydrates" and also have not highlighted quantitative consumption goals (Refs. 2, 3, and 4). Thus, FDA did not propose to require the mandatory declaration of complex carbohydrates in nutrition labeling. The IOM report also recommended that the declaration of sugars and complex carbohydrates be voluntary (Ref. 1).

As stated above, 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) is necessary to assist consumers in maintaining healthy dietary practices and, if not, to delete such nutrients from the required list of nutrients in nutrition labeling. Accordingly, FDA has considered its option to continue to make the inclusion of sugars and complex carbohydrates

optional rather than mandatory elements of nutrition labeling. However, a preliminary review of comments received by the agency on the mandatory nutrition labeling proposal shows consumer interest in having sugars and complex carbohydrates as a mandatory part of nutrition labeling. In addition, while current dietary guidance recommendations (Refs. 2, 3, and 4) have not specified quantitative amounts, the general directions of the recommended modifications in current intakes—i.e., increase complex carbohydrates and limit sugars—are specified. Based on these factors FDA has tentatively concluded that consumers would find the inclusion of these food components useful in maintaining healthy dietary practices. Therefore, in accordance with the 1990 amendments and consistent with consumer comments, FDA is proceeding to amend its mandatory nutrition labeling proposal by proposing in § 101.9(c)(6)(i) and (c)(6)(ii)(A) to include sugars and complex carbohydrates as mandatory elements of nutrition labeling.

However, the preliminary review of comments also shows support for voluntary, rather than mandatory declaration of sugars and complex carbohydrates. The agency acknowledges that the mandatory approach is potentially controversial for several reasons, and that there is some basis to question the appropriateness of this approach. First, the inclusion of complex carbohydrates and sugars within the mandatory nutrition label may be misleading to consumers because it may suggest that these food components have greater public health significance than has been established by existing diet and health studies. More specifically, the identification of a specific benefit for complex carbohydrates is confounded by the fact that diets high in complex carbohydrates 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 fat (Ref. 2). Thus, it is unclear the extent to which complex carbohydrates impart health benefits separate from such factors as the presence of fiber, vitamins, minerals, and reduced levels of fat. For sugars, the major public health concern relates to the relationship between sugars and dental caries. However, other factors, such as the characteristics of the food that contains the sugars (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).

Second, as noted above, the Surgeon General's report (Ref. 2) and NAS's Diet and Health report (Ref. 3) have not specified a recommended level of intake for either complex carbohydrates or sugars. FDA has tentatively concluded that without targeted recommendations from these major consensus reports, it would not be appropriate to establish reference values, i.e., DRV's, for these food components. Moreover, FDA is proposing DRV's for all the other food components required to be declared in nutrition labeling except for protein, vitamin A, vitamin C, calcium, and iron, for which RDI's are being established. The agency anticipates that the reference value DRV's and RDI's will be helpful for consumers in planning overall diets, and the agency does not know the extent to which the absence of DRV's for complex carbohydrates and sugars will be problematic or confusing for consumers.

Third, the terms "complex carbohydrates" and "sugars" have not been clearly or consistently defined. While it is most appropriate to chemically define these terms in a way that reflects the physiological effects and health benefits associated with food substances, available consensus reports have not attempted to do so (Refs. 1 through 4). In its mandatory nutrition labeling proposal in which sugars and complex carbohydrates were proposed as voluntary, FDA proposed to define sugars as the sum of all free mono- and oligosaccharides and (and their derivatives) that contain four or fewer saccharide units (55 FR 29487 at 29513). This definition includes tri- and tetrasaccharides primarily to avoid underdeclaration of the sugars content of foods rich in corn syrups. It also includes sugar alcohols because they have sweetening, nutritional, and metabolic effects similar to sugars. This definition differs from that used by Canada (Ref. 5), the Codex Alimentarius Commission (Ref. 6), and the European Community (Ref. 7), all of which limit the definition of sugars to mono- and disaccharides.

FDA defined complex carbohydrates in the mandatory nutrition labeling proposal as the sum of dextrans and starches, i.e., those carbohydrate components that contain 10 or more saccharide units exclusive of dietary fiber (55 FR 29487 at 29497). However, the inclusion of dextrans (saccharide units of 10 or more) within the definition of complex carbohydrates may inappropriately classify the relatively low molecular weight carbohydrates in

some nutritive sweeteners as complex carbohydrates. This definition may result in some foods, such as coffee whiteners and ice cream, that contain large amounts of low conversion (i.e., low dextrose equivalent) corn sweeteners being classified as sources of complex carbohydrates. These low molecular weight carbohydrates may have nutritional or metabolic effects different from those of commonly recognized complex carbohydrates. Thus, it may be misleading to consumers if these foods are labeled as containing complex carbohydrate.

FDA specifically requested comments on these suggested definitions and solicited alternative suggestions in the mandatory nutrition labeling proposal. FDA has not yet reviewed the comments that were submitted. Therefore, the agency has not modified the definition of sugars, although it has added a more precise definition of dextrans, as "saccharide units of 10 or more," to the definition of complex carbohydrates in § 101.9 (c)(6)(i).

Finally, from a compliance perspective, the proposed approach of including complex carbohydrates and sugars as mandatory elements of nutrition labeling poses certain analytical problems. Specifically, available and widely used laboratory methods provide for the analysis of carbohydrate in foods in a manner that may not be sufficiently specific for regulatory purposes. For example, available analytical procedures now measure carbohydrate as either more than 4 saccharide units or as single saccharide units up to 4 units. Suitable analytical procedures would be needed if complex carbohydrates were to be defined as those carbohydrates that contain a specified number of saccharide units that exceeds 4 (e.g., 10 units).

Therefore, because of all of these concerns and because this approach constitutes a change from the mandatory nutrition labeling proposal, FDA requests specific comments on its proposal to include complex carbohydrate and sugars as mandatory elements of nutrition labeling. The agency solicits comments concerning the utility and appropriateness, as well as the feasibility, of requiring declaration of complex carbohydrate and sugars content particularly as such declarations relate to and are supported by public health goals. If the mandatory declaration of these food components is considered necessary to assist consumers in maintaining healthy dietary practices, the agency further requests comments on the physiological

effect of carbohydrate fractions, on appropriate chemical definitions and analytical methodologies for these substances, and on the impact, if any, of the absence of a DRV for these food components. Based on such comments and the other information that it has received, the agency will decide, under section 403(q)(2) of the act, whether to include complex carbohydrate and sugars in the required list of nutrients in nutrition labeling.

B. Protein Quality

While not directed to do so by the 1990 amendments, the agency is including in this supplementary proposal a modification of the mandatory nutrition labeling proposal regarding the determination of protein quality. This action is in response to a citizen petition submitted by Protein Technologies International, Inc. (Docket No. 90P-0052), requesting that the agency accept an amino acid scoring method that is corrected for protein digestibility in addition to the presently accepted procedure, the Protein Efficiency Ratio (PER) method. The agency has decided that the petition has merit, and that the agency's response to it should be integrated into this rulemaking because protein quality is an important part of nutrition labeling. Therefore, the agency is incorporating into this proposal most of the concepts from the petition and providing that any final rule based on this proposal will be a final disposition of the subject petition.

In the mandatory nutrition labeling proposal, FDA indicated that a more flexible approach to determining protein quality was desirable. The preamble stated:

As new methodologies and new information on amino acid requirements of various age groups become available, the agency believes it must become more flexible in regard to permitted protein quality methodologies. Therefore, while the PER method described in the Official Methods of Analysis of the Association of Official Analytical Chemists may continue to be used as one of the methods for assessing the protein quality of foods, alternative acceptable validated procedures may be used as they become available. (55 FR 29487 at 29499).

Dietary protein serves as a source of essential and nonessential amino acids, the building blocks of body protein, and also as a source of energy. Because excess amino acids are not stored in the body, humans need a constant supply of good quality dietary protein to support growth and maintenance of body protein. Primarily, assessment of protein quality is a measure of the content,

proportion, and availability of essential amino acids in food protein. Accurate methods for determining protein quality are necessary because different food protein sources are not equivalent in their ability to support growth and body protein maintenance. When nutrition labeling regulations were promulgated in 1973, FDA used the PER method for measuring protein quality of foods and made a gross separation of protein types into high and low quality proteins with a separate U.S. RDA for each category (38 FR 2128, January 19, 1973). This method continues to be used in current regulations (§ 101.9(c)(7)(ii)).

The need for improved methods of assessing protein quality has been recognized for over a decade, but suitable alternative methods were not available. The PER method measures the ability of a protein source to support growth in young, rapidly growing rats. It is an expensive and time-consuming biological assay that compares weight gain in rats fed a test protein to the gain in rats fed a protein standard, casein. Moreover, as indicated in the agency's proposal on common or usual names for vegetable protein products (43 FR 30472, July 14, 1978), there has been increasing scientific data to demonstrate that the PER method for evaluating protein is not very precise for measuring protein quality for human needs. In brief, PER overestimates the value of some animal proteins for human growth and underestimates the value of some vegetable proteins because rapidly growing rats have a higher need for certain essential amino acids (Ref. 8, p. 4). The continued use of the PER method to assess comparative protein quality for food labeling purposes was discussed in a recent review article published in the *Journal of Nutrition* (Ref. 9).

Following publication of the mandatory nutrition labeling proposal, the Codex Alimentarius Commission accepted a method for assessing protein quality that uses a protein digestibility-corrected amino acid score (PDCAAS) (Ref. 9a, p. 80). This method had been recommended in a report from a joint expert consultative group of the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization (WHO) (Ref. 8). The standard used for assessing protein quality in the PDCAAS method is the amino acid scoring pattern established by FAO/WHO/United Nations University (UNU) in 1985 for preschool children 2 to 5 years of age (Ref. 10). To calculate PDCAAS, the test food is analyzed for protein and amino acid composition and the digestibility of the protein is determined with a

standardized rat balance method. Overall, the most limiting essential amino acid (that is, the amino acid that is present at the lowest level in the test food compared to the standard) is identified in the test food by comparing the levels of individual amino acids in the test food with the FAO/WHO pattern of the essential amino acids established as a standard for children 2 to 5 years of age. The value of the most limiting amino acid (the ratio of the amino acid in the test food over the amino acid value from the pattern) is multiplied by the percent of digestibility of the protein. This resulting number is the PDCAAS.

The FAO/WHO/UNU report proposed separate amino acid scoring patterns for infants, preschool children 2 to 5 years of age, school-aged children 6 to 12 years of age, and adults, implying that protein quality varies with the age of the individual. The report stated that protein and diets containing essential amino acids that met the greater needs of young children were also adequate for older children and adults, whereas the reverse may not be true (Ref. 10). Five years later, the FAO/WHO consultative group evaluated the FAO/WHO/UNU report and concluded that there is no adequate basis to use different scoring patterns for different age groups with the exception of infants who have much greater needs for essential amino acids (Ref. 8). They recommended that the FAO/WHO/UNU amino acid scoring pattern for preschool children should be used to evaluate protein quality for all age groups, except infants. They also concluded that the protein digestibility-corrected amino acid score is the most suitable regulatory method for evaluating protein quality of foods, stating that "Since this method is based on human amino acid requirements, it is inherently more appropriate than animal assays used for predicting protein quality of foods and the Consultation therefore recommends that the procedure be adopted as the preferred method of measuring protein values in reference to human nutrition" (Ref. 8).

The agency has reviewed the FAO/WHO report and tentatively accepts its conclusion that the protein digestibility-corrected amino acid score method is more appropriate for assessing protein quality of foods than animal assays and is preferable for regulatory purposes. Therefore, the agency is proposing in § 101.9(c)(8)(ii) to require the use of the PDCAAS method as the method for determining protein quality for food intended for children over 1 year of age and adults. While this method is

recommended for all children above 1 year of age, it is not recommended for infants, and therefore FDA proposes in § 101.9(c)(8)(ii) to retain the PER method for assessing protein quality and to retain casein as the standard in expressing the percentage of the RDI for protein in foods represented and purported to be for use by infants. FDA notes that there is an inconsistency between the FAO/WHO report cited above (Ref. 8) and a report of the meeting of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) which was held in February 1991 (Ref. 10a). While the CCNFSDU endorsed the use of the PDCAAS method, it adopted a higher standard for protein quality for children 1 to 3 years of age. The CCNFSDU report requires that "The amino acid score * * * should not be less than 70 percent of that of casein." The agency invites comments on the difference between the two reports especially with regard to issues of safety and public health of children between the ages of 1 and 3 years of age.

C. Terminology

1. Food Components

To be consistent with terminology used in the 1990 amendments, FDA is modifying the listing of "fat" to "total fat," "carbohydrates" to "total carbohydrates," "fiber" to "dietary fiber," and "saturated fatty acid" to "saturated fat." The agency had used the abbreviated terms "fat," "carbohydrate," and "fiber" to minimize space requirements for nutrition labeling. However, both the comments on the mandatory nutrition labeling proposal and research that the agency conducted in the fall of 1990 have shown that these abbreviated terms cause some consumer confusion (Ref. 11). FDA's research showed that many consumers did not realize that the "saturated fat" content was a part of the "fat" content, as listed (Ref. 11). The agency learned that many consumers think that it is necessary to add the grams of fat and the grams of saturated fat to get a total fat value (Ref. 11). While nutrition education programs are needed to address this issue, FDA believes that consumer confusion will be reduced by the use of the more explicit term "total fat."

Likewise, now that the agency is proposing to make complex carbohydrates and sugars mandatory elements of nutrition labeling, the use of the term "total carbohydrates" will help make clear that the term includes the two subelements listed beneath it. These

changes in terminology are supported by the IOM report which used the term "total fat" and recommends use of the term "total carbohydrate" when carbohydrate components are listed on the nutrition information panel, with the subgroups indented (Ref. 1).

In contrast to the listings for fat and carbohydrates, the agency does not believe there is a need to add the term "total" in front of "protein" because there are no other protein terms that are permitted to be listed. In addition, it may be helpful to minimize space requirements by the declaration of protein content since the percent RDI may be included on the same line (proposed § 101.9(c)(7)(i), redesignated as § 101.9(c)(8)(i) in this document). In regard to fiber, comments have stated that the use of the more precise term "dietary fiber" would help clarify the type of fiber being declared. FDA agrees with these comments and, as stated above, is using the suggested term in this supplementary proposal.

FDA is also proposing to require the use of the abbreviated terms "saturated fat," "unsaturated fat," "polyunsaturated fat," and "monounsaturated fat" in nutrition labeling in place of the more scientifically correct terms that include "fatty acid." The abbreviated terminology is used in the 1990 amendments and was recommended in the IOM report (Ref. 1). It also is consistent with terminology used in the dietary recommendations given in the Surgeon General's report (Ref. 2) and the Dietary Guidelines for Americans (Ref. 4). The agency has tentatively concluded that use of the abbreviated terms will help to reduce consumer confusion, as well as help to minimize space requirements within nutrition labeling.

2. Reference Values

In its mandatory nutrition labeling proposal (55 FR 29487), FDA acknowledged that the replacement of the U.S. RDA's with two sets of reference values, RDI's and DRV's, could potentially be confusing to consumers if both of the new terms were used on the food label. Although it is necessary to distinguish between RDI's and DRV's for regulatory purposes, FDA does not consider the distinction to be important to a consumer's understanding of the nutrition information presented on the food label. Therefore, FDA asked for comments on the possibility of listing the reference values on the label under a single new term.

On its own, FDA has arrived at "Daily Value" as a possibility for use as this single term. FDA believes that this term

would be appropriate for two reasons. First, it is consistent with section 2(b)(1)(A) of the 1990 amendments, which directs the Secretary to require that information on the nutrition label be presented in a manner that enables consumers to understand the significance of the information presented in the context of a total daily diet. This term makes clear that the reference value is a daily intake level. Second, FDA has conducted consumer research that included discussions of the term "Daily Value" and, in general, the term was correctly interpreted by consumers (Ref. 11). However, consumers did suggest that the use of the word "value" was confusing. They commented that the word implied price or cost, rather than a reference standard.

The agency has received additional comments that also indicate that the term "Daily Value" may not be appropriate and has the potential to cause confusion. Alternative suggestions made to the agency include: Daily allowance, daily level, balanced daily allowance, recommended daily amount (or standard), daily limit, daily need, daily requirements, daily intake, and total daily value.

The agency is not proposing alternative terms that use words such as "recommended," "requirement," or "need" because such terms could be misleading to consumers and complicate nutrition education efforts. For example, some reference values are intended to guide consumers relative to maximum intakes (e.g., total fat), while others are intended to serve as a basis for planning general diets to meet nutrient requirements (e.g., vitamin C) or as minimum intakes (e.g., 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."

FDA is, therefore, specifically reiterating its request for comment on, and suggestions for, appropriate terminology to be used to refer to both RDI's and DRV's when used as reference values on the food label, particularly as to the most meaningful and appropriate term to convey to consumers the purpose and intent of the reference values.

D. Fatty Acids

In its mandatory nutrition labeling proposal, FDA requested comments concerning the definitions of, and content declarations for, the different types of fatty acids (55 FR 29487). FDA stated that the available evidence does not support a cholesterol-raising effect for *trans* isomers when they are

substituted for saturated fatty acids in the diet. New research and commentary have been published (Refs. 12 and 13), however, concerning the effect of *trans* isomers of fatty acids on the serum cholesterol levels. In view of these publications, the agency is requesting comments on the significance of the new findings for nutrition labeling and further requests that persons who submitted comments concerning *trans* isomers in response to the mandatory nutrition labeling proposal reevaluate their comments relative to the newest data and, if appropriate, submit additional or revised comments.

The agency also notes the increased use of fats containing long and very long chain fatty acids (e.g., components of partially hydrogenated menhaden oil) in the food supply and the potential for the marketing of novel compounds in which fatty acids are linked to carbon structures in a manner that will reduce their digestibility. As a result, these compounds will have the technical effects of fat without the calories. The agency is requesting comment concerning the appropriateness of current fat related definitions and analytical procedures for the declaration of these compounds with respect to mandatory nutrition labeling. FDA also requests the submission of the results of any research finding that will assist the agency in arriving at appropriate definitions for fatty acid groups.

In addition, definitions for "saturated" fatty acids and "unsaturated" fatty acids proposed by FDA are at variance with those of Canada (Ref. 5), the Codex Alimentarius Commission (Ref. 6), and the European Community (Ref. 7). Differing definitions among these organizations, Canada, and the United States could result in added analytical expenses for nutrition labeling and to support nutrition claims for internationally marketed products. The agency therefore requests comment on the need for internationally uniform fat definitions for purposes of labeling.

E. Additional Information

Section 2(b)(1)(C) of the 1990 amendments stipulates that regulations shall "permit the label or labeling of food to include nutrition information which is in addition to the information required by such section 403(q) and which is of the type described in subparagraph (1) or (2) of such section * * * ." In its mandatory nutrition labeling proposal, FDA proposed to allow the voluntary declaration of several food components (e.g., unsaturated fat and soluble fiber) and any naturally occurring vitamins and

minerals for which RDI's have been proposed in § 101.9(c)(10)(iv), which is redesignated as § 101.9(c)(11)(iv) in this document. However, the agency requested comment on the merits of allowing a voluntary listing of nutrients and food components beyond those required in nutrition labeling. The agency raised questions about how the presence of these additional nutrients and food components on the label would be interpreted by consumers, and whether the listing of some voluntary nutrients and food components would actually be misleading (55 FR 29493). Through the inclusion of section 2(b)(1)(C) in the 1990 amendments, Congress would appear to have settled this issue, and, accordingly, the proposed regulations will continue to allow specified nutrients and food components, like unsaturated fat and soluble fiber, to be included voluntarily in nutrition labeling. However, the House Report on the 1990 amendments (Ref. 18) states 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 in the nutrition label. Therefore, FDA requests comment on whether it is necessary to include limits on the voluntary information that may be provided.

IV. Nutrition Label Format

As stated above, section 2(b)(1)(A) of the 1990 amendments states that 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." FDA interprets this provision as supporting the proposed DRV's and as a mandate for the agency to continue the effort that it began as part of Secretary Sullivan's food labeling initiative of conducting consumer research to determine the most useful and appropriate format for nutrition labeling.

FDA began its research by testing consumer reactions to alternative label formats in five consumer focus groups (Ref. 11). A focus group session is a qualitative information-gathering technique in which a group of 8 to 10 persons is guided through a discussion of a specific topic by a trained moderator. A session usually lasts about 1 to 2 hours. While the outcomes of these sessions are generally not quantifiable, they can help in guiding the design and interpretation of structured research projects and can provide useful insights into consumer behavior.

The agency's preliminary consumer focus group sessions were designed to provide qualitative information on four types of nutrition label formats, specifically bar graphs, pie charts, adjectival descriptors, and tabular numeric formats (Ref. 11). In designing the focus group sessions, FDA included specific comparison tasks or discussion issues that targeted the participants' ability to use and interpret the format. In this way, the discussions were structured to explore issues beyond stated preference and initial visual appeal. However, the extent to which familiarity with the current label influenced participants' responses could not be determined.

The outcome of the focus group discussions suggested that participants had difficulty using pie charts and bar graphs. In addition, formats based on adjectival descriptors, such as the use of the word "high" to designate the level of a nutrient in a food, did not increase participants' ability to compare levels of nutrients between foods. The tabular numeric format, which was similar to the current label, was readily used and most often appropriately interpreted by participants. Some participants suggested that this type of format required "less work" to interpret than bar graphs or pie charts. Virtually all participants favored some type of label standard or reference value for macronutrients and food components associated with chronic disease conditions (Ref. 11).

The agency also has conducted a large scale quantitative study to evaluate the communication effectiveness of five alternative label formats. The study employed a representative national sample of 1,000 adult primary food shoppers and a separate sample of 500 undereducated shoppers (Ref. 14). The criteria on which labels were evaluated included: Accuracy with which consumers distinguished between nutritionally dissimilar foods, time required to make distinctions, confidence in using formats, and rated helpfulness of formats for food selection and meal planning. Study respondents provided comments about the most helpful and least helpful features of the formats.

On May 20, 1991 (56 FR 23072), FDA published a notice in the *Federal Register* that announced the availability of a report of the results of this study. The notice also asked for comments on the study and on proposed additional format research.

Should FDA ultimately decide, based on comments and the results of the studies, that changes in the format of

nutrition labeling appear to be necessary, it intends to propose those changes in time to include any such changes in the final nutrition labeling regulations that must be published by November 8, 1992.

The proposed DRV's were used in several formats studied in the focus group sessions as well as in some of those investigated in the quantitative study (Refs. 11 and 14). In these and other studies (Ref. 15), consumers indicated a desire to have reference values, such as the proposed DRV's, on food labels. A preliminary review of comments received on the mandatory nutrition labeling and RDI/DRV proposals also indicates great consumer interest in having these reference values become a part of nutrition labeling. The DRV's appear to help fulfill the requirements of section 2(b)(1)(A) of the 1990 amendments in that they enable consumers to "comprehend such information (i.e. nutrition labeling) and to understand its relative significance in the context of a total daily diet."

In light of these responses, the agency is of the opinion that use of the DRV's will help meet the objectives of the 1990 amendments and is therefore proposing to make them mandatory in some form. How they will be expressed within nutrition labeling and in what form is the subject of further format research. However, at this time FDA wishes to advise that it intends to require inclusion of DRV's in nutrition labeling, and it therefore requests further comments on how they might be expressed.

There are certain additional aspects of the current format that are directly affected by the 1990 amendments (i.e., highlighting, use of ranges, and a simplified format). A discussion of these matters follows.

A. Highlighting

Section 403(q)(1) of the act provides that "The Secretary may by regulation require any information required to be placed on the label * * * to be highlighted * * * by larger type, bold type, or contrasting color if the Secretary determines that such highlighting will assist consumers in maintaining healthy dietary practices."

FDA's current regulations do not address this issue. While many examples of highlighting of nutrients in nutrition labeling can be found in the marketplace, the agency has viewed the practice as a marketing activity rather than as a tool for educating or assisting consumers in planning a healthy diet. Highlighting is widely practiced by designers of print communications.

including food package designers, as a means of enhancing the readability of print materials. However, FDA has not conducted any research to determine the effectiveness of highlighting in directing consumer attention to specific nutritional information or in helping consumers to retain the highlighted information.

Comments are requested on the usefulness of highlighted information to consumers. For example, the agency asks for comments on what information, if any, should be highlighted; how, when, or where highlighting should be used; the circumstances in which it may be misleading (e.g., highlighting the cholesterol, but not the fat content of a food); and what costs are involved. Research findings would be particularly useful.

B. Ranges for Nutrients

Section 2(b)(1)(D) of the 1990 amendments directs FDA to permit the quantitative information on nutrition labeling to remain the same (i.e., to be stated as a single value) or to be stated as a range:

* * * even though (i) there are minor variations in the nutritional value of the food which occur in the normal course of the production or processing of the food, or (ii) the food is comprised of an assortment of similar foods which have variations in nutritional value.

FDA, since 1973, has provided guidelines for deriving nutrition label values that are representative of the range of nutrients in a food. Under the guidelines, the label values are established by statistical analyses of data gathered to account for seasonal effects, growing/harvesting regions, storage, and other variables that affect nutrient content. This procedure, together with FDA's compliance standards in § 101.9(e)(4)(ii) and (e)(5) (renumbered as § 101.9(g)(4)(ii) and (g)(5) in this proposal), which allow up to a 20 percent deviation for naturally occurring nutrients, permits most foods to be represented by a single label value for each nutrient, even those that are quite variable.

The agency believes that single values calculated using this procedure are more informative, and are less confusing, for consumers than are ranges of values, especially where the ranges are large. It is true that requiring a single value may result in underdeclaration of some nutrients (e.g., vitamin C) and overdeclaration of others (e.g., sodium) when variability is high. However, the single value will fairly represent the nutrient levels that the consumer can depend upon receiving from the product over time. A single value also permits

manufacturers to avoid frequent product analyses and label changes, and it requires that FDA take compliance action only if a label significantly misrepresents the nutrient content of a food.

The statistical procedures used by FDA are discussed in a guide, "Compliance Procedures for Nutrition Labeling," as noted in the mandatory nutrition labeling proposal (55 FR 29487 at 29507). This guide may be obtained from the Division of Nutrition, Center for Food Safety and Applied Nutrition (address above). A revised guide, to be entitled "FDA Nutrition Labeling Manual—A Guide for Using Data Bases," will be available by the time a final rule in this proceeding is issued. The revised guide will provide a more comprehensive discussion of procedures for using a data base to develop a nutrition label. It will also discuss some suggested alternatives to current procedures. In the revised guide, the agency will provide for the use of a mean value derived from a satisfactory data base for use in nutrition labeling in conformance with § 101.9(g)(4)(ii). In order to ensure that the data base is adequate for this purpose, a maximum coefficient of variation will be incorporated in the revised guide in addition to other requirements. The coefficient of variation is the standard of deviation (a measure of variability) expressed as a percentage of the mean. The mean value that may be used should be derived from an acceptable data base that meets the criteria given in detail in the booklet and summarized below:

Number of samples	Maximum coefficient of variation
5.....	17
10.....	25
20.....	31
30.....	34
40.....	36
50.....	37

Thus, if the sampling plan is acceptable to the agency, and the above number of samples are assayed, then, if the coefficient of variation is equal to or less than the maximum coefficient of variation applicable to the number of samples as specified above, the mean value may be used for labeling purposes instead of the calculated value using the agency formula.

The booklet detailing the requirements of an acceptable data base will have a more complete discussion of the use of mean values and calculated values and when each may be used for reasonable nutrient label values. The

agency intends to publish a notice in the Federal Register when the revised guide is completed to provide an opportunity for public review.

FDA tentatively concludes that the agency's current compliance policy with respect to labeling in the face of nutrient variability, satisfies the requirements of the 1990 amendments. While the legislative history (Ref. 16) states that section 2(b)(1)(D) is to give the Secretary flexibility to permit nutrient values to be declared as a range, the agency does not believe that doing so will assist consumers in maintaining healthy dietary practices and, therefore, is not proposing any changes in its regulations in response to this section. However, the agency solicits specific comment on the use or display of ranges on nutrition labels.

C. Simplified Format

In an effort to keep the space requirements for the nutrition label to a minimum, FDA proposed in the mandatory nutrition labeling proposal that certain nutrients and food components (i.e., calories from fat, saturated fatty acids, cholesterol, fiber, vitamins, and minerals) could be omitted from the tabular listing if they are not present in the food or are present in very small amounts. When these nutrients and food components are omitted from the tabular listing, FDA proposed to require that the statement "Not a significant source of _____," with the blank filled in with the missing items, be included within the nutrition labeling (55 FR 29487 at 29502).

Section 403(q)(5)(C) of the act, takes a somewhat different approach. It states that:

* * * If a food contains insignificant amounts, as determined by the Secretary, of more than one-half the nutrients required by subparagraphs (1) and (2) to be in the label or labeling of the food, the Secretary shall require the amounts of such nutrients to be stated in a simplified form prescribed by the Secretary.

In discussing label format issues, the IOM report (Ref. 1, p. 299) states that "There is an obvious tension between the goal of label uniformity, which will facilitate consumer use of nutrition labeling, and the possible need for modification for specific foods or markets." While the benefits of consistency in the presentation of nutrition information are stressed, the report also states that "It may be appropriate to allow foods that contain very few of the mandatory components of nutrition labeling to use an

abbreviated version of the standards format * * *."

Research conducted in conjunction with selection of the current nutrition label format showed that consumers of all educational backgrounds were consistently more accurate in identifying individual nutrient differences between foods, as well as in making overall comparative judgments about nutrition quality, when nutrients not present at significant levels were omitted from the nutrition label (Ref. 17). These results need to be weighed against other research that showed strong consumer preference for having all nutrients reported on the label rather than only those nutrients that are actually present in the food (Ref. 15).

To reflect the part of section 403(q)(5)(C) that states "* * * If a food contains insignificant amounts, as determined by the Secretary, of more than one-half the nutrients required by subparagraphs (1) and (2) to be in the label or labeling of the food * * *," FDA is proposing in § 101.9(f)(1) to consider all 15 nutrients and food components that would be mandatory under this proposal as "required nutrients." The 15 food components and nutrients to be included are: calories, calories from fat, total fat, saturated fat, cholesterol, total carbohydrate, complex carbohydrate, sugars, dietary fiber, protein, sodium, vitamin A, vitamin C, calcium, and iron. While the agency generally refers in this document to calories as a measure of energy; to fat, fatty acids, cholesterol, carbohydrates, fiber, protein, and sodium as food components; and to vitamins and minerals as nutrients, it is clear in section 403(q)(2)(B) of the 1990 amendments that all of these categories are included under the general term "nutrients." Accordingly, FDA is proposing to use all of them in calculating "* * * one-half the nutrients required * * *." Therefore, FDA interprets the language in section 403(q)(5)(C) quoted above as meaning that if a food contains insignificant amounts of 8 or more required nutrients, it is subject to the simplified format. To ensure that the determination as to when this format is required is not unnecessarily complicated, FDA is proposing not to count nutrients other than the 15 listed above as required nutrients, even if the nutrients are added to a standardized enriched food and therefore would have to be declared in nutrition labeling (§ 101.9(f)(1) and (3)(iii)).

For purposes of determining when a food must bear the simplified format, section 403(q)(5)(C) of the act also directs the Secretary to determine when

a food contains "insignificant amounts" of these required nutrients. For this purpose, FDA is proposing in § 101.9(f)(2) to define "insignificant amount" as that amount that may be rounded to zero in nutrition labeling.

To clarify the point at which very low levels of nutrients or food components may be rounded to zero, the agency is proposing additions in proposed § 101.9 to indicate precisely what analytical amounts may be rounded down to zero: § 101.9(c)(3), calories; § 101.9(c)(3)(i), calories from total fat; § 101.9(c)(3)(ii), calories from saturated fatty acids, unsaturated fatty acids, carbohydrates, and protein; § 101.9(c)(4), total fat; § 101.9(c)(4)(i), saturated fatty acids; § 101.9(c)(4)(ii), unsaturated fatty acids; § 101.9(c)(4)(ii)(A), polyunsaturated fatty acids; § 101.9(c)(4)(ii)(B), monounsaturated fatty acids; § 101.9(c)(6), total carbohydrate; § 101.9(c)(6)(i), complex carbohydrate; § 101.9(c)(6)(ii)(A), sugars; § 101.9(c)(6)(ii)(B), sugar alcohol; § 101.9(c)(7), dietary fiber; § 101.9(c)(7)(i)(A), soluble fiber; § 101.9(c)(7)(i)(B), insoluble fiber; and § 101.9(c)(8), protein. In the case of calories, which are proposed to be declared to the nearest 5-calorie increment in nutrition labeling (up to 50 calories), the amount specified that would be expressed as zero is "less than 5 calories." For total fat, total carbohydrate, complex carbohydrates, sugars, sugar alcohol, dietary fiber, soluble fiber, insoluble fiber, and protein, FDA is proposing less than 0.5 g as the amount that can be expressed as zero. For saturated fatty acids, unsaturated fatty acids, polyunsaturated fatty acids, and monounsaturated fatty acids, FDA is proposing less than 0.25 g as the amount that can be expressed as zero.

Current regulations (§ 101.9(c)(7)(i)) provide that vitamin and mineral values of less than 2 percent of the U.S. RDA are to be declared as zero. This provision was carried forward in the mandatory nutrition labeling proposal as proposed § 101.9(c)(10)(iii), now redesignated as § 101.9(c)(11)(iii). Consequently, FDA is proposing that a value of less than 2 percent of the RDI (set forth in proposed § 101.9(c)(10)(iv), redesignated in this document as § 101.9(c)(11)(iv)) be considered insignificant. This cutoff is supported by the imitation food regulation (§ 101.3(e)(4)(ii)) which identifies 2 percent or more of the RDI as a measurable amount of a nutrient. Anything less than a measurable amount could be considered "insignificant."

Current regulations (§ 101.9(c)(8)(i)) require that sodium content be declared as zero when less than 5 mg are present per serving (portion). This value is consistent with the definition of "sodium free." This requirement for zero declaration was carried forward in the mandatory nutrition labeling proposal in § 101.9(c)(8), which is redesignated as § 101.9(c)(9) in this proposal.

In the case of cholesterol, the agency proposed in § 101.9(c)(5) of its mandatory nutrition labeling proposal that a zero declaration of cholesterol be allowed when the cholesterol content of a food is less than 2 mg per serving (portion). This level is consistent with the definition of "cholesterol free" (55 FR 29456) that FDA has proposed.

Currently no single food composition data base has all of the information needed to determine what, or how many, foods would be required to bear the simplified format using the above criteria. Available data bases lack information particularly on sugars, complex carbohydrates, and dietary fiber. FDA utilized several available data bases to create a file that contains information on all required nutrients (Ref. 18). This file makes it possible to obtain some information on the types and number of traditional foods that would be required to bear the simplified format. Using this file, it appears that the proposed rules would require that the following types of foods bear the simplified format: beverages such as sweetened coffee and tea, soft drinks, and fruit and fruit-flavored drinks; fats and oils including some salad dressings; all types of sugar; sweets such as syrups, gelatin desserts, jams, jellies, and some candies; pickles; some condiments and sauces; salt and seasoning salts; and a limited number of grain products, fruits, and vegetables.

FDA is proposing in § 101.9(f)(3)(i) to prescribe a simplified format that resembles the minimum label requirements as described in the mandatory nutrition labeling proposal (55 FR 29487 at 29502) in that total calories, total fat, total carbohydrate, protein, and sodium would be declared as a minimum (i.e., as a core requirement). In addition, FDA is proposing in § 101.9(f)(3)(ii) that any other nutrients or food components that are required components of the full nutrition label and identified in § 101.9(f)(1) be declared in the simplified format if they are present in more than insignificant amounts.

The minimum label requirements stated in the mandatory nutrition labeling proposal allowed nutrients and food components [other than the core

requirements—that is, total calories, total fat, total carbohydrate, protein, and sodium) to be omitted from the tabular listing if a statement was added within the nutrition label stating "Not a significant source of _____," with the blank filled in by the missing nutrients or food components. The primary difference between that format and the simplified format being proposed here is that, as long as no additional nutrients (e.g., potassium) are declared, the nutrients or food components (other than the core requirements) that are required parts of the full nutrition label but that are present in insignificant amounts would not be identified on the simplified label. In these circumstances, manufacturers would not have to include the statement "Not a significant source of _____" on their label.

However, under proposed § 101.9(f)(4), if manufacturers voluntarily choose to declare additional nutrients or food components that are not among the 15 required nutrients (e.g., potassium), as allowed by section 2(b)(1)(C) of the 1990 amendments, they will then be required to use the statement "Not a significant source of _____," with the blank filled in with the name of any required nutrients or food components that are missing or present in insignificant amounts. The agency is also proposing in § 101.9(f)(4) that if the product is voluntarily enriched or fortified with added vitamins or minerals, any such nutrients must be declared within the simplified format and followed by the above statement. Such a voluntary addition of nutrients is viewed by the agency as an effort to market the food as a significant source of nutrients. The agency believes such action would be misleading under section 201(n) of the act unless consumers are advised about the full nutritional profile of the food.

However, as an exception, under proposed § 101.9(f)(3)(iii), standardized enriched foods that qualify for use of the simplified format may use this format without the added statement even though they include nutrients that are required by the standard to be added (e.g., thiamin, riboflavin, and niacin in enriched flour) but that are not among the 15 required nutrients.

This exception is being proposed because, in many cases, these standardized foods have been enriched because of the food standard and not at the choice of the manufacturer.

A nutrition label for a soft drink that uses the simplified format would state:

NUTRITION INFORMATION PER SERVING

Serving size	12 fl oz (360 mL)
Servings per container	1
Calories	145
Total fat	0 g
Total carbohydrate	36 g
Sugars	36 g
Protein	0 g
Sodium	20 mg

fl oz = fluid ounces
mg = milligram

However, a nutrition label using the simplified format for a vegetable oil that voluntarily declares polyunsaturated and monounsaturated fats would state:

NUTRITION INFORMATION PER SERVING

Serving size	1 tbsp (14 g)
Servings per container	64
Calories	130
Calories from total fat	130
Total fat	14 g
Saturated fat	2 g
Polyunsaturated fat	4 g
Monounsaturated fat	8 g
Total carbohydrate	0 g
Protein	0 g
Sodium	0 mg

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

To save space and to allow greater flexibility in presentation, FDA is proposing in § 101.9(f)(5) that nutrition information for the simplified format may be presented in vertical columns (as above) or in lines. Under the proposal, when a line presentation is used, any nutrients or food components that are subelements that would otherwise be indented under a principal element (e.g., saturated fat as a subelement of total fat) must be put in parentheses in the proper order. Examples of a line presentation for the two products listed above are as follows:

Nutrition Information

Serving size: 12 fl oz (360 mL)
Servings per container: 1
Per serving: 145 calories, 0 g total fat, 36 g total carbohydrate (36 g sugars), 0 g protein, 20 mg sodium.

Nutrition Information

Serving size: 1 tbsp (14 g)
Servings per container: 64
Per serving: 130 calories (130 calories from total fat), 14 g total fat (2 g saturated fat, 4 g polyunsaturated fat, and 8 g monounsaturated fat), 0 g total carbohydrate, 0 g protein, 0 mg sodium. Not a significant source of cholesterol, complex carbohydrate,

sugars, dietary fiber, vitamin A, vitamin C, calcium, or iron.

To attract the consumer's attention to the smaller nutrition label, to clarify the information in the simplified format to the consumer, and in recognition of section 403(q)(1) of the act and of section 2(b)(1)(A) of the 1990 amendments, the agency is also considering the usefulness of requiring that the headings "NUTRITION INFORMATION" and "PER SERVING" be highlighted by larger type, bold type, or contrasting color. Comments are requested on this possible use of highlighting.

V. Exemptions

The 1990 amendments specifically exempt certain foods from the requirements of section 403(q) of the act. Some of these exemptions are the same as those included in FDA's mandatory nutrition labeling proposal. A discussion of the authority for these exemptions and, where differences exist, of the revised exemptions follows.

A. No Nutritional Significance

Section 403(q)(5)(C) of the act states:

If a food contains insignificant amounts, as determined by the Secretary, of all the nutrients required by subparagraphs (1) and (2) to be listed in the label or labeling of food, the requirements of such subparagraphs shall not apply to such food if the label, labeling, or advertising of such food does not make any claim with respect to the nutritional value of such food. * * *

In accordance with this provision of the statute, FDA is revising proposed § 101.9(a). As set out in the mandatory nutrition labeling proposal, this section would have required that nutrition labeling be provided on all foods that are a meaningful source of calories or nutrients. The agency proposed that a food be classified as a "meaningful" source of calories or nutrients if it contained:

- (1) Two percent or more of the RDI for protein, vitamin A, vitamin C, iron, or calcium per serving (portion);
- (2) More than 40 calories per serving (portion) or more than 0.4 calories per g; or
- (3) More than 35 mg of sodium per serving (portion).

FDA is compelled by the statute to revise proposed § 101.9(a) to exempt from nutrition labeling only those foods that contain insignificant amounts of all of the nutrients and food components required within nutrition labeling. Thus, consistent with the preceding discussion on the simplified format, the agency is proposing to define "insignificant" in

§ 101.9(a) as that amount that allows a declaration of zero in nutrition labeling.

FDA is also compelled by the statute to make this exemption available only when there are no nutrition claims in the label, labeling, or advertising for the food. FDA therefore has modified proposed § 101.9(a) to restrict the exemption for foods with insignificant amounts of nutrients to such situations. The proposed provisions point out that nutrition claims or information set forth in any context, and in any form of expression, implicit as well as explicit, will bar a food from an exemption from nutrition labeling under the "no nutritional significance" provisions.

B. Small Business

Section 403(q)(5)(D) of the act establishes a small business exemption by providing that:

If a person offers food for sale and has annual gross sales made or business done in sales to consumers which is not more than \$500,000 or has annual gross sales made or business done in sales of food to consumers which is not more than \$50,000, the requirements of subparagraphs (1), (2), (3), and (4) (of section 403(q)) shall not apply with respect to food sold by such person to consumers unless the label or labeling of food offered by such person provides nutrition information or makes a nutrition claim.

This section of the statute requires a modification of the relevant provision that FDA included in the mandatory nutrition labeling proposal. That provision, § 101.9(h)(1), would have provided an exemption for foods offered for retail sale by firms that have an annual amount of food sales of not more than \$500,000.

Under section 403(q)(5)(D) of the act, however, a food product is exempt from nutrition labeling if it is offered for sale by a person who has annual gross sales made, or business done in sales, of food and other merchandise to consumers of not more than \$500,000 or annual gross sales made, or business done in sales, of food alone of not more than \$50,000. Accordingly, the food products sold by a company would be exempt if the company had annual gross sales, made, or business done in sales, to consumers of more than \$500,000 but less than \$50,000 worth of sales made, or business done in sales, of food to consumers, or if it had annual gross sales, or business done in sales, to consumers of less than \$500,000 even though it had more than \$50,000 worth of sales made, or business done in sales, of food to consumers. Only businesses having more than \$500,000 in gross sales made, or business done in sales, to consumers and more than \$50,000 in sales, or business done in sales, of food alone to consumers

would not be exempt. Proposed § 101.9(h)(1), redesignated in this proposal as § 101.9(j)(1), has been revised accordingly.

For the purposes of this regulation, FDA is proposing in § 101.9(j)(1)(ii) that a person who offers food for sale, or who has business done in sales, to consumers is 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. This proposed provision clarifies the coverage of the small business exemption.

As discussed in the June 13, 1990, report of the Committee on Energy and Commerce, House of Representatives (Ref. 16), wholesale business, that is, sales not involving consumers, is not included in calculations of gross sales. Sales from all stores or other outlets owned by a particular corporation or other business, however, must be added together in determining whether the business qualifies for the exemption (Ref. 16).

In proposed § 101.9(j)(1)(iii), FDA is carrying forward from the mandatory nutrition labeling proposal its position that the calculation of the amount of sales should be based on the most recent two year average of business sales, and that, where firms have been in business less than two years and wish to claim the small business exemption, reasonable estimates of sales must indicate that annual sales will not exceed the dollar amounts specified. The agency recognizes that foreign firms may also be entitled to the small business exemption. In order to provide comparable treatment to such firms, FDA is proposing in § 101.9(j)(1)(iii) that the total sales of a foreign firm in the United States would be the level of business activity used in determining whether the firm has less than \$500,000 sales to consumers or less than \$50,000 in food sales to consumers.

C. Restaurant Food

Sections 403(q)(5)(A)(i) and (ii) of the act exempt from the nutrition labeling requirements foods that are served in restaurants or similar food service establishments, that are principally processed and prepared in a retail establishment, that are ready for consumption although not necessarily for consumption at the place of sale, and that are not offered for sale outside the establishment. FDA tentatively concludes that proposed § 101.9(h)(2) and (h)(3), which are redesignated as § 101.9(j)(2) and (j)(3) in this document, appropriately reflect these provisions of the legislation. Therefore, FDA is not

modifying § 101.9(j)(3). However, to reflect the exemption contained in section 403(q)(5)(F) of the act, FDA is modifying § 101.9(j)(2) to exempt foods sold by a distributor who sells principally to restaurants and other food service establishments from the nutrition labeling requirements. Manufacturers, packers, or distributors of foods for restaurant use should nutrition label their food products if there is a reasonable possibility that the food will be purchased directly by consumers (Ref. 25).

D. Small Packages

Section 403(q)(5)(B) of the act provides an exemption from nutrition labeling on labels of foods that are in packages that are so small that it is impracticable to comply with the statutory requirements and that do not contain any nutrition information. According to the House Committee Report (Ref. 16):

* * * In order to qualify for the exemption, the Secretary must find that the information on the label would be difficult to read, while leaving a reasonable amount of room for the name of the product and other information that is required by law to be on the label. * * *

FDA had attempted to exempt very small packages by proposing an exemption in § 101.9(h)(11) for small individually packaged "bite-size" pieces of food. The agency has been made aware of the confusion over the term "bite size" through the number of requests it has received to define it. Therefore, in response to the 1990 amendments and to the requests for clarification that it has received, FDA is revising proposed § 101.9(h)(11), which is redesignated as § 101.9(j)(11) in this document, to specify a standard for a package that is sufficiently small to be exempt from nutrition labeling. To promote consistency within its food labeling regulations, the package size that the agency is proposing as its standard is the same package size that it uses as the standard in § 101.2(c)(3)(i) for exempting small packages of foods from type size requirements, namely that the "package is designed such that it has a total surface area available to bear labeling of less than 12 square inches." Thus, under this proposal, foods sold in packages of this size or smaller will not be required to bear nutrition labeling on their label unless, as provided in section 403(q)(5)(B) of the act, nutrition information (e.g., nutrition claims) is presented on the label.

By focusing on the size of the label, FDA is complying with the direction from the House Committee on Energy

and Commerce (Ref. 16, p. 16) that the agency not permit manufacturers to avoid section 403(q) of the act by increasing the size of the name and other legally required information so that insufficient space is left for nutrition information. Because the size of the label is the deciding factor in determining eligibility for the exemption, the manufacturer is left with the responsibility for determining how the required information is to be fit into the available label space if that space is of the requisite size.

FDA believes, however, that nutrition information about the food in very small packages can still be provided to consumers through alternative means. Section 403(q)(5)(B) of the act states only that the nutrition labeling requirements shall not apply to the label of the food. It says nothing about the labeling. The absence of clear statutory direction for labeling exemptions for these packages gives the agency discretion to decide whether labeling should also be exempted. Under these circumstances, FDA believes that it should only provide an exemption for this labeling if compliance with nutrition labeling requirements is impracticable. FDA knows of no reason why firms could not provide nutrition information on placards or through display of the label for the container in which the small packages are shipped (e.g., the label of a box containing "penny candy"). Therefore, the agency is proposing in § 101.9(j)(11) to require that nutrition information that would otherwise be required on the label be displayed clearly at the point of purchase according to § 101.9(a)(2) for food not in packaged form.

The agency believes that relatively few food packages will qualify as "small" under the proposed exemption. FDA has reviewed information from the agency's 1982 Food Labeling and Packaging Survey (FLAPS) and found that, for the foods in the survey, the proposed exemption for packages with less than 12 square inches of total surface area available for labels would primarily exempt candy rolls, breath sweeteners, and a few very small individual-serving size canned foods (Ref. 19). However, because FLAPS did not consider every brand of food in the marketplace, additional foods may be included.

E. Medical Foods

Section 403(q)(5)(A)(iv) of the act exempts medical foods from the nutrition labeling requirements. This section defines a "medical food" by incorporating by reference the definition in section 5(b) of the Orphan Drug Act

(21 U.S.C. 360ee(b)(3)). Medical foods are currently exempted from the nutrition labeling regulations in § 101.9(h)(4), which was redesignated as § 101.9(h)(7) in the mandatory nutrition labeling proposal.

FDA is amending proposed § 101.9(h)(7) (and redesignating it as § 101.9(j)(7)) to reflect the wording of the explicit exemption of medical foods in the act and to incorporate the statutory definition of "medical food" into the nutrition labeling regulations. That definition is:

The term *medical food* means 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.

The agency advises that it considers the statutory definition of medical foods to narrowly constrain the types of products that can be considered to fall within this exemption.

For the efficient enforcement of the act, under section 701(a), FDA is proposing to clarify this definition by providing criteria in § 101.9(j)(7) for use in identifying a medical food. These criteria are based on the agency's expertise on medical foods and on a survey of the literature on this subject.

Medical foods are distinguished from the broader category of foods for special dietary use and from foods that make health claims (e.g., fiber in relation to cancer) by the requirement that medical foods be used under medical supervision. In general, to be considered a medical food, a product must, at a minimum, meet the following criteria: The product must be a food for oral or tube feeding; the product must be labeled for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and the product must be intended to be used under medical supervision (Ref. 20).

The term "medical foods" does not pertain to all foods fed to sick patients. Medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in its natural state) for the patient who is seriously ill or who requires the product as a major treatment modality. Typical medical foods are enteral nutrition products. Enteral nutrition is defined as nutrition provided through the gastrointestinal tract, taken by mouth, or provided through a tube or catheter that delivers nutrients beyond the oral cavity (i.e., directly to the stomach) (Ref. 21).

Medical foods may require special quality control procedures, adequate and appropriate directions for use, and substantiation of labeling claims (Ref. 22). They are generally not available on the retail shelf.

Medical foods are intended for the partial or exclusive dietary management of patients under medical supervision who, because of specific therapeutic or chronic medical needs, have limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who have other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone (Ref. 22). Medical foods are intended for the dietary management of such patients by providing nutrition specifically modified to include as many nutrients as necessary while minimizing adverse signs and symptoms that might result from the provision of other nutrients that are not ingested, digested, absorbed, or metabolized normally by the patient (Ref. 22).

The statute requires that a medical food be consumed or administered enterally under the supervision of a physician. *Under the supervision of a physician* means that the intended use of a medical food is for the dietary management of a patient receiving active and ongoing medical supervision (e.g., in a health care facility or as an outpatient). The physician determines that the medical food is necessary to the patient's overall medical care. The patient sees the physician on a recurring basis for, among other things, instructions on the use of the medical food.

Medical foods are not foods that are simply recommended by a physician or other health care professional as part of an overall diet designed to reduce the risk of a disease or medical condition or as weight loss products. Moreover, medical foods are not dietary supplements for the general population that can be openly purchased from retail shelves or by mail order, although it is true that dietary supplements may be recommended by a physician for a specific condition or disease. The intended use and degree of medical oversight for these latter products is not sufficient to qualify them as medical foods, and such products will continue to be regulated as foods for special dietary use.

Single ingredient nutrient products that are promoted for the treatment of specific disease states will continue to be regulated under existing drug law

(e.g., zinc sulfate for the treatment of acrodermatitis enteropathica), as will all injectable nutrient formulations (Ref. 20). Parenteral nutrients also are drugs and not medical foods. By definition, medical foods are consumed or administered enterally (21 U.S.C. 360ee(b)(3)).

FDA's traditional policy has been to regulate medical foods as foods for special dietary use. However, in light of the existing definition of foods for special dietary use and the definition of medical food that has been enacted by Congress (see 21 U.S.C. 350(c) and 360ee(b)(3)), FDA is reevaluating its policy. FDA intends to address the issue of medical foods at length in a future Federal Register document.

Section 101.9(h)(7), as proposed in the mandatory nutrition labeling proposal, contained the phrase, " * * * except that such products shall be labeled in compliance with part 105 of this chapter" (55 FR 29487 at 29516). FDA recognizes that there are currently no regulations in 21 CFR part 105 or elsewhere in the CFR that specify labeling requirements for medical foods. To avoid confusion to readers of this proposal, the agency is deleting this phrase until at least such time as labeling regulations are developed for these foods. However, FDA believes 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. Therefore, the agency intends to develop regulations covering these aspects of medical foods in the near future.

F. Infant Formula

Section 403(q)(5)(A)(iii) of the act specifically exempts infant formula from the nutrition labeling requirements. In its mandatory nutrition labeling proposal (55 FR at 29505), the agency proposed to exempt infant formula from nutrition labeling because it is already subject to special labeling requirements which are set out in 21 CFR part 107. (See proposed § 101.9(h)(4).)

FDA is now proposing § 101.9(j)(6) to incorporate the statutory exemption for infant formula into its regulations. Further, the agency is proposing to add the phrase, "except that such foods shall be labeled in compliance with part 107 of this chapter," to direct the reader to the location of the appropriate regulations for the labeling of infant formula.

G. Foods Represented for Use as the Sole Item of the Diet

Foods represented for use as the sole item of the diet currently are exempted from the nutrition labeling regulation by § 101.9(h)(3) [redesignated in the mandatory nutrition labeling proposal as § 101.9(h)(6)] with the proviso that "such foods shall be labeled in compliance with part 105 of title 21, Chapter 1, Code of Federal Regulations." Section 403(q)(5) of the act does not provide a specific exemption for foods represented for use as the sole item of the diet. Further, the agency recognizes that there are no regulations in 21 CFR part 105 at this time that explicitly deal with the labeling of such foods. Therefore, FDA has reconsidered the proposed exemption.

The agency is not aware of any reason why foods that are neither medical foods nor infant formula, but that are represented as the sole item of the diet (e.g., formulated weight loss products), should not be labeled with at least the amount of nutrition-related information that is now being proposed for traditional foods in the general food supply. Accordingly, FDA is deleting the exemption for foods represented for use as the sole item of the diet from its proposed regulations. After the current round of rulemaking to implement the 1990 amendments to the act, FDA will consider whether there should be additional or different requirements for the nutrition labeling of these products. The exemption can then be established if regulations are developed to deal specifically with these foods.

H. Foods Shipped in Bulk Form

Section 403(q)(5)(A)(v) of the act exempts food described in section 405(2) of the act from nutrition labeling. Section 405(2) of the act exempts from any labeling requirement food that is to be processed, labeled, or repacked at a site other than that where it was originally processed or packed. Such food is currently exempted by § 101.9(h)(8), redesignated in this supplementary proposal as § 101.9(j)(8). The redesignated § 101.9(j)(8) has been revised to more closely reflect the statutory language of section 405(2) of the act.

I. Raw Agricultural Commodities and Raw Fish

Section 403(q)(4) of the act provides for the dissemination of nutrition information for raw fruit, vegetables, and fish to consumers at retail locations. The act provides that by November 8, 1991, FDA is to issue:

(1) Voluntary guidelines that advise food retailers on how to provide the nutrition information specified in the statute to consumers;

(2) Regulations that identify the 20 varieties of most frequently consumed raw vegetables, fruit, and fish to which the guidelines will apply; and

(3) Regulations that define the circumstances that constitute substantial compliance by retailers with the guidelines.

After issuing these guidelines and regulations, the agency is to survey retailers of raw produce and fish, and by May 8, 1993, it is to issue a report on actions taken by food retailers to provide consumers with nutrition information under the voluntary guidelines. If the agency finds that food retailers are in substantial compliance with the guidelines, it need not take any further action for 2 years, at which time, it is to conduct a new survey. This cycle will repeat every 2 years. If, however, the agency finds that there is not substantial compliance with the guidelines, it is directed to issue proposed regulations that mandate nutrition labeling on the top 20 varieties of raw fruit, vegetables, and fish.

FDA is taking steps to implement this section of the 1990 amendments. First, the agency is withdrawing the exemption that it proposed (§ 101.9(h)(10) (55 FR 29516)) for fresh fruit and vegetables in containers of not more than 1 dry quart. FDA proposed to exempt these containers because of the statutory exemption for fresh produce in small containers in section 405(1) of the act. The 1990 amendments, however, provide that this exemption does not apply to nutrition labeling and health claims (section 5 of the 1990 amendments).

Secondly, consistent with section 403(q)(4)(A) of the act, FDA is proposing in § 101.9(j)(10) to exempt raw fruits and vegetables and raw fish from the nutrition labeling regulations. FDA will propose to remove this exemption if, and when, the agency finds that there is not substantial compliance with the voluntary guidelines. In exempting raw fish, FDA interprets the exemption of the 1990 amendments to apply to unpackaged raw fish and to fish packaged by the retailer for immediate sale, not to products such as frozen fish fillets or canned oysters that are packaged by the manufacturer or packer for direct sale to the consumer. Because these products have been processed in some way and not simply iced, they cannot be considered to be raw for purposes of section 403(q)(4)(B)(i)(II) of the act. Fish products such as frozen

fillets and canned oysters are required to bear nutrition labeling under the act.

Thirdly, FDA published in the *Federal Register* (56 FR 30468, July 2, 1991) proposed voluntary guidelines for labeling raw produce and fish; a proposed regulation that defines the applicability of the guidelines by listing the 20 most frequently consumed varieties of raw fruits, vegetables, and fish; and a proposed regulation that defines "substantial compliance" with the voluntary guidelines. This action is being followed by publication elsewhere in this issue of the *Federal Register* of the guidelines and final regulations. In addition, FDA is planning for the biennial survey of food retailers.

J. Foods Sold From Bulk Containers

Section 403(q)(3) of the 1990 amendments states: "For food that is received in bulk containers at a retail establishment, the Secretary may, by regulation, provide that the nutrition information required by subparagraphs (1) and (2) be displayed at the location in the retail establishment at which the food is offered for sale." Congress intended that this section cover foods received in, and sold from, bulk containers where the consumer selects and packages the food (Ref. 16).

In its mandatory nutrition labeling proposal, the agency stated its intention that foods sold from bulk containers be nutritionally labeled:

* * * 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 proposes to require nutrition information for such foods. (55 FR 29505)

The agency continues to believe that 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) for ingredient labeling of bulk foods. This position is supported by the legislative history (Ref. 16) that points to the impracticality of requiring nutrition labeling to be printed on the bags that the consumer would put the food into for purchase.

To prevent any confusion or misunderstanding on this issue, FDA is proposing to add an exemption, § 101.9(j)(14), for foods sold from bulk containers at a retail establishment provided that the nutrition labeling be displayed prominently and conspicuously at the point of purchase.

VI. Other Nutrition Labeling Provisions

A. Corrections

The agency is proposing to make a few nonsubstantive changes to its mandatory nutrition labeling proposal to make the following corrections:

(1) In its mandatory nutrition labeling proposal, the agency inadvertently omitted a sentence in proposed § 101.9(c)(4)(ii) that specifies how the amount of unsaturated fat is to be expressed on the nutrition label. FDA has corrected this omission by adding a sentence that states that unsaturated fat is to be declared in grams, to the nearest gram, with exceptions noted if the amount present is less than 1 g.

(2) In proposed § 101.9(c)(6), the agency redefined carbohydrate to exclude dietary fiber. The result of this proposed change is that the definition of a carbohydrate would no longer include those components that were traditionally considered part of carbohydrates but that are not digested and, therefore, do not contribute calories to the diet. However, the agency overlooked that a parallel change was needed in § 101.9(c)(3) to delete the direction to subtract dietary fiber from carbohydrate when determining the number of calories by the general Atwater factors of 4, 4, and 9 calories per gram for protein, carbohydrate, and fat, respectively. To correct this oversight, FDA is proposing to amend § 101.9(c)(3) to no longer require the subtraction of dietary fiber from carbohydrate since this correction has already been made in defining carbohydrate content. The agency also is proposing in § 101.9(c)(6) to add a more complete description of the method to be used in calculating total carbohydrate by subtracting the sum of crude protein, total fat, dietary fiber, moisture, and ash from the total weight of the product.

(3) In the mandatory nutrition labeling proposal, the paragraphs pertaining to dietary fiber (§ 101.9(c)(6)(iii) through (c)(6)(iii)(B)) were placed within the larger section pertaining to carbohydrates (§ 101.9(c)(6)). Because FDA is defining total carbohydrate to exclude dietary fiber, the agency believes that there will be less confusion if the paragraphs relating to dietary fiber are redesignated as § 101.9(c)(7). Therefore, the agency is proposing this redesignation and, consequently, the redesignation of the remaining paragraphs within § 101.9(c).

(4) The last sentence in proposed § 101.9(c)(10)(ii) in the mandatory nutrition labeling proposal is repeated in the last sentence in proposed § 101.9(c)(10)(iii). FDA is proposing to

eliminate this unnecessary repetition by deleting the sentence from the paragraph now redesignated as § 101.9(c)(11)(iii).

(5) In § 101.9(c)(11)(i) which was published as part of the RDI/DRV proposal, the agency referred to the reference caloric intake of 2,350 calories as the " * * * population-adjusted mean of the recommended caloric intake (i.e., 2,350 calories)." While this statement correctly refers to the NAS's recommended caloric intakes (Ref. 24), some persons were confused, interpreting the statement to mean that FDA was recommending a caloric intake of 2,350 calories. To prevent this erroneous interpretation, FDA is proposing to amend § 101.9(c)(11)(i), now redesignated as § 101.9(c)(12)(i), to state " * * * a reference caloric intake of 2,350 calories * * *"

(6) To be consistent with the manner in which percent RDI's are reported in nutrition labeling, the agency is proposing to include a requirement in § 101.9(c)(12) that when a nutrition profile is given, the percent DRV's be 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. The mandatory nutrition labeling proposal did not specify this manner of declaring amounts.

(7) In the RDI/DRV proposal, the agency proposed DRV's for total fat (75 g) and carbohydrates (325 g) based on a reference caloric intake of 2,350 calories. The agency did not propose a DRV for protein, but it did propose an RDI value of 50 g for protein for adults and children 4 or more years of age. The agency recognizes that clarification may be necessary concerning these values because the caloric value of the DRV's for total fat (675 calories) and total carbohydrates (1,300 calories) when coupled with the caloric value of the RDI for protein (200 calories) do not sum to the reference caloric intake of 2,350 calories.

The dietary recommendations that serve as the basis for the DRV's for total fat and carbohydrate (i.e., 30 percent and 55 percent of calories, respectively (Ref. 3)) result in the assumption that protein intake will furnish the remaining calorie requirements, i.e., protein will comprise approximately 15 percent of calories. The assumption is made by persons developing dietary guidance materials that protein will be used not only to meet protein requirements but also to meet some of the caloric needs. This level of protein intake (15 percent

of calories) is consistent with current U.S. dietary consumption patterns and is not considered to be a level of intake inconsistent with good health (Ref. 3). The RDI for protein, on the other hand, is based on the human requirement for protein and reflects the levels of high quality protein needed to maintain body stores and to support growth and development. Therefore, the RDI for protein does not provide the same level of caloric value as the level of protein intake that is incorporated into dietary pattern recommendations. To clarify this issue, FDA is proposing to add a note to the DRV listing in § 101.9(c)(11)(i), redesignated as § 101.9(c)(12)(i) in this proposal, to state that the caloric contribution of protein is assumed to be approximately 15 percent.

(8) FDA is proposing to amend the regulations by removing current § 101.9(c)(7)(v) (proposed § 101.9(c)(11)(iv) (55 FR 29515)). This section allowed for general claims of significance and nutritional superiority. However, the 1990 amendments suggest a somewhat different approach. Section 403(r)(2)(A)(i) of the act only allows such claims if they use terms defined in regulations, and under section 3(b)(1)(A)(iii) (V) and (VI) of the 1990 amendments, "less" and "high" are among the terms that FDA must define. In light of these facts, FDA will define and provide for the proper use of such terms in a separate Federal Register document on nutrient content claims.

(9) FDA proposed changes in current § 101.9 (e)(5) and (e)(6) in its mandatory nutrition labeling proposal to specify the food components that it expects will vary by less than 20 percent from the labeled value, and to specify where reasonable excesses or deficiencies would be allowed in nutrition labeling. To complete this activity, the agency should also have proposed changes in current § 101.9(e)(4) so that the nutrients and food components specified in that paragraph are the same as those for which reasonable excesses are allowed in § 101.9(e)(6). Paragraphs (e)(4) through (e)(6) would then identify the upper and lower boundaries for all nutrients and food components declared in nutrition labeling. Accordingly, FDA is proposing to add total carbohydrate, complex carbohydrate, unsaturated fat, and potassium to § 101.9(e)(4), (e)(4)(i), and (e)(4)(ii), which are redesignated as § 101.9(g)(4), (g)(4)(i), and (g)(4)(ii) in this proposal, to specify the amount of variability allowed. Likewise, total carbohydrate was inadvertently left out of § 101.9(e)(6), and the agency is now proposing to insert it in that paragraph,

redesignated as § 101.9(g)(6) in this proposal.

(10) The agency failed to explain its rationale in the mandatory nutrition labeling proposal for rearranging the order of some food components within the nutrition label and to specifically request comment on that order. The rationale was based on comments that FDA had received over time that many consumers were finding it difficult to pick out information on fats in the current nutrition label. The agency determined that there was a potential benefit in ordering the information, at least in part, according to its public health significance. To accomplish this goal, FDA proposed in its mandatory nutrition labeling proposal to rearrange the order of the three sources of energy (i.e., fat, carbohydrate, and protein) in § 101.9(c) to state fat first, followed by carbohydrates and protein. This ordering was selected to support the position of the Department of Health and Human Services, as stated in the forward to the Surgeon General's Report on Nutrition and Health, that "Of highest priority among the (dietary) changes (that can improve the health prospects of many Americans) is to reduce intake of foods high in fats and to increase intake of foods high in complex carbohydrates and fiber" (Ref. 2, p. v.). Subelements of fat and carbohydrates are proposed to be listed immediately under the declaration of each element. Comments are requested on this proposed arrangement.

B. Increments

In addition to the above corrections, FDA is proposing to change the increments for declaring fats and fatty acids. The agency is proposing in § 101.9(c)(4), (c)(4)(i), (c)(4)(ii), (c)(4)(ii)(A), and (c)(4)(ii)(B) to require declaration of total fat, saturated fat, unsaturated fat, polyunsaturated fat, and monounsaturated fat, respectively, in ½ g increments. The agency is proposing this change to increase the consistency between the probable quantitative declaration of a food component and its level of significance. For example, sodium, which has a DRV of 2,400 mg, may be reported to the nearest 10-mg increment when the serving contains more than 140 mg of sodium. This reporting represents a ratio of the increment to the DRV of 10/2400, which is equivalent to 0.4 percent (hereafter the ratio will be reported parenthetically following the percent equivalent). This ratio is similar to that for carbohydrates, which are to be declared to the nearest g and for which the ratio of the increment to the DRV of 325 g is 0.3 percent (1/325). These values

differ significantly from the comparable ratios for total fat and fatty acids, which are to be reported to the nearest g. The ratio for total fat with a DRV of 75 g is 1 percent (1/75); for saturated fat with a DRV of 25 g, 4 percent (1/25); and for unsaturated fat with a DRV of 50 g, 2 percent (1/50). DRV s were not proposed for polyunsaturates or monounsaturates, therefore similar calculations cannot be made for them. The ratio of the increment to the DRV for cholesterol (300 mg) is 2 percent (5/300) and of the increment to the RDI for protein (50 g for adults and children over 4 years of age) is 2 percent (1/50).

In reviewing all of these ratios, the ratio for saturated fat is clearly the highest. Requiring ½ g increments for all fatty acids lowers the ratio to 2 percent for saturated fat (0.5/25) and to 1 percent for unsaturated fat (0.5/50). A similar change for total fat that would allow all fat entries to be rounded to the same increment lowers the ratio to 0.7 percent (0.5/75). These ratios are more comparable to those for sodium, carbohydrate, cholesterol, and protein.

The agency believes the proposed change to allow declaration of fat and fatty acids in ½ g increments will provide consumers with more precise information and a greater ability to discriminate among products. It will also make calculation of the number of calories from fat more consistent with the declared amount of fat, because calories are to be reported to the nearest 5-calorie increment up to and including 50 calories. The disadvantages are that, because of natural variability in fat content in some foods, the 0.5 g increment will convey to the consumer a degree of precision that may not be supported by the analytical measurements and thus the degree of reliability of the value for some foods may be decreased. Moreover, where the food matrix complicates fat extraction, the cost of analysis will be higher. The agency therefore requests comment on this proposed change, and whether it would be preferable to maintain 1 g increments for declaring fat and fatty acids.

A similar argument can be made for requiring that dietary fiber (with a ratio of the increment to the DRV of 25 g of 4 percent (1/25)) be declared to the nearest 1/2 g. However, the precision of the analytical methodology for determining quantitative amounts of fiber does not allow for that degree of accuracy. Therefore, FDA is not proposing to change the current procedure of declaring amounts of dietary fiber to the nearest g.

VII. Labeling of Dietary Supplements of Vitamins and Minerals

A. History

The agency has a long history relating to the labeling of dietary supplements. In the *Federal Register* of November 22, 1941 (6 FR 5921), FDA promulgated regulations on food for special dietary uses under 403(j) of the act, which states that a food shall be deemed to be misbranded:

*** if it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

In the *Federal Register* of August 2, 1973 (38 FR 20708 and 20730), FDA adopted new regulations to govern the labeling and composition of dietary supplements and other foods that purport or are represented to be for special dietary use because of vitamin or mineral properties (the 1973 regulations). These regulations were codified in §§ 80.1, 125.1, 125.2, and 125.3 (21 CFR 80.1, 125.1, 125.2, 125.3). They were recodified as §§ 105.3, 105.60, 105.77 and 105.85 (21 CFR 105.3, 105.60, 105.77, and 105.85) as part of the general agency reorganization and republication of its regulations in 1977 (42 FR 14302 at 14328 and 14331, March 15, 1977).

The 1973 regulations set forth definitions, standards of identity, and labeling statements for vitamin and mineral dietary supplements. The standards permitted only five basic types of preparations (a multivitamin supplement, a multiminerals supplement, a multivitamin supplement with iron, and a supplement consisting of any single vitamin or mineral); prescribed the vitamin, mineral, and other ingredient composition of multinutrient supplements; and specified maximum and minimum potencies for vitamins and mineral ingredients. These potencies were stated in terms of U.S. RDA's which were derived by FDA from the recommended dietary allowances (RDA's) established by the Food and Nutrition Board of the NAS in 1968 (Ref. 24). In general, the minimum potency for a nutrient in a dietary supplement was established at 50 percent of the U.S. RDA for the nutrient, the maximum potency at 150 percent of the U.S. RDA.

Fifteen petitions for review of this rulemaking were filed in various United States courts of appeals and eventually consolidated in the United States Court of Appeals for the Second Circuit. After extensive briefing and oral argument, the Court on August 15, 1974, held that it

was "broadly sustaining the regulations," but it remanded them to the agency for certain further actions (*National Nutritional Foods Association v. Food and Drug Administration*, 504 F.2d 761, 786 (2d Cir. 1974)).

A petition for certiorari, asking the U.S. Supreme Court to review the decision by the U.S. Court of Appeals for the Second Circuit, was filed, but on February 24, 1975, it was denied (420 U.S. 946). Thereafter, FDA began the process of implementing the remand instructions of the U.S. Court of Appeals. On May 28, 1975, FDA published a preliminary notice in the *Federal Register* (40 FR 23244) (the 1975 proposal) inviting applications for additional formulations of dietary supplements as the court had directed, proposing certain other revisions in the regulations consistent with the court's opinion, and announcing the reopening of the administrative hearing on which the regulations were based.

While FDA was in the process of completing the hearing and revising the vitamin and mineral regulations pursuant to the instructions of the U.S. Court of Appeals, Congress enacted legislation (Pub. L. 94-278, title V, April 22, 1976) that became section 411 of the act (known as "the Proxmire Amendment"). This amendment restricted the agency's authority to limit both the maximum potency of vitamins and minerals in dietary supplements and the ingredient composition of multinutrient supplements that are offered for use by adults (other than pregnant or lactating women). Dietary supplements represented for use by pregnant or lactating women, by children under the age of 12, or by individuals in the treatment or management of specific diseases or disorders were excluded from the Proxmire Amendment (i.e., the agency retained authority to limit the maximum potency and ingredient composition of these products).

The agency issued a final regulation in the *Federal Register* of October 19, 1978 (41 FR 46156), that amended the 1973 regulations to comply with the court's 1974 remand instructions and with the Proxmire Amendment. The agency received petitions to reconsider the propriety of issuing a final rule without having first issued a proposed rule. FDA denied these petitions on the ground that a proposed rule was unnecessary because the rule merely "recognized the will of Congress."

The petitioners appealed to the U.S. Court of Appeals for the Second Circuit, and the appeals were consolidated. On February 16, 1978, the Second Circuit vacated the regulations and remanded

them to the agency for further proceedings (*National Nutritional Foods Association v. Kennedy*, 572 F.2d 377 (2d Cir. 1978)). The court made clear that the agency had to issue proposed regulations, and that the issue for comment was whether the proposed regulations were "suitable in light of what Congress had done." In the *Federal Register* of March 16, 1979 (44 FR 16005), FDA revoked the 1976 regulations and reinstated portions of the 1973 regulations. The agency has not taken any further action on the 1976 regulations.

B. Legal Authority

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 subparagraphs (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."

Currently, dietary supplements, including dietary supplements of vitamins and minerals to which section 411 of the act applies (except for dietary supplements in conventional food form, e.g., breakfast cereals), are exempt from the nutrition labeling regulations (21 CFR 101.9(h)(2)). FDA carried this exemption forward in the mandatory nutrition labeling proposal, redesignated as § 101.9(h)(5) (55 FR 29487 at 29516).

To now comply with the new section 403(q)(5)(E) of the act, the agency is proposing to amend § 101.9(h)(2), now redesignated as § 101.9(j)(5), to provide that dietary supplements of vitamins and minerals (except those in conventional food form) bear appropriate nutrition labeling. FDA is also proposing a new section, § 101.36 entitled "Nutrition labeling of dietary supplements of vitamins and minerals," under Part 101—Food Labeling, Subpart C—Specific Nutrition Labeling Requirements and Guidelines, to establish nutrition labeling regulations that the agency believes are appropriate for dietary supplements of vitamins and minerals.

In accordance with section 403(q)(5)(E) of the act, § 101.36(a) proposes that vitamin and mineral supplements provide nutrition labeling. Vitamin and mineral supplements that do not contain any of the 15 nutrients required to be in nutrition labeling are not required by section 403(q)(5)(E) of the act to bear nutrition labeling. However, the agency believes that these

supplements are required to bear nutrition labeling under section 403(g)(5)(C) of the act. This section provides that nutrition labeling is not required when a food contains insignificant amounts of all of the nutrients required to be listed in nutrition labeling unless a claim is made with respect to the nutritional value of the food. Thus, when such a claim is made, nutrition labeling is required. With respect to dietary supplements of vitamins and minerals, the agency believes that a statement of identity, such as "Vitamin E," on the label of a product is a claim about the nutritional value of the food. Therefore, such products must bear nutrition labeling under the act.

However, the agency is providing in § 101.9(j)(5) that such supplements are to be labeled in accordance with proposed § 101.36. Although the 1990 amendments are silent with respect to whether these products should bear nutrition labeling specific for dietary supplements or for conventional foods, because these products are more similar to those regulated under section 411 of the act than to conventional foods, the agency tentatively finds that it is appropriate that they bear nutrition labeling specific for dietary supplements in accordance with proposed § 101.36. The agency requests comments on this issue.

Under § 101.9(a)(4), dietary supplements to which vitamins and minerals have been added, and that contain 50 percent or more of the RDI of any one of the added vitamins or minerals, are foods for special dietary use to which section 403(j) of the act applies. Therefore, to the extent that the regulations that FDA is proposing apply to foods for special dietary use, FDA is proposing these regulations under section 403(j) of the act as well as section 403(q) of the act.

FDA is not proposing a specific exception for dietary supplements that do not contain vitamins or minerals. Under this proposal, these products are subject to the general provisions set forth in § 101.9(a).

The agency emphasizes that § 101.36 pertains only to the nutrition labeling of dietary supplements of vitamins and minerals. This section does not authorize the use of any particular vitamins or minerals as components of vitamin and mineral supplements. The use of vitamins and minerals in food must be in accordance with the appropriate regulations (i.e., food additive, generally recognized as safe, or prior-sanctioned food ingredient regulations). Dietary supplements of selenium, fluoride, and chromium, for example, are not permitted.

C. Provisions of Proposed Section 101.36

To reduce consumer confusion, the agency is proposing that nutrition labeling of vitamin and mineral supplements appear as similar as possible to the nutrition labeling of other foods.

The agency is proposing in § 101.36(b) to require that the overall heading of the nutrition label be "NUTRITION INFORMATION" rather than "NUTRITION INFORMATION PER SERVING." The agency is not proposing that the term "per serving" be used in the heading for vitamin and mineral supplements because the information presented may be declared per day as well as per unit (or serving). The agency prefers the use of the term "unit" rather than "serving" for supplements because the word "serving" is customarily used to describe conventional foods.

The agency is proposing in § 101.36(b)(1) that the listing of "Units per day" be required for supplements in place of "Serving (portion) size" as required in § 101.9(c)(1) because more than one unit of a supplement is often consumed per day, and it is important that the amount recommended by the manufacturer for consumption over the period of 1 day be clearly stated. Proposed § 101.36(b)(1) allows for the use of terms such as "tablets," "capsules," or "teaspoonsful," to be used in lieu of "units" throughout the nutrition label depending on whether the product is in tablet, capsule, or liquid form (e.g., the nutrition label on a bottle of vitamin tablets could state "Tablets per day"). The agency believes that use of the more precise terms will aid consumer understanding. The quantity specified must be reasonable and suitable for daily dietary consumption and consistent with any intake recommendations on the label or in labeling.

The agency is proposing in § 101.36(b)(2) to require the listing of "Units per container" in lieu of "Servings (portions) per container" as required in § 101.9(c)(2) for conventional foods. Again, the word "units" could be replaced with the appropriate term for the type of product.

The agency is proposing in § 101.36(b)(3) that only those nutrients or food components listed in § 101.9(c) that are present in more than insignificant amounts must be declared in the nutrition label of vitamin and mineral supplements. FDA is not proposing to require that the label of such supplements follow the simplified format described in proposed § 101.9(f) for conventional foods. Conventional foods that contain insignificant amounts

of 8 or more of the 15 nutrients and food components required under proposed § 101.9(c) are required to declare 5 elements (i.e., calories, total fat, total carbohydrate, protein, and sodium) even when the amounts declared are zero (proposed § 101.9(f)(3)(i)). However, because vitamin and mineral supplements that are not in conventional food form generally do not contain the five food components required in the simplified format, FDA believes that it would not be confusing or misleading to consumers to omit the required declaration of these elements when they are absent or present in insignificant amounts. Therefore, FDA tentatively concludes it is not necessary to require that these elements be declared on such supplements when they are present in insignificant amounts.

Similarly, proposed § 101.9(f)(4) would require that when amounts of nutrients and food components other than the 15 required nutrients are declared in the simplified nutrition label on conventional foods, the statement "Not a significant source of _____" be included at the bottom of the nutrition label with the blank filled in by whichever of the following are present in insignificant amounts: Calories from total fat, saturated fat, cholesterol, complex carbohydrate, sugars, dietary fiber, vitamin A, vitamin C, calcium, and iron. FDA is not aware of any consumer expectations that these nutrients or food components are present in vitamin or mineral supplements if they are not, in fact, declared on the label. Therefore, the agency does not believe a statement declaring that these components are not present in the supplements in significant amounts is needed. Such a statement could even be confusing to consumers. FDA therefore is not proposing that vitamin and mineral supplements need to include the statement "Not a significant source of _____" as required by proposed § 101.9(f)(4).

FDA believes that what is needed for full consumer understanding of the content of dietary supplements of vitamins and minerals is full declaration of any of the 15 required nutrients as well as any additional vitamins and minerals for which RDI's are proposed that are present in more than insignificant amounts. Accordingly, FDA is proposing in § 101.36(b)(3) that the quantitative amounts of all nutrients and food components that must be included in nutrition labeling in accordance with § 101.9(c) be declared in addition to the percent of the RDI. The agency points out that § 101.9(c)(7)(iii) (redesignated here as

§ 101.9(c)(11)(ii) requires the declaration within nutrition labeling of all vitamins and minerals that have been added as a nutrient supplement or that are the subject of a claim. Most dietary supplements currently include information on both the quantitative amounts and the percent of the U.S. RDA. The agency believes that continuation of this type of labeling will help to ensure that consumers are fully informed about the content of these products.

FDA also is proposing in § 101.36(b)(3) that the required nutrition information shall be presented in columns under the heading "PER UNIT." If more than one unit is specified for consumption per day, the information shall also be presented in a second set of columns under the heading "PER DAY." The agency is requiring that nutrition information should be declared by both the unit and daily amounts where label directions suggest consumption of more than one unit per day to more fully inform the consumer.

FDA is proposing in § 101.36(b)(3)(i) that nutrients and food components to be declared in nutrition labeling of vitamin and mineral supplements be listed in the order that the nutrients and food components are listed in nutrition labeling of conventional foods (i.e., as specified in § 101.9(c)) with the exception that calcium and iron shall be listed with the other minerals following the complete list of vitamins present.

Proposed § 101.36(b)(3)(ii) specifies the manner in which the quantitative nutrition information shall be presented. FDA is proposing that the information be given in a column under the heading of "Amount." In addition, the quantitative amounts should be expressed in the increments and units of measure (e.g., mg) specified in proposed § 101.9(c). Although the agency is not requiring that the quantitative amounts of vitamins and minerals be included in nutrition labeling of conventional foods, the agency believes that this additional information is useful on the labels of supplements because these products are represented and sold for their vitamin and mineral content. FDA is proposing that the quantitative amounts of vitamins and minerals should be declared to the nearest unit of measure of the same level of significance as that given in § 101.9(c)(11)(iv) for that nutrient. For example, 2.775 mg of thiamin would be declared as 2.8 mg, whereas 2.775 niacin equivalents (mg

NE) of niacin would be declared as 3 mg NE.

Proposed § 101.36(b)(3)(iii) would require that the percent of the RDI specified in § 101.9(c)(11)(iv) be declared for each vitamin and mineral present under the heading "Percent of Daily Value." In section III.C.2. above, the agency requested further comment on the appropriateness of the single term "daily value" on the label to represent both RDI's and DRV's. If the agency is persuaded by comments to specify a different term in § 101.9(c)(11) in the final regulations, the new terminology will also apply to proposed § 101.36(b)(3)(iii). FDA therefore requests comments on the use of the term "Daily Value" in the labeling of dietary supplements as well as conventional foods.

Proposed § 101.36(b)(3)(iii)(A) requires that, unless the supplement is represented or purported to be for adults and children 4 or more years of age, column headings must clearly specify the group for which the RDI values are being declared. This proposed requirement is consistent with the current practice of manufacturers of vitamin and mineral supplements and with regulations governing nutrition labeling of conventional foods. It is based on the reasonable assumption that a product is for use by the general population unless specified to the contrary.

Consistent with the manner in which percent RDI's are reported in nutrition labeling, FDA is proposing in § 101.36(b)(3)(iii)(B) that percent RDI's be 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.

The agency is proposing in § 101.36(b)(3)(iv) that vitamin and mineral supplements intended for use by more than one group for which RDI's have been proposed must list the percent daily value for each group. This proposed requirement is consistent with proposed § 101.9(c)(11)(i) which requires that foods represented or purported to be for use by more than one group for which RDI's exist, state the percent of daily values based on the RDI values for each group separately and in equal prominence.

As discussed previously, the agency has tentatively decided to require that DRV's listed in § 101.9(c)(11)(i) be

declared in nutrition labeling of conventional foods. If this requirement appears in the final rule for § 101.9, then dietary supplements of vitamins and minerals will also be required to present this information 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). The agency requests comments on the usefulness of this information on the nutrition labeling of dietary supplements of vitamins and minerals.

Consistent with nutrition labeling of conventional foods, FDA is proposing in § 101.36(b)(3)(v) to allow the use of synonyms for certain nutrients. The synonyms to be allowed are "folacin" for "folate," "ascorbic acid" for "vitamin C," and "energy" for "calories." The agency's position on synonyms is spelled out in the mandatory nutrition labeling proposal (55 FR 29487 at 29502).

FDA believes dietary supplements of vitamins and minerals should be subject to the same compliance policies as conventional processed foods and is therefore proposing in § 101.36(c) that compliance shall be determined in accordance with proposed § 101.9(g).

The following hypothetical sample labels illustrate proposed nutrition labeling of dietary supplements of vitamins and minerals:

DAILY VITAMINS PLUS IRON, MULTIPLE
VITAMINS PLUS IRON

Nutrition Information

Tablets per day 1 Tablets per container 365	Per unit	
	Amount	Per- cent of daily value
Calories	15
Total fat	1 g
Total carbohydrate	1 g
Sugars	1 g
Sodium	10 mg
Vitamin A	875 µg RE	100
Vitamin C	60 mg	100
Vitamin D	6.5 µg	100
Vitamin E	9 mg α-TE	100
Thiamin	1.2 mg	100
Riboflavin	1.4 mg	100
Niacin	16 mg NE	100
Folate	180 µg	100
Vitamin B ₁₂	2 µg	100
Pantothenic acid	5.5 mg	100
Iron	12 mg	100

B-VITAMINS—TAKE ONE WITH EACH MEAL

Nutrition Information

Tablets per day: 3
Tablets per container: 100

	Per unit		Per day	
	Amount	Percent of daily value	Amount	Percent of daily value
Calories.....	10.....		25 ¹	
Total Carbohydrate, g.....	2.....		6.....	
Sugars, g.....	2.....		6.....	
Sodium, mg.....	15.....		45.....	
Thiamin.....	0.4 mg.....	35	1.2 mg.....	100
Riboflavin.....	0.5 mg.....	35	1.4 mg ¹	100
Niacin.....	5 mg NE.....	35	16 mg NE ¹	100

¹ Values are not a straight multiplication due to rounding rules.

VIII. Other Actions

A. Effective Date

In its July 19, 1990 proposals, FDA proposed to make these regulations effective 1 year after the publication of a final rule. FDA requested comment on this deviation from the agency's normal practice of making food labeling regulations effective on the uniform compliance date that follows publication of the final rule. However, section 10(a)(1)(A) of the 1990 amendments requires that these regulations become effective 6 months after the date of promulgation of all final regulations required to implement section 403(q) of the act, or, if no final regulations have issued by November 8, 1992, this proposal, which incorporates the RDI/DRV and the mandatory nutrition labeling proposals of July 19, 1990, is statutorily mandated to be considered a final rule on November 8, 1992, with an effective date of May 8, 1993. FDA invites comments on this effective date taking into consideration the provisions of section 10 of the act.

FDA notes, however, that in section 10(a)(3)(B) of the 1990 amendments, Congress provides that if the Secretary of Health and Human Services (the Secretary), and by delegation FDA, finds that requiring compliance with section 403(q) of the act, on mandatory nutrition labeling, or with section 403(r)(2) of the act, on nutrient content claims, 6 months after publication of the final rules in the *Federal Register* would cause undue economic hardship, the Secretary may delay the application of these sections for no more than 1 year. In light of the agency's tentative findings in its regulatory impact analysis that compliance with the 1990 amendments by May 8, 1993, will cost \$1.5 billion, and that 6 month and 1 year extensions of that compliance date will result in savings that arguably outweigh the lost benefits, FDA believes that the question of whether it can and should provide for

an extension of the effective date of sections 403(q) and (r)(2) of the act is squarely raised.

FDA has carefully studied the language of section 10(a)(3)(B) of the 1990 amendments and sees a number of questions that need to be addressed. The first question is the meaning of "undue economic hardship." FDA recognizes that the costs of compliance with the new law are high, but those costs derive in large measure from the great number of labels and firms involved. The agency questions whether the costs reflected in the aggregate number represent "undue economic hardship." Therefore, FDA requests comments on how it should assess "undue economic hardship." Should it assess this question on a firm-by-firm basis, as was provided in the bill that passed the House Committee on Energy and Commerce (H. Rept. 101-538, 101st Cong., 2d sess., 24 (1990)), an industry-by-industry basis, or should it assess this question on an aggregate basis? If the agency should take the latter approach, comments should provide evidence that would permit the agency to make a determination that there is "undue economic hardship" for most companies. FDA also points out that assessing hardship on a firm-by-firm basis would likely be extremely burdensome because of the likely number of requests.

FDA will consider the question of the meaning and appropriate application of section 10(a)(3)(B) of the 1990 amendments as soon as possible after the comment period closes. The agency intends to publish a notice in advance of any final rule announcing how it will implement this section to assist firms in planning how they will comply with the act. The early publication of this notice is to assist firms in avoiding any unnecessary expenses that could be incurred by trying to comply with a

compliance date that may cause "undue economic hardship."

B. Consumer Education Program

Section 2(c) of the 1990 amendments directs the Secretary of the Department of Health and Human Services to carry out a consumer education program related to the nutrition label and its importance in maintaining healthy dietary practices. The agency discussed its intention to undertake such activities in its mandatory nutrition labeling proposal (55 FR 29487 at 29508). This program will require many varied activities, such as identification of key educational needs; target populations; appropriate educational strategies; educational messages; materials development; establishment of a food label education network to include representatives from health professionals and educators, consumers, and the food industry to assist in dissemination and implementation of educational materials and programs; and evaluation of the program's impact. FDA intends to begin to develop and implement these activities as quickly as possible, so that materials will be available to consumers as revised food labels begin appearing in the marketplace.

C. Preemption

In its July 19, 1990 proposal, FDA acknowledged the numerous comments that it received at the public hearings and as a result of its advance notice of proposed rulemaking (54 FR 32610, August 8, 1989) that suggested that Federal nutrition labeling rules should explicitly preempt any State nutrition labeling regulations. Because of the complexity of this issue, however, the agency requested additional comments on the appropriateness of preemption before deciding on a course of action.

Section 6 of the 1990 amendments settled the issue by amending the act to

include several provisions pertaining to Federal preemption of State and local labeling requirements. The 1990 amendments prohibit a State or a political subdivision of a State from establishing or continuing in effect any requirement for food in interstate commerce that would conflict with certain provisions of section 403 of the act. Specifically, section 403A(a)(4) of the act, which was added by the 1990 amendments, prohibits any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) of the act. The only exceptions provided in this section are for nutrition labeling of foods sold in restaurants, restaurant-type facilities, or ready-to-eat foods sold in retail establishments such as delicatessens that are exempt under section 403(q)(5)(A)(i) or (q)(5)(A)(ii) of the act from Federal nutrition labeling provisions (section 403A(a)(4) of the act).

Congress included the preemption provisions in the 1990 amendments because it recognized that it would be difficult or impossible for food companies to operate in interstate commerce if they were confronted with State and local requirements that were in conflict with, or were inconsistent with, the applicable Federal requirements (Ref. 25). However, Congress also recognized that Federal preemption should only apply in matters where a strong Federal regulatory system is in place (Ref. 25). Congress recognized a role for the States, permitting them to petition the Secretary for exemption from the preemption provisions in situations where a State requirement does not conflict with Federal law, does not burden interstate commerce, and addresses a need that is not met by the provisions of the act that have preemptive effect (section 403A(b) of the act).

The preemption provision concerning nutrition labeling of foods established under section 403(q) of the act becomes effective upon the effective date of the proposed regulations (section 10(b)(1)(D) of the 1990 amendments). Accordingly, the proposed revisions in § 101.9 that address nutrition labeling will preempt any State or local requirement to the contrary when these revisions become effective.

D. Redesignation

In the July 19, 1990 proposal, FDA did not republish existing § 101.9(i), which pertains to the circumstances in which labeling relating to the nutritional properties of a product can misbrand it. The agency had planned to revise this section as part of its rulemaking on health claims (see the Federal Register

of February 13, 1990 (55 FR 5176)). However, in light of the 1990 amendments, FDA believes that it is appropriate to retain this paragraph and to deal with health claims in a separate section of the regulations. However, FDA believes that § 101.9(k)(1) is so closely related to the health claims issue that it is appropriate to discuss that provision in the proposal on health claims. Consequently, FDA is retaining paragraph (i) and redesignating it as paragraph (k) to reflect the other provisions of this proposal. However, FDA is reserving § 101.9(k)(1) and repositing that provision in the companion document.

IX. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the \$100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the *Federal Register*. The agency requests comments on the RIA.

X. Environmental Impact

The agency has previously considered the environmental effect of this rule as announced in the July 19, 1990, mandatory nutrition labeling proposal (55 FR 29487). No new information or comments have been received, nor have there been any changes effected by the 1990 amendments, that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

XI. Comments

Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. to 4 p.m., Monday through Friday.

In accordance with section 2(b)(1) of the 1990 amendments, FDA must issue by November 8, 1992, final regulations for mandatory nutrition labeling. If the agency does not promulgate final

regulations by November 8, 1992, the 1990 amendments provide that the regulations proposed in this document shall be considered as the final regulations. The agency has determined that 90 days is the maximum time that it can provide for the submission of comments and still meet this statutory timeframe for the issuance of final regulations. Thus, the agency is advising that it will not consider any requests under 21 CFR 10.40(b) for extension of the comment period beyond February 25, 1992. The agency must limit the comment period to no more than 90 days to assure sufficient time to develop a final rule based on this proposal and the comments it receives.

XII. References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Committee on the Nutrition Components of Food Labeling, Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, "Nutrition Labeling, Issues and Directions for the 1990s," Washington, DC, National Academy Press, 1990.
2. U.S. Department of Health and Human Services, Public Health Service, "The Surgeon General's Report on Nutrition and Health," Washington, DC, DHHS (PHS) Publication No. 88-50210, U.S. Government Printing Office, 1988.
3. Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, National Research Council, "Diet and Health: Implications for Reducing Chronic Disease Risk," Washington, DC, National Academy Press, 1989.
- 3a. Letter to Senator Frank Lautenberg from Hugh C. Cannon, dated March 4, 1991.
4. U.S. Department of Agriculture and U.S. Department of Health and Human Services, "Nutrition and Your Health, Dietary Guidelines for Americans," Washington, DC, Home and Garden Bulletin No. 232, 3rd ed., U. S. Government Printing Office, 1990.
5. Minister of Supply and Services, Canada, "Departmental Consolidation of the Food and Drugs Act and of the Food and Drug Regulations with Amendments to May 3, 1990," Department of National Health and Welfare, Canada, 1991.
6. Joint Food and Agriculture Organization/World Health Organization Food Standards Program, "Codex Standards and Guidelines for the Labeling of Foods and Food Additives," Codex Alimentarius Commission, vol. VI, 2d ed., Rome, 1987.
7. Saccomandi, V., "Council Directive of 24 September 1990 on Nutrition Labeling for Foodstuffs," Council of the European Communities, Brussels, September 24, 1990.
8. Food and Agriculture Organization of the United Nations, "Protein Quality Evaluation, Report of a Joint FAO/WHO Expert Consultation," Food and Agriculture Organization of the United Nations, Rome,

and World Health Organization, Geneva, 1990.

9. Young, V. R., and P. L. Pellett, "Protein Evaluation, Amino Acid Scoring and the Food and Drug Administration Proposed Food Labeling Regulations," *Journal of Nutrition*, 121:145-150, 1991.

9a. Codex Alimentarius Commission, Report of the 18th Session, Geneva, 3-12 July 1989, Alinorm 89/40, Food and Agriculture Organization and World Health Organization, Rome, Italy, 1989.

10. Joint Food and Agriculture Organization/World Health Organization/United Nations University Expert Consultation, "Energy and Protein Requirements," Tech. Report Ser. No. 724, World Health Organization, Geneva, Switzerland, 1985.

10a. Codex Alimentarius Commission, Report of the 17th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, Bonn-Bad Godesberg, Germany, 18-22 February 1991, Alinorm 91/26, Food and Agriculture Organization and World Health Organization, Rome, Italy, 1991.

11. Market Facts, Inc., "Summary Report, FDA Nutrition Labeling Focus Groups," prepared under FDA Contract No. 223-89-2170, Washington, DC, Food and Drug Administration, U.S. Department of Health and Human Services, 1990.

12. Mensink, R. P., and M. B. Katan, "Effect of Dietary Trans Fatty Acids on High-Density and Low-Density Lipoprotein Cholesterol Levels in Healthy Subjects," *The New England Journal of Medicine*, 323:439-445, 1990.

13. Grundy, S. M., "Trans Monounsaturated Fatty Acids and Serum Cholesterol Levels," *The New England Journal of Medicine*, 323:480-1, 1990.

14. Levy, A. S., S. B. Fein, and R. E. Schucker, Division of Consumer Studies (HFF-240), Center for Food Safety and Applied Nutrition, Food and Drug Administration, "A Study of Nutrition Label Formats: Performance and Preference," 200 C St. SW., Washington, DC 20204, March 1991.

15. National Food Processors Association, "Summary of Findings, Food Labeling and Nutrition * * * What Americans Want," Washington, DC, 1990.

16. Committee on Energy and Commerce, Report 101-538, Nutrition Labeling and Education Act of 1990, U.S. House of Representatives, June 13, 1990.

17. Stokes, R. C., and R. Haddock, "Interim Report of the First Two Phases of the CRI/FDA Nutritional Labeling Research Program," August 1972, Consumer Research Institute, Inc., Washington, DC.

18. Park, Youngmee K., Division of Nutrition (HFF-265), Center for Food Safety and Applied Nutrition, Food and Drug Administration, memo to file, March 15, 1991.

19. Bender, M., Division of Consumer Studies (HFF-240), Center for Food Safety and Applied Nutrition, memo to file, January 18, 1991.

20. Food and Drug Administration, "Compliance Program Guidance Manual," Chapter 21, Program No. 7321.002 (1988-1991), Food and Drug Administration, 1990.

21. American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.), "Definitions

and Terms Used in A.S.P.E.N. Guidelines and Standards," A.S.P.E.N., Silver Spring, MD, 1988.

22. Talbot, J.M., "Guidelines for the Scientific Review of Enteral Food Products for Special Medical Uses," prepared for the Food and Drug Administration under Contract No. FDA 223-88-2124 by the Life Sciences Research Office, Bethesda, MD, 1990.

23. Subcommittee on the 10th Edition of the RDA's, Food and Nutrition Board, Commission on Life Sciences, National Research Council, "Recommended Dietary Allowances, 10th Edition," Washington, DC, National Academy Press, 1989.

24. Food and Nutrition Board, Division of Biology and Agriculture, National Research Council, "Recommended Dietary Allowances, 7th ed., 1968," Publication 1694, Printing and Publishing Office, National Academy of Sciences, Washington, DC, 1968.

25. Congressional Record, July 30, 1990, H5840-41.

List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it proposed that 21 CFR Part 101 be amended as follows:

PART 101—FOOD LABELING

1. 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).

2. 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 that contain more than insignificant amounts of nutrients or food components required in paragraph (c) of this section, or whose label, labeling, or advertising contains a nutrition claim or any other nutrition information, in conformity with the requirements of this section unless an exemption is provided for the product in paragraph (j) of this section. An insignificant amount of a nutrient or a food component shall be that amount that allows a declaration of zero in nutrition labeling. A nutrition claim or any other nutrition information in any context, and in any form of expression, implicit, as well as explicit, shall 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)(11)(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 shall contain the following information except for that which is voluntary as set forth in this paragraph or for those food products where a simplified format shall be used as provided for in paragraph (f) of this section. Information shall be presented in the following order, using the headings specified and displayed with equal type size, under the overall heading of "NUTRITION INFORMATION PER SERVING (PORTION)." Alternatively, the terms "PER SERVING (PORTION)" may be placed directly below the terms "NUTRITION INFORMATION."

(1) "Serving (portion) size": A statement of the serving (portion) size.

(2) "Servings (portions) per container": The number of servings (portions) per container.

(3) "Caloric content" or "Calories": A statement of the caloric content per serving (portion), 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 (portion) may also be expressed in kilojoule units, added in parentheses immediately following the statement of the caloric content. Caloric content may be calculated by using specific Atwater food factors or by using the general factors of 4, 4, and 9 calories per gram for protein, carbohydrate, and fat, respectively, as described in A. L. Merrill and B. K. Watt, "Energy Value of Foods—Basis and Derivation," USDA Handbook 74 (1955). The definition of carbohydrate is given in paragraph (c)(6) of this section. These methods of calculation are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the references 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 available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC.

(i) "Calories from total fat": A statement of the caloric content derived from the total fat content of the food per serving (portion), 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 total fat" is not required on products that contain less than ½ gram of fat in a serving (portion) and amounts less than 5 calories may be expressed as zero. This statement shall be indented under the statement of calories, or, alternatively, calories from fat may be declared adjacent to the statement of fat content and aligned with the statement of total calories, in a column headed "Calories." Except as provided for in paragraph (f) of this section, if "Calories from total fat" is not required and, as a result, not declared, the statement "Not a significant source of calories from total fat" shall directly follow the declaration of sodium (or potassium if declared) in the same type size.

(ii) "Calories from saturated fat," "Calories from unsaturated fat," "Calories from carbohydrate," and "Calories from protein" (VOLUNTARY): A statement of the caloric content derived from a serving (portion) of any one or more of the following components may be declared voluntarily: Saturated fat, unsaturated fat, total carbohydrate, and protein. Caloric values shall be 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.

(A) "Calories from saturated fat" or "Calories from saturated": A statement of the caloric content derived from saturated fat as defined in paragraph (c)(4)(i) of this section. This statement shall be indented under the statement of calories from total fat, or alternatively the calories from saturated fat may be declared adjacent to the statement of saturated fat content.

(B) "Calories from unsaturated fat" or "Calories from unsaturated": A statement of the caloric content derived from unsaturated fat as defined in paragraph (c)(4)(ii) of this section. This statement shall be indented under the statement of calories from total fat, and follow calories from saturated fat, if present; or alternatively calories from unsaturated fat may be declared adjacent to the statement of unsaturated fat content.

(C) "Calories from total carbohydrate": A statement of the caloric content derived from total carbohydrate as calculated in paragraph (c)(6) of this section. This statement shall be indented under the statement of calories from total fat, and follow calories from saturated fat and unsaturated fat, if present; or alternatively calories from total carbohydrate may be declared adjacent to the statement of carbohydrate content and aligned with the statement of total calories, in a column headed "Calories."

(D) "Calories from protein": A statement of the caloric content derived from protein as calculated in paragraph (c)(8) of this section. This statement shall be indented under the statement of calories from total fat, and follow calories from saturated fat, unsaturated fat, and total carbohydrate, if present; or alternatively calories from protein may be declared adjacent to the statement of protein content and aligned with the statement of total calories, in a column headed "Calories."

(4) "Total fat content" or "Total fat": A statement of the number of grams of total fat in a serving (portion) expressed to the nearest ½ gram. If the serving (portion) contains less than 0.5 gram, the content shall be expressed as zero.

(i) "Saturated fat content," "Saturated fat," or "Saturated": A statement of the number of grams of saturated fat in a serving (portion) calculated as triglycerides and defined as the sum of lauric, myristic, palmitic, and stearic acids, except that label declaration of saturated fat content information is not required for products that contain less than 1/2 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 directly follow the declaration of sodium (or potassium if declared) in the same type size. Saturated fat content shall be indented and expressed as grams per serving (portion) to the nearest 1/2 gram. If the serving (portion) contains less than 0.25 gram, the content shall be expressed as zero.

(ii) "Unsaturated fat content," "Unsaturated fatty acid," or "Unsaturated (VOLUNTARY)": A statement of the number of grams of unsaturated fat in a serving (portion) calculated as triglycerides and defined as the sum of all polyunsaturated and monounsaturated fatty acids (both *cis* and *trans* isomers) may be declared voluntarily, except that when a claim is made on the label or in labeling about fatty acid or cholesterol content or when "calories from unsaturated fat" is declared, label declaration shall be required. Unsaturated fat content shall be indented and expressed as grams per serving (portion) to the nearest ½ gram. If the serving (portion) contains less than 0.25 gram, the content shall be expressed as zero. Alternatively, separate statements may be declared for polyunsaturated and monounsaturated fat, except that if a claim is made on the label or in labeling about a particular type of unsaturated fatty acid, separate statements shall be declared as follows in lieu of the collective term "Unsaturated":

(A) "Polyunsaturated fat" or "Polyunsaturated": A statement of the number of grams of polyunsaturated fat defined as *cis,cis*-methylene-interrupted polyunsaturated fatty acids, indented and expressed as grams per serving to the nearest 1/2 gram. If the serving (portion) contains less than 0.25 gram, the content shall be expressed as zero; and

(B) "Monounsaturated fat" or "Monounsaturated": A statement of the number of grams of monounsaturated fat defined as *cis*-monounsaturated fatty acids, indented and expressed as grams per serving to the nearest ½ gram. If the serving (portion) contains less than 0.25 gram, the content shall be expressed as zero.

(5) "Cholesterol content" or "Cholesterol": A statement of the cholesterol content in a serving (portion) 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 (portion) 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 directly follow the declaration of sodium (or potassium if declared) in the same type size. If the food contains 2 to 5 milligrams of cholesterol per serving (portion), the content may be stated as "less than 5 milligrams."

(6) "Total carbohydrate content" or "Total carbohydrate": A statement of the number of grams of total digestible carbohydrate in a serving (portion) expressed to the nearest gram, except that if a serving (portion) 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 (portion) 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, dietary fiber, 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 (1955) which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 except that total dietary fiber as described in paragraph (c)(7)(ii) of this section shall also be subtracted). Copies of the method may be obtained 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 available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC.

(i) "Complex carbohydrate content" or "Complex carbohydrate": A statement of the number of grams of digestible complex carbohydrate, defined as the sum of dextrans (saccharide units of 10 or more) and starches, except that label declaration of complex carbohydrate content is not required for products that contain less than 1 gram of complex carbohydrate in a serving. Except as provided for in paragraph (f) of this section, if a statement of the complex carbohydrates content is not required and, as a result, not declared, the statement "Not a significant source of complex carbohydrate" shall directly follow the declaration of sodium (or potassium if declared) in the same type

size. Complex carbohydrate content shall be indented and expressed to the nearest gram, except that if a serving (portion) 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 (portion) contains less than 0.5 gram, the content may be expressed as zero.

(ii)(A) "Sugars content" or "Sugars": A statement of the number of grams of sugars in a serving (portion), 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 directly follow the declaration of sodium (or potassium if declared) in the same type size. Sugars shall be defined as the sum of all free mono- and oligosaccharides through four saccharide units (such as glucose, fructose, lactose, sucrose, and glucose polymers up to four saccharide units) and their derivatives whose use in the food is approved by the Food and Drug Administration or is generally recognized as safe that have similar sweetening, nutritional, and metabolic effects (such as sugar alcohols). Sugars content shall be indented and expressed to the nearest gram, except that if a serving (portion) 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 (portion) contains less than 0.5 gram, the content may be expressed as zero.

(B) "Sugar alcohol content" or "Sugar alcohol" (VOLUNTARY): A statement of the number of grams of sugar alcohols in a serving (portion) 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 mannitol, sorbitol, xylitol, and any other sugar alcohols whose use in the food is approved by FDA or is generally recognized as safe and that meet the definition of sugars as described in paragraph (c)(6)(ii)(A) of this section. Sugar alcohol content shall be indented under sugars content and expressed to the nearest gram, except that if a serving (portion) 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 (portion) contains less than 0.5 gram, the content may be expressed as zero.

(7) "Dietary fiber content" or "Dietary fiber": A statement of the number of grams of total dietary fiber in a serving (portion), expressed to the nearest gram, except that if a serving (portion) 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 (portion) 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 directly follow the declaration of sodium (or potassium if declared) in the same type size.

(i) Soluble and insoluble fiber (VOLUNTARY): A statement of the number of grams of soluble and insoluble dietary fiber in a serving (portion) may be declared voluntarily except that when a claim is made on the label or in labeling about either type of fiber, label declaration of both types shall be required as follows:

(A) "Soluble fiber": A statement of the number of grams of soluble dietary fiber, indented and expressed to the nearest gram, except that if a serving (portion) 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 (portion) contains less than 0.5 gram, the content may be expressed as zero, and

(B) "Insoluble fiber": A statement of the number of grams of insoluble dietary fiber, indented and expressed to the nearest gram except that if a serving (portion) 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 (portion) contains less than 0.5 gram, the content may be expressed as zero.

(ii) Total dietary fiber, soluble dietary fiber, and insoluble dietary fiber content shall be determined by the method "Total Dietary Fiber in Foods, Enzymatic Gravimetric Method, First Action," in the *Journal of the Association of Official Analytical Chemists* (JAOAC), 68:399, 1985, as amended in JAOAC, 69:370 1986 and as modified in JAOAC 71:1017, 1988. These methods are 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 available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC.

(8) "Protein content" or "Protein": A statement of the number of grams of protein in a serving (portion), expressed to the nearest gram, except that if a serving (portion) 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 (portion) 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, the protein content statement shall be modified by an adjacent statement "not a significant source of protein" regardless of the actual amount of protein present. The same statement is required when the protein quality in a food as measured by the protein digestibility-corrected amino acid score is less than 40 percent of the reference standard (casein) for a food represented or purported to be for children greater than 1 but less than 4 years of age; or when the protein quality in a food as measured by Protein Efficiency Ratio (PER) is less than 40 percent of the reference standard (casein) for a food represented or purported to be for infants. 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 current edition of the Official Methods of Analysis of the Association of Official Analytical Chemists, 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 the Association of Official Analytical Chemists, 2200 Wilson Blvd., suite 400, Arlington, VA 22201-3301, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC.

(i) A statement of the corrected amount of protein per serving, as determined in paragraph (c)(8)(ii) of this section, calculated as a percentage of the RDI for protein 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. However, the percentage of the RDI for protein shall not be declared if 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 protein digestibility-corrected amino acid score of less than 20 expressed as a percent, or if the food is represented or purported to be for use by infants or children under 4 years of age and the protein quality value is less than 40 percent of the reference standard.

(ii) The "corrected amount of protein (gram) per serving (portion)" 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 (portion) 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 the method given in "Protein Quality Evaluation," Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation, Rome, 1990, which 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 available for inspection at the Office of the Federal Register, 1100 L St. NW., 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 (portion) 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) For the purpose of labeling with a percent of the RDI, a value of 50 grams of protein shall be the RDI for adults and children 4 or more years of age, 16 grams of protein for children less than 4 years of age, and 14 grams of protein for infants.

(9) "Sodium content" or "Sodium": A statement of the number of milligrams of sodium in a specified serving (portion) of food expressed as zero when the serving (portion) contains less than 5 milligrams of sodium, to the nearest 5-milligram increment when the serving (portion) contains 5 to 140 milligrams of sodium, and to the nearest 10-milligram increment when the serving (portion) contains greater than 140 milligrams.

(10) "Potassium content" or "potassium" (VOLUNTARY): A statement of the number of milligrams of potassium in a specified serving (portion) 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 (portion) contains less than 5 milligrams of potassium, to the nearest 5-milligram increment when the serving (portion) contains less than or equal to 140 milligrams of potassium, and to the nearest 10-milligram increment when the serving (portion) contains more than 140 milligrams.

(11) Under the heading "Percent of Daily Value": A statement of the amount per serving (portion) of the vitamins and minerals as described in this paragraph, expressed as a percent of the RDI.

(i) For purposes of declaration of Percent of Daily Value, 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)(11)(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 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 also 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)(11)(iv) of this section when they are added as a nutrient supplement, or when a claim is made about them. The declaration may also include any of the other vitamins and minerals listed in paragraph (c)(11)(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)(11)(iv) of this section.

(iii) The percentages shall be 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. Vitamins and minerals present in amounts 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 that refers to another asterisk 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)." Except as provided for in paragraph (f) of this section, if vitamin A, vitamin C, calcium, or iron is omitted, the statement "Not a significant source

of _____ (listing the vitamins or minerals omitted)" shall directly follow the listing of percentages of the RDI.

(iv) The following RDI's and nomenclature are established for the following vitamins and minerals which are essential in human nutrition:

Nutrient	Unit of measurement ¹	Adults and children 4 or more years of age	Children less than 4 years of age ²	Infants ³	Pregnant women	Lactating women
Vitamin A	Retinol equivalents ⁴	875	400	375	800	1,300
Vitamin C	Milligrams	60	40	33	70	95
Calciumdo	900	800	500	1,200	1,200
Irondo	12	10	8.0	30	15
Vitamin D	Micrograms ⁵	6.5	10	9.0	10	10
Vitamin E	α-Tocopherol equivalents ⁴	9.0	6.0	3.5	10	12
Vitamin K	Micrograms	65	15	7.5	65	65
Thiamin	Milligrams	1.2	0.7	0.4	1.5	1.6
Riboflavindo	1.4	0.8	0.5	1.6	1.8
Niacin	Niacin equivalents ⁴	16	9.0	5.5	17	20
Vitamin B ₆	Milligrams	1.5	1.0	0.5	2.2	2.1
Folate	Micrograms	180	50	30	400	280
Vitamin B ₁₂do	2.0	0.7	0.4	2.2	2.6
Biotindo	60	20	13	65	65
Pantothenic acid	Milligrams	5.5	3.0	2.5	5.5	5.5
Phosphorusdo	900	800	400	1,200	1,200
Magnesiumdo	300	80	50	320	355
Zincdo	13	10	5.0	15	19
Iodine	Micrograms	150	70	45	175	200
Seleniumdo	55	20	13	65	75
Copper	Milligrams	2.0	0.9	0.6	2.5	2.5
Manganesedo	3.5	1.3	0.8	3.5	3.5
Fluoridedo	2.5	1.0	0.5	3.0	3.0
Chromium	Micrograms	120	50	33	130	130
Molybdenumdo	150	38	26	160	160
Chloride	Milligrams	3,150	1,000	650	3,400	3,400

¹ The following abbreviations are allowed: "mg" for "milligrams"; "mcg" or "µg" for "micrograms"; "µg RE" for "retinol equivalents"; "mg α-TE" for "α-tocopherol equivalents"; "mg NE" for "niacin equivalents."

² The term "children less than 4 years of age" means persons 13 through 47 months of age.

³ The term "infants" means persons not more than 12 months of age.

⁴ 1 retinol equivalent=1 microgram retinol or 6 micrograms β-carotene; 1 α-tocopherol equivalent=1 milligram d-α-tocopherol; 1 niacin equivalent=1 milligram niacin or 60 milligrams of dietary tryptophan.

⁵ As cholecalciferol.

(v) The following synonyms may be added in parentheses immediately following the name of the nutrient or dietary component:

Vitamin C	Ascorbic acid
Folate	Folacin
Calories	Energy

(12) Under the heading "Nutrition Profile": A statement of the percent of the Daily Reference Value (DRV) present in a serving (portion) for food components for which DRV's are given in paragraph (c)(12)(i) of this section shall be declared, followed by a statement of the DRV for each component. The percent and DRV shall be declared for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, and sodium. Unsaturated fat and potassium also may be included. The percents of DRV's shall be 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.

(i) The following DRV's are established for the following food components based on a reference caloric intake of 2,350 calories (Note: The caloric contribution from protein is assumed to be approximately 15 percent.):

Food component	Unit of measurement ¹	DRV
Total fat	grams	75
Saturated fatdo	25
Unsaturated fatdo	50
Cholesterol	milligrams	300
Total carbohydrate	grams	325
Dietary fiberdo	25
Sodium	milligrams	2,400
Potassiumdo	3,500

¹ The following abbreviations are allowed: "g" for "grams" and "mg" for "milligrams."

(ii) The following format shall be used to present a food product's nutrition profile:

Food component	Percent	Daily value
Total fat	(percent)	75 grams. ¹
Saturated fat	(percent)	25 grams. ¹
Cholesterol	(percent)	300 milligrams.
Total carbohydrate	(percent)	325 grams. ¹
Dietary fiber	(percent)	25 grams. ¹
Sodium	(percent)	2,400 milligrams.

¹ As part of a 2,350 calorie diet.

(iii) In addition, the percent of the DRV for unsaturated fat may be listed in the Nutrition Profile immediately following saturated fat and the percent

of the DRV for potassium immediately following sodium as follows:

Unsaturated fat... (percent)	50 grams.*
Potassium..... (percent)	3,500
	milligrams.

(d) [Reserved]

(e) Products with separately packaged ingredients, 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 food (e.g., assorted candy mixtures) in the same package, nutrition labeling of the total product shall be located on the outer container 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.

(2) 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 the nutrient contents on the basis of the food as consumed in the same format required in paragraph (c) of this section for the food alone (e.g., a dry ready-to-eat cereal may be described with one set of 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 whole milk); and a cake mix may be labeled with one set of 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.

(f)(1) The declaration of nutrition information shall be presented in the simplified format set forth herein when a food product contains insignificant amounts of eight or more of the following: calories, calories from total fat, total fat, saturated fat, cholesterol, total carbohydrate, complex carbohydrate, sugars, dietary fiber, protein, sodium, vitamin A, vitamin C, calcium, and iron.

(2) An "insignificant amount" shall be defined as that amount that may be rounded to zero in nutrition labeling.

(3) The simplified format shall include:

(i) Serving size, number of servings per container, calories, total fat (grams), total carbohydrate (grams), protein (grams), and sodium (milligrams);

(ii) Any other nutrients or food components identified in paragraph (f)(1) of this section that are present in the food in more than insignificant amounts; and

(iii) Any other vitamins and minerals listed in paragraph (c)(11)(iv) of this section when they are required to be added as a nutrient supplement to foods for which a standard of identity exists.

(4) Other nutrients or food components that are present in the food in more than insignificant amounts may be voluntarily declared as part of the simplified format. Any vitamins or minerals that are added to the food as nutrient supplements shall be declared as part of the simplified format. If additional nutrients or food components are declared as part of the simplified format for either of these reasons, the statement "Not a significant source of _____" (with the blank filled in with the name of any nutrient or food component identified in § 101.9(f)(1) present in insignificant amounts) shall be included at the bottom of the nutrition label.

(5) Nutrient information in the simplified format may be presented in vertical columns or in lines. When lines are used, any subcomponents declared shall be listed parenthetically after principal components (e.g., saturated fat shall be parenthetically listed after total fat).

(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 15th edition 1990 of the Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC) which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51

or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures. Copies of the incorporation by reference are available from the Association of Official Analytical Chemists, 2200 Wilson Blvd., suite 400, Arlington, VA 22201-3301, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC. Alternative methods of analysis may be submitted to FDA to determine their acceptability.

(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, complex carbohydrate, dietary fiber, unsaturated 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, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat, 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, complex carbohydrate, dietary fiber, unsaturated 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 which 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.

(6) Reasonable excesses of a vitamin, mineral, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated 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) The compliance provisions set forth in paragraphs (g)(1) through (g)(6) of this section do not apply to products for which nutrition labeling is founded on FDA approved data bases and is computed following FDA guideline procedures and that 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 Using Data Bases," 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.

(8) When it is not technologically feasible, or some other circumstance makes it impracticable, for firms to develop adequate nutrient profiles to comply with the requirements of paragraph (c) of this section, FDA may establish by regulation alternative means of compliance or additional exemptions to deal with the situation. Firms in need of such a regulation may submit a petition for initiation of rulemaking proceedings to the Dockets Management Branch in the form established by § 10.30 of this chapter.

(h) Nutrition information provided by a manufacturer or distributor directly to professionals (e.g., physicians, dietitians, educators) may vary from the requirements of this section but shall also contain or have attached to it the nutrition information exactly as required by this section.

(i) 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 person who has annual gross sales made or business done in sales to consumers which 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, a person who offers food for sale, or who has business done in sales, to consumers is 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.

(iii) For purposes of this paragraph, calculation of the amount of sales shall be based on the most recent 2-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 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)). Foods sold to restaurants 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.

(3) Food products provided by grocery stores that are offered for sale from:

- (i) Self-service food bars (e.g., salad bars); or
- (ii) Behind delicatessen or bakery counters.

(4) Foods, other than infant formula, represented or purported to be specifically for infants and toddlers less than 2 years of age shall bear nutrition labeling, except that such labeling shall not include calories from fat or saturated fat and cholesterol content information.

(5) Dietary supplements of vitamins and minerals that are labeled in compliance with § 101.36, except that the labeling of a dietary supplement of vitamins and minerals in food form, e.g., a breakfast cereal, shall conform to the labeling established in paragraph (c) of this section, including the order for listing vitamins and minerals established in paragraph (c)(11)(iv) of this section.

(6) Infant formula subject to section 412 of the act, as amended, except that such foods shall be labeling in compliance with part 107 of this chapter.

(7) 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 provided only to a patient receiving active and ongoing medical supervision wherein the patient seeks medical care on a recurring basis for, among other things instructions on the use of the medical food.

(8) Food products shipped in bulk form that are not for distribution to consumers in such form and that are to be processed, labeled, or repacked at a site other than where originally processed or packed.

(9) Food products that are supplied for institutional food service use only: *Provided*, That the manufacturer or distributor provides the nutrition information required by this section directly to those institutions on a current basis.

(10) Raw fruits, vegetables, and fish subject to section 403(q)(4) of the act, except that 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) 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 information. Nutrition labeling for foods that qualify for this exemption shall be presented to consumers in accordance with the provisions of paragraph (a)(2) of this section.

(12) 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.

(13) 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.

(14) 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 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. Ingredients or products such

as rutin, other bioflavonoids, para-amino-benzoic acid, inositol, and similar substances which have in the past been represented as having nutritional properties but which have not been shown to be essential in human nutrition may not be combined with vitamins and/or minerals, added to food labeled in accordance with this section, or otherwise used or represented in any way which states or implies nutritional benefit. Ingredients or products of this type may be marketed as individual products or mixtures thereof: *Provided*, That the possibility of nutritional, dietary, or therapeutic value is not stated or implied, e.g., their labeling does not state that their usefulness in human nutrition has not been established and does not otherwise disclaim nutritional, dietary, or therapeutic value.

(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.

3. Section 101.36 is added to subpart C to read as follows:

§ 101.36 Nutrition labeling of dietary supplements of vitamins and minerals.

(a) The label and labeling of a dietary supplement of a vitamin or mineral that is listed in § 101.9(c)(11)(iv), other than one in conventional food form (i.e., breakfast cereals), shall bear nutrition labeling in accordance with this regulation.

(b) The declaration of nutrition information on the label and in labeling shall contain the following information, using the headings specified, and displayed with equal type size, under the overall heading of "NUTRITION INFORMATION."

(1) "Units per day": A statement of the number of units to be consumed per day. The quantity specified shall be a reasonable quantity suitable for and practicably of consumption within 1 day and shall be consistent with any intake recommendation on the label or in labeling. Appropriate terms, such as tablets, capsules, or teaspoonfuls, may be used here and elsewhere on the label in place of the term "units".

(2) "Units per container": The number of units per container.

(3) A listing of the quantitative amount and percent of the Reference Daily Intake (RDI), where appropriate, of all nutrients and food components required in § 101.9(c), including any vitamin and mineral listed in § 101.9(c)(11)(iv) present in the supplement, in a column under the heading of "PER UNIT" except that nutrients and food components that are

present in the total number of units specified for consumption per day at insignificant amounts need not be declared. Insignificant amounts shall be defined as amounts that allow a declaration of zero in nutrition labeling as specified in § 101.9(c). Where label directions specify that more than one unit be consumed during a period of 1 day, the required nutrition information shall also be presented in a second column under the heading of "PER DAY."

(i) Nutrients and food components shall be listed in the order specified in § 101.9(c) except that calcium and iron, when present, shall follow the complete listing of vitamins.

(ii) The quantitative amounts of all nutrients and food components declared shall be presented in a column under the heading of "Amount." These amounts shall be expressed in the increments and units of measurement specified in § 101.9(c). Quantitative amounts of vitamins and minerals shall be expressed to the nearest unit of the same level of significance given in § 101.9(c)(11)(iv).

(iii) The percent of the RDI specified in § 101.9(c)(11)(iv) of all vitamins and minerals present shall be presented in a column immediately under the heading "Percent of Daily Value." This column shall be to the right of the column of quantitative amounts.

(A) Values shall be based on the percent of the RDI for adults and children 4 or more years of age unless the product is represented or purported to be for use by infants, children less than 4 years of age, pregnant women, or lactating women in which case the column heading shall clearly state the intended group.

(B) The percentages of RDI's shall be 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.

(iv) If the product is for persons within more than one group for which RDI's are established in § 101.9(c)(11)(iv), the percent of daily value for each group shall be presented in additional columns.

(v) The following synonyms may be added in parenthesis immediately following the name of the nutrient or dietary component:

Vitamin C	Ascorbic Acid
Folate	Folacin
Calories	Energy

(c) Compliance with this section shall be determined in accordance with § 101.9(g).

Dated: August 2, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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21 CFR Part 101

[Docket No. 90N-0165]

RIN 0905-ADO8

Food Labeling; Serving Sizes

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this document as a reproposal of its proposed regulation entitled "Food Labeling; Serving Sizes" (55 FR 29517, July 19, 1990) in response to the recent enactment of the Nutrition Labeling and Education Act of 1990. The agency also is responding to public comments submitted in response to the July 19, 1990 serving sizes proposal and to the public meeting held on April 4, 1991, on serving sizes (56 FR 8084, February 26, 1991). FDA is proposing to: (1) Define serving and portion size on the basis of the amount of food customarily consumed per eating occasion; (2) establish reference amounts customarily consumed per eating occasion (reference amounts) for 131 food product categories; (3) provide criteria for determining label serving size from the reference amounts; (4) require the use of both common household and metric measures to declare serving size; (5) permit the declaration of serving (portion) size in U.S. measures; (6) permit the optional declaration of nutrient content per 100 grams (g), 100 milliliters (mL), 1 ounce (oz), or 1 fluid ounce (fl oz); (7) define a "single-serving container;" and (8) require that the use of claims such as "low sodium" be based on both the serving size declared on the label and the reference amount.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, 301-443-1751.

FOR FURTHER INFORMATION CONTACT:

Youngmee K. Park, Center for Food Safety and Applied Nutrition (HFF-265), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0089.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 19, 1990 (55 FR 29487), FDA published a proposed rule entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" to amend its food labeling regulations to require nutrition labeling on most food products that are meaningful sources of nutrients. In the same issue of the Federal Register (55 FR 29517), FDA published a technical supporting proposal entitled "Food Labeling; Serving Sizes" (hereinafter referred to as the 1990 proposal).

The 1990 proposal stated that in view of the many comments that the agency had received stating the need for more realistic and consistent serving sizes, FDA had concluded that reasonable and standardized serving sizes should be established. The agency proposed to amend the nutrition labeling regulations to: (1) Define serving and portion size on the basis of the amount of food commonly consumed per eating occasion by persons 4 years of age or older, by infants, or by children under 4 years of age (toddlers); (2) require the use of both U.S. (oz, fl oz) and metric measures to declare serving size; (3) permit the declaration of serving (portion) size in familiar household measures; (4) permit the optional declaration of nutrient content per 100 g or 100 mL; (5) define "single-serving containers" as those that contain 150 percent or less of the standard serving size for the food product; and (6) establish standard serving sizes for 159 food product categories to ensure reasonable and uniform serving sizes upon which consumers can make nutrition comparisons among food products. Interested persons were given until November 16, 1990, to submit comments to the agency on the serving size proposal.

On September 26, 1990, the National Academy of Sciences' Institute of Medicine (IOM) issued a report entitled "Nutrition Labeling, Issues and Directions for the 1990s" (hereinafter referred to as the IOM Report) [Ref. 1]. The IOM report was written under contract to the Public Health Service, U.S. Department of Health and Human Services (DHHS) and the Food Safety

and Inspection Service, U.S. Department of Agriculture (USDA). On October 5, 1990, FDA published a notice in the Federal Register (55 FR 40944), announcing the availability of the IOM report and requesting that interested persons comment on the implications of the report for the agency's July 19, 1990, proposals on food labeling. The report makes several recommendations related to serving sizes.

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (hereinafter referred to as the "1990 amendments") (Pub. L. 101-535). The 1990 amendments add section 403(q) to the Federal Food, Drug, and Cosmetic Act (the act). Section 403(q) of the act specifies, in part, that:

*** the serving size *** is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or *** if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food.

The 1990 amendments also require, in section 2(b)(1)(B), that FDA adopt regulations that: "*** establish standards *** to define serving size or other unit of measure for food, ***."

While the requirements of the 1990 amendments that pertain to serving sizes are similar in many respects to FDA's 1990 proposal, differences do exist, and questions about the exact meaning and the implementation of these provisions have been raised.

On February 26, 1991 (56 FR 8084), FDA announced a public meeting to discuss issues related to how serving and portion size should be determined and presented as part of nutrition labeling. The notice stated that several issues arising from the comments on the serving size proposal and two other recent developments (the 1990 amendments and the IOM report) required further public comment. Therefore, FDA held a public meeting on serving sizes on April 4, 1991, to provide an opportunity to submit oral comments, as well as an opportunity for written comments, on the issues identified in the notice.

The notice of the public meeting outlined five major issues for discussion at the meeting: (1) Whether, in determining serving (portion) sizes (hereinafter referred to as "serving size" for simplicity) based on the amount of food customarily consumed, the agency should limit itself to national food consumption data, or whether there is other information that should be considered; (2) whether in declaring