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Food and Drug Administration

21 CFR Part 101 Chapter I, and Part, 190 Food Labeling Regulation, Amendments; Food Regulation Uniform Compliance Date; and New Dietary Ingredient Premarket Notification; Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 95N–0245 and 94P–0110]

RIN 0910–AA59

Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements; Compliance Policy Guide, Revocation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its food labeling regulations to establish requirements for the identification of dietary supplements and for their nutrition labeling and ingredient labeling in response to the Dietary Supplement Health and Education Act of 1994 (the DSHEA). FDA is also responding to a citizen petition from the Council for Responsible Nutrition on type size requirements for these products. In addition, FDA is announcing the revocation of Compliance Policy Guide 530.400 (CPG 7121.02) entitled ''Vitamin Products for Human Use—Low Potency'' to eliminate inconsistencies with the new labeling requirements.

DATES: The regulation is effective March 23, 1999. The Director of the Office of the Federal Register approves the incorporations by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 101.4(h), effective March 23, 1999.

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SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 28, 1995 (60 FR 67194), FDA published a proposed rule entitled ''Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements'' (hereinafter identified as ''the December 1995 proposal''). This document, which specifically responds to the DSHEA, superseded earlier documents responding to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments)(Pub. L. 101–535) and the Dietary Supplement Act of 1992 (the DS act) (Pub. L. 102–571) with respect to dietary supplements.

The 1990 amendments amended the Federal Food, Drug, and Cosmetic Act (the act) in a number of important ways. One of the notable aspects of the 1990 amendments is that they added section 403(q) to the act (21 U.S.C. 343(q)). This section provides that most foods are misbranded unless they bear nutrition labeling.

In particular, section 403(q)(5)(F) (originally section 403(q)(5)(E)) of the act provided that separate regulations on the nutrition labeling of dietary supplements of vitamins and minerals could be established that are distinct from those for other foods. In response to this section, FDA proposed a regulation in § 101.36 (21 CFR 101.36) that was specifically on the nutrition labeling of dietary supplements of vitamins and minerals, and a separate general regulation that was on the nutrition labeling in § 101.9 (21 CFR 101.9) of conventional foods and of all other dietary supplements (those of herbs and other nutritional substances) (56 FR 60366, November 27, 1991).

On October 6, 1992, the President signed into law the DS act. The DS act established a moratorium until December 15, 1993, on the implementation of the 1990 amendments with respect to dietary supplements not in the form of conventional food. Also, it required that a new proposed regulation on the nutrition labeling of dietary supplements be issued by June 15, 1993, and a final rule by December 31, 1993.

In response to the DS act, FDA published a new proposed rule in the **Federal Register** of June 18, 1993 (58 FR 33715), and a final rule on January 4, 1994 (59 FR 354), on the nutrition labeling of dietary supplements. As mandated in section 403(q)(5)(F) of the act, the final rule established a regulation (§ 101.36) on the specific requirements for nutrition labeling of dietary supplements of vitamins and minerals.

On October 25, 1994, the DSHEA (Pub. L. 103–417) was signed into law. The DSHEA amended the act by adding section 201(ff) (21 U.S.C. 321(ff)), which defines a ''dietary supplement,'' in part, as a product, other than tobacco, intended to supplement the diet that contains at least one or more of the following ingredients: A vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any of the previously mentioned ingredients. This section also states that the term ''dietary supplement'' means a product that is labeled as a dietary supplement.

Furthermore, the DSHEA, among other things, amended section 403(q)(5)(F) of the act by adding specific requirements that relate to the labeling of, and ingredient declaration on, dietary supplement products. Previously, this section had applied only to dietary supplements of vitamins and minerals and had not offered any description of how the labeling of these products should differ from the labeling of foods in general. As amended by the DSHEA, section 403(q)(5)(F) of the act provides that dietary ingredients that do not have daily values (i.e., Reference Daily Intakes (RDI's) or Daily Reference Values (DRV's)) must be listed within the nutrition information, that the listing of dietary ingredients must include the quantity of each dietary ingredient (or of a proprietary blend of such dietary ingredients), and that the listing of dietary ingredients may include the source of a dietary ingredient. It also provides that the nutrition information must immediately precede the ingredient information required under the act.

FDA received over 50 letters in response to the December 1995 proposal. Each of these letters contained one or more comments. Responses were received from industry, trade associations, consumers, consumer advocacy organizations, health care professionals, professional societies, and city governments. Many comments supported the proposal generally or supported aspects of the proposal. Other comments objected to specific provisions of the proposal and requested revisions. Some comments addressed issues outside the scope of the proposal and will not be discussed here. A summary of the relevant comments, the agency's responses to the comments, and a discussion of the agency's conclusions follows.

II. The Term ''Dietary Supplement'' in the Statement of Identity

1. A number of comments objected to the proposed requirement in §101.3(g) (21 CFR 101.3(g)) that the term ''dietary supplement'' appear as part of the statement of identity of dietary supplements. Some of these comments requested the flexibility of allowing this term either in the statement of identity or elsewhere on the label, such as on the principal display panel or in the directions for use. A couple of comments stated that, if the nutrition label was given the title ''Dietary Supplement Facts,'' a consumer could utilize the nutrition label to identify the

product as a dietary supplement, making it unnecessary to include the term as part of the statement of identity. Other comments requested that FDA allow for reasonable flexibility in the use of synonyms or modifiers for the term ''dietary supplement,'' such as ''Nutritional Supplement,'' ''Herbal Supplement,'' ''Multivitamin/Multimineral Supplement,'' or ''Amino Acid Blend.''

The comments presented a number of reasons for their disagreement with the proposal. Several comments stated that the inclusion of the term ''dietary supplement'' as part of the statement of identity on the principal display panel overreaches the legislative intent of the DSHEA. These comments stated that the DSHEA does not specify where the term ''dietary supplement'' should be placed, and that, therefore, flexibility of placement of the term is warranted. One comment stated that it objected to FDA transforming an ''identify'' requirement in the DSHEA into an ''identity'' requirement in the use of the term ''dietary supplement.'' The comment asserted that the term ''identify'' in the DSHEA is different from the requirement in 15 U.S.C. 1453(a)(1) (i.e., ''the identity of the commodity''), upon which the identity labeling provisions in § 101.3 are based. Several comments stated that the term ''dietary supplement'' by itself is inappropriate as a common descriptor for dietary supplements because they include a wide range of products, which meet vastly different consumer needs. These comments stated that the term ''dietary'' does not add additional value to the statement of identity, and that consumers might interpret the term ''dietary'' as part of the statement of identity to suggest that the supplement is a weight loss or meal replacement product. These comments stated that the statutory requirement that the term ''identify'' the product could be satisfied with the use of the term ''supplement.'' One comment submitted a market research study on consumer perception of the term ''dietary supplement,'' which indicated that over 50 percent of the subjects were confused by the term when used with the claim ''high potency.'' One comment stated that the United States Pharmacopeia (USP) has established a number of monographs of official names for specific nutritional supplements but they do not include the term ''dietary supplement.'' Several comments pointed out that use of the term ''dietary supplement'' is not part of their products' trademarked terminology.

Several comments suggested that the agency provide alternate requirements for dietary supplements in conventional food form to distinguish them from conventional foods (e.g., cereals, snack bars, drinks), requiring that the term ''dietary supplement'' appear on the principal display panel, although not necessarily as part of the statement of identity. These comments stated that dietary supplements in capsule or tablet form are obviously dietary supplements, are easily distinguished by consumers from conventional foods, and should not have the same identity requirement. A few comments argued that there are space limitations on the principal display panel of some dietary supplements, and that the term ''dietary supplement'' uses up available label space.

The agency has carefully reviewed these comments but concludes that the best reading of the act, as well as the agency's longstanding regulations that implement the act, require that the term ''dietary supplement,'' or some form of this term, appear as part of the statement of identity. Section 201(ff)(2)(C) of the act, in defining the term ''dietary supplement,'' mandates that such a product must be labeled as a dietary supplement. Section 403(s)(2)(B) of the act states that a food shall be deemed to be misbranded if it is a dietary supplement, and the label or labeling of the dietary supplement fails to identify the product by using the term ''dietary supplement, which term may be modified with the name of such an ingredient.'' Section 403(i)(1) of the act requires that a food label must bear the common or usual name of the food, that is, a statement that identifies the food. Dietary supplements are labeled subject to the provisions of section 403(i)(1) of the act (see the last sentence of section 201(ff) of the act). Thus, when the act is read in its entirety, it is clear that sections 201(ff)(2)(C), 403(s)(2)(B), and 403(i)(1) of the act require that the statement of identity of a product that is marketed as a dietary supplement identify the product as such.

FDA's longstanding regulations lead directly to this result. Section 102.5 (21 CFR 102.5) sets out how the common or usual name of a nonstandardized food is to be derived. Under this provision, the common or usual name must accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food. The basic nature of a dietary supplement is that it is a dietary supplement. This is the point made in both sections 201(ff)(2)(C) and 403(s)(2)(B) of the act. Thus, under § 102.5(a), the common or usual name of these products must, at least in part, identify them as a dietary supplement. Section 101.3(b) of FDA's regulation states that the statement of identity of a food shall be in terms of its common or usual name. Thus, § 101.3(g) derives directly from the act and FDA's longstanding regulations that implement the act. Therefore, FDA is adopting § 101.3(g).

However, the agency is persuaded by the comments that flexibility in the use of the term ''dietary'' as part of the name ''dietary supplement''is warranted. The agency notes that section 403(s)(2)(B) of the act states that the product shall be identified ''by using the term 'dietary supplement,' which term may be modified with the name of such an ingredient.'' The agency interprets this provision to mean that the term ''dietary supplement'' may be modified to include the name of a dietary ingredient or ingredients (e.g., ''Vitamin C Supplement''). Furthermore, to provide additional flexibility, an identifying term that describes the types of dietary ingredients contained in the product in appropriately descriptive terms (e.g., ''Multivitamin Supplement,'' ''Herbal Supplement'') may be used. Generic terms that are not descriptive (e.g., ''Food Supplement,'' ''Energy Bar'') would not be appropriate because they do not identify or describe the dietary ingredients (e.g., protein, folic acid, arrowroot) or combination of ingredients that the product supplies.

Accordingly, FDA is revising § 101.3(g) to provide that the term ''dietary supplement'' may be modified by replacing the term ''dietary'' with the name of a dietary ingredient or ingredients or an appropriately descriptive term indicating the type of dietary ingredients that are in the product. The agency notes that, with this increased flexibility, several concerns expressed by the comments (e.g., possible difficulties with space limitations, potential consumer confusion, possible effects on established trademarked names) should be alleviated.

2. One comment asked that the agency change the type size requirements referred to in proposed § 101.3(g), which stated that ''* * * the label shall bear the term 'dietary supplement' as part of the statement of identity in conformance with the provisions of paragraph (d) of this section.'' The comment stated that the type size requirements of § 101.3(d) (i.e., that the statement of identity ''shall be in a size reasonably related to the most prominent printed matter on such panel'') cross-referenced in proposed § 101.3(g) might be counterproductive or impracticable for products in small packages with many dietary ingredients. The comment requested that the agency require the same minimum type size as

that for the declaration of the net quantity of contents (§ 101.105(i)(21 CFR 101.105(i))) because this would permit products to bear the statement of identity in a type size that would be a minimum of one-sixteenth of an inch.

FDA points out that § 101.3(d) does not include minimum type size requirements, but, as noted in the comment, it requires that the size of the statement of identity be related to the size of the most prominent printed matter on the label. Therefore, if the package size is small, and there are many dietary ingredients to be listed, it is reasonable to expect that even the most prominent printed matter will be relatively small, permitting the statement of identity to be proportionally smaller, in some cases as small as one-sixteenth of an inch. Therefore, the agency is taking no action based on this comment. However, because the reference in proposed § 101.3(g) to paragraph (d) of that section is redundant, inasmuch as all foods must meet all regulatory requirements unless specific exceptions are noted, FDA has deleted the reference to paragraph (d).

III. Nutrition Labeling of Dietary Supplements

A. Serving Size

3. Several comments stated that the term ''serving size'' is inappropriate on dietary supplements. One comment stated that the term ''serving size'' should not appear in the nutrition label of dietary supplements, except for products in the physical form of conventional foods or for products with significant amounts of calories and macronutrients, which should be covered by § 101.9. This comment recommended that the directions for use should provide the basis for the quantitative statements contained in the nutrition label. Another comment stated that the term ''serving size'' should not be used in the nutrition label of herbal products and suggested the terms ''recommended use'' or ''suggested use.'' This comment suggested the terms ''dose'' or ''dosage'' in the case of products marketed to health professionals.

The agency is not persuaded by the comments objecting to the term ''serving size.'' As discussed in the final rule of January 4, 1994 (59 FR 354 at 358), information on serving size is as essential on the nutrition label of dietary supplements as it is on that of conventional foods. The agency points out that the directions for use provide the basis for the serving size in the nutrition label of dietary supplements in that serving sizes are derived by the manufacturer in accordance with § 101.12 (21 CFR 101.12). Section 101.12(b), Table 2, states that the reference amount customarily consumed for dietary supplements is ''the maximum amount recommended, as appropriate, on the label for consumption per eating occasion * * *.''

Section 403(q)(1)(A)(i) of the act states that a food is misbranded unless its nutrition information specifies the serving size, and nothing in the DSHEA directs the agency to eliminate the use of this term in the nutrition label of dietary supplements. To the contrary, section 403(q)(5)(F)(ii) of the act, which was added by the DSHEA, states that the listing of dietary ingredients shall include the quantity of each such ingredient per serving. This fact establishes that Congress contemplated that serving size would be a part of the nutrition labeling of dietary supplements.

With respect to using other terms in place of the term ''serving size,'' the agency reiterates that the term ''serving size'' is consistent with the act, and that it would be confusing to consumers if the nutrition labels of dietary supplements used varied terms, such as ''recommended use'' or ''dose,'' in place of the term ''serving size.'' Use of the same term in the same place on all labels will help to avoid confusion. Therefore, the agency has not made any changes in response to these comments.

B. Information on Dietary Ingredients Having RDI's or DRV's

4. Several comments argued that some (sodium, vitamin A, vitamin C, calcium, and iron) or all of the 14 nutrients required under § 101.9(c) should be required to be listed on the labels of dietary supplements only when they are added to the supplement, or when a claim is made about them. These comments argued that dietary supplements of herbs or botanicals, for example, are not generally consumed for their nutritional value, and that, thus, having to determine the levels of the required nutrients would be unduly burdensome and of little use to consumers who rely on the nutrition information to structure their diets to maintain healthy dietary practices. One comment from an independent analytical laboratory stated that mandatory requirements for the listing of nutrients should not pertain to herbal products. This comment stated that official methods of analysis do not apply to herbal products and suggested that these products should be excluded from labeling regulations requiring analysis until such time as official methodology is published. Other comments specifically supported the proposed rule in requiring that macronutrients be declared whenever they are present.

FDA is not persuaded by the comments to modify § 101.36(b)(2). Section 403(q)(1) of the act specifies the nutrients that are to be listed in the nutrition labeling of foods, and section 403(q)(2) of the act gives the Secretary of Health and Human Services (the Secretary) discretion to add to, or subtract from, this list for the purpose of assisting consumers in maintaining healthy dietary practices. Section 403(q)(5)(F) of the act states that the labels of dietary supplements shall comply with the requirements of subparagraphs (q)(1) and (q)(2) in a manner that is appropriate.

In its final rule on nutrition labeling, the agency concluded that information on the calorie, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron content of foods was necessary to assist consumers in maintaining healthy dietary practices (58 FR 2079, January 6,1993). Accordingly, these nutrients are required under § 101.9(c) to be listed in nutrition labeling.

In its December 1995 proposal, the agency tentatively concluded that these nutrients were equally as important to maintaining healthy dietary practices when present in dietary supplements and, therefore, should be mandatory on the labels of dietary supplement products as well. However, to ease label crowding and to be consistent with the DSHEA, FDA proposed that the 14 nutrients need only be listed on dietary supplement labels when present in quantitative amounts by weight that exceed the amount that can be declared as zero in accordance with § 101.9(c). FDA tentatively concluded that this action would provide consumers with the information necessary to determine how dietary supplement products fit into dietary regimens that adhere to dietary recommendations.

Dietary supplements are foods under section 201(ff) of the act, unless they are intended to be used as drugs. Moreover, under section 201(ff) of the act and some of the other changes made by the DSHEA, dietary supplements may well be in conventional food form and contain many of the 14 nutrients required to be listed in the nutrition label under § 101.9. Thus, as foods, it is appropriate to require that their labeling bear the same nutrients as the nutrition labeling on conventional foods, unless evidence is presented that justifies the contrary conclusion.

The comments presented no evidence that would be a basis for the agency to reach a conclusion different than it did for conventional foods, i.e., that the listing of these nutrients will assist consumers in maintaining healthy dietary practices. The agency is not convinced that this requirement should be eliminated because of the argument that herbs and botanicals are not generally consumed for their nutritional value. The fact that a product is not generally consumed for its nutritional value is immaterial under the act and its implementing regulations. For example, certain spices, such as paprika, which are consumed for their flavor-enhancing properties, not for nutritional value, are not exempt from nutrition labeling under § 101.9 if any nutrient is present at more than insignificant levels (§ 101.9(j)(4)). The agency concludes that it is appropriate for the nutrients required in § 101.9 to be mandatory on the labels of dietary supplements. Thus, the agency is not modifying

Moreover, one of the principles underlying the agency's food labeling initiative has been that, if nutrition labeling is to assist consumers in making dietary choices, it should provide consistent information for consumers to use (55 FR 29487 at 29490, July 19, 1990). For example, fat is mandatory on the labels of conventional foods because of scientific consensus that high dietary intakes of total fat are associated with an increased risk of coronary heart disease, some types of cancer, gallbladder disease, and obesity (55 FR 29487 at 29495). Thus, the listing of fat on the nutrition label, when it is present, will assist consumers in meeting dietary recommendations to limit fat intake to no more than 30 percent of calories, irrespective of whether the nutrition labels are for conventional foods or dietary supplements.

With respect to methodology issues, FDA is not persuaded that herbal products should be exempt from labeling until analytical methodology is validated for all herbal products. FDA is aware of the difficulties in adapting analytical methods to different matrices and specifically requested comment on this point in the proposal. The agency received comments from industry groups actively working on the development of official methodology, but these comments did not indicate that problems with methodology necessitate exempting herbs from nutrition labeling. Rather, FDA is aware that the adaptation of existing methods to different matrices (e.g., herbs) is ongoing. In addition, FDA has stated that analysis is not needed for nutrients where reliable data bases or scientific knowledge establish that a nutrient is not present in a serving of the product (58 FR 2079 at 2109). Therefore, it may not be necessary to analyze for several nutrients in herbal products. For example, there is no need to analyze for cholesterol because food composition studies have shown it to be found only in animal products.

Thus, FDA concludes based upon these comments and on its own experience that exempting herbs is unwarranted. Moreover, an exemption would be inconsistent with section 403(q)(5)(F) of the act. Therefore, the agency is not taking any action based on these comments.

5. Several comments requested more flexibility with the language used in place of ''Amount Per Serving.'' The comments requested use of phases such as ''Amount per 2 Tablets'' or ''Two Tablets Contain.''

The agency has no objection to the flexibility requested by these comments. The agency proposed in § 101.36(b)(2)(i)(A) that when the serving size of the product is one unit, a heading consistent with the declaration of the serving size, such as ''Amount Per Tablet'' or ''Each Tablet Contains,'' may be used in place of the heading ''Amount Per Serving.'' In response to these comments, the agency agrees that there is no reason to limit the language that can be used in this way. Therefore, the agency is deleting the words ''when the serving size of the product is one unit'' from § 101.36(b)(2)(i)(A) and adding the example ''Amount Per 2 Tablets.''

6. The agency received a couple of comments that recommended changes in nomenclature for thiamin and riboflavin. These comments requested that the name ''B_1'' be used instead of ''thiamin,'' and that ''B_2'' be used for ''riboflavin.'' One comment stated that consumers do not know that these are B vitamins and have been confused by the listing of thiamin and riboflavin on ''B-complex'' products. The comment stated that the mandatory use of ''thiamin'' and ''riboflavin'' is inconsistent with the educational purposes of the 1990 amendments and the DSHEA and recommended that the use of these names be optional following the numerical names. The comment recommended that this approach be followed on the labels of conventional foods as well.

The agency has previously considered this issue. As discussed in the proposal, the use of numerical terminology for these vitamins is obsolete (29487 at 29502). ''The Handbook of Vitamins'' concurs with this conclusion (Ref. 1, pp. 239 and 285). Also, the National Academy of Sciences' National Research Council (NAS/NRC) publication on ''Recommended Dietary Allowances'' (Ref. 2, pp. 125 and 132) uses the terminology ''thiamin'' and ''riboflavin,'' as does the nutrition labeling of conventional foods. Consistent terminology is needed for consumers to be able to calculate their total intake of these vitamins from all food products.

To provide flexibility in the labeling of dietary supplements, the agency proposed in the December 1995 proposal that the terms ''vitamin B_1'' and ''vitamin B_2'' may be listed as synonyms for thiamin and riboflavin. The agency is adopting this provision, so manufacturers who wish to inform consumers that these nutrients are B vitamins will be free to do so. Thus, they will be able to address any consumer confusion as to why these nutrients are included in B-complex products.

The agency concludes that the regulation it is adopting provides the requisite flexibility and yet ensures that the nutrition label conforms to up-to-date scientific views. Thus, FDA is not accepting the recommendation of these comments.

7. One comment requested that ''folic acid'' be listed instead of ''folate,'' stating that the use of ''folic acid'' is consistent with the final rule entitled ''Food Additives Permitted for Direct Addition to Food for Human Consumption; Folic Acid (Folacin),'' published in the **Federal Register** (61 FR 8797, March 5, 1996).

The agency agrees that the term ''folic acid'' can be listed in place of ''folate.'' The December 1995 proposal stated in § 101.36(b)(2)(i)(B)*(2)* that ''folic acid'' and ''folacin'' may be added in parentheses immediately following the listing of ''folate'' (60 FR 67194 at 67198). However, the health claims final rule on folate and neural tube defects, amended the nutrition labeling regulations that FDA had adopted for dietary supplements and conventional foods[1] to allow the terms ''folic acid'' or ''folacin'' to be used synonymously (61 FR 8752 at 8759, March 5, 1996)). In that final rule, the agency acknowledged that the terms ''folic acid'' and ''folate'' are interchangeable in common usage, although technically ''folic acid'' refers

[1] The regulations in place at that time were §§ 101.9(c)(8)(v) for conventional foods and § 101.36(b)(3)(v) for dietary supplements. Thus, FDA amended these regulations. FDA had yet to implement § 101.36(b)(3)(v), however (see 60 FR 7711, February 9, 1995), and, as part of the changes included in the December 1995 proposal, it renumbered this provision as § 101.36(b)(i)(B)*(2)*.

to the synthetic form of this vitamin, and ''folate'' is a general term that refers to both the synthetic and naturally-occurring forms.

Thus, the agency agrees with the comment that it is appropriate for ''folic acid'' to be listed by itself in place of ''folate.'' For clarity, the agency is modifying the language in §§ 101.36(b)(2)(i)(B)*(2)* and 101.9(c)(8)(v) to state ''alternatively, folic acid or folacin may be listed without parentheses in place of folate.''

8. Several comments recommended that the agency require that information on the quantitative amount by weight of each dietary ingredient be placed immediately after the name of the dietary ingredient, rather than in a separate column. The comments requested this change because of space constraints on the label and the cost of reformatting. One of these comments stated that consumers are already familiar with a format in which amounts immediately follow names on both dietary supplement and traditional food labels, and that there is no evidence that they have difficulties understanding this information. Other comments stated that the use of a single column should be optional. At least one comment specifically supported the proposed two columns because of readability.

The agency is persuaded that information on names and the corresponding amounts of dietary ingredients should be allowed to appear in one column to save space. In the January 4, 1994, final rule on labeling of dietary supplements, the agency required that the name of the nutrient and the quantitative amount by weight appear in a single column despite several comments that argued for a separate column for amounts. When the DSHEA amended the act to allow the source of a dietary ingredient to be listed in the nutrition label following the name, the agency's tentative view was that the additional information added sufficient complexity to make it appropriate to have the information on amount in a separate column. Some consumers buy dietary supplements on the basis of quantitative amounts, and FDA tentatively concluded that a separate column would help consumers to locate this information more readily . However, based on the facts the comments pointed out, that one column would make the dietary supplement nutrition label consistent with that on conventional foods, and that there are space and cost advantages to such a format, the agency has no objection to the optional listing of the quantitative information by weight immediately following the listing of names. The agency is modifying § 101.36(b)(2)(ii) accordingly.

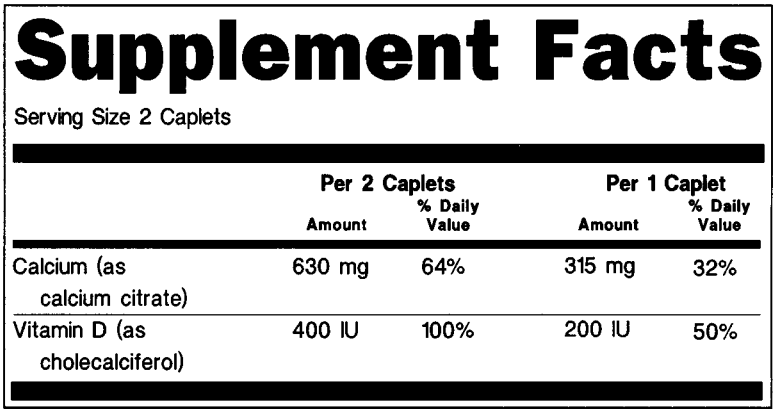
9. A few comments stated that quantitative information should not be declared on the basis of ''per serving.'' Some of these comments requested that information be declared ''per day.'' These comments argued that what is consumed per day is more important than per serving. A couple of other comments preferred dual listing. One suggested ''per unit and per day,'' and the other suggested ''per serving and per day.'' Other comments specifically favored a ''per serving'' basis and opposed dual listing.

The agency does not agree that quantitative information should be declared on a ''per unit'' or a ''per day'' basis instead of ''per serving.'' In its proposal on June 18, 1993 (58 FR 33715 at 33716), FDA tentatively concluded that listing information on the basis of ''per serving'' was preferable to ''per day'' because consumers might not actually consume the amount indicated ''per day.'' With respect to ''per unit,'' FDA expressed concern that this basis alone could confuse consumers when more that 1 unit is to be consumed at one time (e.g. two capsules with each meal) because they might assume that the information is on a ''per serving'' basis because the labels of conventional foods are presented in this manner. For these reasons, the agency required a ''per serving'' basis in the final rule of January 4, 1994 (59 FR 354 at 359), and carried this forward in the December 1995 proposal (60 FR 67194 at 67198). More importantly, the act states in section 403(q)(5)(F)(ii) that the listing of dietary ingredients shall include the quantity of each such ingredient ''per serving.'' Therefore, FDA is not changing § 101.36(b)(2)(ii), which requires that quantitative information be listed on the basis of ''per serving.''

However, with respect to dual listing, the agency is persuaded that there may be some products on which the unit amount may be of interest to consumers, and, therefore, FDA is modifying the regulation to allow the option of listing information on a ''per unit'' basis in addition to a ''per serving'' basis. The agency notes that § 101.9(b)(10)(ii) permits the percent of Daily Value (DV) on the labels of conventional foods to be listed in this manner when the product is in discrete units, and a serving is more than 1 unit. Thus, the agency is adding § 101.36(b)(2)(iv) to provide for quantitative information to be presented voluntarily on the basis of ''per unit'' in addition to the required declaration ''per serving'' as noted in § 101.36(b)(2)(ii). When information is presented on a ''per unit'' basis, it must be declared in additional columns to the right of the ''per serving'' information and must be clearly identified by appropriate headings, as illustrated in Figure 1.

BILLING CODE 4190–01–F

Figure 1



Supplement Facts

Serving Size 2 Caplets

	Per 2 Caplets		Per 1 Caplet	
	Amount	% Daily Value	Amount	% Daily Value
Calcium (as calcium citrate)	630 mg	64%	315 mg	32%
Vitamin D (as cholecalciferol)	400 IU	100%	200 IU	50%

Other ingredients: Polyethylene glycol, carnauba wax, magnesium stearate, and beeswax.

BILLING CODE 4190–01–C

10. One comment requested different rounding rules for sugars. The comment wanted to be able to declare amounts under 2 grams (g) in tenths of a g or to be able to declare 0, 0.5, 1.0, 1.5 and 2.0 g. This comment stated that sugars are present in much smaller amounts in dietary supplements than in conventional foods, and that the proposed rounding rules are inappropriate.

The agency is not persuaded by the comment. Section 101.9(c)(6)(ii) provides that sugars are expressed to the nearest g, except that if a serving contains less than 1 g, the statement ''less than 1 gram'' may be used, and if the serving contains less than 0.5 g, the content may be expressed as zero. While sugars may be present in much smaller amounts in dietary supplements than in conventional foods, FDA points out that the comment did not justify why amounts of sugars that are under 2 g should be listed any differently on the labels of dietary supplements than on the labels of conventional foods. Moreover, given that amounts under 0.5 g are considered nutritionally insignificant, the agency is not convinced that being able to declare sugars in tenths of a g or half-gram increments up to 2 g is useful in helping consumers to maintain a healthy diet. Accordingly, the agency is not changing § 101.36 in response to this comment.

11. One comment requested clarification of the use of the word ''actual'' in proposed § 101.36(b)(2)(ii)(B), which states ''The amounts of vitamins and minerals, excluding sodium and potassium, shall be the actual amount of the vitamin or mineral included in one serving of the product * * *.'' This comment stated that overages of dietary ingredients that are subject to degradation are added to dietary supplement products to ensure that the products provide the labeled quantities throughout their shelf life. The comment asked FDA to acknowledge in the preamble of the final rule that the labeled amounts of vitamins and minerals are not necessarily the actual amounts added at the time of manufacture, and that the corresponding percent DV is based on the labeled amount.

The agency agrees that the proposed language is not clear with respect to what amount is to be declared. The agency does not intend that the declared amount include any overages that a manufacturer includes in anticipation of degradation. By use of the word ''actual,'' the agency was trying to draw a distinction between sodium and potassium, which are required to be declared in the increments prescribed in § 101.9(c), and other vitamins and minerals, for which increments are not prescribed in § 101.9(c). (Section 101.9(c) does not require declaration of the quantitative amounts by weight for these other vitamins and minerals, only that they be declared as a percent of the DV for the nutrient. Thus, the increments for declaration of the quantitative amount of these nutrients are not specified in § 101.9(c).)

Given the reaction to §§ 101.36(b)(2)(ii)(B) and 101.36(b)(2)(iii)(B) that is reflected in the comments, FDA concludes that use of the word ''actual'' in these provisions is confusing. Therefore, the agency is revising these paragraphs to delete this word.

12. Several comments agreed that the regulation should allow the use of ''<1%'' in place of ''less than 1%'' to save space. Some of these comments supported the use of ''<1%'' on the labels of conventional foods as well as on the labels of dietary supplements. One of these comments stated that this symbol for ''less than'' is taught in elementary math and science classes nationwide and is universally recognized. One comment from a trade association that represents manufacturers of conventional foods stated that the food industry has not been permitted the use of this symbol as there was no information demonstrating that consumers understand its meaning. This comment was opposed to the use of the symbol on the labels of dietary supplements until conventional foods are also able to use it.

FDA is persuaded by the comments to allow for the use of the symbol ''<'' for ''less than'' on the labels of dietary supplements and conventional foods to provide more flexibility when space is limited on the label. While there is no consumer survey data to show the level of consumer understanding of the symbol, the agency acknowledges that elementary and secondary schools are teaching its use, so that a growing number of consumers can be expected to understand its meaning. In addition, the agency is aware that the symbol ''<'' is being used on the labels of some conventional foods, and FDA has not received any consumer complaints about its use. Given these unique circumstances, FDA concludes that it is reasonable to allow use of the symbol, thereby reducing the possibility of overcrowding of information on some nutrition labels. Accordingly, § 101.36(b)(2)(iii)(C) is finalized as proposed.

The agency stated in the December 1995 proposal (60 FR 67194 at 67200)

that if it allowed the symbol on the nutrition labels of dietary supplements, it intended ''to provide for such use'' on the nutrition labels of conventional foods as well. FDA finds that it reasonably follows from this statement, and from the conclusions that it has reached with respect to dietary supplements, for it to take this action. Accordingly, the agency is amending § 101.9(c)(8)(iii) and (d)(7)(i) to allow the use of the symbol ''<'' in place of the words ''less than.''

13. Several comments supported the proposed use of the footnote ''Daily Value not established''(§ 101.36(b)(2)(iii)(F)). However, three comments were against the use of this footnote in some cases. These comments stated that the footnote implied that a DV was not ''yet'' established. Consequently, they stated that it should only be permitted for components having some legitimate claim to nutritional value. One comment said that dietary ingredients such as choline should have an asterisk and a footnote, while dietary ingredients such as bee pollen should have no asterisk and no footnote. This comment said that a product composed solely of dietary ingredients such as bee pollen should have no ''% Daily Value'' column, no asterisks, and no footnote.

The agency does not agree with the comments that argued that the footnote apply only to dietary ingredients that ''have nutritional value.'' The comments did not suggest a definition for dietary ingredients that have a ''claim to nutritional value,'' or how to distinguish such dietary ingredients from the other dietary ingredients for which no DV has been established. Thus, the agency does not know how it would implement the suggested change. The act makes it clear in section 403(q)(5)(F)(i) that dietary ingredients not having a recommendation for daily consumption established by the Secretary are to be identified as ''having no such recommendation.'' Accordingly, FDA is adopting § 101.36(b)(2)(iii)(F) unchanged from the proposal.

C. Other Dietary Ingredients

14. Several comments recommended that ''other dietary ingredients'' (those not having recommendations, i.e., no RDI's or DRV's) should be listed outside the ''box'' format for nutrition information, and that products composed solely of these dietary ingredients, such as herbal supplements, should not be required to use the ''box'' format. One of these comments suggested not requiring a ''box'' format unless a claim is made. These comments stated that herbal supplements are not consumed for their nutritional value, and that it is not appropriate to use a format that mimics that of the Nutrition Facts panel. They said that the use of such a format would confuse consumers and would not convey any meaningful information. They argued that such a format goes beyond the intention of the DSHEA.

One comment stated that simple ingredient listing should be an option in lieu of nutrition labeling. Another comment, which requested more flexibility, said that the agency should allow the ''labeler to present the information to the consumer in the best way they see fit.'' One other comment stated that flexibility in format was needed because of space constraints and recommended that the special labeling provisions in § 101.9(j)(13) should apply to dietary supplements.

The agency is not persuaded by these comments that the format that it proposed goes beyond the intention of the DSHEA. To the contrary, the agency concludes that the format is consistent with the DSHEA.

As a result of the DSHEA, the act requires that nutrition information immediately precede the ingredient information (section 403(q)(5)(F)(iv)), requires that the nutrition information list dietary ingredients not having recommendations (section 403(q)(5)(F)(i)), and defines herbs and other botanicals as dietary ingredients when present in dietary supplements (section 201(ff)(1)). Taken together, the only logical reading of these provisions is that herbal dietary ingredients are to be listed in the nutrition information. Accordingly, the agency is not making any change in § 101.36 in response to these comments. The agency notes that § 101.36(i)(2) provides that dietary supplements are subject to the special labeling provisions specified for small and intermediate-sized packages in § 101.9(j)(13).

15. Several comments requested that the ''other dietary ingredients,'' those not having RDI's or DRV's, including those in a proprietary blend, should be allowed to be declared in paragraph form beneath the bar required in § 101.36(e)(6)(ii) (i.e., in a linear format with the quantity of each dietary ingredient immediately following the name of the ingredient itself) to save space. An example of such a label was included in one comment. One comment from a dietary supplement manufacturer stated that the majority of its products would qualify for an exemption or a linear layout under the special provisions for small or intermediate-sized packages in § 101.9(j)(13) if they were labeled as conventional foods.

FDA points out, as stated in response to the previous comment, that § 101.36(i)(2) provides that dietary supplements are subject to the special labeling provisions specified in § 101.9(j)(13) for foods in small or intermediate-sized packages, which includes the option of a linear layout when there is insufficient space for the vertical or tabular display. Also, § 101.36(c)(2) provides that the ''other dietary ingredients'' contained in a proprietary blend may be listed in linear fashion indented under the term ''Proprietary Blend.'' In addition to the flexibility that these sections provide, FDA has no objection if a linear display is used for the listing of all ''other dietary ingredients'' on the labels of dietary supplement products, regardless of package size. However, as discussed in comment 18 below, when constituents (i.e., subcomponents) of ''other dietary ingredients'' are listed, they must be indented under the listing of the dietary ingredient. Thus, it is not possible to use a linear display for ''other dietary ingredients'' when constituents are listed for any of them.

Therefore, the agency is revising § 101.36(b)(3)(i) and (b)(3)(ii) to provide explicitly that other dietary ingredients may be declared in a linear display as long as none of the dietary ingredients list constituents. Figure 2 illustrates the declaration of other dietary ingredients in a linear display.

BILLING CODE 4190–01–F

Figure 2

Supplement Facts

Serving Size 2 Capsules

Amount Per 2 Capsules		% Daily Value
Vitamin C	30 mg	50%
Calcium (from dicalcium phosphate)	200 mg	20%
Phosphorous (from dicalcium phosphate)	125 mg	12%

Choline (from choline bitartrate), 30 mg*; Inositol, 15 mg*; Alfalfa Powder, 25 mg*

* Daily Value not established.

Other ingredients: Gelatin, cellulose, magnesium stearate, water.

BILLING CODE 4190–01–C

16. One comment recommended that the listing of other dietary ingredients be alphabetical. The comment stated that this order would be user-friendly and assist consumers in making comparisons between various products. Several other comments specifically stated that they agreed with the proposed rule, which would allow the manufacturer to determine the order of these dietary ingredients. One of these comments stated that there is no obvious benefit to alphabetical order or to descending order of predominance by weight because the quantity of each dietary ingredient is included. Another comment stated that order based on predominance by weight could confuse consumers by incorrectly implying that the dietary ingredients that are present in greater predominance are of greater value.

As discussed in the proposal (60 FR 67194 at 67210), the agency considered proposing to require alphabetical order but did not because it is not scientifically meaningful. The agency requested comments on this issue. Because the majority of the comments supported the flexibility provided in the proposal, the agency is not persuaded that it is necessary to require that other dietary ingredients be listed in alphabetical order. Manufacturers may, of course, do so if they choose.

17. Several comments strongly opposed the statement in proposed § 101.36(b)(3)(ii) that ''or any dietary ingredients that are liquid extracts, the weight shall not include the weight of solvents.'' The comments stated that the proposal is not practicable because in many cases there are no methods to determine the identity and quantity of entities dissolved in solvents. One comment from a trade association of manufacturers of natural food products stated that FDA should allow a truthful and nonmisleading description of the content of an extract, such as the ratio of the weight of the starting material to the volume of the solvent used. This comment said that the association is working with other industry groups to develop a uniform method of reporting this information that is not false or misleading. Another comment pointed out that the ratio method could be misleading in the absence of compendial standards because different supplies of the same herb can yield various strengths and potencies. For this reason, the comment discouraged the use of indicators of activity until compendial standards are established.

Another comment stated that FDA should defer action on this issue until there is scientific agreement on appropriate methodology and, in the interim, require that extracts be listed with the weight of the entire extract. A comment from a trade association for herbal product manufacturers agreed that extracts should be listed with the weight of the entire extract, e.g. ''Dandelion root extract (0.5 fl oz).'' This comment said that the identity of the dietary ingredients of botanical liquid extracts are the herbal extracts themselves.

The agency is persuaded by the comments that the proposed manner of declaring extracts is not appropriate. The agency acknowledged in the proposal that this matter is a difficult one and specifically requested comment on how these provisions should be implemented. The comments pointed out that the dietary supplement industry and others are developing methods that will result in better information on the composition of such extracts. However, FDA does not agree that it should defer action until validated methods are available or, in the meantime, require only that manufacturers list the weight of the entire extract. The agency is persuaded by the comment that recommended that extracts should be described by a ratio of the weight of the starting material to the volume of the solvent or a description of these values, which would indicate the concentration of the extract. The agency notes that the label must state whether the starting material is fresh or dry. Because fresh botanicals contain water, it is important that the label have this information so that consumers can determine whether the weight listed includes the weight of any water.

FDA has subdivided proposed § 101.36(b)(3)(ii) to address the listing of liquid extracts in § 101.36(b)(3)(ii)(B) and of dried extracts in (b)(3)(ii)(C). The agency is requiring in § 101.36(b)(3)(ii)(B) that the label of liquid extracts clearly state whether the

starting material is fresh or dry, what solvent is used, and the concentration of the botanical in the solvent, e.g., ''fresh dandelion root extract, x mg (y:z) in 70% ethanol'' where ''x'' is the number of mg of the entire extract, ''y'' is the number of mg of the starting material and ''z'' is the number of milliliters of solvent. Where the solvent has been partially removed (not to dryness), the final concentration should be stated (e.g., if the original extract had a ratio of 1:5, and 50 percent of the solvent were removed, the concentration listed would be 1:2.5).

Section 101.36(b)(3)(ii)(C) of this final rule states that where the solvent is removed to dryness, the weight of the dried extract must be listed. Also, the dried extract must be described in a manner that includes the identity of the solvent because the solvent used determines the composition of an extract. For example, hexane as a solvent would concentrate nonpolar constituents, and water would concentrate polar constituents. These two dried extracts could have very different compositions. Thus, the type of extract (e.g., ''dried hexane extract of _____'' or ''_____, dried hexane extract'') is a material fact under sections 201(n) and 403(a) of the act and must be specified on the label, even when the solvent is removed during processing.

The agency points out that solvents removed during processing that do not have any technical or functional effect in a food are exempt from being listed in ingredient labeling in accordance with § 101.100(a)(3)(ii)*(a)* (21 CFR 101.100(a)(3)(ii)*(a)*. However, solvent information is needed in the nutrition label of dietary supplements to appropriately describe extracts because dietary ingredients do not have individual regulations, like the regulations for food additives, that specify how they are to be made, and, when needed for identity or safety reasons, what solvent can be used in the processing. For example, § 172.580(b) (21 CFR 172.580(b)) states that safrole-free extract of sassafras is to be obtained by extracting the bark specified with dilute alcohol. There is no parallel provision for, nor is § 172.580(b) applicable to, the use of this substance in a dietary supplement. Therefore, in the absence of individual regulations on dietary ingredients, the agency is requiring in § 101.36(b)(3)(ii) that a dried extract be described by an appropriately descriptive term that identifies the solvent used.

18. Several comments requested the flexibility of listing both a dietary ingredient and one or more of its constituents (i.e., subcomponents) to provide consumers with more information. One of the comments favoring this approach stated that, while two different supplements may both contain the same amount of a botanical, one product may yield twice as much of a particular constituent as the other brand. Most of these comments suggested that constituents of a dietary ingredient should be indented under the listing of the dietary ingredient because consumers are familiar with this format, as it is comparable to the format used for certain DRV nutrients and their subcomponents in the nutrition labeling of conventional foods. Alternatively, a couple of comments suggested that constituent information immediately follow the listing of the dietary ingredient within parentheses. Most of the comments gave examples where both the constituents and the dietary ingredients do not have RDI's or DRV's, but one comment suggested that vitamin A and vitamin C should be indented under fish oil. One comment stated that if FDA does not allow information about constituents inside the ''Supplement Facts'' box, it should clarify that such information is allowed elsewhere on the label.

The agency is persuaded by the comments to allow more flexibility with respect to the listing of constituents of dietary ingredients that do not have RDI's or DRV's, as long as the resultant labels are not inconsistent with the act and are not confusing to consumers. The agency is requiring that constituents, when they are listed, be indented under the listing of the dietary ingredient in either a column or, to save space, in a horizontal linear display. Quantitative amounts of the constituents must be listed and also must be included in the total quantitative amount listed for the dietary ingredient. The agency is requiring that the dietary ingredient and its weight be presented on one line, and that any information on constituents be indented under the declaration of the dietary ingredient to help clarify to consumers that the constituents are contained in the dietary ingredient. Accordingly, the agency is adding new § 101.36(b)(3)(iii) to provide that the constituents of dietary ingredients not having RDI's or DRV's may be listed. Proposed § 101.36(b)(3)(iii) is redesignated as § 101.36(b)(3)(iv).

When constituents of other dietary ingredients are dietary ingredients described in § 101.36(b)(2), they are to be listed in accordance with § 101.36(b)(2). Section 403(q)(5)(F)(i) of the act provides that dietary ingredients having recognized dietary recommendations are to be listed first to be followed by the dietary ingredients not having recommendations. Accordingly, with respect to the fish oil example, § 101.36(b)(2) requires that vitamin A and vitamin C be listed in the top half of the nutrition label, and that source information may be included following the listing of each in accordance with section 403(q)(5)(F)(iii) of the act , e.g., ''vitamin A (from fish oil).'' Listing vitamin A and vitamin C as constituents under the listing of fish oil is inconsistent with section 403(q)(5)(F) of the act.

D. Proprietary Blends

19. One comment stated that there is no need to require a dietary supplement that is a proprietary blend to be identified specifically as a ''proprietary blend.'' This comment gave an example that used the word ''blend'' in place of ''proprietary blend'' and noted that there are synonyms of ''blend'' that would also accurately describe these products. However the comment did not list specific synonyms. The comment stated that there is no reason to limit label flexibility in this regard. Other comments supported the use of the term ''proprietary blend.'' One comment stated that, while a company has the obligation to identify such blends, most users of these blends have devised fanciful or trademarked names for them, and the term ''proprietary blend'' should not have to be repeated in the top half of the nutrition label when source information is included in parentheses, and the blend is a source of one or more of the 14 mandatory nutrients.

FDA is persuaded by the comment that it is not necessary to include the term ''proprietary blend'' when the blend is identified by another term or fanciful or trademarked name. Inasmuch as the act does not require use of the term ''proprietary blend,'' and the formatting requirements (i.e., declaration of total weight of blend followed by listing of dietary ingredients in the blend) will make the presence of a proprietary blend apparent, the agency is modifying § 101.36(c), (c)(2), and (c)(3) to state that the blend may be identified by the term ''Proprietary Blend'' or another appropriately descriptive term or fanciful name.

Regarding the comment that stated that the name of a proprietary blend should not have to be repeated each time it is a source of a nutrient, the agency points out that this would not happen. Firms are to list the specific ingredient in a proprietary blend that supplies a nutrient, rather than list the name of the proprietary blend.

20. Another comment requested that the words ''Proprietary Blend'' be allowed in bold type. The comment stated that in some instances, a bold type heading may be easier to see and to understand than an indented list of ingredients below the heading. The comment did not include a sample label illustrating its recommendation.

The agency is not persuaded that bolding the term ''Proprietary Blend'' is preferable to indenting the dietary ingredients in the blend under the term to show that these ingredients are included in the blend. Indentation is used in other situations to convey the concept of inclusion (e.g., in the listing of subcomponents of nutrients in nutrition labels on conventional foods in § 101.9(c) and on dietary supplements in § 101.36(b)(2)(i)(B)). As an example, § 101.9(c)(2)(i) provides that ''Saturated Fat'' be indented under the listing of ''Total Fat.''

At the same time, § 101.9(d)(1)(iv) provides that nutrients that are not indented, such as ''Total Fat'' and ''Total Carbohydrate,'' are to be bolded. Consequently, while the agency has decided to retain the requirement in § 101.36(c)(2) that dietary ingredients contained in a proprietary blend be indented under the term ''Proprietary Blend'' or descriptive term or fanciful name used in its place, FDA does not object to the voluntary bolding of this term. Accordingly, the agency is changing § 101.36(c) to permit bolding.

21. One comment objected to the requirement that a proprietary blend list its dietary ingredients in descending order of predominance by weight. This comment requested that the agency permit the listing of a ''lesser ingredient'' first when the weight of the ingredient is specified. The comment did not give a reason for this request.

FDA is rejecting this request. To allow a dietary ingredient in a proprietary blend to be listed first when its weight is voluntarily declared would create an implication that there is less of the other dietary ingredients in the blend than the ingredient that is listed first. The only way to avoid creating this impression would be to list the weight of each of the other ingredients. Yet, by definition, the amounts of the ingredients in the blend are proprietary. Thus, the agency concludes that, when a proprietary blend is involved, the only way to avoid misleading consumers is to require that the ingredients of the blend be listed in descending order of predominance. If a manufacturer wishes to voluntarily list the weights of ingredients, it is free to do so, but FDA is not requiring such a disclosure for other dietary ingredients in a proprietary blend. Therefore, FDA is not changing § 101.36(c)(2) in response to this comment.

E. Sources

22. Several comments requested that dietary ingredient sources be permitted to be declared in the nutrition label without parentheses or without the word ''as'' or ''from.'' One of these comments stated that these points should be left up to the judgment of the manufacturer. This comment stated that the meaning of ''calcium from calcium carbonate'' is clear without the use of parentheses, and that flexibility is needed to save space. One comment expressed support for the proposal and stated that the format proposed will help consumers to understand the relationship between the dietary ingredient and its source.

The agency is not persuaded that space constraints justify making the use of parentheses, or of the words ''as'' or ''from,'' optional. In fact, some dietary supplements in small or intermediate-sized containers currently use the words ''as'' or ''from'' to help consumers understand that such compounds are the source of the dietary ingredients.

The agency continues to be concerned that allowing flexibility in the manner in which dietary ingredient sources are listed in the nutrition label could lead to consumer confusion. FDA has received many inquiries over the years that questioned whether amounts specified on labels refer to the weight of a particular nutrient or to the salt of that nutrient used to make the supplement. Having parentheses around the source compound makes it clear that the quantitative amount and % DV pertain to the dietary ingredient listed and not to the source. Thus, FDA concludes that the format that it proposed is the most clear and should not be optional. Accordingly, FDA is not changing § 101.36(d) in response to these comments.

23. The agency received a comment on the proposed requirement (see proposed §§ 101.4(g) and 101.36(d)) that the ingredient list on dietary supplements be preceded by the word ''Ingredients'' or, when some ingredients (i.e., sources) are identified within the nutrition label, by the words ''Other ingredients.'' The comment, which was from a trade association for conventional foods, noted that the term ''Ingredients'' is in common usage in the labeling of conventional foods to denote the ingredient declaration but is not required. The comment stated that this requirement would set an adverse precedent for the labeling of conventional foods and requested that the use of these identifying terms be optional.

The agency acknowledges that the ingredient declaration on the labels of conventional foods are not required to be preceded by the word ''Ingredient.'' However, the labels of conventional foods do not allow ingredient information in the nutrition label, so the potential for consumer confusion is not an issue. Given the fact that the DSHEA requires dietary ingredients not having RDI's or DRV's to be listed in the nutrition label of dietary supplements along with their amounts and also permits the sources of these dietary ingredients to be included in the nutrition label, the agency concludes that it is important that the nutrition information and the ingredient information on labels of dietary supplements be clearly identified. Inasmuch as no comments from the dietary supplement industry objected on this point, and as the situation presented by dietary supplements is distinguishable from that presented by conventional foods, FDA does not view this regulatory action as setting a precedent for conventional foods. Thus, the agency is not making any changes in § 101.36(d) or § 101.4(g) on the designation of ingredients in response to this comment.

24. One comment urged the agency to abandon the requirement in proposed §§ 101.36(d) and 101.4(h) that the common or usual name of ingredients that are botanicals be followed by the Latin binomial name of the plant. This comment stated that Latin binomials are generally meaningless to consumers and take up valuable label space. Another comment stated that Latin binomials should only be used on dietary supplements sold to health professionals because they have the training to understand them. Several other comments pointed out that the book *Herbs of Commerce* (Ref. 11) establishes individual common names for over 600 of the most prominent botanical ingredients in trade and gives the corresponding Latin name for each common name. These comments recommended that the agency require the use of these standardized common names in labeling and not require the listing of Latin names when they are available in this reference. Other comments did not object to listing Latin binomials but did object to including the designation of the author who published the name. Another comment requested that abbreviations of Latin binomials be allowed to save space.

The agency is persuaded by the comments that the common names for botanicals standardized in the book

Herbs of Commerce (Ref. 11) should be used in labeling. Because this reference lists the Latin binomial for each standardized common name, the agency is persuaded that a Latin binomial need not be included on labels when this information is available in *Herbs of Commerce* (Ref. 11). Thus, the agency is changing §§ 101.36(d)(1) and 101.4(h) accordingly. Latin binomials will be required except when the common or usual name of the botanical is available in this reference, and the designation of the author will be needed when a positive identification can not be made in its absence (§ 101.4(h)(2)). The agency reiterates that when a Latin binomial is required, the complete binomial is required for each botanical present, even when multiple species of the same genus are present.

With respect to the use of abbreviations of Latin binomials, the agency proposed that any name in Latin form shall be in accordance with internationally accepted rules on nomenclature, such as those found in the *International Code of Botanical Nomenclature*, which does not include rules for the use of abbreviations (Ref. 12). The comment that requested that abbreviations be permitted did not address why they should be permitted when they are not included in the *International Code of Botanical Nomenclature* (Ref. 12). In the absence of clearly defined rules, the agency is concerned that allowing abbreviations would cause a great deal of confusion. For example, there are 66 plant names that could be represented by the abbreviation ''*A. alba*.'' For this reason, the agency is not changing the regulation to allow for Latin binomials to be abbreviated.

25. One comment requested that FDA not require the declaration of the part of the plant for botanical ingredients that are used as a source material for other dietary ingredients. This comment stated that section 403(s)(2)(C) of the act requires that the labeling identify the part of the plant from which an herb or other botanical dietary ingredient is derived. Thus, the comment contends that this information should not be required when an herb or other botanical is the source of a dietary ingredient.

The agency agrees with this comment. As stated, the act, as a result of the DSHEA, requires identification of the part of a plant when a supplement contains a dietary ingredient that is an herb or other botanical. However, a constituent (i.e., a chemical component) of a botanical may be a dietary ingredient under section 201(ff)(1)(F) of the act. When a constituent is listed, the agency agrees that information on the part of the plant is not required by the act.

26. Several comments objected to the requirement that the part of the plant be listed in parentheses after the listing of the Latin binomial. These comments requested that, as an alternative to allow flexibility and to save space, the listing of the part of the plant be permitted without parentheses following the common name of the plant. One of these comments stated that listing the part of the plant in this manner was more comprehensible.

The agency points out that these final regulations do not require that Latin binomial names be included when they are available in *Herbs of Commerce* (Ref. 11) (see comment 24 in section III.E. of this document). In these cases, the part of a plant would immediately follow the listing of the common name. When a Latin binomial name is required, the agency has no objection to having it be listed after the part of the plant. Furthermore, FDA is persuaded that, to save space, the listing of the part of the plant should be permitted to follow the common name of the plant without parentheses. Therefore, the agency is reversing the order of proposed § 101.4(h)(1) and (h)(2) to reflect the order in which the information is to be provided and is revising the paragraph renumbered as § 101.4(h)(2) in response to these comments. The agency notes that § 101.36(d)(1) does not need to be changed in response to these comments as it cross references § 101.4 and does not provide specific information on how to list the part of a plant.

27. One comment requested the option of listing each of the separate parts of a plant instead of the words entire ''plant,'' when all parts of a plant are used. The comment stated that it is quite rare to actually use all parts of a plant. This comment also requested that the word ''herb'' be permitted to refer to the above ground parts of a plant. The comment said that Webster's *New Universal Dictionary* (2d ed., 1983) gives ''herbage'' as a definition of ''herb,'' and that ''herbage'' is defined as ''the green foliage and juicy stem of herbs.''

The agency does not object to the listing of each of the separate parts of a plant instead of the words ''entire plant.'' While this point was not addressed in the codified section of the proposal, the agency did make the statement in the preamble that when an entire plant is used, the label should specify ''entire plant'' to meet the requirements of the act. The agency made this statement assuming that manufacturers would not want to list all the parts of a plant. However, the agency would not object if a manufacturer listed all the individual parts of a plant because such a listing is consistent with the DSHEA.

Regarding the request that the word ''herb'' be permitted to describe the above ground parts of a plant, the agency is not convinced that this usage is appropriate. FDA notes that the primary definition of the word ''herb'' in many dictionaries refers to a type of a plant, i.e., a nonwoody plant whose aerial portion is relatively short lived (only a single growing season in the temperate zone), rather than a part of a plant. Accordingly, the agency is not persuaded by the comment that consumers would understand the term ''herb'' to mean that part of the plant grown above ground and is denying this request. However, the agency has no objection to the use of the term ''aerial part'' to describe the above ground parts of a part.

F. Format

28. Several comments requested that the nutrition label be entitled ''Nutrition Facts'' for all dietary supplements. These comments stated that ''Nutrition Facts'' should be used for a variety of reasons, including that: (1) These products are marketed for their nutritional value, (2) the information presented is about nutrition, (3) the DSHEA uses the term ''nutrition information'' (see section 403(q)(5)(F)(i) of the act), (4) the heading should be consistent with the heading used for conventional foods, (5) some conventional foods do not have nutritional value; thus, ''Nutrition Facts'' on dietary supplements is acceptable, and (6) consumers would be confused by the heading ''Supplement Facts'' and think that the products are of lesser value than conventional foods. One of these comments said that the heading ''Supplement Facts'' is a misnomer because it implies that the information is supplemental and not complete. Another comment stated that the heading ''Supplement Facts'' would be a violation of § 101.9(k)(6), which provides that a food is misbranded if its label differentiates in any way between vitamins that are naturally present and those that are added.

Other comments recommended that the use of the heading ''Nutrition Facts'' or ''Supplement Facts'' should depend on the composition of a particular dietary supplement. Some of these comments stated that a product containing even one vitamin or mineral having a DV-nutrient should be able to use the heading ''Nutrition Facts'' because the product would have nutritional value. Another comment

wanted products containing only DV-nutrients to use the heading ''Nutrition Facts'' and had no opinion on other products. Other comments said that products that were mostly DV-nutrients should use the heading ''Nutrition Facts,'' and products that were mostly herbals should use the heading ''Supplement Facts.'' One comment wanted the option of using both headings in one nutrition label, listing DV-nutrients under the heading of ''Nutrition Facts'' and other dietary ingredients under a secondary heading of ''Supplement Facts.'' Some of these comments recommended that the use of ''Nutrition Facts'' or ''Supplement Facts'' for combination products should depend upon how a product is marketed (i.e, the focus of the claims). A couple of these comments wanted the option of using ''Dietary Supplement Facts'' or ''Herbal Facts'' in place of ''Supplement Facts.'' Additionally, at least one of these comments said that all dietary supplements in conventional food form should use the heading ''Nutrition Facts.''

Several other comments supported the proposed heading of ''Supplement Facts'' for all dietary supplements. One of these comments said that this heading is consistent with the DSHEA, and another said that it will help consumers recognize the differences between dietary supplements and conventional foods.

FDA is not persuaded that the heading should be ''Nutrition Facts'' because the DSHEA uses the term ''nutrition information,'' because the information presented, at least in part, is about nutrition, or because these products are marketed for their nutritional value. The nutritional value of a particular product does not determine whether it is a dietary supplement or a conventional food. Many dietary supplements contain many DV-nutrients; many contain none. Additionally, the agency is not persuaded by the argument that consumers will be confused by the heading ''Supplement Facts'' and think that products labeled in this manner are of lesser value. ''Supplement'' is the single word that must be used in the statement of identity for all dietary supplements (see comment 1 in section II. of this document), so use of the term in the title of the nutrition label can assist consumers in identifying dietary supplement products. The agency is not convinced that the name ''Supplement Facts'' will result in any consumer judgment of the value of the product. Dietary supplements have been known as ''supplements'' for years, and FDA is not aware of any confusion caused by this term. Also, the supplemental nature of these products is supported by the new definition in section 201(ff)(2)(B) of the act, which states that a dietary supplement can not be ''represented for use as the sole item of a meal or the diet.''

The agency does not agree that use of the title ''Supplement Facts'' is a violation of § 101.9(k)(6). The distinguishing characteristic between products bearing nutrition labeling entitled ''Supplement Facts'' and those bearing nutrition labeling entitled ''Nutrition Facts''is whether the products are dietary supplements or conventional foods, not whether the vitamins are natural or synthetic. Both conventional foods and dietary supplements can include natural and synthetic vitamins.

Furthermore, the agency does not accept the suggestion that some dietary supplement products should have the heading ''Nutrition Facts,'' while others have various headings (''Supplements Facts,'' ''Herbal Facts,'' and ''Dietary Supplements Facts'') or even two headings (''Nutrition Facts'' for the top half and ''Supplement Facts'' for the bottom half). The act does not support treating supplements of vitamins and minerals any differently than other types of supplements. Therefore, the agency is not doing so. In addition, if the agency consented to these recommendations, it would be possible for some chemically identical products to use up to four different headings. The agency concludes that so many different headings would only serve to confuse consumers.

FDA agrees with the comments that said that the heading of the nutrition label for all dietary supplements should be entitled ''Supplement Facts.'' While dietary supplements are a category of foods, the act distinguishes dietary supplements from conventional foods in many important ways, e.g., different requirements with respect to safety, to the types of claims that can be made, and to the kind of information that must be provided in the nutrition label. As stated in the preamble of the proposal and in one of the comments, the heading ''Supplement Facts'' will help consumers to clearly distinguish between dietary supplements and conventional foods. Nothing in the comments has persuaded FDA that the heading ''Supplement Facts'' would not help consumers to readily identify these products as dietary supplements. Therefore, the agency is not changing § 101.36(e)(1) in response to the comments.

However, the agency does advise that the decision whether a product is sold as a dietary supplement is made by the manufacturer. Under the act, as amended by the DSHEA, the term ''dietary supplement'' is defined as a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients (section 201(ff)(1) of the act). Section 201(ff)(2) of the act further states that dietary supplements are intended for ingestion in a form described in section 411(c)(1)(B)(i) of the act (21 U.S.C. 350 (c)(1)(B)(i)) or in compliance with section 411(c)(1)(B)(ii) of the act, are not represented as conventional food or as a sole item of a meal or the diet, and are labeled as a dietary supplement.

Thus, dietary supplements may be similar to conventional foods in composition and form. Whether a product is a dietary supplement or a conventional food, however, will depend on how it is represented. To be a dietary supplement, a product must bear the term ''dietary supplement'' as part of its common or usual name. (As stated in comment 1 in section II. of this document, this term may be modified to include the name of the dietary ingredient or type of dietary ingredient, such as ''Vitamin C Supplement'' or ''Multivitamin Supplement.'')

Products that are not represented as dietary supplements will be subject to regulation as conventional foods. For example, the manufacturer of a product that is in the form of a tablet or capsule that has nutritive value or a powdered herbal product with no nutritive value may choose to market the product as a conventional food that bears nutrition labeling in accordance with § 101.9. In that situation, the nutrition labeling on the package of tablets with nutritive value would use the title ''Nutrition Facts,'' while the herbal product with no nutritive value would be exempt from nutrition labeling under § 101.9(j)(4). Should the manufacturer choose to do this, however, the label or labeling could not represent the food as a ''dietary supplement,'' and the product could not rely on any of the special provisions for dietary supplements that were added by the DSHEA. Thus, for example, the ingredients of the product would not be eligible for the exception for dietary ingredients from the definition of a ''food additive,'' and the product could not bear statements under the authority of section 403(r)(6) of the act.

29. Several comments objected to the use of hairlines in the nutrition label for space and readability reasons. One of these comments said that the use of hairlines should be optional, and another said that hairlines should not be required if there are more than eight dietary ingredients to be declared. Another comment requested that dots be allowed instead of hairlines when the use of hairlines would cause the type size to fall under 4.5 points. This comment sent sample labels with hairlines, without hairlines, and with dots. The dots connected the name of a dietary ingredient to the quantitative amount and the amount to the percent DV (see sample label in Figure 3).

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Figure 3

Supplement Facts
Serving Size 1 Caplet

Amount Per Caplet		% Daily Value
Vitamin A (20% as beta-carotene)	5000 IU	100%
Vitamin C	90 mg	150%
Vitamin D	400 IU	100%
Vitamin E	30 IU	100%
Vitamin K	28 mcg	35%
Thiamin	3 mg	200%
Riboflavin	3.4 mg	200%
Niacin	20 mg	100%
Vitamin B_6	3 mg	150%
Folate	400 mcg	100%
Vitamin B_{12}	9 mcg	150%
Biotin	30 mcg	10%
Pantothenic Acid	10 mg	100%
Calcium	40 mg	4%
Iron	18 mg	100%
Phosphorous	31 mg	3%
Iodine	150 mcg	100%
Magnesium	100 mg	25%
Zinc	15 mg	100%
Selenium	21 mcg	30%
Copper	2 mg	100%
Manganese	3.5	175%
Chromium	26 mcg	22%
Molybdenum	32 mcg	43%
Chloride	10 mg	<1%
Potassium	10 mg	<1%
Boron	150 mcg	*
Nickel	5 mcg	*
Silicon	2 mg	*
Tin	10 mcg	*
Vanadium	10 mcg	*

* Daily Value not established

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The comments did not provide information to show that the legibility of the nutrition label is maintained if hairlines are allowed to be used optionally. Section 2(b)(1)(A) of the 1990 amendments directed the Secretary (and by delegation FDA) to require that the information required in nutrition labeling be conveyed in a manner that enables the public to readily observe and comprehend such information. To implement this provision of the 1990 amendments, FDA issued a rule that required hairlines in the nutrition label. Hairlines make the nutrition label easier to read by aiding consumers' eye movement from the name of the nutrient to the percent DV. Consumer surveys have shown that the graphic requirements in the nutrition labeling in § 101.9 were successful in that the majority of shoppers who are aware of the new label think it is clear and understandable (Ref. 3). Therefore, FDA is not willing to remove the requirement for hairlines without evidence that the legibility and readability of the nutrition label will be maintained on dietary supplement products, particularly when the product contains a large number of dietary ingredients.

However, the agency finds that the sample label submitted that uses dots to connect the nutrient name to the weight and percent DV is a satisfactory substitute to assist eye movement when the only other option would be to reduce type size below 4.5 points, the minimum type size consistent with the Nonprescription Drug Manufacturers Association (NDMA) Label Readability Guidelines used for over-the-counter drugs (Ref. 4). This suggested flexibility appears to offer a reasonable balance between the competing needs for label space and readability on small and intermediate-sized packages. Accordingly, the agency is adding § 101.36(i)(2)(v) to provide that dots connecting columns of nutrient names and quantitative amounts are allowed in place of hairlines between rows of type on small and intermediate-sized packages when it is not possible to meet the minimum type size requirements of 4.5 points if hairlines are used.

30. Several comments objected to the bar that separates the dietary ingredients having RDI's or DRV's from other dietary ingredients because it may imply to consumers that other dietary ingredients are of lesser importance and it takes up space. One comment said that the bar should be optional because the asterisk and footnote ''Daily Value not established'' are sufficient to distinguish other dietary ingredients. One trade association said that some of their members disliked this bar because it creates an artificial and illogical separation in some cases, e.g., for a product containing only vitamins and minerals, but with some minerals for which an RDI has not been established. This comment said that other members liked the bar because it highlights the second portion of the list of dietary ingredients. Other comments supported the proposed use of the bar.

The agency is not persuaded by the comments that the bar should be eliminated because it may imply that the dietary ingredients below it are of lesser importance. While the agency acknowledges that the use of a bar is not expressly required by the act, section 403(q)(5)(F)(i) of the act states that ''nutrition information shall first list those dietary ingredients * * * for which a recommendation for daily consumption has been established by the Secretary * * * and shall list any other dietary ingredient present and identified as having no such recommendation.'' As discussed in the December 1995 proposal (60 FR 67194 at 67206), the bar helps consumers to readily distinguish these two types of dietary ingredients, just as a bar differentiates between macronutrients and vitamins or minerals in the nutrition labeling of conventional foods. The agency does not agree that the asterisk and the footnote are sufficient for consumers to readily distinguish between these two groups because there are some cases where the asterisk and the footnote would be required for dietary ingredients listed above the bar (e.g., sugars). For these reasons, the agency is not willing to eliminate the bar to conserve space. The agency points out that it has made a number of changes to save space, such as allowing the names of dietary ingredients and the corresponding amounts to appear in one column. Thus, the agency is not making any change in § 101.36(e)(6)(ii) in response to these comments.

G. Compliance

31. Several comments objected to the statement in proposed § 101.36(f)(1) that compliance will be determined in accordance with § 101.9(g)(1) through (g)(8). In particular, the comments objected to the application of § 101.9(g)(4)(i), which provides that the content of added nutrients should be at least 100 percent of the value declared in the nutrition label, except for variability because of analytical methods. One comment supported the proposal and said that products should contain the levels that are declared.

Many of the comments in opposition requested that § 101.36(f)(1) be revised to state that supplements claiming to comply with compendial standards shall be judged ''based on compliance procedures specified or incorporated by reference in the compendial specifications.'' Specifically, these comments requested that the compliance level be a fixed minimum of 90 percent that does not allow for variability because of methods, in accordance with standards in the USP.

A comment from USP stated that its lower limit is not a moving target depending on analytical precision or on whose laboratory is performing the test.

Another comment explained that some nutrients are subject to degradation. This comment said that overages of these nutrients are added to dietary supplement products to ensure that the products provide the labeled amounts throughout their shelf life. To avoid excessive overages, the USP has required that at any time that a product is analyzed during its shelf life, the product must be shown to supply at least 90 percent of the labeled amount of any ingredient. These comments argued that Congress called for compendial products to meet compendial specifications (see section 403(s)(2)(D) of the act), and that FDA should not alter those requirements.

The agency is not persuaded that a fixed minimum of 90 percent of the labeled amount should be acceptable for the nutrition panel of dietary supplements. FDA agrees that section 403(s)(2)(D) of the act provides that a dietary supplement is misbranded if it is covered by the specifications of an official compendium, is represented as conforming to those specifications, but fails to do so. Thus, dietary supplement products that are represented to meet the specifications of an official compendium, such as the USP, and fail to do so are misbranded under this section. However, the agency points out that products not misbranded under this section may be misbranded under other sections of the act.

The issue of the acceptable amount of an added vitamin or mineral in a dietary supplement has been raised in earlier final rules (58 FR 2079 at 2171, January 6, 1993; and 59 FR 354 at 369, January 4, 1994). As discussed in those final rules, the agency informed USP in 1991 that anything less that 100 percent of the value declared on the label was not acceptable with the exception of a deviation that is attributable to the analytical method (Ref. 5). FDA finds nothing in the comments that would justify accepting less than 100 percent of the value declared as compliance for added nutrients in dietary supplements. The argument that 90 percent is appropriate because some nutrients degrade is not sufficient justification for the agency to change its position. Because the degradation is foreseeable, FDA expects that manufacturers will take it into account when fabricating dietary supplements. Manufacturers have complete control over the level of dietary ingredients added to their products. Thus, the manufacturers are appropriately charged with ensuring that the amounts present are at least 100 percent of the amounts declared throughout the shelf life of their products, except for any variability that is attributable to methods. The agency concludes that a dietary supplement not meeting this requirement is misbranded under section 403(a)(1) of the act. Therefore, the agency is not modifying § 101.36(f)(1) in response to these comments.

Furthermore, FDA advises that it is aware that Compliance Policy Guide 530.400 (CPG 7121.02), entitled ''Vitamin Products for Human Use—Low Potency,'' is inconsistent with § 101.36(f)(1). CPG 530.400 sets forth the criteria for multivitamin products and states that legal action is recommended when a deficiency is found in excess of 20 percent in one or more nutrients. Because this position is contrary to § 101.36(f)(1), FDA is revoking CPG 530.400.

Additionally, based on its review of the proposed regulations in preparation of this final rule, FDA has come to recognize that the requirement in § 101.9(g)(2) that a sample for analysis shall consist of a composite of 12 subsamples (consumer units) taken 1 from each of 12 different shipping cases is impractical for many dietary supplement products. The agency has found that it is not always possible to locate 12 different shipping cases of dietary supplement products. Inventories of dietary supplement products are often smaller than those of conventional foods, particularly at distribution and retail sites. Accordingly, when 12 shipping cases are not available, it is not possible for FDA to collect a compliance sample that complies with § 101.9(g)(2).

To provide for greater flexibility, the agency is modifying § 101.36(f)(1) to eliminate the requirement that consumer units come from 12 different shipping cases. The agency is requiring only that the consumer units come from the same inspection lot (that is, the product available for inspection at a specific location) and be randomly selected to be representative of that lot.

Furthermore, the agency is providing flexibility with respect to the number of consumer units that are to be collected. FDA is requiring in § 101.36(f)(1) that the ''sample for analysis shall consist of a composite of 12 subsamples (consumer packages) or 10 percent of the number of packages in the same inspection lot, whichever is smaller''. In other words, the entire contents of 12 packages would be needed when there are over 120 packages available. Fewer packages would be needed when the total number of consumer units available is less than 120. In this case, the agency concludes that a 10 percent sample is sufficiently representative for compliance purposes. While not statistically based, the 10 percent sample has been well accepted in enforcement proceedings (Ref. 6, pp. 818 through 821). This approach allows the agency to take compliance actions as necessary, without being impeded by the low availability of the product in question. At the same time, FDA is introducing the term ''packages'' to clarify that this section pertains to packages labeled for retail sale rather than individual units of the product, e.g., tablets or capsules, as the term ''unit'' is defined in other parts of this document.

This provision is a logical outgrowth of the proposal because by cross-referencing § 101.9(g)(1) through (g)(8) in the proposal, FDA raised the question of whether these provisions appropriately apply to dietary supplements. Based on the factors discussed above, FDA concludes that the requirements regarding the number of consumer units in § 101.9(g)(2) should not apply to dietary supplements and is modifying § 101.36(f)(1) accordingly.

H. Special Provisions and Misbranding

32. One comment stated that small-sized packages (i.e., those having a total surface area available to bear labeling of less than 12 square inches) should be allowed to use a minimum type size of 4.0 point when there are more than eight dietary ingredients to be listed in the nutrition label. The comment stated that the proposed minimum of 4.5 point is impractical for certain dietary supplements products, and that a type size of 4.0 point is still legible. The comment included sample labels using a type size of 4.0 point. Another comment requested that small-sized packages be allowed to use a minimum type size of 3 point. This comment did not include sample labels.

FDA is not persuaded by these comments. As discussed in the final rule of January 4, 1994, FDA set the minimum type size at 4.5 point in response to the majority of the comments, which stated that this minimum is consistent with the NDMA's Label Readability Guidelines used for over-the-counter drugs (Ref. 4). FDA has received information from NDMA that shows that it did not set this minimum arbitrarily or subjectively, but that it arrived at this minimum type size based on studies of visual acuity and demographics (Ref. 7). While one of the comments that objected included sample labels using a type size of 4.0

point, it did not present any visual acuity studies in support of its contention that a type size of 4.0 point is legible. FDA has been persuaded by NDMA's data and points out that the vast majority of comments did not object to a minimum type size of 4.5 point. Moreover, firms in need of special allowances may seek alternative means of compliance or an exemption under § 101.36(f)(2). Therefore, FDA is not modifying § 101.36(i)(2)(i) in response to this comment.

33. Several comments requested that § 101.2(c) be amended to include § 101.36. This amendment would allow type size smaller than 1/16th inch in certain instances. One of these comments said that this request is reasonable because the labels of dietary supplements commonly include information not found on the labels of conventional foods, e.g., the iron warning statement.

The agency is not persuaded by these comments. As discussed in the December 1995 proposal, the request to amend several paragraphs in § 101.2(c) to include § 101.36 was included in a citizen petition (Docket No. 94P–0110/CP1) submitted to FDA by the Council for Responsible Nutrition in 1994. The agency denied this request because § 101.36 addresses the type size requirements for information in the nutrition label of dietary supplements (60 FR 67194 at 67208). The agency noted that § 101.9 covers the corresponding requirements for conventional foods. The purpose of § 101.2(c)(1) through (c)(3) was to encourage voluntary declaration of nutrition information and complete ingredient listing on all foods before declaration became mandatory under the 1990 amendments. FDA gave notice of its intention to revoke the exemptions in § 101.2(c)(1), (c)(2), and (c)(3) in its December 1995 proposal (60 FR 67194 at 67208), and proposed to do so in the **Federal Register** of June 12, 1996 (61 FR 29708), because they are obsolete. Therefore, FDA is not accepting these comments.

34. At least one comment recommended that a minimum type size of 4.5 point be allowed for dietary supplement packages that have a total surface area available to bear labeling of less than 40 square inches and have more than 8 dietary ingredients to be listed in the nutrition label. The comment said that it is impracticable to comply with the proposed type size requirements for dietary supplement products that contain many dietary ingredients.

FDA is not persuaded by the comment that a minimum type size of 4.5 point should be allowed on dietary supplement packages with 20 to less than 40 square inches of total surface area available to bear labeling that have more than 8 dietary ingredients to be listed. The agency proposed to require a minimum type size of 4.5 point for packages of less than 12 square inches and 6 point for packages of 12 to 40 square inches, except that it proposed that 4.5 point may be used on packages of less than 20 square inches that have more than 8 dietary ingredients to be listed in the nutrition label. This exception for packages of less than 20 square inches was in response to a citizen petition filed by the Council for Responsible Nutrition (Docket No. 94P–0110/CP1).

In its proposal (60 FR 67194 at 67208), FDA explained how it arrived at its tentative determination that a minimum of 4.5 point should be allowed only on packages of less than 20 square inches that have more than 8 dietary ingredients. Agency precedent provided that not more than 30 percent of the total surface area of a package should be required to be devoted to FDA-required information that is not on the principal display panel. The agency calculated that this 30 percent level would likely be exceeded on packages of 12 to 20 square inches of surface area available to bear labeling if more than 8 dietary ingredients were listed using 6 point type size. Accordingly, FDA proposed to allow those packages to bear nutrition labeling that uses the smaller type.

Applying the same calculations as discussed in the preamble of the proposed rule, the agency estimates that listing 24 dietary ingredients in 6 point type size plus 1 point leading between each line of type could use up to 6 square inches of label space. This would be equivalent to 30 percent of the total surface area of a package having 20 square inches of surface area available to bear labeling (i.e., 20 X 0.3). Accordingly, in response to the comment, the agency will allow for the use of a minimum 4.5 type size in such situations. In addition, based on the agency's observation that about 20 percent of dietary ingredients listed in sample labels submitted with comments that include ingredient information require two lines of type, the agency concludes that it is reasonable to allow the minimum type size of 4.5 point for packages with 20 to 40 square inches of label space available to bear labeling having more than 16 dietary ingredients. Section 101.36(i)(2)(ii) is revised accordingly.

This final rule represents a full response to the Council for Responsible Nutrition's citizen petition referred to above (Docket No. 94P–0110/CP1), in accordance with 21 CFR 10.30(e).

35. Several comments supported the proposed deletion of § 101.9(k)(2) and (k)(5). Some of these comments recommended that all of § 101.9(k) be deleted, asserting that it is not scientifically defensible, and that it is not consistent with the protection of free speech provided in the First Amendment and the Supreme Court decision of *Rubin* v. *Coors Brewing Co*., 517 U.S.____, 115 S. Ct. 1585 (1995). While these comments specifically addressed the deletion of § 101.9(k)(3), (k)(4), and (k)(6), none addressed § 101.9(k)(1).

Two comments addressed § 101.9(k)(3) and (k)(4), which prohibit statements that represent, suggest, or imply that the suboptimal nutritional quality of a food because of soil conditions or storage, transportation, or processing methods may be responsible for an inadequacy in the quality of the daily diet. One comment argued that these paragraphs should be deleted because any conditions that adversely affect the nutritional quality of foods will ultimately affect the nutritional quality of diets, even if such effects are not so extensive as to lead to widespread nutritional deficiencies. Two other comments addressed § 101.9(k)(4) specifically, citing evidence to show that various food processing techniques do cause nutrient losses and stating that national food consumption patterns are changing, leading to reduced consumption of fresh foods and increased use of processed convenience foods.

A few comments recommended deletion of § 101.9(k)(6), which prohibits any representation that naturally-occurring vitamins are superior to added or synthetic vitamins or any differentiation between added and naturally occurring vitamins. The comments argued that FDA should not forbid truthful representations on the label of the composition and biochemical forms of natural and synthetic vitamins, citing biochemical distinctions between naturally occurring and synthetic vitamins and stating that this information enables consumers to make more informed purchasing decisions.

FDA has considered the comments pertaining to § 101.9(k)(3) and (k)(4) and is not persuaded that they are no longer supportable. The agency agrees with the comments that stated that the nutritional quality of a diet is affected by the nutritional quality of the foods contained in that diet. However, when diets are inadequate, many factors must

be considered as causal, and it would be misleading to attribute such a result only to soil conditions and storage, transportation, and processing methods. For example, the food choices a person makes are a major determinant of the quality of his/her diet. Recent research has shown that the more a diet adheres to the Food Guide Pyramid (Ref. 8) and to dietary recommendations to eat a variety of foods and to moderate the consumption of fat, saturated fat, cholesterol, and sodium, the greater the likelihood that nutrient requirements will be met (Ref. 9).

The comment that suggested that the consumption of fresh fruits and vegetables is decreasing is not supported by recent research on the U.S. food supply by the U.S. Department of Agriculture Economic Research Service. This research found that the per capita consumption of fresh fruits rose 25 percent from 1970 to 1994, while the per capita consumption of fresh vegetables rose 33 percent from 1970 to 1994 (Ref. 10, pp. 18–19).

Accordingly, FDA concludes that it is still appropriate to prohibit misleading and unsubstantiated generalizations on the label or in labeling about dietary inadequacies because of nutrient losses resulting from poor soil conditions or storage, transportation, or processing methods. Nothing in *Rubin* v. *Coors Brewing Co.*, *supra*, prevents the government from regulating misleading speech. (See 115 S. Ct. at 1589.)

As stated earlier, current § 101.9(k)(3) and (k)(4) (redesignated as § 101.9(k)(2) and (k)(3)) do not preclude a producer, manufacturer, or vendor from indicating a higher nutrient retention in a particular product as compared to other similar products. Nor do they preclude an indication that such retention results from special handling of the product, provided that such indications are factual and is not misleading (58 FR 2079 at 2167).

In regard to § 101.9(k)(6), FDA has stated in the past that this section permitted truthful designation of any nutrient as natural in origin (38 FR 6950 at 6958, March 14, 1973; and 58 FR 2079 at 2167). However, the agency is persuaded by the comments that the phrase ''differentiate in any way between vitamins naturally present from those added'' in § 101.9(k)(6) is easily misinterpreted to mean that labels cannot identify nutrients as naturally-occurring or synthetic. Accordingly, FDA is modifying that paragraph (renumbered as § 101.9(k)(4)) to remove the prohibition on differentiating between naturally-occurring and synthetic vitamins.

It should be noted that FDA addressed the use of the term ''natural'' in rulemaking implementing the 1990 amendments (58 FR 2302 at 2407, January 6, 1993). At that time, the agency said it was not establishing a definition for ''natural,'' but that it would maintain its policy not to restrict truthful and non-misleading use of the term, except for products with added color, synthetic substances, or artificial flavors as provided in § 101.22, for which use of the term ''natural'' on the label would be considered misleading. However, the agency advises that the term ''natural'' should not be used when referring to a vitamin that is only obtained through chemical synthesis (e.g., use of ''natural vitamin E'' for a product containing dl-alpha tocopheryl acetate).

Comments did not specifically address that part of current § 101.9(k)(6) that prohibits any suggestion that a natural vitamin is superior to an added vitamin. Comments pointed out, and FDA is in agreement, that differences between natural and synthetic vitamins are often really differences in the form of the nutrient. For example, comments pointed out that vitamin E occurs in natural oils in the d-alpha form and exists in synthetic products as a racemic mixture, with less biological activity. Comments did not, however, provide information to support any difference between a natural or synthetic version of the same form of a nutrient. Thus, the agency is aware of nothing that establishes that a claim of difference between the natural and synthetic version of the same form of a nutrient is not misleading. Therefore, FDA is maintaining the prohibition against statements that a natural vitamin is superior to an added one in § 101.9(k)(4).

However, the agency advises that there are no restrictions in the regulations on identification of the chemical form of the nutrient. In fact, such identification is helpful on certain nutrients, such as carotene, whose biological activity varies according to its isomeric composition. FDA notes that when the chemical form of the vitamin is identified on the label or in labeling, manufacturers are free to use statements that characterize the structure and function of that stereoisomer. Label statements may thus differentiate between the different forms of a vitamin.

I. Miscellaneous Issues

36. One comment asked whether nutrition labeling is required on samples of dietary supplements that are distributed free of charge, such as at trade shows.

The nutrition labeling requirements of the 1990 amendments apply to foods offered for sale (section 403(q)(1) of the act). Nutrition labeling would not be required on dietary supplements that are not offered for sale because there is nothing in the DSHEA that requires dietary supplements to be treated any differently than conventional foods in this respect. FDA inadvertently did not make this clear in the December 1995 proposal. Accordingly, FDA is revising § 101.36(a) to state ''The label of a dietary supplement that is offered for sale shall bear nutrition labeling in accordance with this regulation unless an exemption is provided for the product in paragraph (h) of this section.''

37. One comment stated that products composed only of mixtures of free amino acids should be able to declare ''protein'' in the nutrition label and list the total weight of the amino acids as the amount of protein in the product. The comment said that the only difference between free amino acids and protein is that the amino acids in protein are connected to each other by peptide bonds. Another comment stated that amino acids that are essential should be distinguished from those that are nonessential. This comment also stated that the dangers of using single amino acids should also be listed with a warning that many of the uses are unproven. With respect to protein supplements, the comment said that such products should indicate their sources of protein, and ''when collagen with a little tryptophan added is called a protein supplement it should be stated that this is not a complete protein and cannot support life or tissue building on its own.'' The comment recommended that protein supplements used for body building should contain a statement that muscle building requires not only protein, but calories and especially carbohydrates.

FDA agrees that protein differs from free amino acids in that protein is composed of amino acids connected to each other by peptide bonds (60 FR 67194 at 67198). In recognition of this difference, FDA proposed that the nutrition label of dietary supplements list whatever is actually present, i.e., protein or individual amino acids. The comment did not justify why it was not misleading to declare protein content in the nutrition label of a dietary supplement that contains only free amino acids. Therefore, FDA concludes that this requirement is appropriate and consistent with section 201(ff)(1) of the act, which lists amino acids in

subparagraph (D) as a separate entity from protein, which would be covered in subparagraph (E) as a dietary substance.

Furthermore, FDA is not persuaded to require that amino acids be identified as essential or nonessential in the nutrition label of dietary supplements because the act does not require this information in the nutrition label, and the comment did not provide any reason for this approach. In fact, the comment in question did not state clearly where this information should be presented. FDA points out that such information may be stated outside of the nutrition label on the labels of dietary supplements and conventional foods as well.

In response to the comment that requested that the source of protein supplements should be identified, the agency points out that, under the act, manufacturers of dietary supplements, including protein supplements, may choose either to list the source of any dietary ingredient in the nutrition label or in the ingredient statement that appears below the nutrition label. While the concerns of the comment would apparently be better addressed by the former approach, FDA is not aware of any reason to require it. The other points in this comment about warning or other statements are beyond the scope of this rulemaking.

38. One comment recommended that herbal products be required to declare any possible drug interactions. The comment stated that herbs were the first medicines and should be treated as such.

FDA disagrees with this comment. The herbal products that are the subject of this rulemaking are foods and not drugs. To the extent that herbal products are intended for use as medicines, they are drugs under the act and subject to regulation under Chapter V of the act, not Chapter IV (the food provisions). As for possible drug interactions, FDA will consider the need for warnings under sections 201(a), 403(a), and 701(a) of the act (21 U.S.C. 371(a)), but warnings about drug interactions are not typically the subject of food labeling requirements.

IV. Other Provisions

FDA has made a few editorial changes in certain provisions of § 101.36. Specifically, § 101.36(h)(2) (designated as § 101.36(f)(2) in the final rule on small business exemptions in the **Federal Register** of August 7, 1996 (61 FR 40963), has been revised to make it clear that either a manufacturer, packer, or distributor may file a claim for an exemption. This change is consistent with the language in § 101.9(j)(18). Also, to avoid confusion, the first sentence in § 101.36(h)(1) through (h)(3) reads ''foods'' instead of ''dietary supplements.''

FDA did not receive any comments that dealt specifically with the other provisions of the proposal. In the absence of any basis for doing otherwise, FDA is adopting those provisions as proposed.

V. Effective Date

39. Several comments recommended that the compliance date of this final rule be coordinated with other final rules on dietary supplements. Most of these comments requested that a uniform effective date be set at 18 months after the publication of the last final rule concerning dietary supplements based on any pending proposals, although 3 comments requested 12 months, and 1 comment requested 24 months. One comment stated that multiple effective dates will balloon the cost of all label changes to the industry and to consumers, who ultimately will bear the cost of multiple revisions. Other comments stated that an 18-month extension is needed because of the great number of labels to be redesigned. One comment said that they may manufacture an identical multivitamin product for more than 100 different retail customers that sell the product under their own private label name, e.g., store brand names. Thus, this manufacturer has to make new labels for each customer, not for each product. Another comment stated that a manufacturer of ''private label'' products may have over 10,000 labels to redesign.

FDA is persuaded by the majority of the comments that it is appropriate to have the effective date of this final rule be 18 months after its publication, consistent with the time period allowed for the labels of conventional foods to comply with the final rules implementing the 1990 amendments. As discussed in section VI. of this document, an 18-month compliance period will minimize the cost of the changeover compared to a 12-month compliance period. The agency does not agree with the comment that requested a 24-month compliance period because the majority of the comments stated that an 18-month compliance period is sufficient.

Moreover, the agency agrees that it is reasonable and practical to have the same date apply to the other final rules on dietary supplement labeling that are published elsewhere in this issue of the **Federal Register**, as multiple effective dates will increase costs and are unjustified. Therefore, the agency concludes that the effective date of this final rule is 18 months from the date of its publication and that this date shall apply to the other final rules on dietary supplements that are published in this issue of the **Federal Register**.

The same will also apply to the enforcement of prescribed iron statements on products that currently bear voluntary iron warning statements, as discussed in the final rule on iron statements (62 FR 2218, January 15, 1997). In that final rule, the agency stated that it intended to use enforcement discretion for these products that bear a voluntary warning until the date for label changes made in response to the DSHEA (62 FR 2218 at 2246).

The agency notes that this effective date is not in accordance with the uniform compliance date of January 1, 2000, established by regulation on December 27, 1996 (61 FR 68145). As stated in that document, ''If any food labeling regulation involves special circumstances that justify a compliance date other than January 1, 2000, the agency will determine for that regulation an appropriate compliance date, which will be specified when the final regulation is published'' (61 FR 68145 at 68146). The DSHEA states that dietary supplement products shall be labeled in accordance with its amendments after December 31, 1996. Because final rules were not published in sufficient time for the industry to be in compliance with them by January 1, 1997, FDA stated on April 15, 1996, that it would exercise its enforcement discretion such that it would not enforce the provisions of the DSHEA until January 1, 1998 (61 FR 16423). At this time, FDA is extending this period of nonenforcement until March 23, 1999. Any further extension (i.e., to January 1, 2000) would be unresponsive to the directives of the statute, as well as unnecessary based on comments received.

In addition, in response to the directive in the DSHEA that dietary supplements ''be labeled'' after December 31, 1996, and consistent with the approach taken by Congress in the 1990 amendments, the agency advises that the effective date of this regulation, the other dietary supplement regulations published in this issue of the **Federal Register**, and the final rule on iron statements, will apply to the attachment of labels to dietary supplement products rather than to the introduction of products into interstate commerce as specified in the agency's final rule on uniform compliance dates for food labeling regulations (61 FR

68145). In other words, products bearing labels that are affixed prior to March 23, 1999 do not have to be in compliance with these final rules, and products labeled after March 23, 1999 do.

Although the effective date is 18 months hence, FDA encourages manufacturers to have new labels that are in compliance with these final rules printed as soon as current inventories are exhausted to assure a smooth and timely changeover. The agency does not anticipate extending its use of enforcement discretion any further.

VI. Analysis of Impacts

FDA has examined the economic implications of the final rule as required by Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approach which maximizes net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. If a rule has a significant impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze options that would minimize the economic impact of that rule on small entities. FDA finds that this final rule is not an economically significant rule as defined by Executive Order 12866 and finds under the Regulatory Flexibility Act, that the final rule will have a significant impact on a substantial number of small entities.

There are several different types of products that may be considered to be dietary supplements. These products include but are not limited to vitamin or mineral supplements, herbal products, and products that contain other similar nutritional substances. An estimate of the number of such products is approximately 29,000. The number of stockkeeping units, a more accurate count of the number of labels, is approximately 75,000. Estimates of the number of dietary supplements are approximate because no one source collects information on all types of dietary supplements. In fact, until the DSHEA, there was no agreed upon definition of a dietary supplement. Some sources include only dietary supplements of vitamin or minerals, others include herbals or botanicals, and still others include other types of products that may or may not be dietary supplements, such as sports nutrition products and ''functional foods,'' a term for which there is no recognized definition.

In its proposed analysis, FDA estimated the number of dietary supplement firms to be between 150 and 650 firms. According to Duns Market Identifiers, there are approximately 250 manufacturers of vitamin and mineral products. According to *Nutrition Business Journal* (August 1996), the dietary supplement industry includes 850 supplement manufacturing companies. The *Journal* reports 1995 industry revenues at $4.5 billion. Although FDA concludes that there are clearly at least 250 firms, the *Journal's* estimate of 850 is most likely an overestimate of the dietary supplement industry because it includes homeopathic products, which are drugs by statutory definition, and ''functional foods'' and sports nutrition products, which may be either conventional foods or dietary supplements depending on how they are marketed and used. Although the *Journal* does not break down the number of firms by the type of dietary supplement produced, it does specify that 250 firms produce herbal or botanical products. FDA received one comment on its proposed analysis that suggested that estimates of the number of firms should include the product manufacturer, label printer, product packager, label/brand owner, and brand wholesaler. FDA notes that, with the exception of administrative costs, costs of labeling regulations are calculated on a per product or per label basis, not on a per firm basis. Administrative costs, which are typically calculated on a per firm basis, include the cost of reading and interpreting the regulation and formulating a compliance policy which must be done once for each regulation, not for each product.

For purposes of determining the costs of this regulation, FDA will use 850 as an upper bound estimate of the number of firms. As a lower bound estimate, FDA will use 500 (250 vitamin/mineral firms + 250 herbal/botanical firms).

A. Costs

Categories of costs for relabeling include administrative, analytical, printing, and inventory disposal.

The administrative costs associated with a labeling regulation result from the incremental administrative labor expended in order to comply with a regulation. FDA received one comment objecting to the estimated administrative costs. The comment stated that administrative costs fail to include both scientific and legal review, but the comment did not provide any information to help FDA modify its previous estimate. Therefore, FDA will continue to estimate administrative costs at $425 per firm for a 1-year compliance period and approximately $320 for an 18-month compliance period. Longer compliance periods decrease administrative effort because firm executives often delegate downward decisions that are less immediate. Total administrative costs are estimated to be between $160,000 ($320 x 500 firms) and $272,000 ($320 x 850 firms) with an 18-month compliance period.

FDA received one comment stating that its estimate of analytical costs substantially underestimated the true costs. The comment estimated analytical costs at $340 per product. FDA notes, however, that although the comment stated that FDA's estimates were too low, the comment's per product estimate is lower than FDA's estimate of $615 per product. Therefore, FDA will continue to estimate costs at $615 per product for each of 29,000 products. All products will be tested once during the 18-month compliance period in order to determine initial compliance. In the proposed rule, FDA assumed that products would undergo retesting once every 5 years. FDA received no objections to that assumption. Therefore, FDA estimates total discounted analytical costs of $75 million (discounted to infinity at 7 percent), of which $17.8 million ($615 x 29,000 products) will occur during the 18-month compliance period.

FDA received several comments that its estimates of printing/redesign costs were too low. One comment suggested that costs would be $1,370 for each printed label and $3,870 for each direct-printed package label. Estimates from other comments ranged from $50 to $3,500 per label. Based on an average of the estimates provided by the comments, FDA estimates that the average per label redesign cost for a 1-year compliance period is $1,700. However, because FDA is allowing a compliance period of 18 months, firms will be able to combine planned label changes with mandated changes, thus lowering redesign costs. Redesign costs associated with an 18-month compliance are typically 3/4 of those for a 1-year compliance period. Therefore, FDA estimates redesign costs to be $1,300 for each of 75,000 labels, or a total $97.5 million.

FDA received one comment indicating that inventory disposal costs would range between $8 and $15

million depending on the length of the compliance period. In the analysis to the proposed rule, FDA estimated inventory disposal costs at $6.5 million assuming the rules would become effective 12 months after publication of the final regulations. FDA will not alter its previous estimates based on the comment because dietary supplement firms have known about these label changes since at least January 1994, and the majority of firms have been taking the necessary steps to reduce their label inventories. However, because FDA is providing firms with 18 months to comply, firms will have an additional 6 months to dispose of label inventory. As with redesign costs, inventory disposal costs associated with an 18-month compliance period are approximately 3/4 of the costs associated with a 1-year compliance period. Therefore, disposal costs for this rule are estimated at $4.8 million.

FDA has estimated the impact of the final regulations and has determined that administrative costs would be between $160,000 and $272,000, discounted analytical costs would be $75 million (discounted to infinity at 7 percent), redesign costs would be $97.5 million, and inventory disposal costs would be $4.8 million. Therefore, total discounted costs are estimated to be $177.8 million (discounted to infinity at 7 percent). Costs during the 18-month compliance period are estimated to be $120 million. If we assume that the rate at which firms comply is evenly distributed throughout the compliance period, then costs during the most expensive 12-month period, the first year, would be $80.3 million. Costs in the second year would be $39.7 million. Recurring costs would be $17.8 million every 5 years. According to basic economic principles, firms are profit maximizers. Therefore, it is logical to assume that firms will select the least costly alternative. The supply of label redesign and analytical laboratory services is limited in the short run. When demand for those services increases as a result of regulatory requirements, the cost of those services also increases. If compliance were skewed toward one end of the compliance period, then the demands places on those services would cause prices to increase more than if the demand were more evenly distributed. Firms are aware of this phenomenon and will, therefore, attempt to spread out the demands on the redesign and laboratory services. Also, because the capacity for these services is fixed in the short run, the suppliers of redesign and laboratory services will force firms to space out their demand. Because it is unlikely that the rate at which firms comply is heavily skewed toward one end of the compliance period, it is unlikely that costs will exceed $100 million during any single year. Therefore, FDA concludes that this rule is not economically significant as defined by Executive Order 12866.

B. Benefits

Although almost all dietary supplements of vitamins and minerals currently contain substantial nutrition information, many other dietary supplements do not. This regulation will benefit consumers by assuring that adequate and complete nutrition information is provided accurately and consistently to aid consumers in their choices.

C. Regulatory Flexibility

According to the Regulatory Flexibility Act, the definition of a small entity is a business independently owned and operated and not dominant in its field. The Small Business Administration (SBA) has set size standards for most business categories through use of four-digit Standard Industrial Classification codes. For dietary supplements of vitamins and minerals, a business is considered small if it has fewer than 750 employees. According to Duns Market Identifiers, there are approximately 250 producers of vitamin and mineral supplements, of which 200 have fewer than 750 employees. The remaining dietary supplement products come closest to the industry groups Food Preparations N.E.C. (SIC 2099) and Medicinal Chemicals and Botanical Products (SIC 2834). The SBA size standards are 500 or fewer employees for food preparations and 750 or fewer employees for medicinal and botanical products. Under either employee-based size standard, virtually all firms could be classified as small, including some firms that are among the leaders in sales revenues. Therefore, FDA is basing size classifications on sales revenue rather than employees.

According to *Nutrition Business Journal*, of the 850 dietary supplement manufacturing firms, 11 have total revenues over $100 million, accounting for 53 percent of total sales; 30 firms have sales revenues between $20 and $100 million, accounting for 28 percent of industry sales; and 809 firms have sales under $20 million, accounting for 19 percent of industry sales. The 809 firms in the under $20 million category have an average sales revenue of $800,000 and will be considered small by FDA. The SBA sales revenue standard for businesses that cannot be classified into a specific industry is $5 million. FDA concludes therefore that as many as 809 firms in the dietary supplement industry, or 95 percent of firms, could be considered small (sales under $20 million). As stated previously in this analysis, this may be an overestimate because it counts firms that produce homeopathic products, which are drugs, and sports nutrition products and ''functional foods,'' which may be foods or dietary supplements. If there are as few as 500 dietary supplement firms, there may be 475 small dietary supplement firms.

The agency has published an exemption from mandatory nutrition labeling for small businesses in § 101.9(j)(1) and has proposed an exemption for low-volume food products of small businesses in § 101.9(j)(18) (59 FR 11872, March 14, 1994). These regulations are cross-referenced in this final rule on labeling of dietary supplements, in § 101.36(h)(1) and (h)(2), respectively. As of January 1, 1997, § 101.9(j)(1) will only apply to retailers. As of May 1997, § 101.9(j)(18) will apply to manufacturers, packers, distributors, or retailers of low volume products, defined as fewer than 100,000 units, produced by firms with fewer than 100 employees. FDA does not have information to show how many dietary supplement products would be exempted under this provision. Comments to the proposed analysis suggested that very few products will qualify for exemptions for low volume products. According to the limited information available to the FDA, approximately 72 percent of vitamin/mineral producers and 86 percent of herbal/botanical producers have fewer than 100 employees. Even if every firm with fewer than 100 employees produced low volume products, between 9 and 13 percent of the firms with annual sales less than $20 million would still not meet the definition. Therefore, although it is likely that many firms will be able to take advantage of the small business exemption, FDA concludes that this rule will impact on a substantial number of small entities.

Dietary supplement firms each produce between 3 and over 50 distinct products. A firm that produces three products will incur costs of $14,000 during the compliance period. A firm that produces 50 products will incur costs of $236,000 during the compliance period. If the average small firm incurs costs of $125,000 ((14,000 + 236,000)/2), using an average annual sales of $800,000, the increase in costs due to this regulation will be 16 percent of

sales for the average small firm. Therefore, FDA concludes this rule will result in a significant economic impact on a substantial number of small entities.

The Regulatory Flexibility Act requires agencies to examine regulatory alternatives that would minimize the impact on small entities. Because the DSHEA mandates nutrition labeling for all dietary supplement products, except low-volume products as described above, there are very few alternatives available to the agency. However, as discussed elsewhere in this document, FDA received many comments requesting that firms be given 18 months to comply with these regulations. FDA has examined the impact of different compliance periods and has determined that extending the compliance to 18 months reduces the burden on small entities. With a 12-month compliance period, first year costs for an average small entity would be $158,500, or 20 percent of sales. Extending the compliance period to 18 months reduces first year costs to the average small firm by $33,500. If FDA did not extend the compliance period, the total discounted costs of this regulation would be $209.5 million, of which $152 million would occur in the first year. The longer compliance period reduces total discounted costs of the regulation by $31.2 million.

D. Summary

Total discounted costs of this regulation are estimated to be between $177.8 million (discounted to infinity at 7 percent). These costs include administrative, analytical, printing, and inventory disposal costs. The benefits are improved and more consistent information with which consumers can refine their choices for health or other reasons. FDA is unable to quantify this benefit.

FDA has analyzed the costs and benefits of this proposed rule and has determined that, because neither costs nor benefits are likely to exceed $100 million in any single year, it does not constitute an economically significant rule as defined by Executive Order 12866.

FDA has also analyzed the impacts on small firms according to the Regulatory Flexibility Act and has determined that these rules will have a significant impact on a substantial number of small entities. FDA has reviewed alternatives to reduce the burden on small entities and has concluded that providing for a compliance period of 18 months will alleviate that burden.

E. Public Outreach

FDA has conducted extensive outreach to a wide audience, including small businesses, on the labeling of dietary supplements. This outreach included independent FDA activities as well as cooperative efforts between FDA and professional trade organizations.

FDA has informed small businesses of the requirements in the DSHEA regarding dietary supplements and of FDA's implementation of these requirements in a number of ways. Since passage of the DSHEA, FDA representatives have responded on a daily basis to numerous inquiries on supplements, including inquiries from small businesses. In addition, FDA has had meetings on the regulation of dietary supplements with representatives of at least four trade organizations that include small businesses in their membership. Furthermore, FDA has participated in a number of trade organization conferences on dietary supplements and has cooperated with the Drug Information Association, which has sponsored conferences on botanicals.

FDA has issued a number of publications on dietary supplements that have been available to small businesses, including an article in the *FDA Consumer* of November 1993 and an ''FDA Backgrounder'' of August 1995, which described the DSHEA. FDA has distributed about 500 reprints of its December 1995 proposals on the labeling of dietary supplements to various interested parties, including small businesses. FDA has also placed information on these proposed rules in the FDA News section of the agency's home page on the World Wide Web. In response to these proposals, FDA has received numerous comments from small businesses. FDA concludes that its efforts to inform small businesses of activity in this area have been successful.

VII. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (60 FR 67194, December 28, 1995). No new information or comments have been received 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.

VIII. Paperwork Reduction Act

This rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing procedures, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Requirements for Nutrition and Ingredient Labeling of Dietary Supplements.

Description: In a final rule, FDA is amending § 101.36 to require that most dietary supplements provide on their labels, and in their labeling, information on the quantity of specific nutrients present in them, along with the daily value for each, and the quantity of other dietary ingredients. This requirement implements the requirements of the 1990 amendments and the DSHEA. The agency is also providing a mechanism by which firms may request an alternative approach to providing the necessary nutrition information.

Section 101.36(b)(2) specifies the nutrients for which the amount must be present on the labels of dietary supplements and § 101.36(b)(3) provides for the listing of the quantity of other dietary ingredients, respectively. Other paragraphs of § 101.36 provide information to assist manufacturers and distributors of dietary supplements in determining how the amount of nutrients that their products contain should be disclosed on the labels of the products. Section 101.36(f)(2) provides a mechanism whereby firms may request in writing from FDA alternative means of compliance or additional exemptions when it is not technologically feasible, or some other circumstance makes it impracticable, for the firm to comply with the requirements of § 101.36.

FDA had submitted these information collection requirements to OMB for review under section 3504(h) of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) at the time the December 1995 proposal was published. In response, OMB disapproved the information collection but gave an OMB control number, 0910–0314, and requested that FDA respond to the following concerns at the time of resubmission for OMB approval of the information collection package at the final rule stage:

OMB does not approve this package. OMB is concerned about the accuracy of the cost and hour burden estimates, as well as the utility of the nutrition info. required to be disclosed on the labels of dietary supplements and whether the labels are sufficiently clear to the third party recipients

of this information. When the package is resubmitted to OMB for approval at the final stage, the agency will address OMB's concerns and the public comments received on these issues in the preamble of the final rule and in the paperwork submission package.

FDA estimates the total annual disclosure and reporting hour burden for the information collection requirements contained in this final rule to be 136,040 hours, as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Hours	Hours per Response	Total Annual Hours	Total Operating & Maintenance Costs
101.36 (b)(2) and (b)(3) (disclosure)	850	40	34,000	4	136,000	40,000,000
101.36(f)(2) (reporting)	20	1	20	2	40	0
Totals			34,020		136,040	40,000,000

FDA estimates that each supplier of dietary supplements will revise the labels for each product that is not otherwise exempt to comply with the requirements for nutrition labeling within the first 18 months after publication of the final rule. The agency estimates that, on average, each supplier will have 40 products whose labels will require revision. The agency expects that the number of respondents and corresponding annual burden hours will decrease over succeeding years because it does not believe that firms will modify the composition of each of their products and revise the labeling for each of their products each year. Similarly requests for alternative approaches for providing nutrition information are most likely to be submitted within the first 18 months. The agency estimated the number of such requests based on its experience with the similar requirement that is provided in § 101.9(g)(9) for conventional foods. Thus, there will be a significant decrease in the number of respondents and product labels requiring revision in succeeding years with a corresponding decrease in annual burden hour cost. The hour burden estimates contained above are for the information collection requirements established by regulation alone and do not include those that stem solely from the act or the DSHEA.

FDA has estimated that the total annualized operating and maintenance costs will approximate $40,000,000 over the next 3 to 4 years. This is based on annualized estimated relabeling costs of $32.5 million, analytical costs of $6 million, and labor and overhead costs of $1.5 million over the next 3 to 4 years. The agency believes that these costs will decrease significantly over succeeding years. FDA will reexamine these estimates at the end of 3 to 4 years. The agency has determined that the requirements in § 101.36 do not require capital costs on the part of respondents.

The first concern expressed by OMB was about the accuracy of the cost and hour burden estimates for the information collection requirements. FDA received one comment in response to the proposal that estimates of the number of firms should include the product manufacturer, label printer, product packager, label/brand owner, and the brand wholesaler. FDA received no comments that suggested alternative costs or hour burdens from the agency's estimates. As discussed in more detail in section V. of this document and as indicated in the preceding table ''Estimated Annual Reporting Burden,'' the agency has modified the number of respondents that will be affected by the information collection requirements from 600 to 850 but has retained the estimates of hour burden per response that was contained in the December 1995 proposal.

OMB also expressed its concern about the utility of the nutrition information required to be disclosed on the labels of dietary supplements and whether the labels are sufficiently clear to the third-party recipients of this information. Several comments to the December 1995 proposal recommended that nutrients should be listed on dietary supplements only when they are added. Other comments expressed concerns about the format requirements for the nutrition facts panel. As discussed in more detail above, FDA is not persuaded by the comments that it should change the requirements for the listing of nutrients on dietary supplements. As also noted above, the agency points out that, except for certain specified exceptions, section 403(q) of the act requires nutrition labeling on most foods. With respect to dietary supplements, section 403(q)(5)(F) of the act, as amended by the DSHEA, specifies that the labels of dietary supplements shall comply with the requirements for nutrition labeling contained in subparagraphs (q)(1) and (q)(2) in a manner which is appropriate. Furthermore, the agency believes that nutrition information on dietary supplements is essential for those that are interested to be able to calculate their daily intakes of nutrients.

As to OMB's concern that the information will be sufficiently clear to the third-party recipients, FDA notes that consumer surveys have indicated that the graphic requirements in the nutrition labeling rules for food (i.e., § 101.9) were successful in that the majority of shoppers who are aware of the new label think it is clear and understandable. FDA has no reason to believe that the requirements for nutrition labeling of dietary supplements will be any less clear.

FDA has resubmitted the information collection requirements contained in this rule to OMB for its review under the Paperwork Reduction Act of 1995. Interested persons are requested to send comments regarding information collection by October 23, 1997 to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., rm. 10235, Washington, DC 20503, ATTN: Desk Officer for FDA. No person may be required to respond to, or may be subjected a penalty for failure to comply with, these information collection requirements until they have been approved by OMB and FDA has displayed the assigned OMB control number. The OMB control number, when assigned, will be announced by separate notice in the **Federal Register**.

IX. References

The following references have 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. Machlin, L. J., editor, *Handbook of Vitamins*, 2d ed., pp. 239 and 285, Dekker, NY, 1991.

2. Subcommittee on the 10th Edition of the RDA's, Food and Nutrition Board, Commission of Life Sciences, National Research Council, ''Recommended Dietary Allowances, 10th Ed.,'' pp. 125 and 132, Washington, DC, National Academy Press, 1989.

3. Food Marketing Institute Prevention Magazine Report, ''Shopping for Health 1995,'' Food Marketing Institute, Washington, DC, and *Prevention Magazine*, Emmaus, PA, 1995.

4. Nonprescription Drug Manufacturers Association's Special Task Force on Label Readability, ''Label Readability Guidelines,'' Washington, DC, 1991.

5. Tanner, J. T., letter to V. Srinivasan, U.S. Pharmacopeial Convention, Inc., May 7, 1991.

6. Deming, W. E., ''On the Presentation of the Results of Sample Surveys as Legal Evidence,'' *The Journal of the American Statistical Association*, 49:818–821, December 1954.

7. Memorandum between Bill Bradley, Nonprescription Drug Manufacturers Association, and Susan Thompson, CFSAN, FDA, October 15, 1993.

8. U.S. Department of Agriculture, Human Nutrition Information Service, ''The Food Guide Pyramid,'' Home and Garden Bulletin Number 252, August 1992.

9. U.S. Department of Agriculture, Center for Nutrition Policy and Promotion, ''The Healthy Eating Index,'' October 1995.

10. U.S. Department of Agriculture, Economic Research Service, ''Food Consumption, Prices, and Expenditures, 1996,'' Statistical Bulletin Number 928, pp. 18–19.

11. Foster, S., editor, *Herbs of Commerce*, Amercian Herbal Products Association, Bethesda, MD, 1992.

12. Greuter, W., editor (chairperson), *International Code of Botanical Nomenclature (Tokyo Code)*, adopted by the 15th International Botanical Congress, Koeltz Scientific Books, D–61453 Konigstein, Germany, 1994.

List of Subjects in 21 CFR Part 101

Food labeling, Incorporation by reference, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is 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 101.2 is amended by revising paragraphs (b), (d)(1), and (f) to read as follows:

§ 101.2 Information panel of package form food.

* * * * *

(b) All information required to appear on the label of any package of food under §§ 101.4, 101.5, 101.8, 101.9, 101.13, 101.17, 101.36, subpart D of part 101, and part 105 of this chapter shall appear either on the principal display panel or on the information panel, unless otherwise specified by regulations in this chapter.

* * * * *

(d)(1) Except as provided by §§ 101.9(j)(13) and (j)(17) and 101.36(i)(2) and (i)(5), all information required to appear on the principal display panel or on the information panel under this section shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, except as provided by §§ 101.9(j)(17) and 101.36(i)(5), any vignettes, designs, and other nonmandatory label information shall not be considered. If there is insufficient space for all of this information to appear on a single panel, it may be divided between these two panels, except that the information required under any given section or part shall all appear on the same panel. A food whose label is required to bear the ingredient statement on the principal display panel may bear all other information specified in paragraph (b) of this section on the information panel.

* * * * *

(f) If the label of any package of food is too small to accommodate all of the information required by §§ 101.4, 101.5, 101.8, 101.9, 101.13, 101.17, 101.36, subpart D of part 101, and part 105 of this chapter, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, e.g., a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph, shall be submitted under part 10 of this chapter.

3. Section 101.3 is amended by adding new paragraph (g) to read as follows:

§ 101.3 Identity labeling of food in packaged form.

* * * * *

(g) Dietary supplements shall be identified by the term ''dietary supplement'' as a part of the statement of identity, except that the word ''dietary'' may be deleted and replaced by the name of the dietary ingredients in the product (e.g., calcium supplement) or an appropriately descriptive term indicating the type of dietary ingredients that are in the product (e.g., herbal supplement with vitamins).

4. Section 101.4 is amended by revising paragraph (a)(1) and adding new paragraphs (g) and (h) to read as follows:

§ 101.4 Food; designation of ingredients.

(a)(1) Ingredients required to be declared on the label or labeling of a food, including foods that comply with standards of identity, except those ingredients exempted by § 101.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of § 101.2, except that ingredients in dietary supplements that are listed in the nutrition label in accordance with § 101.36 need not be repeated in the ingredient list. Paragraph (g) of this section describes the ingredient list on dietary supplement products.

* * * * *

(g) When present, the ingredient list on dietary supplement products shall be located immediately below the nutrition label, or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label and shall be preceded by the word ''Ingredients,'' unless some ingredients (i.e., sources) are identified within the nutrition label in accordance with § 101.36(d), in which case the ingredients listed outside the nutrition label shall be in a list preceded by the words ''Other ingredients.'' Ingredients in dietary supplements that are not dietary ingredients or that do not contain dietary ingredients, such as excipients, fillers, artificial colors, artificial sweeteners, flavors, or binders, shall be included in the ingredient list.

(h) The common or usual name of ingredients of dietary supplements that are botanicals (including fungi and algae) shall be consistent with the names standardized in *Herbs of Commerce*, 1992 edition, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Herbal Products Association, 4733 Bethesda Ave., suite 345, Bethesda, MD 20814, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 Capital St. NW., suite 700, Washington, DC. The listing of these names on the label shall be followed by statements of:

(1) The part of the plant (e.g., root, leaves) from which the dietary ingredient is derived (e.g., ''Garlic bulb'' or ''Garlic (bulb)''), except that this designation is not required for algae. The name of the part of the plant shall

pressed in English (e.g., ''flower'' rather than ''flos'');

(2) The Latin binomial name of the plant, in parentheses, except that this name is not required when it is available in the reference entitled: *Herbs of Commerce* for the common or usual name listed on the label, and, when required, the Latin binomial name may be listed before the part of the plant. Any name in Latin form shall be in accordance with internationally accepted rules on nomenclature, such as those found in the *International Code of Botanical Nomenclature* and shall include the designation of the author or authors who published the Latin name, when a positive identification cannot be made in its absence. The *International Code of Botanical Nomenclature* (Tokyo Code), 1994 edition, a publication of the International Association for Plant Taxonomy, is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the *International Code of Botanical Nomenclature* may be obtained from Koeltz Scientific Books, D–61453 Konigstein, Germany, and University Bookstore, Southern Illinois University, Carbondale, IL 62901–4422, 618–536–3321, FAX 618–453–5207, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington DC.

(3) On labels of single-ingredient dietary supplements that do not include an ingredient list, the identification of the Latin binomial name, when needed, and the part of the plant may be prominently placed on the principal display panel or information panel, or included in the nutrition label.

5. Section 101.9 is amended by removing paragraphs (k)(2) and (k)(5), by redesignating paragraphs (k)(3), (k)(4), and (k)(6) as paragraphs (k)(2), (k)(3), and (k)(4), respectively, and by revising paragraphs (c)(8)(iii), (c)(8)(v), (d)(7)(i), (j)(6), and newly redesignated (k)(4) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(c) * * *

(8) * * *

(iii) The percentages for vitamins and minerals shall be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level. Amounts of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared in nutrition labeling but may be declared by a zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement ''Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)'' or ''Contains < 2 percent of the Daily Value of this (these) nutrient (nutrients).'' Alternatively, except as provided for in paragraph (f) of this section, if vitamin A, vitamin C, calcium, or iron is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement ''Not a significant source of _____ (listing the vitamins or minerals omitted)'' is placed at the bottom of the table of nutrient values. Either statement shall be in the same type size as nutrients that are indented.

* * * * *

(v) The following synonyms may be added in parentheses immediately following the name of the nutrient or dietary component:
Calories—Energy,
Vitamin C—Ascorbic acid,
Thiamin—Vitamin B_1,
Riboflavin—Vitamin B_2,
Folate—Folic acid or Folacin.
Alternatively, folic acid or folacin may be listed without parentheses in place of folate.

* * * * *

(d) * * *

(7) * * *

(i) The name of each nutrient, as specified in paragraph (c) of this section, shall be given in a column and followed immediately by the quantitative amount by weight for that nutrient appended with a ''g'' for grams or a ''mg'' for milligrams as shown in paragraph (d)(12) of this section. The symbol ''<'' may be used in place of ''less than.''

* * * * *

(j) * * *

(6) Dietary supplements, except that such foods shall be labeled in compliance with § 101.36.

* * * * *

(k) * * *

(4) That a natural vitamin in a food is superior to an added or synthetic vitamin.

6. Section 101.12 is amended in paragraph (b), Table 2, under the subheading ''Miscellaneous category'' by revising the entry ''Dietary supplements not in conventional food form'' to read as follows:

§ 101.12 Reference amounts customarily consumed per eating occasion.

* * * * *

(b) * * *

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY[1,2,3,4]

Product category	Reference amount	Label statement[5]
* *	* *	* * *
Miscellaneous category:		
Dietary supplements	The maximum amount recommended, as appropriate, on the label for consumption per eating occasion, or, in the absence of recommendations, 1 unit, e.g., tablet, capsule, packet, teaspoonsful, etc.	_____tablet(s), _____capsule(s), _____packet(s), _____tsp(s), (_____g), etc.
* *	* *	* * *

[1] These values represent the amount (edible portion) of food customarily consumed per eating occasion and were primarily derived from the 1977–78 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e, heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (e.g., dry mixes; concentrates; dough; batter; fresh and frozen pasta) is the amount required to make the reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked).

[3] Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

[4] Copies of the list of products for each product category are available from the Office of Food Labeling (HFS–150), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

[5] The label statements are meant to provide guidance to manufacturers on the presentation of serving size information on the label, but they are not required. The term ''piece'' is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for ice cream bars). The guidance provided is for the label statement of products in ready-to-serve or almost ready-to-serve form. The guidance does not apply to the products which require further preparation for consumption (e.g., dry mixes, concentrates) unless specifically stated in the product category, reference amount, or label statement column that it is for these forms of the product. For products that require further preparation, manufacturers must determine the label statement following the rules in § 101.9(b) using the reference amount determined according to § 101.12(c).

* * * * *

7. Section 101.36 is revised to read as follows:

§ 101.36 Nutrition labeling of dietary supplements.

(a) The label of a dietary supplement that is offered for sale shall bear nutrition labeling in accordance with this regulation unless an exemption is provided for the product in paragraph (h) of this section.

(b) The declaration of nutrition information on the label and in labeling shall contain the following information, using the subheadings and the format specified in paragraph (e) of this section.

(1) *Serving size*—(i) The subheading ''Serving Size'' shall be placed under the heading ''Supplement Facts'' and aligned on the left side of the nutrition label. The serving size shall be determined in accordance with §§ 101.9(b) and 101.12(b), Table 2. Serving size for dietary supplements shall be expressed using a term that is appropriate for the form of the supplement, such as ''tablets,'' ''capsules,'' ''packets,'' or ''teaspoonfuls.''

(ii) The subheading ''Servings Per Container'' shall be placed under the subheading ''Serving Size'' and aligned on the left side of the nutrition label, except that this information need not be provided when it is stated in the net quantity of contents declaration.

(2) *Information on dietary ingredients that have a Reference Daily Intake (RDI) or a Daily Reference Value (DRV) as established in § 101.9(c) and their subcomponents (hereinafter referred to as ''(b)(2)-dietary ingredients'')*—(i) The (b)(2)-dietary ingredients to be declared, that is, total calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium and iron, shall be declared when they are present in a dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in nutrition labeling of foods in accordance with § 101.9(c). Calories from saturated fat and polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, sugar alcohol, and other carbohydrate may be declared, but they shall be declared when a claim is made about them. Any other vitamins or minerals listed in § 101.9(c)(8)(iv) or (c)(9) may be declared, but they shall be declared when they are added to the product for purposes of supplementation, or when a claim is made about them. Any (b)(2)-dietary ingredients that are not present, or that are present in amounts that can be declared as zero in § 101.9(c), shall not be declared (e.g., amounts corresponding to less than 2 percent of the RDI for vitamins and minerals). Protein shall not be declared on labels of products that, other than ingredients added solely for technological reasons, contain only individual amino acids.

(A) The names and the quantitative amounts by weight of each (b)(2)-dietary ingredient shall be presented under the heading ''Amount Per Serving.'' When the quantitative amounts by weight are presented in a separate column, the heading may be centered over a column of quantitative amounts, described by paragraph (b)(2)(ii) of this section, if space permits. A heading consistent with the declaration of the serving size, such as ''Each Tablet Contains,'' or ''Amount Per 2 Tablets'' may be used in place of the heading ''Amount Per Serving.'' Other appropriate terms, such as capsule, packet, or teaspoonful, also may be used in place of the term ''Serving.''

(B) The names of dietary ingredients that are declared under paragraph (b)(2)(i) of this section shall be presented in a column aligned on the left side of the nutrition label in the order and manner of indentation specified in § 101.9(c), except that calcium and iron shall follow pantothenic acid, and sodium and potassium shall follow chloride. This results in the following order for vitamins and minerals: Vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B_6, folate, vitamin B_{12}, biotin, pantothenic acid, calcium, iron, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, sodium, and potassium. The (b)(2)-dietary ingredients shall be listed according to the nomenclature specified in § 101.9 or in paragraph (b)(2)(i)(B)*(2)* of this section.

(1) When ''Calories'' are declared, they shall be listed first in the column of names, beneath a light bar separating the heading ''Amount Per Serving'' from the list of names. When ''Calories from fat'' or ''Calories from saturated fat'' are declared, they shall be indented beneath ''Calories.''

(2) The following synonyms may be added in parentheses immediately following the name of these (b)(2)-dietary ingredients: Vitamin C (ascorbic acid), thiamin (vitamin B_1), riboflavin (vitamin B_2), folate (folacin or folic acid), and calories (energy). Alternatively, the term ''folic acid'' or ''folacin'' may be listed without parentheses in place of ''folate.'' Energy content per serving may be expressed in kilojoules units, added in parentheses immediately following the statement of caloric content.

(3) Beta-carotene may be declared as the percent of vitamin A that is present as beta-carotene, except that the declaration is required when a claim is made about beta-carotene. When declared, the percent shall be declared to the nearest whole percent, immediately adjacent to or beneath the name vitamin A (e.g., ''Vitamin A (90% as beta-carotene)''). The amount of beta-carotene in terms of international units (IU) may be included in parentheses following the percent statement (e.g., ''Vitamin A (90% (4500 IU) as beta-carotene)'').

(ii) The number of calories, if declared, and the quantitative amount by weight per serving of each dietary ingredient required to be listed under paragraph (b)(2)(i) of this section shall be presented either in a separate column aligned to the right of the column of names or immediately following the listing of names within the same column. The quantitative amounts by weight shall represent the weight of the dietary ingredient rather than the weight of the source of the dietary ingredient (e.g., the weight of calcium rather than that of calcium carbonate).

(A) These amounts shall be expressed in the increments specified in § 101.9(c)(1) through (c)(7), which includes increments for sodium and potassium.

(B) The amounts of vitamins and minerals, excluding sodium and potassium, shall be the amount of the vitamin or mineral included in one serving of the product, using the units of measurement and the levels of significance given in § 101.9(c)(8)(iv), except that zeros following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (e.g., the RDI for zinc is given in whole milligrams (mg), but the quantitative amount may be declared in tenths of a mg).

(iii) The percent of the Daily Value of all dietary ingredients declared under paragraph (b)(2)(i) of this section shall be listed, except that the percent for protein may be omitted as provided in § 101.9(c)(7); no percent shall be given for subcomponents for which DRV's have not been established (e.g., sugars); and, for labels of dietary supplements of vitamins and minerals that are represented or purported to be for use by infants, children less than 4 years of age, or pregnant or lactating women, no percent shall be given for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, vitamin K, selenium, manganese, chromium, molybdenum, chloride, sodium, or potassium.

(A) When information on the percent of Daily Values is listed, this information shall be presented in one column aligned under the heading of ''% Daily Value'' and to the right of the column of amounts. The headings ''% Daily Value (DV),'' ''% DV,'' ''Percent Daily Value,'' or ''Percent DV'' may be substituted for ''% Daily Value.'' The heading ''% Daily Value'' shall be placed on the same line as the heading ''Amount Per Serving.'' When the acronym ''DV'' is unexplained in the heading and a footnote is required under (b)(2)(iii)(D), (b)(2)(iii)(F), or (b)(3)(iv) of this section, the footnote shall explain the acronym (e.g. ''Daily Value (DV) not established'').

(B) The percent of Daily Value shall be calculated by dividing the quantitative amount by weight of each (b)(2)-dietary ingredient by the RDI as established in § 101.9(c)(8)(iv) or the DRV as established in § 101.9(c)(9) for the specified dietary ingredient and multiplying by 100, except that the percent of Daily Value for protein, when present, shall be calculated as specified in § 101.9(c)(7)(ii). The quantitative amount by weight of each dietary ingredient in this calculation shall be the unrounded amount, except that for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber, the quantitative amount by weight declared on the label (i.e, rounded amount) may be used. The numerical value shall be followed by the symbol for percent (i.e., %).

(C) The percentages based on RDI's and on DRV's shall be expressed to the nearest whole percent, except that for dietary ingredients for which DRV's have been established, ''Less than 1%'' or ''<1%'' shall be used to declare the ''% Daily Value'' when the quantitative amount of the dietary ingredient by weight is great enough to require that the dietary ingredient be listed, but the amount is so small that the ''% Daily Value'' when rounded to the nearest percent is zero (e.g., a product that contains 1 gram of total carbohydrate would list the percent Daily Value as ''Less than 1%'' or ''<1%'').

(D) If the percent of Daily Value is declared for total fat, saturated fat, total carbohydrate, dietary fiber, or protein, a symbol shall follow the value listed for those nutrients that refers to the same symbol that is placed at the bottom of the nutrition label, below the bar required under paragraph (e)(6) of this section and inside the box, that is followed by the statement ''Percent Daily Values are based on a 2,000 calorie diet.''

(E) The percent of Daily Value shall be based on RDI and DRV values 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. If the product is for persons within more than one group, the percent of Daily Value for each group shall be presented in separate columns as shown in paragraph (e)(10)(ii) of this section.

(F) For declared subcomponents that have no DRV's and, on the labels of dietary supplements of vitamins and minerals that are represented or purported to be for use by infants, children less that 4 years of age, or pregnant or lactating women, for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, vitamin K, selenium, manganese, chromium, molybdenum, chloride, sodium, or potassium, a symbol (e.g., an asterisk) shall be placed in the ''Percent Daily Value'' column that shall refer to the same symbol that is placed at the bottom of the nutrition label, below the last heavy bar and inside the box, and followed by the statement ''Daily Value not established.''

(G) When calories, calories from fat, or calories from saturated fat are declared, the space under the ''% Daily Value'' column shall be left blank for these items. When there are no other (b)(2)-dietary ingredients listed for which a value must be declared in the ''% Daily Value'' column, the column may be omitted as shown in paragraph (e)(10)(vii) of this section. When the ''% Daily Value'' column is not required, but the dietary ingredients listed are subject to paragraph (b)(2)(iii)(F) of this section, the symbol required in that paragraph shall immediately follow the quantitative amount by weight for each dietary ingredient listed under ''Amount Per Serving.''

(iv) The quantitative amount by weight and the percent of Daily Value may be presented on a ''per unit'' basis in addition to on a ''per serving'' basis, as required in paragraph (b)(2)(ii) of this section. This information shall be presented in additional columns and clearly identified by appropriate headings.

(3) *Information on dietary ingredients for which RDI's and DRV's have not been established*—(i) Dietary ingredients for which FDA has not established RDI's or DRV's and that are not subject to regulation under paragraph (b)(2) of this section (hereinafter referred to as ''other dietary ingredients'') shall be declared by their common or usual name when they are present in a dietary supplement, in a column that is under the column of names described in paragraph (b)(2)(i)(B) of this section or, as long as the constituents of an other dietary ingredient are not listed, in a linear display, under the heavy bar described in paragraph (e)(6) of this section, except that if no (b)(2)-dietary ingredients are declared, other dietary ingredients shall be declared directly beneath the heading ''Amount Per Serving'' described in paragraph (b)(2)(i)(A) of this section.

(ii) The quantitative amount by weight per serving of other dietary ingredients shall be presented in the same manner as the corresponding information required in paragraph (b)(2)(ii) of this section or, when a linear display is used, shall be presented immediately following the name of the other dietary ingredient. The quantitative amount by weight shall be the weight of the other dietary ingredient listed and not the weight of any component, or the source, of that dietary ingredient.

(A) These amounts shall be expressed using metric measures in appropriate units (i.e., 1,000 or more units shall be declared in the next higher set of units, e.g., 1,100 mg shall be declared as 1.1 g).

(B) For any dietary ingredient that is a liquid extract from which the solvent

has not been removed, the quantity listed shall be the weight of the total extract with information on the concentration of the dietary ingredient, the solvent used, and the condition of the starting material (i.e., whether it is fresh or dried), e.g., ''fresh dandelion root extract, x mg (y:z) in 70% ethanol,'' where x is the number of mg of the entire extract, y is the weight of the starting material and z is the volume (milliliters) of solvent. Where the solvent has been partially removed (not to dryness), the final concentration shall be stated (e.g., if the original extract was 1:5 and 50 percent of the solvent was removed, then the final concentration shall be stated as 1:2.5).

(C) For a dietary ingredient that is an extract from which the solvent has been removed, the weight of the ingredient shall be the weight of the dried extract. The dried extract shall be described by an appropriately descriptive term that identifies the solvent used, e.g., ''dried hexane extract of _____'' or ''_____, dried hexane extract.''

(iii) The constituents of a dietary ingredient described in paragraph (b)(3)(i) of this section may be listed indented under the dietary ingredient and followed by their quantitative amounts by weight, except that dietary ingredients described in paragraph (b)(2) of this section shall be listed in accordance with that section. When the constituents of a dietary ingredient described in paragraph (b)(3)(i) of this section are listed, all other dietary ingredients shall be declared in a column; however, the constituents themselves may be declared in a column or in a linear display.

(iv) Other dietary ingredients shall bear a symbol (e.g., an asterisk) in the column under the heading of ''% Daily Value'' that refers to the same symbol placed at the bottom of the nutrition label and followed by the statement ''Daily Value not established,'' except that when the heading ''% Daily Value'' is not used, the symbol shall follow the quantitative amount by weight for each dietary ingredient listed.

(c) A proprietary blend of dietary ingredients shall be included in the list of dietary ingredients described in paragraph (b)(3)(i) of this section and identified by the term ''Proprietary Blend'' or other appropriately descriptive term or fanciful name and may be highlighted by bold type. Except as specified in this paragraph, all other requirements for the listing of dietary ingredients in dietary supplements are applicable.

(1) Dietary ingredients contained in the proprietary blend that are listed under paragraph (b)(2) of this section shall be declared in accordance with paragraph (b)(2) of this section.

(2) Dietary ingredients contained in the proprietary blend that are listed under paragraph (b)(3) of this section (i.e., ''other dietary ingredients'') shall be declared in descending order of predominance by weight, in a column or linear fashion, and indented under the term ''Proprietary Blend'' or other appropriately descriptive term or fanciful name.

(3) The quantitative amount by weight specified for the proprietary blend shall be the total weight of all other dietary ingredients contained in the proprietary blend and shall be placed on the same line to the right of the term ''Proprietary Blend'' or other appropriately descriptive term or fanciful name underneath the column of amounts described in paragraph (b)(2)(ii) of this section. A symbol (e.g., asterisk), which refers to the same symbol placed at the bottom of the nutrition label that is followed by the statement ''Daily Value not established,'' shall be placed under the heading ''% Daily Value,'' if present, or immediately following the quantitative amount by weight for the proprietary blend.

(4) The sample label shown in paragraph (e)(10)(v) of this section illustrates one method of nutrition labeling a proprietary blend of dietary ingredients.

(d) The source ingredient that supplies a dietary ingredient may be identified within the nutrition label in parentheses immediately following or indented beneath the name of a dietary ingredient and preceded by the words ''as'' or ''from'', e.g., ''Calcium (as calcium carbonate),'' except that manner of presentation is unnecessary when the name of the dietary ingredient (e.g., Oriental ginseng) or its synonym (e.g., ascorbic acid) is itself the source ingredient. When a source ingredient is identified in parentheses within the nutrition label, or when the name of the dietary ingredient or its synonym is the source ingredient, it shall not be required to be listed again in the ingredient statement that appears outside of the nutrition label. When a source ingredient is not identified within the nutrition label, it shall be listed in an ingredient statement in accordance with § 101.4(g), which shall appear outside and immediately below the nutrition label or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label.

(1) Source ingredients shall be identified in accordance with § 101.4 (i.e., shall be listed by common or usual name, and the listing of botanicals shall specify the part of the plant from which the ingredient is derived) regardless of whether they are listed in an ingredient statement or in the nutrition label.

(2) When source ingredients are listed within the nutrition label, and two or more are used to provide a single dietary ingredient, all of the sources shall be listed within the parentheses in descending order by weight.

(3) Representations that the source ingredient conforms to an official compendium may be included either in the nutrition label or in the ingredient list (e.g., ''Calcium (as calcium carbonate USP)'').

(e) Nutrition information specified in this section shall be presented as follows:

(1) The title, ''Supplement Facts,'' shall be set in a type size larger than all other print size in the nutrition label and, unless impractical, shall be set full width of the nutrition label. The title and all headings shall be bolded to distinguish them from other information.

(2) The nutrition information shall be enclosed in a box by using hairlines.

(3) All information within the nutrition label shall utilize:

(i) A single easy-to-read type style,

(ii) All black or one color type, printed on a white or other neutral contrasting background whenever practical,

(iii) Upper- and lowercase letters, except that all uppercase lettering may be utilized for packages that have a total surface area available to bear labeling of less than 12 square inches,

(iv) At least one point leading (i.e., space between lines of text), and

(v) Letters that do not touch.

(4) Except as provided for small and intermediate-sized packages under paragraph (i)(2) of this section, information other than the title, headings, and footnotes shall be in uniform type size no smaller than 8 point. Type size no smaller than 6 point may be used for column headings (e.g., ''Amount Per Serving'' and ''% Daily Value'') and for footnotes (e.g., ''Percent Daily Values are based on a 2,000 calorie diet'').

(5) A hairline rule that is centered between the lines of text shall separate each dietary ingredient required in paragraph (b)(2) and (b)(3) of this section from the dietary ingredient above and beneath it, as shown in paragraph (e)(10) of this section.

(6) A heavy bar shall be placed:

(i) Beneath the subheading ''Servings Per Container'' except that if ''Servings Per Container'' is not required and, as a result, not declared, the bar shall be

placed beneath the subheading ''Serving Size,''

(ii) Beneath the last dietary ingredient to be listed under paragraph (b)(2)(i) of this section, if any, and

(iii) Beneath the last other dietary ingredient to be listed under paragraph (b)(3) of this section, if any.

(7) A light bar shall be placed beneath the headings ''Amount Per Serving'' and ''% Daily Value.''

(8) If the product contains two or more separately packaged dietary supplements that differ from each other (e.g., the product has a packet of supplements to be taken in the morning and a different packet to be taken in the afternoon), the quantitative amounts and percent of Daily Value may be presented as specified in this paragraph in individual nutrition labels or in one aggregate nutrition label as illustrated in paragraph (e)(10)(iii) of this section.

(9) In the interest of uniformity of presentation, FDA urges that the information be presented using the graphic specifications set forth in Appendix B to part 101, as applicable.

(10) The following sample labels are presented for the purpose of illustration:

BILLING CODE 4190–01–F

(i) Multiple vitamins:

Supplement Facts

Serving Size 1 Tablet

	Amount Per Serving	% Daily Value
Vitamin A (as retinyl acetate and 50% as beta-carotene)	5000 IU	100%
Vitamin C (as ascorbic acid)	60 mg	100%
Vitamin D (as cholecalciferol)	400 IU	100%
Vitamin E (as dl-alpha tocopheryl acetate)	30 IU	100%
Thiamin (as thiamin mononitrate)	1.5 mg	100%
Riboflavin	1.7 mg	100%
Niacin (as niacinamide)	20 mg	100%
Vitamin B_6 (as pyridoxine hydrochloride)	2.0 mg	100%
Folate (as folic acid)	400 mcg	100%
Vitamin B_{12} (as cyanocobalamin)	6 mcg	100%
Biotin	30 mcg	10%
Pantothenic Acid (as calcium pantothenate)	10 mg	100%

Other ingredients: Gelatin, lactose, magnesium stearate, microcrystalline cellulose, FD&C Yellow No. 6, propylene glycol, propylparaben, and sodium benzoate.

(ii) Multiple vitamins for children and adults:

Supplement Facts

Serving Size 1 Tablet

Amount Per Serving		% Daily Value for Children Under 4 Years of Age	% Daily Value for Adults and Children 4 or more Years of Age
Calories	5		
Total Carbohydrate	1 g	†	< 1%*
Sugars	1 g	†	†
Vitamin A (50% as beta-carotene)	2500 IU	100%	50%
Vitamin C	40 mg	100%	67%
Vitamin D	400 IU	100%	100%
Vitamin E	15 IU	150%	50%
Thiamin	1.1 mg	157%	73%
Riboflavin	1.2 mg	150%	71%
Niacin	14 mg	156%	70%
Vitamin B_6	1.1 mg	157%	55%
Folate	300 mcg	150%	75%
Vitamin B_{12}	5 mcg	167%	83%

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Sucrose, sodium ascorbate, stearic acid, gelatin, maltodextrins, artificial flavors, dl-alpha tocopheryl acetate, niacinamide, magnesium stearate, Yellow 6, artificial colors, stearic acid, palmitic acid, pyridoxine hydrochloride, thiamin mononitrate, vitamin A acetate, beta-carotene, folic acid, cholecalciferol, and cyanocobalamin.

(iii) Multiple vitamins in packets:

Supplement Facts

Serving Size 1 Packet
Servings Per Container 10

	AM Packet		PM Packet	
Amount Per Serving		**% Daily Value**		**% Daily Value**
Vitamin A	2500 IU	50%	2500 IU	50%
Vitamin C	60 mg	100%	60 mg	100%
Vitamin D	400 IU	100%		
Vitamin E	30 IU	100%		
Thiamin	1.5 mg	100%	1.5 mg	100%
Riboflavin	1.7 mg	100%	1.7 mg	100%
Niacin	20 mg	100%	20 mg	100%
Vitamin B_6	2.0 mg	100%	2.0 mg	100%
Folic Acid	200 mcg	50%	200 mcg	50%
Vitamin B_{12}	3 mcg	50%	3 mcg	50%
Biotin			30 mcg	10%
Pantothenic Acid	5 mg	50%	5 mg	50%

Ingredients: Sodium ascorbate, ascorbic acid, calcium pantothenate, niacinamide, dl-alpha tocopheryl acetate, microcrystalline cellulose, artificial flavors, dextrin, starch, mono- and diglycerides, vitamin A acetate, magnesium stearate, gelatin, FD&C Blue #1, FD&C Red #3, artificial colors, thiamin mononitrate, pyridoxine hydrochloride, citric acid, lactose, sorbic acid, tricalcium phosphate, sodium benzoate, sodium caseinate, methylparaben, potassium sorbate, BHA, BHT, ergocalciferol and cyanocobalamin.

(iv) Dietary supplement containing dietary ingredient with and without RDI's and DRV's:

Supplement Facts

Serving Size 1 Capsule

Amount Per Capsule	% Daily Value
Calories 20	
Calories from Fat 20	
Total Fat 2 g	3%*
Saturated Fat 0.5 g	3%*
Polyunsaturated Fat 1 g	†
Monounsaturated Fat 0.5 g	†
Vitamin A 4250 IU	85%
Vitamin D 425 IU	106%
Omega-3 fatty acids 0.5 g	†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Ingredients: Cod liver oil, gelatin, water, and glycerin.

(v) A proprietary blend of dietary ingredients:

Supplement Facts

Serving Size 1 tsp (3 g) (makes 8 fl oz prepared)
Servings Per Container 24

	Amount Per Teaspoon	% Daily Value
Calories	10	
Total Carbohydrate	2 g	< 1%*
Sugars	2 g	†
Proprietary blend	0.7 g	
German Chamomile (flower)		†
Hyssop (leaves)		†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Fructose, lactose, starch, and stearic acid.

(vi) Dietary supplement of an herb

Supplement Facts

Serving Size 1 Capsule

Amount Per Capsule	
Oriental Ginseng, powdered (root)	250 mcg*

* Daily Value not established.

Other ingredients: Gelatin, water, and glycerin.

(vii) Dietary supplement of amino acids:

Supplement Facts

Serving Size 1 Tablet

Amount Per Tablet	
Calories	15
Isoleucine (as L-isoleucine hydrochloride)	450 mg*
Leucine (as L-leucine hydrochloride)	620 mg*
Lysine (as L-lysine hydrochloride)	500 mg*
Methionine (as L-methionine hydrochloride)	350 mg*
Cystine (as L-cystine hydrochloride)	200 mg*
Phenylalanine (as L-phenylalanine hydrochloride)	220 mg*
Tyrosine (as L-tyrosine hydrochloride)	900 mg*
Threonine (as L-threonine hydrochloride)	300 mg*
Valine (as L-valine hydrochloride)	650 mg*

* Daily Value not established.

Other ingredients: Cellulose, lactose, and magnesium stearate.

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(11) If space is not adequate to list the required information as shown in the sample labels in paragraph (e)(10) of this section, the list may be split and continued to the right as long as the headings are repeated. The list to the right shall be set off by a line that distinguishes it and sets it apart from the dietary ingredients and percent of Daily Value information given to the left. The following sample label illustrates this display:

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Supplement Facts

Serving Size 1 Packet

Amount Per Packet		% Daily Value
Vitamin A (from cod liver oil)	5,000 IU	100%
Vitamin C (as ascorbic acid)	250 mg	417%
Vitamin D (as ergocalciferol)	400 IU	100%
Vitamin E (as d-alpha tocopherol)	150 IU	500%
Thiamin (as thiamin mononitrate)	75 mg	5000%
Riboflavin	75 mg	4412%
Niacin (as niacinamide)	75 mg	375%
Vitamin B_6 (as pyridoxine hydrochloride)	75 mg	3750%
Folic Acid	400 mcg	100%
Vitamin B_{12} (as cyanocobalamin)	100 mcg	1667%
Biotin	100 mcg	33%
Pantothenic Acid (as calcium pentothenate)	75 mg	750%
Calcium (from oystershell)	100 mg	10%
Iron (as ferrous fumarate)	10 mg	56%
Iodine (from kelp)	150 mcg	100%
Magnesium (as magnesium oxide)	60 mg	15%

Amount Per Packet		% Daily Value
Zinc (as zinc oxide)	15 mg	100%
Selenium (as sodium selenate)	25 mcg	36%
Copper (as cupric oxide)	1 mg	50%
Manganese (as manganese sulfate)	5 mg	250%
Chromium (as chromium chloride)	50 mcg	42%
Molybdenum (as sodium molybdate)	50 mcg	67%
Potassium (as potassium chloride)	10 mg	< 1%
Choline (as choline chloride)	100 mg	*
Betaine (as betaine hydrochloride)	25 mg	*
Glutamic Acid (as L-glutamic acid)	25 mg	*
Inositol (as inositol monophosphate)	75 mg	*
para-Aminobenzoic acid	30 mg	*
Deoxyribonucleic acid	50 mg	*
Boron	500 mcg	*

* Daily Value not established

Other ingredients: Cellulose, stearic acid and silica.

(f)(1) Compliance with this section will be determined in accordance with § 101.9(g)(1) through (g)(8), except that the sample for analysis shall consist of a composite of 12 subsamples (consumer packages) or 10 percent of the number of packages in the same inspection lot, whichever is smaller, randomly selected to be representative of the lot. The criteria on class I and class II nutrients given in § 101.9(g)(3) and (g)(4) also are applicable to other dietary ingredients described in paragraph (b)(3)(i) of this section. Reasonable excesses of these other dietary ingredients over labeled amounts are acceptable within current good manufacturing practice.

(2) When it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of this section, FDA may permit alternative means of compliance or additional exemptions to deal with the situation in accordance with § 101.9(g)(9). Firms in need of such special allowances shall make their request in writing to the Office of Food Labeling (HFS–150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(g) Except as provided in paragraphs (i)(2) and (i)(5) of this section, the location of nutrition information on a label shall be in compliance with § 101.2.

(h) Dietary supplements are subject to the exemptions specified as follows in:

(1) Section 101.9(j)(1) for foods that are offered for sale by a person who makes direct sales to consumers (i.e., a retailer) who has annual gross sales or business done in sales to consumers that is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers of not more than $50,000, and whose labels, labeling, and advertising do not provide nutrition information or make a nutrient content or health claim;

(2) Section 101.9(j)(18) for foods that are low-volume products (that is, they meet the requirements for units sold in § 101.9(j)(18)(i) or (j)(18)(ii)); that, except as provided in § 101.9(j)(18)(iv), are the subject of a claim for an exemption that provides the information required under § 101.9(j)(18)(iv), that is filed before the beginning of the time period for which the exemption is claimed, and that is filed by a person, whether it is the manufacturer, packer, or distributor, that qualifies to claim the exemption under the requirements for average full-time equivalent employees in § 101.9(j)(18)(i) or (j)(18)(ii), and whose labels, labeling, and advertising do not provide nutrition information or make a nutrient content or health claim;

(3) Section 101.9(j)(9) for foods shipped in bulk form that are not for distribution to consumers in such form and that are for use solely in the manufacture of other dietary supplements or that are to be processed, labeled, or repacked at a site other than where originally processed or packed.

(i) Dietary supplements are subject to the special labeling provisions specified in:

(1) Section 101.9(j)(5)(i) for foods, other than infant formula, represented or purported to be specifically for infants and children less than 2 years of age, in that nutrition labels on such foods shall not include calories from fat, calories from saturated fat, saturated fat, polyunsaturated fat, monounsaturated fat, and cholesterol;

(2) Section 101.9(j)(13) for foods in small or intermediate-sized packages, except that:

(i) All information within the nutrition label on small-sized packages, which have a total surface area available to labeling of less than 12 square inches, shall be in type size no smaller than 4.5 point;

(ii) All information within the nutrition label on intermediate-sized packages, which have from 12 to 40 square inches of surface area available to bear labeling, shall be in type size no smaller than 6 point, except that type size no smaller than 4.5 point may be used on packages that have less than 20 square inches available for labeling and more than 8 dietary ingredients to be listed and on packages that have 20 to 40 square inches available for labeling and more than 16 dietary ingredients to be listed.

(iii) When the nutrition information is presented on any panel under § 101.9(j)(13)(ii)(D), the ingredient list shall continue to be located immediately below the nutrition label, or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label as specified in § 101.4(g).

(iv) When it is not possible for a small or intermediate-sized package that is enclosed in an outer package to comply with these type size requirements, the type size of the nutrition label on the primary (inner) container may be as small as needed to accommodate all of the required label information provided that the primary container is securely enclosed in outer packaging, the nutrition labeling on the outer packaging meets the applicable type size requirements, and such outer packaging is not intended to be separated from the primary container under conditions of retail sale.

(v) Where there is not sufficient space on a small or intermediate-sized package for a nutrition label that meets minimum type size requirements of 4.5 points if hairlines are used in accordance with paragraph (e)(5) of this section, the hairlines may be omitted and replaced by a row of dots connecting the columns containing the name of each dietary ingredient and the quantitative amounts (by weight and as a percent of Daily Value).

(3) Section 101.9(j)(15) for foods in multiunit food containers;

(4) Section 101.9(j)(16) for foods sold in bulk containers; and

(5) Section 101.9(j)(17) for foods in packages that have a total surface area available to bear labeling greater than 40 square inches but whose principal display panel and information panel do not provide sufficient space to accommodate all required label information, except that the ingredient list shall continue to be located immediately below the nutrition label, or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label as specified in § 101.4(g).

(j) Dietary supplements shall be subject to the misbranding provisions of § 101.9(k).

7. Section 101.65 is amended by revising paragraph (b)(4) to read as follows:

§ 101.65 Implied nutrient content claims and related label statements.

* * * * *

(b) * * *

(4) A statement of identity for a food in which an ingredient constitutes essentially 100 percent of a food (e.g., ''corn oil,'' ''oat bran,'' ''dietary supplement of vitamin C 60 mg tablet'').

* * * * *

Dated: September 11, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

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