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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 90N-135D]
RIN 0905-AD96

Food Labeling; General Requirements for Nutrition Labeling for Dietary Supplements of Vitamins, Minerals, Herbs, or Other Similar Nutritional Substances

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 nutrition labeling of dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances (hereinafter referred to as dietary supplements). This action is in response to certain provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) and the Dietary Supplement Act of 1992 (the DS act).

EFFECTIVE DATE: July 5, 1995.

FOR FURTHER INFORMATION CONTACT: Susan Thompson, Center for Food Safety and Applied Nutrition (HFS-165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5587.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of June 18, 1993 (58 FR 33715), FDA published a proposed rule entitled ``Food Labeling; General Requirements for Nutrition Labeling for Dietary Supplements of Vitamins, Minerals, Herbs, or Other Similar Nutritional Substances'' (hereinafter identified as ``the nutrition labeling proposal for dietary supplements'') to establish regulations on the nutrition labeling of dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances. A document correcting various editorial errors in that proposed rule was published in the Federal Register of July 27, 1993 (58 FR 40104).

The proposed rule was issued to implement the 1990 amendments (Pub. L. 101-535), which were signed into law on November 8, 1990. This new law 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 it added section 403(q) to the act (21 U.S.C. 343(q)). This section requires that most foods bear nutrition labeling.

In response to section 403(q) of the act, FDA published a proposed rule on nutrition labeling in the Federal Register of November 27, 1991 (56 FR 60366 at 60393). That document proposed, among other things, a regulation specifically for the nutrition labeling of dietary supplements of vitamins or minerals (proposed Sec. 101.36). It also proposed to make the nutrition labeling of dietary supplements of herbs or other similar nutritional substances subject to Sec. 101.9 (21 CFR 101.9), the general regulation on nutrition labeling. This distinction reflects section 403(q)(5)(F) (formerly section 403(q)(5)(E)) of the act. This section provides that if a food to which section 411 of the act (21 U.S.C. 350) applies (i.e., a dietary supplement of vitamins or minerals) contains one or more of the nutrients required to be listed in nutrition labeling, ``the label or labeling of such food shall comply with requirements of subparagraph (1) and (2) [of section 403(q) of the act] in a manner which is appropriate for such food and which is specified in regulations of the Secretary.'' Other dietary supplements are not subject to section 403(q)(5)(F) of the act and thus are subject to regulation under section 403(q) of the act as any other food.

In response to the proposed rule on nutrition labeling of November 27, 1991, FDA received over 45 responses, each containing one or more comments, that pertained to the nutrition labeling of dietary supplements. The agency summarized and discussed the issues in these comments in the preamble of the mandatory nutrition labeling final rule that it issued on January 6, 1993 (58 FR 2079 at 2167). However, the

regulations that FDA adopted in that final rule applied only to the nutrition labeling of foods in conventional food form (Sec. 101.9). They did not apply to dietary supplements because of a moratorium established by the DS act.

The DS act (Pub. L. 102-571) was signed into law on October 6, 1992. In section 202(a)(1), the DS act established a moratorium until December 15, 1993, on the implementation of the 1990 amendments, with respect to dietary supplements. Thus, FDA did not finalize the proposed rules pertaining to the nutrition labeling of dietary supplements of vitamins and minerals (Sec. 101.36) or of herbs or other nutritional substances.

Section 202(a)(2) of the DS act required that the Secretary of Health and Human Services, and by delegation FDA, issue new proposed regulations that are applicable to dietary supplements no later than June 15, 1993, and final regulations by December 31, 1993. In response to this provision, FDA issued the June 18, 1993 (58 FR 33715) proposal and is now issuing this final rule. In addition, elsewhere in this issue of the Federal Register, FDA is issuing final regulations that address the use of nutrient content claims and health claims on dietary supplements.

In addition, section 203 of the DS act instructed FDA not to promulgate regulations before November 8, 1993, that establish recommended daily allowances for vitamins or minerals other than those recommended allowances specified in Sec. 101.9(c)(7)(iv) as in effect on October 6, 1992. Therefore, in the January 6, 1993, mandatory nutrition labeling final rule, FDA retained the U.S. Recommended Daily Allowances (U.S. RDA) values specified in Sec. 101.9(c)(7)(iv), as in effect on October 6, 1992. These U.S. RDA values were in large measure based on the RDA's in the National Academy of Sciences' (NAS) publication ``Recommended Dietary Allowances,'' 7th edition, 1968 (Ref. 1). The agency did, however, change the terminology for these values from ``U.S. RDA's'' to ``Reference Daily Intakes (RDI's).''

FDA received over 400 responses to its June 18, 1993, proposed rule on the nutrition labeling of dietary supplements, each of these responses contained one or more comments. Responses were received from consumers, consumer advocacy organizations, health care professionals, professional societies, universities, industry, trade associations, and State and local governments. Many comments addressed issues covered by other proposals that are a part of this overall food labeling initiative, and they will be addressed in those documents. Other comments were outside the scope of these proposals and will not be discussed here.

About half of the comments supported the proposal; about half of these comments supported it without modification. These comments were primarily from health professionals, although a few were from that segment of the food industry that produces foods in conventional food form. The remainder of the comments that supported the proposal suggested modifications in various provisions of the proposal. About half of the comments opposed the proposal. These comments were primarily from consumers who opposed FDA's regulation of dietary supplements. A summary of the comments that suggested changes and the agency's responses follow:

II. Scope of New Sec. 101.36

1. One comment from a manufacturer of dietary supplements supported the proposed rule to allow only vitamins and minerals that have RDI's or Daily Reference Values (DRV's) to be listed in the nutrition label of dietary supplements of vitamins and minerals. However, several comments wanted non-RDI vitamins and minerals to be listed, particularly those in the NAS's ``Recommended Dietary Allowances'' (i.e., chloride, chromium, fluoride, manganese, molybdenum, selenium, and vitamin K). The comments pointed out that advances in scientific knowledge have shown that these nutrients are considered essential to human health. Some comments also suggested listing nutrients such as arsenic, boron, silicon, tin, and vanadium that they stated are of major significance in human nutrition.

Some of these comments suggested that an asterisk in the ``Percent Daily Value'' column could refer to a footnote, such as ``No Daily Value has been established for this nutrient.'' Another comment suggested that these additional nutrients could be listed in a subsection of the nutrition panel below the bar after the last nutrient for which there is an RDI or DRV. One comment stated that to put information on nutrients of this type outside of the ``Nutrition Facts'' box would be inconvenient and may cause some consumers to overlook the presence of these additional nutrients, some of which should not be consumed in excess.

The agency is persuaded that it is appropriate to allow the nutrients that are listed as being essential to humans in the NAS's ``Recommended Dietary Allowances'' (Refs. 2 and 10), but for which FDA has not established RDI's, to be declared in the nutrition label of dietary supplements of vitamins and minerals when they are present in supplements at more than insignificant amounts. The agency agrees that there have been significant advances in scientific knowledge with respect to essential nutrient requirements since 1968. In 1989, the NAS updated its RDA's to include values for vitamin K and selenium and to make significant revisions in the allowances for several nutrients including vitamin B6, folate (folic acid), vitamin B12, magnesium, iron and zinc (Ref. 2). In addition, scientific advances permitted the NAS to revise the values, known as ``Estimated Safe and Adequate Daily Dietary Intakes'' (ESADDI's) in 1980 for chloride (Ref. 10) and in 1989, for three nutrients (biotin, pantothenic acid, and copper), for

which FDA established U.S. RDA's in 1973, and to establish new ESADDI's for manganese, fluoride, chromium, and molybdenum (Ref. 2).

It was in response to these scientific advances that FDA proposed RDI's in the Federal Register of November 27, 1991 (56 FR 60366 at 60390 and 60393) for the nutrients mentioned previously that are included in the 1980 and the 1989 NAS RDA's but for which RDI's have not been established (i.e., chloride, chromium, fluoride, manganese, molybdenum, selenium, and vitamin K). The establishment of RDI's would have allowed these nutrients to be listed on the nutrition label of dietary supplements of vitamins and minerals as well of foods in conventional food form. However, as stated above, section 203 of the DS act instructed FDA not to promulgate regulations that require the use of, or that are based upon, recommended daily allowances of vitamins or minerals before November 8, 1993, other than those specified in Sec. 101.9(c)(7)(iv), as in effect on October 6, 1992. In accordance with this provision of the DS act, the agency issued a final rule on January 6, 1993 (58 FR 2206) that retained the former U.S. RDA values. As a result, the final rule did not include RDI's for chloride, chromium, fluoride, manganese, molybdenum, selenium, and vitamin K.

Because the prohibition in section 203 of the DS act has now expired, the agency is proposing, elsewhere in this issue of the Federal Register, to establish RDI values for those nutrients listed by the NAS as being essential to humans and that do not already have RDI values. The agency is proposing this action because these nutrients are essential for the maintenance of good health in humans.

In recognition of the essentiality of these nutrients and in response to the comments summarized above, the agency is requiring in new Sec. 101.36(b)(3) that chloride, chromium, fluoride, manganese, molybdenum, selenium and vitamin K be included in the nutrition label when present in the dietary supplement. The agency also is providing in Sec. 101.36(b)(4)(vi) that if any of these nutrients are declared, they are to be followed by an asterisk in the ``Percent Daily Value'' column. The asterisk is to refer to another asterisk that is placed at the bottom of the table and that is followed by the statement ``Daily Value not established.'' This action is a logical outgrowth of the nutrition labeling proposal for dietary supplements because that proposal put into issue the question of whether the list of nutrients that FDA proposed be included in the nutrition label under Sec. 101.36 was the appropriate list. The comments have persuaded FDA that the list needs to be expanded in the manner described in this final rule.

FDA is not persuaded, however, that other trace elements for which the NAS has not established RDA's or ESADDI's should be declared within the nutrition label. The comments that suggested that such elements be included on the label provided some published reports that certain of these elements have been found to be essential in the diets of various animals but did not provide sufficient evidence for the agency to conclude that there is scientific consensus about their essentiality for the maintenance of good health in humans. The agency strongly believes that evidence of the usefulness of a nutrient for humans is necessary before that nutrient can be allowed to be listed within the nutrition label. This policy is consistent with current Sec. 101.9(i)(5) (redesignated and revised in the January 6, 1993, final rules, as Sec. 101.9(k)(5)) which prohibits a food's label from stating or implying that the food has special dietary properties because of the presence of a substance when, in fact, the usefulness of the substance has not been established in human nutrition.

In addition, in its proposed rule on mandatory nutrition labeling (55 FR 29487 at 29493, July 19, 1990), FDA stated that it was concerned about the possibility of a large number of nutrients being listed in nutrition labeling and about the way in which their presence on the label may be interpreted by consumers. FDA expressed concern that the presence of a large number of nutrients could be misinterpreted as implying that a food has a greater public health significance than may be the case. The potential for this happening and misleading the consumer about the contribution of the food to human nutrition is especially likely if the nutrition label were to include nutrients not known to be important to humans. Therefore, FDA believes that foods that list such nutrients in the nutrition label would be misbranded under section 403(a) of the act which prohibits misleading information on the labels and labeling of foods. However, statements about amounts and percentages can be made outside of the nutrition label as discussed in the final rule on nutrient content claims published elsewhere in this issue of the Federal Register.

The agency is specifying that the new nutrients to be listed appear in an order that reflects the order that FDA proposed in the nutrition labeling proposal of November 27, 1991 (56 FR 60390). Vitamin K is to be listed after vitamin E with the fat soluble vitamins, selenium is to be listed before copper, and the remaining nutrients (manganese, fluoride, chromium, molybdenum, and chloride) are to be listed after copper at the bottom of the list.

The agency points out that it is not allowing the listing of these nutrients on the nutrition labels of foods in conventional food form. Under Sec. 101.9(c)(8), quantitative amounts by weight of vitamins and minerals are not listed within the nutrition label of foods in conventional food form. As a result, the listing of only an asterisk in conjunction with the statement ``Daily Value not established'' would provide consumers with no indication of the amount of chloride, chromium, fluoride, manganese, molybdenum, selenium and vitamin K present in the food. Therefore, FDA has not provided in Sec. 101.9 for a provision comparable to that in Sec. 101.36(b)(3) and (b)(4) that allows for the placement of these nutrients on the nutrition label.

FDA wishes to point out that Sec. 101.36(a) only requires the label

of a dietary supplement of a vitamin or mineral to bear nutrition labeling in accordance with the provisions of Sec. 101.36 if the vitamins or minerals in the supplement have an RDI or DRV. Accordingly, dietary supplements containing only chloride, chromium, fluoride, manganese, molybdenum, selenium, or vitamin K need not adhere to Sec. 101.36 until such time as RDI's are established for them.

2. A couple of comments said that nutrients such as fat and sodium should not be required to be declared in the nutrition labeling of dietary supplements of vitamins and minerals. One of these comments said that dietary supplements are not taken because of their fat or sodium levels, and that these substances should not be declared. Other comments specifically supported the proposed rule in requiring that nutrients of this type be declared when they are present.

The agency is not persuaded that nutrients such as fat and sodium should not be declared in the nutrition labeling of dietary supplements of vitamins and minerals when present in significant amounts. The majority of the comments supported FDA's view that this information is needed to fully inform consumers of the nutrient content of these products. Although dietary supplements of vitamins and minerals are not consumed because of their fat or sodium levels, this type of information on products that contain significant levels of such nutrients will assist consumers in maintaining healthy dietary practices. Therefore, the agency is not making the requested change in the regulation.

3. A few comments stated that dietary supplements of herbs and of other nutritional substances should be labeled under Sec. 101.36. One of these comments said it would be less confusing if all supplements were labeled in the same manner. Other comments agreed that dietary supplements of herbs should be labeled in accordance with Sec. 101.9 for foods in conventional food form. However, at least one comment requested that dietary supplements of herbs be exempt from declaring the ``core'' nutrients if they have to be labeled in accordance with Sec. 101.9, and another comment said that these dietary supplements should not have to list ``Percent Daily Values.'' At least one comment stated that dietary supplements of herbs should have their own format for nutrition labeling, and a few other comments requested that dietary supplements of herbs be exempt from all nutrition labeling. One of these comments agreed that FDA did not have the authority to exempt dietary supplements of herbs from Sec. 101.9 and wanted an amendment to the 1990 amendments that would exempt these dietary supplements from nutrition labeling. This comment said that dietary supplements of herbs are not normally consumed for their nutritive value, and that nutrition labeling on these products is irrelevant and unimportant to consumers.

As explained in the nutrition labeling proposal for dietary supplements (58 FR 33715 at 33716, June 18, 1993), the difference in the labeling of dietary supplements of vitamins or minerals and of dietary supplements of herbs and of other similar nutritional substances is a result of section 403(q)(5)(F) of the act. As stated above, this section provides that if a food to which section 411 of the act applies (i.e., a dietary supplement of vitamins or minerals) contains one or more of the nutrients required to be listed in nutrition labeling, the label or labeling of such food is to comply with the requirements of section 403(q)(1) and (q)(2) of the act in a manner that FDA determines, by regulation, is appropriate for such food. Other dietary supplements are not subject to section 403(q)(5)(F) of the act and thus are subject to regulation under section 403(q) of the act in the same manner as any other food. There is nothing in the 1990 amendments, or elsewhere in the act, that would allow the agency to exempt the broad category of dietary supplements of herbs and of other similar nutritional substances from section 403(q)(1) and (q)(2) of the act. Thus, supplements that are not dietary supplements of vitamins and minerals are appropriately subject to nutrition labeling under Sec. 101.9.

Under Sec. 101.9, the nutrition label of dietary supplements of herbs and of other similar nutritional substances may be presented in either a full or simplified format as specified in Sec. 101.9(d) or (f). The simplified format in Sec. 101.9(f) may be used when a supplement of herbs or of other similar nutritional substances contains insignificant amounts of seven or more of the following nutrients: Calories, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron.

FDA is not persuaded that nutrition labels on dietary supplements of herbs using the simplified format should be exempt from the requirement to declare the ``core'' nutrients (i.e., calories, total fat, sodium, total carbohydrate, and protein). The agency has stated its belief in the mandatory nutrition labeling final rule (58 FR 2079 at 2142) that this core information is essential to aid consumers in learning about the relative nutritional qualities of all foods, and the information allows consumers to judge the consequences of the food selections they make. No new information was presented in the comments to change FDA's position on this issue.

The agency also advises that Sec. 101.9(j)(4) provides that foods subject to Sec. 101.9, including dietary supplements of herbs and of other similar nutritional substances, are exempt from nutrition labeling requirements when all of the nutrients required to be declared under Sec. 101.9(c) are absent or are present in insignificant amounts.

FDA is also not persuaded that nutrition labels on supplements of herbs should be excused from listing ``Percent Daily Values.'' As called for in section 2(b)(1)(A) of the 1990 amendments, a primary purpose of the nutrition label is to help consumers make informed food choices by enabling them to both comprehend the nutritional value of

the food and to understand its relative significance in the context of the total daily diet. The consumer research that the agency reviewed in the mandatory nutrition labeling final rule supports FDA's assertion that the listing of percent Daily Value improves consumers' abilities to make correct dietary judgments about a food in the context of a total daily diet (58 FR 2079 at 2125). In part, this improved ability to make judgments is achieved by the use of a consistent system of percentages, so that virtually all the nutrients on the label can be declared in equivalent units. Also, the percentages communicate information about the nutrient level in a food without the consumer having to be concerned about the absolute level or units of the underlying scale being used.

Therefore, for the reasons stated, the agency has not acceded to the requests that dietary supplements of herbs and of other similar nutritional substances be labeled under Sec. 101.36, have their own format for nutrition labeling, be exempt from all nutrition labeling, or be exempt from declaring the ``core'' nutrients and the ``Percent Daily Values'' in Sec. 101.9.

4. One comment requested that the language of Secs. 101.36(a) and 101.9(j)(6) be revised to refer to ``dietary supplements that are represented as a source of vitamins and minerals,'' instead of ``dietary supplements of vitamins and minerals.'' This comment was concerned that alfalfa tablets that have calcium as a binder would be required to be labeled under Sec. 101.36.

The agency would like to make clear that it does not consider a product that contains a substance that is a vitamin or a mineral, but that is used in the food solely for technological purposes, to be a dietary supplement of a vitamin or mineral because of the presence of that substance. In these circumstances, the product would not be represented as supplying a vitamin or mineral (see section 411(c) of the act). Thus, alfalfa tablets that have calcium as a binder would be required to be labeled under Sec. 101.9.

5. A few comments requested clarification of the type of nutrition labeling that would be required for ``combination'' products that contain herbs with added vitamins.

The agency advises that the type of nutrition labeling that would be required for products that contain herbs and added vitamins would depend upon the contents of the product as well as how the product is represented. If a ``combination'' product is primarily a dietary supplement of vitamins and minerals and is marketed as such, the product would have to be labeled in accordance with Sec. 101.36. If the product is not primarily a dietary supplement of vitamins or minerals and is not represented as such, it would have to be labeled in accordance with Sec. 101.9. The agency believes that the manufacturer makes the determination as to whether a product is primarily a dietary supplement of an herb, of vitamins or minerals, or of a ``similar nutritional substance'' based on how it labels and formulates the product.

The types of claims that are made on a dietary supplement will both determine, and be limited by, whether it is a dietary supplement of vitamins or minerals or of herbs or of other nutritional substances. Section 411(b)(2)(B) of the act states that the labeling and advertising for dietary supplements of vitamins and minerals may not give prominence to or emphasize ingredients that are not vitamins, minerals, or represented as a source of vitamins or minerals. Thus, if, for example, a dietary supplement of an herbal extract adds vitamins and minerals yet remains primarily a dietary supplement of the herbal extract and is advertised as such, section 411(b)(2)(B) of the act would not apply to the product. This would be the case when the label of such a product made no reference to any added vitamins or minerals other than in the ingredient list and nutrition label. Section 411(b)(2)(B) is discussed in more detail in the companion document on nutrient content claims for dietary supplements, which is published elsewhere in this issue of the Federal Register.

6. One comment requested that the language of Sec. 101.36(a) be revised to delete ``and labeling.'' The comment says that nutrition labeling is not required on labeling under Sec. 101.9.

The agency agrees with this comment and is revising the first sentence of Sec. 101.36(a) to delete the words ``and labeling,'' thereby requiring that the required nutrition information appear on the label of dietary supplements of vitamins and minerals. FDA notes that Sec. 101.9(a)(2) allows the required nutrition information to be placed on labeling of foods in conventional food form when such foods are not in packaged form. The types of labeling that are identified in Sec. 101.9(a)(2) and that allow the required information to be clearly displayed at the point of purchase are counter cards, signs, tags affixed to the product, booklets, looseleaf binders, and other appropriate devices. The only manner in which the agency envisions that dietary supplements of vitamins and minerals would not be sold in packaged form is when they would be sold directly from bulk containers. If and when dietary supplements of vitamins and minerals are sold in this manner, Sec. 101.36(g) specifically provides that they are subject to the special labeling provisions in Sec. 101.9(j)(16) for foods sold from bulk containers. Section 101.9(j)(16) allows for the required nutrition information to be displayed to consumers either on the labeling of the bulk container plainly in view or in accordance with Sec. 101.9(a)(2).

III. Nutrition Labeling of Dietary Supplements

A. Serving Size Information

7. At least one comment stated that information on serving size is not needed because it is given in the directions for use. Other comments supported the proposed rule stating that serving size information should be declared in the nutrition label.

The agency believes that information on serving size is as essential on the nutrition label of dietary supplements of vitamins and minerals as it is on that of foods in conventional food form. First, this information may not be given in the directions. For instance, the directions may state ``take 3 tablets a day'' without indicating if they are to be taken at one setting as one serving or spread out throughout the day in three separate servings. Thus, it is fair to conclude that in many instances the serving size will not be duplicative.

Additionally, this information quickly informs the consumer about the amount of the product that contains the levels of nutrients declared. It also provides a degree of consistency between the nutrition labels of dietary supplements of vitamins and minerals and those of foods in conventional food form. FDA concluded in the mandatory nutrition labeling final rule that if the nutrition label was to be readily observable and comprehensible, it must be presented in as consistent a manner as possible from label to label (58 FR 2079 at 2136 and 2139). This consistent look to the required nutrition information on packages of both dietary supplements of vitamins and minerals and foods in conventional food form will help consumers to find and recognize the information. Consistent treatment is important for the effective use of the nutrition label by consumers. As a result, the agency is not changing Sec. 101.36 to delete the requirement for serving size information.

8. One comment stated that the reference amounts for dietary supplements should be specified in absolute terms but did not provide any data. The comment argued that absolute amounts are needed so that if comparative claims are made, one product recommending consumption of, for example, one tablespoon per day is not compared to a product recommending five tablespoons per day. A few other comments supported the proposed definition for reference amounts.

The agency has defined the reference amount customarily consumed for a dietary supplement in Sec. 101.12(b) as ``the maximum amount recommended on the label for consumption per eating occasion or, in the absence of recommendations, one tablet, capsule, packet, or teaspoonful, as appropriate.'' As discussed in the nutrition labeling proposal on dietary supplements (54 FR 33715 at 33716), the agency relied upon labeling recommendations in this definition because it believed that consumption is determined in large part by the amount recommended on the label of these products, and it lacked the data to specify absolute amounts. The agency requested comments on this approach in the proposal. No comments provided data for the agency to use in determining absolute amounts that could be used as reference amounts. Therefore, the reference amount for dietary supplements will continue to be based on labeling recommendations.

The agency does not agree with the comment that absolute amounts are needed to prevent a product with a 1 tablespoon serving from being compared to a product with a 5 tablespoon serving. Lacking data to the contrary, the agency must assume that the recommended amount on the label is the amount customarily consumed. Based on that assumption, it is consistent with Sec. 101.13, General Principles for Nutrient Content Claims, which provides for comparative claims to be based on reference amounts customarily consumed. This topic as it relates to comparative claims is further discussed in the companion document on nutrient content claims for dietary supplements, published elsewhere in this issue of the Federal Register.

9. A few comments stated that the term ``Serving Size'' is confusing on dietary supplements. A few comments had questions about the determination of serving size, and one of these comments requested that the term ``Recommended Intake'' be used instead of the term ``Serving Size.'' Another comment suggested that the term ``Minimum Recommended Serving Size'' be used when the label directions specify a range of possible intakes for a product (e.g., two to three tablets per day). This comment was concerned that ``someone reading only the nutritional information portion of the label will think that the serving amount listed there is the recommended amount when it is really the maximum recommended amount.'' Other comments disagreed with this position and supported the proposed rule which stated that the serving size should refer to the maximum amount when a range is specified for a product.

One comment asked what the serving size is when the label recommends one to four tablets per day. This comment also asked about serving size when the label recommends two tablets a day. Another comment supported the statement in the proposal that if there is no amount recommended on the label, the serving size is one unit of the supplement. This comment observed that the issue arises as to how a determination can be made of ``servings per container'' if there is no recommendation as to serving size. The comment stated that this issue needs to be considered to avoid a regulatory gap.

The agency is not persuaded that a term other than ``serving size'' should be used to describe the basis for nutrient declaration for dietary supplements. It would be confusing for consumers if dietary supplements of vitamins and minerals used a term such as ``Recommended Intake'' and other foods used the term ``Serving Size.'' As discussed in the nutrition labeling proposal on dietary supplements (58 FR 33715 at 33716), the agency proposed that the nutrition labeling of vitamin or mineral supplements be presented in a manner that is as similar as possible to the nutrition labeling of other foods. The agency believes

that use of the same term on all labels will help to avoid confusion. As use of the new nutrition label becomes more widespread, and consumers become familiar with it, they will come to understand that the serving size represents the amount of product that they are likely to consume in one eating occasion. Thus, they will come to understand that for a dietary supplement, the serving size represents the amount of that product that they are likely to consume at those times that they decide to take the supplement.

As explained in the proposal of June 18, 1993 (58 FR 33715 at 33716), the agency believes that it is more useful for consumers to have the serving size be based on the maximum amount recommended, and to have the nutrition information be reported on this basis, than to have serving size be based on the minimum or the average amount. However, in some cases, the serving size is the same regardless of whether the maximum or minimum amount is used. For example, if label directions recommend a range of one to three tablets per day, the serving size is one tablet based on the fact that there are three separate eating occasions per day. If label directions recommend a range of one to four tablets per day, the serving size is also one tablet given the rounding rules (i.e., four divided by three, rounded off to one). As for the question what is the serving size if the label recommends two tablets per day, the serving size would also be one tablet because of rounding. In the absence of recommendations on the label, a serving size of one unit is appropriate for determining the ``Serving Size'' and the ``Servings Per Container.''

When the serving is one unit, the number of servings per container would duplicate the number of units declared on the principal display panel. To avoid redundancy the agency is providing in Sec. 101.36(b)(2), as proposed, that information on servings per container need not be provided when the identical information is stated in the net quantity of contents declaration. However, dietary supplements in liquid or powdered form will have to declare ``Servings Per Container'' because the net quantity of contents information will be reported in net volume or net weight measures, such as fluid ounces or grams (g), while the serving size will be expressed in common household measures, such as teaspoonfuls.

In conclusion, the agency has reexamined the proposed rule with respect to these comments on serving size and believes that no changes are needed.

B. ``Amount Per Serving''

10. A few comments stated that nutrition information should not be reported on the basis of ``per serving.'' These comments requested that the heading ``Amount Per Serving'' be replaced by the term ``Amount Per Day'' or by the terms ``Amount Per Tablet'' or ``Each Tablet Contains.''

The agency does not agree with the comment that nutrition information should be reported as ``amount per day.'' As explained in the nutrition labeling proposal for dietary supplements (58 FR 33715 at 33717), the agency proposed in the November 27, 1991, document (56 FR 60366 at 60383) that nutrition information be presented under the heading of ``Per Unit,'' but that when label directions specified that more than one unit be consumed during a day, it also be presented under the heading of ``Per Day'' (i.e., dual declaration). The agency proposed dual declaration when more than one unit was to be consumed per day to more fully inform consumers.

The agency received a number of comments opposing the dual declaration of nutrition information on supplements. Some of these comments supported declaration on the basis of ``per day'' because they believed that it is the total daily amount of nutrients that is important. Other comments favored a ``per unit'' basis because some consumers may deviate from the recommended intake, or the intake may be presented as a range. In the preamble of the mandatory nutrition labeling final rule of January 6, 1993 (58 FR 2079 at 2168), the agency stated that dual declaration may create a readability problem for consumers, and that in general a ``per unit'' approach was more useful than a ``per day'' approach.

In the nutrition labeling proposal for dietary supplements (58 FR 33715 at 33717), however, the agency took a different approach. It stated that it had tentatively concluded that declaration on the basis of ``per serving'' is preferable because reporting information solely on a ``per unit'' basis could confuse consumers when more that one unit is to be consumed at one time (e.g., two capsules with each meal). The agency expressed concern that if consumers do not notice or do not understand the heading that states ``per unit,'' they might assume that the information is for the amount specified for consumption at one time (i.e., ``per serving''), particularly because information for foods in conventional food form is expressed on a ``per serving'' basis. Furthermore, the agency tentatively concluded that consistency with the labeling of foods in conventional food form in this regard is the best approach because it will reduce consumer confusion (58 FR 33715 at 33717).

Inasmuch as most of the comments supported the proposed rule on this issue, and comments opposing did not provide any information demonstrating that there is enhanced consumer understanding or ease of use when information is expressed on a daily basis, the agency is not changing Sec. 101.36(b)(3) in response to these comments. FDA has reconsidered its position in response to comments requesting use of the terms ``Amount Per Tablet'' and ``Each Tablet Contains,'' however, in light of the comments. The agency concludes that where the serving size is one tablet, there is little, if any, chance for misunderstanding if

either of these terms is used in place of the term ``Amount Per Serving.'' Therefore, the agency is revising Sec. 101.36(b)(3) to state that when the serving size of the product is one unit, a heading consistent with the declaration of serving size, such as ``Amount per Tablet'' or ``Each Tablet Contains,'' may be used in lieu of ``Amount Per Serving.'' Other appropriate terms, such as ``capsule,'' ``packet,'' or ``teaspoonful,'' may be used in place of the term ``Serving.'' While a consistent change in Sec. 101.9(d)(4) appears reasonable, FDA believes that it is necessary to address such a change through notice-and-comment rulemaking. The agency intends to propose such a change in the near future.

C. Nutrient Information

1. Listing of Nutrient Names and Amounts

11. Several comments recommended that information on the quantitative amount by weight for the nutrients listed should be presented in a separate column, rather than immediately following nutrient names. These comments stated that some consumers buy on the basis of amounts, using them to make product comparisons, and that separate columns would help consumers to more readily locate this information. An additional comment requested that information on amounts be presented either in a separate column or after the ``Percent Daily Value'' in parenthesis. On the other hand, several comments supported the proposed rule, arguing that the format for dietary supplements of vitamins or minerals should follow the format for foods in conventional food form.

The agency disagrees with the recommendation that information on the quantitative amount by weight for the nutrients listed should be presented in a separate column. The agency observes that space on the label is conserved by not requiring a separate column. Furthermore, FDA believes that the comprehensibility of this information will be enhanced when it is presented immediately next to the name of the nutrient. As discussed in the mandatory nutrition labeling final rule (58 FR 2079 at 2117), multiple column nutrient information displays are much more difficult than single column displays for consumers to use for product comparisons. Both FDA's first experimental format study and the major industry format study found that declaring nutrient amounts per serving in adjacent columns of grams per milligram (g/mg) amounts and percent Daily Value led consumers to make more mistakes and to take longer on the product comparison type of task (Refs. 3 and 4). FDA's second experimental study, however, showed that when g/mg nutrient amount information was placed immediately next to the nutrient name in an unordered array, and percents were placed in a column array, the adverse effects on product comparison performance disappeared (Ref. 5). Thus, the agency is requiring in Sec. 101.36(b)(3) that the name of each nutrient listed shall be immediately followed by the quantitative amount by weight of the nutrient, to be consistent with Sec. 101.9(d)(7)(i).

12. A few comments requested that only the calcium portion of calcium gluconate be listed in the nutrition panel and on the principal display panel. Similarly, another comment requested that the agency clarify that vitamin B6 refers to pyridoxine, not pyridoxine hydrochloride.

The agency wishes to emphasize that the declaration of the quantitative amount by weight in the nutrition label is to indicate the weight of a particular nutrient and not the weight of the salt of that nutrient used to make the supplement. For example, only the calcium portion of calcium gluconate is to be declared in the nutrition label, although in some circumstances the weight of the whole substance may appear on the principal display panel if it clearly refers to the whole substance, such as when the statement of identity states ``calcium gluconate, 600 mg.'' Similarly, only the pyridoxine portion of pyridoxine hydrochloride is to be declared in the nutrition label. The agency believes that no changes in Sec. 101.36 are necessary based on these comments.

13. One comment recommended that biotin and folate be declared in terms of micrograms (g), not mg, and that calcium and phosphorus be declared in terms of mg, not g. The comment stated that consumers are more familiar with these nutrients being expressed in this manner.

FDA proposed on July 19, 1990 (56 FR 29476) to change to the units suggested in this comment. However, section 203 of the DS act prohibited FDA from adopting any reference values for vitamins and minerals different from the U.S. RDA's contained in Sec. 101.9(c)(7)(iv), as in effect on October 6, 1992, until after November 8, 1993. Accordingly, FDA adopted those U.S. RDA values as the RDI's, with biotin and folate expressed in terms of mg and calcium and phosphorus expressed in terms of g.

Since the prohibition in section 203 of the DS Act has now expired, the agency is proposing elsewhere in this issue of the Federal Register to amend Sec. 101.9 to change the units of declaration for biotin and folate to g and for calcium and phosphorus to mg. This proposal responds fully to the comment.

14. One comment was opposed to the agency's proposal, in Sec. 101.36(b)(3), to allow amounts of protein below 1 g to be left off the nutrition label. This comment requested that such amounts of protein be declared because individuals who are highly sensitive to monosodium glutamate (MSG) may have adverse reactions.

FDA has recognized that certain individuals are sensitive to MSG and believes that the appropriate means to convey the presence of this ingredient to consumers is by use of the ingredient statement because

MSG is a food ingredient. The agency reiterates that dietary supplements of vitamins and minerals are required to comply with Sec. 101.4 (21 CFR 101.4), which requires full ingredient labeling of food. Furthermore, in the Federal Register of January 6, 1993, the agency proposed changes in the regulations pertaining to ingredient labeling to accommodate those individuals who are sensitive to MSG. Proposed Sec. 101.22 (58 FR 2950) would require that when the amount of free glutamate in hydrolyzed protein reaches a specified level, the declaration in the ingredient statement must include the parenthetical ``(contains glutamate).''

The agency has reexamined proposed Sec. 101.36 in response to this comment and notes that there is an inconsistency in the labeling of protein, total carbohydrate, and dietary fiber between Sec. 101.9 and proposed Sec. 101.36. For example, 0.5 g to 0.99 g of these substances in a dietary supplement of a vitamin or mineral would not be declared under proposed Sec. 101.36(b)(3), yet these amounts in a food in conventional food form would be declared either as ``1 g'' or ``less than 1 g'' under Sec. 101.9(c). To correct this inconsistency, the agency is modifying Sec. 101.36(b)(3) to provide that amounts of nutrients that can be declared as zero in the nutrition label of foods in conventional food form shall not be declared in the nutrition labeling of dietary supplements of vitamins and minerals. Thus, the agency is requiring the declaration of protein, as well as total carbohydrate and dietary fiber, when they are present in amounts of 0.5 g to 1 g. Amounts under 0.5 g would continue to not be listed in the nutrition label of dietary supplements of vitamins and minerals, because these amounts would allow a declaration of zero in the nutrition labeling of foods in conventional form.

15. One comment recommended that ``active'' ingredients present at less than 2 percent of the Daily Value be allowed to be listed in the nutrition label.

The agency is not allowing vitamins and minerals (except sodium and potassium, which are not included in Sec. 101.9(c)(8)(iv)) present at less than 2 percent of the Daily Value to be listed because the declaration of such amounts would be misleading. Such values are insignificant under Sec. 101.9(f) and may be declared as 0 percent of the RDI in the nutrition labeling of foods in conventional food form. They are amounts that are dietetically trivial and physiologically inconsequential. In addition, FDA is concerned that some consumers will be misled by the mere presence of names of nutrients within the nutrition label, because they would assume that products with more nutrients listed have a greater public health significance than those with less, regardless of the amount of each nutrient present.

The agency is unaware of any reason, nor does the comment present any reason, for allowing the declaration of nutrients that are present in such small amounts. Thus, the agency is making no change in response to this comment.

16. One comment requested that FDA revise Sec. 101.36(b)(3)(i) to more clearly state the increments to be used for expressing the quantitative amounts by weight of vitamins and minerals. Another comment stated that amounts should not be rounded. This comment stated, ``We really see no reason why products should not be formulated to contain the amounts stated on the label, subject to reasonable overages based on shelf-life considerations and the like and reasonable analytical variation.''

The agency inadvertently did not address the increments to be used for expressing the quantitative amounts by weight of vitamins and minerals. Proposed Sec. 101.36(b)(3)(i) stated that amounts of vitamins and minerals are to be expressed in the increments specified in Sec. 101.9(c) using the units of measure and the level of significance given in Sec. 101.9(c)(8)(iv), except that zeros following decimal points may be dropped. While the agency is adopting this rule, FDA recognizes that, as the comment points out, Sec. 101.9(c) does not address the question of the increments in which the quantitative amounts of vitamins and minerals are to be declared because in the nutrition labeling of foods in conventional food form, vitamins, and minerals are declared only as a percentage of the Daily Value. The quantitative amounts by weight of these nutrients, except for potassium and sodium, which are considered electrolytes, are not required in the nutrition label of conventional foods.

The agency has considered this issue and notes that dietary supplements, unlike most foods in conventional food form, are fabricated to contain specific amounts of vitamins and minerals. It is for this reason that the vitamins and minerals in dietary supplements are categorized as Class I nutrients, and that under Sec. 101.9(g)(4), a food is misbranded if it contains less of an added vitamin or mineral than the amount declared on the label. In view of how dietary supplements of vitamins and minerals are made, the agency agrees that it makes no sense to permit the amounts of vitamins and minerals in such products to be rounded and declared only in specified increments. Therefore, the agency has modified Sec. 101.36(b)(3)(i) to provide that the actual amounts of vitamins and minerals in the supplement are to be declared using the units of measure specified in Sec. 101.9(c)(8)(iv), except that zeros following decimal points may be dropped.

With respect to levels of significance, that is, the number of decimal places used in declaring amounts, the agency proposed that only the levels of significance shown in Sec. 101.9(c)(8)(iv) could be presented. In some cases, however, the number of decimal places allowed is not sufficient to express actual amounts of certain vitamins and minerals because the amounts are very small. For example, a product that contains 10 percent of the Daily Value for copper would contain 0.2 mg of copper. If the amount of copper had to be expressed using the

same level of significance as that used in Sec. 101.9(c)(8)(iv) for expressing its RDI (i.e., 2 mg), the lowest amount that could be declared would be 1 mg, which would be inaccurately high.

To ensure that amounts of vitamins and minerals that have nutritional significance can be declared, the agency is modifying Sec. 101.36(b)(3)(i) to provide that amounts shall be expressed in the increments specified in Sec. 101.9(c), except that 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 copper is given in whole mg, but the quantitative amount may be declared in tenths of a mg). Additionally, the agency is modifying Sec. 101.36(b)(3)(i) to describe how amounts of the nutrients from NAS' 9th and 10th editions (Refs. 2 and 10) for which RDI's have not been established are to be declared. Amounts for chloride, fluoride, and manganese shall be expressed in mg, and amounts for chromium, molybdenum, selenium, and vitamin K shall be expressed in g. These values shall be expressed in whole numbers, except that tenths may be used for fluoride. These values reflect the amounts in which the RDI's or EASDDL's for these nutrients are given (Refs. 2 and 10).

17. One comment stated there was an apparent inconsistency between the requirement in Sec. 101.36(b)(3)(ii) that nutrients ``be listed in the order specified in Sec. 101.9(c) except that calcium and iron, when present, should be grouped with other minerals,'' and the sequence of vitamin D and vitamin E in the examples provided in Sec. 101.36(c)(8). The comment recommended that the appropriate order of nutrients be clarified in the regulations.

While FDA finds no inconsistency with the sequence of vitamin D and vitamin E in the sample labels provided in Sec. 101.36(c)(8), the agency points out that there was an error in the order of nutrients in Sec. 101.9(c)(8)(iv) in the Federal Register of January 6, 1993 (58 FR 2227). FDA published a correction in the Federal Register of April 1, 1993 (58 FR 17104), which listed the order as follows: Vitamin A, vitamin C, calcium, iron, vitamin D, vitamin E, thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, and copper. This order is the one used by FDA in the June 18, 1993, proposal on nutrition labeling of dietary supplements of vitamins and minerals, except that calcium and iron were listed with the minerals, following pantothenic acid.

The agency wishes to make these regulations as clear as possible. Therefore, in response to the comment's request for clarification of the appropriate order of nutrients, and to make clear where in the list to include the nutrients that have no RDI but that are required to be included in the nutrition label on dietary supplements of vitamins and minerals when they are present, FDA is revising Sec. 101.36(b)(3)(ii) to specify the exact order in which vitamins and minerals are to be declared (see section II. comment 1. of this document). Any nutrients not present in the supplement, or present at insignificant levels, must be omitted from the list.

18. At least one comment requested that vitamins be listed in alphabetical order. Another comment requested that calcium and magnesium be the first minerals to be listed.

The agency has not accepted these suggestions. As discussed in the nutrition labeling proposal for dietary supplements (58 FR 33719), with the exception of calcium and iron, FDA proposed in Sec. 101.36(b)(3)(ii) that nutrients declared in the nutrition labeling of vitamin or mineral supplements be listed in the order that nutrients are listed in the nutrition labeling of foods in conventional food form. The agency proposed that calcium and iron be listed after the listing of any vitamins that are present so that all of the vitamins will be grouped together. While vitamin A and vitamin C are to be listed first, consistent with Sec. 101.9(c), they are then followed by the fat-soluble vitamins, then the water-soluble vitamins and the minerals. The NAS in its RDA publications has traditionally grouped the fat-soluble vitamins ahead of the water-soluble vitamins. The agency notes that this order is followed on the labels of many vitamin supplements in the marketplace. The comment requesting alphabetical order gave no convincing justification for following a different order, and, thus, FDA is not changing the order.

Additionally, the comment requesting that calcium and magnesium be the first minerals to be listed presented no reason for the agency to make this change. Calcium and iron are required to be the first minerals listed on the labels of foods in conventional food form. In the absence of any reason for why calcium and magnesium should be the first minerals to be declared on the labels of supplements of vitamins and minerals, the agency is making no change in the order for minerals.

19. One comment requested that Sec. 101.36(b)(3)(ii) be revised to require that potassium be listed with the other minerals, preferably last on the list. This comment and others expressed confusion about whether potassium could be listed and requested clarification. One comment requested that Sec. 101.36(b)(3) be clarified to allow for the voluntary listing of potassium in dietary supplements because, according to the comment, potassium is usually present at less than 100 mg per tablet, primarily because of existing FDA restrictions on potassium salt preparations.

The agency agrees that the listing of potassium needs clarification. Potassium is not required to be listed on the nutrition label of foods in conventional food form. However, it can be listed voluntarily, and when it is, it is to be listed under sodium, as an electrolyte rather than with the minerals. In contrast, the agency proposed that potassium be required to be listed on the nutrition label of dietary supplements of vitamins and minerals when present in supplements at more than insignificant amounts (i.e., 5 mg and above),

consistent with the listing of other vitamins and minerals. The agency knows of no reason why potassium in supplements of vitamins and minerals should be treated differently from other vitamins and minerals in these products, and the comment did not provide a reason for why the listing of potassium should be voluntary rather than mandatory. Therefore, the agency is not making this change. However, the agency is modifying the language of Sec. 101.36(b)(3) to make it clear that the declaration of potassium is required when it is present at more than insignificant amounts. To this end, FDA has revised the second sentence of Sec. 101.36(b)(3) to state: ``In addition, potassium * * * shall be declared, except when present at an amount that allows a declaration of zero * * *. ''

With respect to the placement of potassium within the nutrition label, FDA agrees with the comment that the regulation should be modified. The proposal stated that nutrients that are present shall be listed in the order specified in Sec. 101.9(c), which would mean that potassium, as well as sodium, would precede the listing of any other vitamins or minerals present in a supplement. FDA has concluded that it is not appropriate and might confuse consumers to have the declaration of potassium, as well as that of sodium, precede the declaration of other vitamins and minerals on these labels because traditionally vitamins have appeared first. The agency agrees with the comment that it is appropriate for potassium to be listed at the bottom of the list because it is an electrolyte, and the electrolyte, chloride, is listed at the bottom. For the same reason, the agency concludes that sodium should be listed with the other electrolytes. Accordingly, the agency is revising Sec. 101.36(b)(3)(ii) to state that sodium and potassium should be listed, in that order, following the electrolyte chloride at the bottom of the list of minerals.

20. One comment requested clarification regarding the labeling to be used on a package that has two compartments, each containing a different supplement to be taken at the same time, three times daily with meals. The company asked if the regulations permit the information for both supplements to be reported aggregately in one nutrition label that has one column of names and amounts and one column of percent Daily Values. The firm requested that if an aggregate label is not permitted, the additional nutrition label be permitted in a package insert. The company also asked how the information should be presented if children one to four years of age are to take the same amount as adults, and how it is to be presented if such children are to take half the amount of adults.

The agency advises that if two supplements are to be taken at the same time, one unit of each three times daily, the nutrition information for both supplements must be reported aggregately. In this situation, the serving size must clearly state that a serving includes one of each supplement, with one column listing names and the total quantitative amount by weight for both supplements and another column containing the total percent Daily Values. If this product is also represented for use by children one to four years of age, the percent Daily Values for this age group would have to be presented in a third column. In the case where the serving size is different for children, a nutrition label for adults and a separate nutrition label for children must be used to avoid confusion.

21. A few comments requested that the declaration of the percent of vitamin A present as beta-carotene be mandatory. These comments argued that this information is needed to help consumers compare the amounts of beta-carotene in various products. They stated that this information would help consumers understand claims such as ``Now with beta-carotene.'' One of these comments requested the voluntary declaration of the quantitative amount of beta-carotene in addition to the percentage of vitamin A present as beta-carotene. This comment stated that calculations of vitamin A and beta-carotene values are difficult even for scientists, and that merely providing a percentage will not allow consumers to readily determine just how much beta-carotene is present in the product. The comment requested that the amount of beta-carotene be expressed in mg. Two comments requested that the percent of vitamin A present as retinol also be mandatory. One of these comments explained that most people are better off getting their vitamin A from beta-carotene rather than from retinol because beta-carotene is safer in high doses and may help reduce the risk of certain cancers, heart disease, cataracts, and other health problems.

FDA is not persuaded that the declaration of the percent of vitamin A present as beta-carotene should be mandatory because quantitative recommendations about the intake of beta-carotene have not yet been established by the scientific community. In the July 19, 1990, mandatory nutrition labeling proposal (55 FR 29476 at 29493), the agency set out the factors that it considered in deciding whether a nutrient or food component should be mandatory or voluntary in nutrition labeling:

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

nutrient or component voluntary.
(55 FR 29487 at 29493.)

The agency concludes that its decision to have the percent of vitamin A present as beta-carotene be voluntary is consistent with these guidelines because quantitative intake recommendations have not been established. On the other hand, if a claim about beta-carotene is made, information on the percent of vitamin A present as beta-carotene is needed to help consumers to understand the claim. Therefore, the agency is modifying Sec. 101.36(b)(3)(iv) to require declaration of the percent of vitamin A present as beta-carotene when a claim is made about beta-carotene. The agency tentatively concludes that a parallel change in Sec. 101.9(c)(8)(vi) for the labels of foods in conventional food form is appropriate. The agency intends to propose this change in the near future.

The agency is accepting the comment's suggestion to provide that when the percent of vitamin A present as beta-carotene is declared, the quantitative amount of beta-carotene may also be declared voluntarily. The agency is persuaded by the comment that this information on the labels of dietary supplements of vitamins and minerals would be useful to those individuals who are interested in maintaining a certain quantitative intake of beta-carotene in their diets.

The agency notes that the comment requested that the amount of beta-carotene be declared in terms of mg. However, the agency is requiring that international units (IU) be used in place of mg to be consistent with the declaration of vitamin A. FDA finds the usefulness of this added information would be reduced if the units used to quantify vitamin A and beta-carotene levels differ.

Accordingly, the agency is amending Sec. 101.36(b)(3)(iv) to provide that when the percent of vitamin A present as beta-carotene is declared, the quantitative amount in terms of IU may also be declared, e.g., ``Vitamin A 5000 IU (90 percent (4500 IU) as beta-carotene''). The agency intends to propose a parallel change in Sec. 101.9(c)(8)(vi) as soon as possible. Until the agency does so, the agency advises that it is unlikely that it will take enforcement action against foods regulated under Sec. 101.9 that declare beta-carotene in a manner consistent withSec. 101.36(b)(3)(iv) as long as they comply with Sec. 101.9 in all other respects.

Additionally, the provision on type size requirements for the added statement on beta-carotene in Sec. 101.36(c)(6) is corrected to refer to paragraph (b)(3)(iv) instead of to (b)(3)(ii). There was an inadvertent error in this reference in the proposal.

With respect to retinol, the agency concludes that, in accordance with the guidelines set out above, the declaration of retinol should be neither mandatory nor voluntary because of the absence of quantitative intake recommendations and of public health significance. Thus, the agency is not changing the proposed rule to provide for the inclusion of retinol in the nutrition label.

22. One comment requested that Sec. 101.36(b)(3)(v) be revised to ``permit common synonyms,'' instead of only the synonyms specified. This comment stated that allowing all synonyms would provide people with more information and would ensure that the contents of products were, in fact, comprehensible to more people. The comment mentioned, for example, that niacin is known by many as vitamin B3 and vitamin E by the name alpha-tocopherol. Another comment expressed support for restricting the use of synonyms to the ones allowed in the proposed rule.

The agency is not persuaded that the provision on synonyms should be revised to ``permit common synonyms,'' instead of only the synonyms specified. The terminology that the agency has recognized is that which is used in NAS' RDA table (Ref. 2). These include: Vitamin C (ascorbic acid), thiamin (vitamin B1), riboflavin (vitamin B2), folate (folacin), and calories (energy). The agency has restricted the use of synonyms to simplify nutrition labeling and to avoid potential confusion among consumers. The agency believes that allowing the unrestricted use of other synonyms will contribute to confusion about the nutrients that are present in the product. It will also make product comparisons more difficult because of the absence of consistent terminology. Therefore, FDA is not making the change requested by the comment.

23. At least one comment requested that the nutrition label of vitamins with iron, for example, be allowed to highlight the listing of iron. The comment stated that such highlighting is a useful and necessary tool to differentiate various product lines.

The agency is not persuaded that the highlighting of iron in the example described in the comment is necessary for consumers to differentiate between various product lines because the name, or statement of identity, of the product must identify the product as a multivitamin with iron. This identification is sufficient to differentiate the product from other multivitamin products. As discussed in the mandatory nutrition labeling final rule (58 FR 2079 at 2138), FDA is not permitting highlighting of this type because it can be used inconsistently in a way that would be potentially misleading to consumers. Among products with similar nutrition profiles, some would highlight certain nutrients and others would not. Consumers could not depend on the fact that all labels of similar products would look the same, and the differences in highlighting could undermine the credibility of the information on the nutrition label and lead to consumer confusion. Accordingly, the agency is not providing for the highlighting requested by the comment.

24. A number of comments suggested that the source of a vitamin or mineral be included in the nutrition label immediately following the listing of that vitamin or mineral, in a manner similar to the allowed listing of beta-carotene as a source of vitamin A. One comment stated

that this information should be listed in a separate column entitled ``Source.'' One comment requested that the source information should at least be optional. The comments stated that if this suggestion is adopted, it will be unnecessary to repeat source information in the ingredient statement, and one comment requested that the regulations on ingredient labeling be revised accordingly. The comments said that this approach would conserve space and more effectively communicate source information to consumers.

The agency notes that the parenthetical listing of the source of a vitamin or mineral in the nutrition label is a common practice by some, but not all, manufacturers in the dietary supplement industry. The agency finds, however, that the comments submitted failed to provide adequate justification and supporting information demonstrating that adoption, on an industry-wide basis, of this manner of expressing nutrition and ingredient information would result in a nutrition label that is readily observable and comprehensible, as required by the act. Comments have not demonstrated that consumers will be able to distinguish and understand the meaning of both the nutrition and ingredient information provided. FDA has no means on which to determine, for example, whether the name of the source of the nutrient is indeed that and not the chemical name of the nutrient. The comments also failed to provide data to demonstrate that this manner of presentation truly conserves label space, especially if additional columns are added to the nutrition label. Further, if as suggested by one comment, source information within the nutrition label were made optional, the consistency of presentation of information that has been a guiding principle of the agency throughout the food label reform efforts would be violated. Accordingly, the agency is not providing for the parenthetical listing of nutrient source within the nutrition label.

The agency advises, however, that it would be receptive to a adequately supported petition on this issue, and that it will act expeditiously on such petition. Given that, elsewhere in this issue of the Federal Register, the agency is establishing a date of applicability of July 1, 1995, for the regulation governing nutrition labeling of dietary supplements, if a petition is promptly submitted, that petition could be acted upon before the date of applicability.

Any petition submitted to permit source declaration within the nutrition label would have to address, in detail, at least the issues of how the source information is to be consistently and clearly expressed, and why this manner of expression is advantageous to the consumer.

Because a primary purpose of the nutrition label is to allow consumers to compare the nutrition profile of products at the point of purchase, it is imperative that there be a high degree of consistency in the presentation of nutrition information for all dietary supplements. FDA would also need information on precisely how source information should be expressed within the nutrition label. For example, how would the source information be expressed if a single ingredient (e.g., fish liver oil) is a source of a number of nutrients (e.g., vitamins A and D) within a dietary supplement? If the source is required to be listed multiple times, how does this conserve label space? Also, would multiple listing of a source mislead consumers about the amount of the ingredient in the food? Conversely, if a nutrient in a supplement is provided from several sources (e.g., iodine from kelp and potassium iodide), how would this information be clearly and consistently conveyed? Would the source listed be all sources, or only the primary source, of the nutrient? If source listing in the nutrition label were to be limited to the primary source, how would the primary source be determined? Are safeguards necessary to ensure that consumers are not misled by inappropriate emphasis on certain sources of nutrients? For example, how would consumers be fully informed and be protected from being misled if a nutrient is derived from more than one source, and only the primary source is listed, particularly if a valued ingredient provides some, but not all, of the nutrient in question?

Should source information be permitted in the nutrition label only when there is some significance to the source? For example, because there are potential safety concerns about high intakes of vitamin A from some other sources, FDA found that there is was a public health reason for permitting beta-carotene to be shown as a source of vitamin A. Should such a finding be a prerequisite for permitting source labeling? If source labeling is limited to cases in which the source is significant (e.g., particularly valued sources, concern about other potential sources), how should such significance be consistently determined?

Also, any petition on source labeling in the nutrition label should address the issue of clarity of presentation. Section 2(b)(1)(A) of the 1990 amendments states that the nutrition information should be readily observable and comprehensible. Would adding information about the source of nutrients detract from the comprehensibility of the nutrition label? Given that source information will be available in the ingredient statement, would source declarations unnecessarily burden the nutrition label and detract from its primary purpose of providing a nutrient profile of the product? Would it be more difficult for consumers to find the listing of the quantitative amounts by weight of nutrients in the nutrition label when source information is given? Petitions on this issue would be strengthened by the inclusion of consumer survey or other similar data showing that consumers readily observe and comprehend information presented in the manner suggested by the comments.

As discussed in the mandatory labeling final rule (58 FR 2079 at 2170), dietary supplements of vitamins and minerals, like other foods,

are required to bear a complete list of ingredients. Under section 403(i)(2) of the act, the statement of ingredients must list all ingredients of these foods, including , for example, lactose and other fillers, artificial colors, flavors, binders, and excipients, as well as the source of the vitamins and minerals in the dietary supplement. This section of the act provides FDA with authority to grant exemptions from the ingredient listing requirements, but such exemptions have not been sought by the dietary supplement industry. The agency advises that the fact that the name of an ingredient appears elsewhere on the label is not, in and of itself, sufficient justification to grant such exemptions. Therefore, any petition on this subject must address the issue of how this manner of presentation of the source of nutrients continues to fulfill the primary purpose of the ingredient label to adequately inform consumers about all ingredients used to make a food, including those that might be of concern because of personal health reasons (e.g., lactose).

The agency advises that its current policy, as stated in the Federal Register of August 2, 1973 (38 FR 20730) and March 16, 1979 (44 FR 16005), and in subsequent correspondence with industry (Refs. 6 and 7), is that the label for dietary supplements of vitamins and minerals must contain a list of nutrients and a separate full statement of ingredients, except those exempted by section 403(i)(2) of the act, declared by their common or usual name. This policy is consistent with the ingredient declaration requirements for other types of products.

Therefore, for all the reasons cited above, FDA has decided not to take the action requested by these comments, pending receipt and review of petitions on this issue.

2. Listing of Percent Daily Value

25. The agency received a number of comments that opposed the use of the term ``Percent Daily Value'' and that stated that they preferred to continue to use the term ``percent U.S. RDA.''

The agency disagrees with these comments. As explained in the final rule on RDI's that published in the Federal Register of January 6, 1993 (58 FR 2206 at 2207 and 2208), the agency has established two sets of label references values (i.e., RDI's, which were previously the U.S. RDA's, and DRV's). Because the agency believed the use of the two terms on food labels could be confusing to consumers, it established a single term, ``Daily Value'' to refer to both the RDI's and DRV's (58 FR 2079 at 2124). The comments did not provide any new arguments or data that were not considered in that rulemaking. Furthermore, the agency advises that it knows of no reason why dietary supplements of vitamins and minerals should not use the terminology prescribed for foods in general. Consistency in terminology will assist consumers in maintaining healthy dietary practices by facilitating their use of the nutrition label to construct a healthy diet that includes both dietary supplements and foods in conventional food form. Therefore, the agency is not making any change in the regulations in response to these comments.

26. One comment requested that the agency eliminate the use of the term ``RDI'' and use the term ``DRV'' for both macronutrients and micronutrients. The comment stated that it is confusing to have more the one term.

The comment appears to be requesting new terms not only for the nutrition label of dietary supplements of vitamins and minerals but also for the nutrition label of foods in conventional food form. The terms ``RDI'' and ``DRV'' were established in the final rule on RDI's (58 FR 2206).As discussed in the proposed rule of July 19, 1990 (55 FR 29476 at 29479), the distinction between the RDI's and DRV's is necessary for several reasons. First, the RDI's are based on the RDA's, which are considered intake levels to be achieved. However, while some DRV's are based on recommendations to increase or maintain intake of the particular food component, other DRV's reflect levels that are limitations on intake. Furthermore, many of the DRV's must be based on a specific caloric intake, and, unlike the RDI's, the DRV's are not relevant for infants and young children. Finally, the RDI's serve as criteria for use in several regulatory functions, such as the application of the agency's food fortification policy and the assessment of the nutritional equivalency of imitation foods. The DRV's do not have such uses. Therefore, FDA believes that it is appropriate to treat RDI's and DRV's as two different sets of reference values. However, the agency notes that both terms are referred to as ``Daily Values'' on the nutrition label. The agency believes that the use of a single term on the label will limit consumer confusion. Thus, the concern articulated by the comment is fully addressed by FDA's current regulatory scheme. Accordingly, the agency is not making the requested change.

27. One comment requested that products containing 5 to 17 mg of potassium should be allowed to state, ``Contains less than 1 percent of the Daily Value of this nutrient.'' The comment explained that 17 mg of potassium expressed to the nearest whole percent comes to ``0 percent Daily Value'' (3,500 mg divided by 17, which rounds to zero), yet Sec. 101.9(c)(5) only allows amounts less than 5 mg to be considered as zero. As a result, the nutrition label of such a product would state 15 mg potassium and 0 percent Daily Value. The comment expressed concern that such apparently contradictory statements would be confusing to consumers.

The comment identifies a concern applicable to dietary supplements and foods in conventional food form, namely that consumers may find it confusing when there is a quantitative amount by weight for a nutrient, and yet the percent Daily Value states 0 percent. This seeming conflict can occur with sodium, potassium, and total carbohydrate on labels of both supplements and foods in conventional food form, and with some

vitamins and minerals in dietary supplements, when both quantitative amounts by weight and percent Daily Values are given. To avoid any possible confusion that these apparently inconsistent declarations may cause, the agency is modifying Sec. 101.36(b)(4)(ii) to provide for the declaration of ``less than 1%'' in the percent of Daily Value column when the declaration of the quantitative amount by weight is greater than zero, and the calculation of percent Daily Value yields a value that is less than 1 percent. The agency believes that a parallel change in Sec. 101.9(d)(7)(ii) for foods in conventional food form is appropriate. The agency intends to propose this change in the near future.

Additionally, the agency notes that, consistent with Sec. 101.9(d)(7)(ii), as modified in the technical amendments (58 FR 44063 at 44077, August 18, 1993), it is modifying Sec. 101.36(b)(4)(i) to specify that the percent of Daily Value shall be calculated by dividing either the amount declared on the label for each nutrient or the actual amount of each nutrient (i.e., before rounding) by the RDI or DRV for the specified nutrient and multiplying by 100. The agency is making this change to provide for consistency on the food label between the percent Daily Value and the quantitative amount by weight. The agency had previously provided only that the amount declared be used in the calculation.

28. One comment requested clarification of Sec. 101.36(b)(4)(iii), which provides that when a product is represented or purports to be for use by a group other than adults and children older than 4 years of age, the percent Daily Value for each group must be presented in separate columns. The comment asked if the label of a product represented for use ``for the family'' would have to include information for all of the groups for which FDA has established RDI's.

The agency believes that it is appropriate for the label of a product represented for use ``for the family'' to include information for adults and children older than 4 years of age and for children younger than 4 years of age because families often include children in this age group. Inasmuch as there generally would be safety concerns in feeding infants supplements intended for use by adults, FDA also advises that the statement ``for the family'' should be modified to specifically exclude infants if a firm wants to include only a single list of RDI values. The agency does not believe that this comment requires any change in the language of the proposed rule. However, the agency advises that for clarity, it has changed the word ``additional'' in Sec. 101.36(b)(4)(iii) to ``separate.''

D. Format

29. One comment requested that the first sentence in Sec. 101.36(c)(1), ``The title of 'Nutrition Facts' shall be set in type size larger than all other print size in the nutrition label and, unless impractical, shall be set full width of the nutrition label,'' be revised to use the term ``nutrition panel'' instead of ``nutrition label.'' The comment stated that the ``nutrition label'' could be interpreted to mean the whole label, in which case the phrase ``Nutrition Facts'' would have to be the biggest print on the label.

The agency is not persuaded that this revision is needed. In proposed Sec. 101.36 and in Sec. 101.9, the agency has consistently used the term ``nutrition label'' to refer to the nutrition information set off in a box presented under the heading of ``Nutrition Facts.'' Extensive changes would be required in both regulations to make consistent changes wherever the term ``nutrition label'' is used. Because no other comments indicated a similar concern, the agency is not making the requested change.

30. One comment requested that Sec. 101.36 be revised to clarify that selective reverse printing may not be used as a form of highlighting, consistent with Sec. 101.9(d)(1)(iv).

The agency agrees with this comment. It unintentionally failed to address reverse printing in Sec. 101.36. In the nutrition labeling final rule, FDA decided not to permit reverse printing as a form of highlighting because it would interfere with the ``consistent'' look of the label (56 FR 2079 at 2138). For the same reason, the agency is not permitting reverse printing on the nutrition labels of dietary supplements of vitamins or minerals. Accordingly, the agency has revised the second sentence of Sec. 101.36(c)(1) to read ``The title and all headings shall be highlighted (reverse printing is not permitted as a form of highlighting) to distinguish them from other information.''

31. One comment stated that labels of multivitamin supplements and multivitamin/multimineral supplements that have a total surface area available to bear labeling of 10 or less square inches should be exempt from the requirement in Sec. 101.36(c)(4) that all information within the nutrition label shall have at least one point leading (i.e., space between two lines of text). Other comments stated that this provision of the proposed rule is appropriate.

The agency is not persuaded that the nutrition label on small labels should be exempt from the requirement of at least one point leading. This requirement is much less than that required for foods in conventional food form (e.g., four point is required between nutrients in Sec. 101.9(d)(1)(ii)(C) and does little more than insure that lines of text do not touch). As discussed in the nutrition labeling proposal for dietary supplements (58 FR 33715 at 33721), the agency proposed at least one point leading because of concerns about legibility. To maintain a consistent and distinctive format that is legible, some leading is necessary. Accordingly, FDA is providing for the minimal leading of one point in the nutrition labeling of dietary supplement of

vitamins and minerals and encourages manufacturers to use more leading whenever possible. FDA is not making a similar change for dietary supplements of herbs and of other similar nutritional substances because comments did not demonstrate space concerns with those products that would justify such a change.

Many of the changes in this document will help reduce space requirements (e.g., type size changes). If a manufacturer finds that it is still technologically infeasible or impracticable to fit the nutrition label on a particular package, it may write to the Office of Food Labeling as provided in Sec. 101.36(d)(2).

32. One comment requested that the kerning requirements be deleted, and that instead, the regulation state that ``letters should never touch,'' consistent with the technical amendments to Sec. 101.9 published on August 18, 1993 (58 FR 44063 at 44065). Another comment requested that labels that are less than 10 square inches should be exempt from the requirement in proposed Sec. 101.36(c)(5) that all information within the nutrition label shall have type that is kerned (i.e., has proximity of placement) no tighter than -4 setting. At least one comment supported this provision of the proposed rule.

The agency agrees that the kerning requirements should be made consistent with that for the nutrition labels on packages of foods in conventional food form. As pointed out in a similar comment with respect to the labeling of foods in conventional food form (58 FR 44063 at 44065), a numeric kerning value (which in effect limits the proximity of one letter to another) has meaning only for a particular type setting system. Each such system has a unique numeric scale, and, as a result, a setting of -4 is meaningless for systems other than the one that FDA used in designing its sample labels. The agency acknowledges its error in including a single kerning limit that would be required for all type setting systems. Accordingly, FDA is revising Sec. 101.36(c)(5), consistent with Sec. 101.9(d)(1)(ii)(D), to delete the requirement for a -4 setting and to state that letters should never touch.

33. A couple of comments supported the provision in proposed Sec. 101.36(c)(6) regarding type size, but more than ten comments strongly opposed the provision. The agency proposed to require type size no smaller than 8 point for nutrient information within the nutrition label and to allow no smaller than 6 point type for column headings and footnotes. In addition, the agency proposed to allow no smaller than 6 point type for all of the information within the nutrition label of packages having a total surface area available to bear labeling of 40 or less square inches. The comments said that the total surface area available for labeling for most dietary supplements is well under 40 square inches. They stated that the proposed 6 point minimum type size is far too large for many labels to include all of the required nutrition information and to still allow space for the ingredient statement, necessary product codes, lot number, expiration dates, Universal Product Code (UPC) symbols, front panel copy, and other information commonly provided on dietary supplement labels. To alleviate this space problem, a number of comments requested that FDA allow smaller type size. One comment requested a minimum type size of 3.0 point and another 4.0 point. However, most of the comments suggested a minimum type size of 4.5 point, which they said is consistent with the Nonprescription Drug Manufacturers Association (NDMA) Label Readability Guidelines used for over-the-counter (OTC) drugs.

The comments were divided about when FDA should allow smaller print size. A few comments believed that smaller type is needed on labels having up to 40 square inches of total surface area. Other comments suggested that such type is necessary on various-sized labels, such as those with surface areas of less than 25, 15, 12, and 10 square inches. Finally, a few comments suggested that the regulation should state that type size should be ``as large as possible,'' or that it should permit manufacturers to decide for themselves.

After reviewing many dietary supplement labels, the agency is persuaded that the 6 point minimum type size proposed for nutrition labeling information is too large for many multivitamin and multimineral supplement labels. The agency acknowledges that these products often have many nutrients to declare in the nutrition label, are often sold in relatively small packages/jars, and include on the label other information not required for foods in conventional food form. Therefore, FDA is accepting the recommendation, supported by the NDMA Label Readability Guidelines, that 4.5 point minimum type size be allowed on smaller labels. Throughout rulemaking to implement the 1990 amendments, FDA has responded to consumer concerns that the required nutrition information be presented in a manner that will improve legibility, particularly to help older and vision-impaired consumers who otherwise would be effectively denied access to the nutrition information. Because type size is a major determinant of legibility, FDA does not believe type sizes less than 4.5 points should be allowed on package labels and encourages manufacturers to use larger type size when label space allows.

The agency finds that this minimum type size of 4.5 points is appropriate on packages having less than 12 square inches of surface area available to bear labeling. The agency selected less than of 12 square inches of area available to bear labeling as a result of its review of the comments and because it promotes consistency within food labeling regulations inasmuch as Sec. 101.2(c)(3)(i) uses this package size as the standard for exempting small packages of foods from type size requirements, and Sec. 101.9(j)(13)(i) uses it to differentiate which food packages may use a telephone number or address for consumers to use in obtaining nutrition information as the functional equivalent

of a nutrition label if no nutrient content or health claims are made on the label. The agency also finds that this decision is reasonable considering the practical need for smaller packages containing supplements composed of many vitamins and minerals to have smaller print, and the need for all labels to be as legible as possible. Therefore, the agency is modifying Sec. 101.36(c)(6) to allow for packages that have a total surface area available to bear labeling of less than 12 square inches to use 4.5 point type size. FDA is not making a similar change for dietary supplements of herbs and of other similar nutritional substances because comments did not demonstrate the same space concerns for those products. Additionally, the agency is correcting Sec. 101.36(c)(6) to refer to paragraph (b)(3) instead of to (b)(4) and to refer to paragraph (b)(4) instead of to (b)(4)(ii). There were inadvertent errors in these references in the proposal.

FDA advises that under Sec. 101.36(g), dietary supplements of vitamins and minerals may also use all provisions allowed in Sec. 101.9(j)(13) to help accommodate the nutrition label on small and intermediate-sized packages.

If, despite these provisions, there are still packages for which there is insufficient area available to print all required information, the agency advises manufacturers to write to the Office of Food Labeling, FDA (HFS-150), on a case-by-case basis requesting alternative means of compliance (e.g., reduced type size or leading) in accordance with Sec. 101.36(d)(2).

34. One comment requested that all upper case lettering be allowed for multivitamin and multimineral labels that are less than 25 square inches in total available surface area to facilitate readability. Other comments agreed with proposed Sec. 101.36(c)(3), which requires that all information within the nutrition label utilize upper and lower case letters.

In the technical amendments published in the Federal Register of August 18, 1993, the agency modified Sec. 101.9(j)(13)(i)(B) to allow all upper case lettering to be used on packages of food in conventional food form that have less than 12 square inches of surface area available to bear labeling (58 FR 44063 at 44072). To be consistent, the agency has modified Sec. 101.36(c)(3) to allow packages of dietary supplements of vitamins and minerals that have less than 12 square inches of surface area available to bear labeling to use all upper case lettering. To maximize legibility and to preserve the readily identifiable image of the nutrition label, FDA is limiting this special provision to small packages (i.e., those with less than 12 square inches of surface area) rather than the 25 square inches requested in the comment.

35. A few comments suggested ways to alleviate space problems other than by using a smaller type size. One comment wanted to be able to present the nutrition label on any package panel, to use the tabular or linear method of listing nutrients, and to use the abbreviations specified in Sec. 101.9(j)(13)(ii). Another comment requested that the entire labeling, not just the label on the primary container, be allowed to be used to relate nutrition information. One comment requested that all supplements with less than 40 square inches of label space be exempt from having a large heading entitled ``Nutrition Facts,'' a box that surrounds the nutrition panel, and the lines that separate each individual nutrient and the headings. Other comments requested that the nonfunctional slack-fill regulations be revised to allow containers to be bigger.

The agency notes that Sec. 101.36(g) provides, in part, that dietary supplements of vitamins and minerals are subject to, among other provisions, the special labeling conditions set out in Sec. 101.9(j)(13) for foods in small and intermediate-sized packages. Section 101.9(j)(13)(i) defines a small package as one that has a total surface area available to bear labeling of less than 12 square inches and allows for the use of an address or telephone number that a consumer can use to obtain the required information (e.g., ``For nutrition information, call 1-800-123-4567'') as the functional equivalent of a nutrition label if no nutrient content or health claims are made on the label. When foods in small packages either voluntarily or because of nutrition claims bear nutrition labeling, Sec. 101.9(j)(13)(i)(B) also allows the use of smaller type size than that required on larger packages.

Section 101.9(j)(13)(ii) defines an intermediate-sized package as one that has a total surface area available to bear labeling of 40 or less square inches. This section of the regulations provides several additional special labeling provisions to assist manufacturers in fitting the required information on both small and intermediate-sized packages. These provisions, which can apply to dietary supplements of vitamins and minerals in small or intermediate-sized packages, include using specified abbreviations and presenting the required nutrition information on any label panel. Additionally, this section provides for presenting the required information in a tabular (i.e., horizontal) display or linear (i.e., string) fashion: (1) If the product has a total surface available to bear labeling of less than 12 square inches, or (2) if the product has a total surface area available to bear labeling of 40 or less square inches, and the package shape or size cannot accommodate a column display on any panel. Nutrition information may be given in a linear fashion only if the label will not accommodate a vertical or tabular display.

In response to the comment requesting use of labeling, not just the label on the primary container, to convey nutrition information, the agency advises that it has traditionally required that all required information (e.g., the statement of identity, net weight statement, ingredient list, name and place of manufacture, and nutrition

information) appear on the label of packaged foods. Labeling, which includes materials not affixed to the package (such as posters, notebooks, leaflets, and brochures available at the point of purchase), may become separated from the packaged food and are inappropriate for the delivery of required information. Therefore, FDA concludes that it would not be appropriate to grant the request in this comment.

However, FDA considers outer packaging that securely encloses a primary container and that is not intended to be separated from the primary container under conditions of retail sale to be the equivalent of the product label. Therefore, when a bottle containing a dietary supplement in tablet, granular, or liquid form is placed within a sealed box, the required information must be present on the outer container where it is available to the consumer at the point of purchase. While FDA regulations do not require that the information be repeated on the primary container inside the box, the agency encourages manufacturers to do so, so that consumers will have easy access to the information once the container is removed from the outer box. Likewise, if supplements are sold in sealed packaging that provides a cardboard display around the primary container, the full display seen by the consumer becomes the product label. In these situations, the required information shall be placed on appropriate panels as directed in Secs. 101.1 and 101.2, pertaining to the principal display panel and the information panel, respectively.

It would not be consistent with section 2(b)(1)(A) of the 1990 amendments to allow packaging with less than 40 square inches of label space to be exempt from graphic requirements such as having the title ``Nutrition Facts'' in the largest print within the nutrition label, having the required information enclosed within a box, and using hairlines to separate nutrients and headings. As stated above, the agency concluded in the mandatory nutrition labeling final rule (58 FR 2079 at 2136) that if the nutrition label was to be readily observable and comprehensible, it must be presented in as consistent a manner as possible from label to label. Thus, in establishing the requirements for the nutrition label, the agency went to great lengths to give the format a distinctive look (e.g., through the use of a prominent heading, highlighting of key nutrient information, and enclosure of the information in a box) to facilitate consumer recognition of the label and to encourage use of the information. Consistency of appearance begins to be lost if these graphic elements are omitted on certain packages. Such action would make it likely that some consumers would fail to recognize the nutrition information and to understand the significance of the information that it presented. For this reason, FDA is not providing the flexibility requested.

However, the agency has reviewed the format requirements in response to these comments concerned about space problems. To help alleviate space problems, the agency has concluded that it can provide for flexibility in the placement of the heading,``% Daily Value.'' When a dietary supplement contains less than 5 calories per serving, ``Calories'' need not be declared. In this situation, shown in the sample labels in Sec. 101.36(c)(8) of the proposal (58 FR 33715 at 33728 through 33730), the heading ``% Daily Value'' is placed to the right and under the bar beneath the heading ``Amount Per Serving.'' Because there is sufficient space on one line for both headings, the agency is modifying Sec. 101.36(b)(4) to provide that the heading ``% Daily Value'' may be placed on the same line as the heading ``Amount Per Serving,'' when calorie information is not required to be declared.

Also, consistent with provisions in Sec. 101.9(d)(11)(i) and (ii) that allow lower portions of the vertical format to be split and moved to the contiguous right, FDA is providing in Sec. 101.36(c)(10) that, if space is not adequate to list the required information in one vertical list (as shown in the sample labels in Sec. 101.36(c)(9)), the list may be split and the lower information moved to the right as long as the headings are repeated. The list to the right should be set off by a line that distinguishes it and sets it apart from the nutrients and the percent Daily Value information given to the left. A sample of this split format is included in Sec. 101.36(c)(10).

The agency is not convinced by the comment that the nonfunctional slack-fill regulations should be revised to allow containers of dietary supplements to be larger than otherwise necessary to accommodate the labeling requirements. As discussed in the final rule on nonfunctional slack-fill (58 FR 64123 at 64134, December 6, 1993), the agency knows of no reason for treating dietary supplements differently from foods in conventional food form. In response to this and the other comments suggesting ways to alleviate space constraints, the agency advises that many of the changes that FDA has made from the proposal will help to reduce space requirements (e.g., reduced type size requirements on packages of dietary supplements of vitamins and minerals). If manufacturers find that it is still technologically infeasible or impracticable to fit the nutrition label on a particular package, they may write to the Office of Food Labeling as directed in Secs. 101.9(g)(9) and 101.36(d)(2). The agency points out that any information, other than the net quantity of contents and statement of identity, may be printed parallel to the base of a package. Thus, the nutrition label may be printed parallel to the base of a package, which may provide more space for this information. However, FDA urges manufacturers to strive for consistency of presentation of nutrition information in the market.

36. One comment requested that hairlines be required to separate lines of nutrient declarations, and that these hairlines be centered between the lines of text. This comment also requested clarification that Appendix B to part 101, which is referenced in Sec. 101.36(c)(8), contains several nonrequired elements, such as Helvetica typeface, at

least 13 point type for ``Nutrition Facts,'' and a specific thickness for the separating bars on the nutrition label.

As discussed in the nutrition labeling proposal for dietary supplements (58 FR 33715 at 33716), the agency intends that the nutrition labeling on vitamin or mineral supplements be presented in a manner that is as similar as possible to the nutrition labeling of foods in conventional food form. Hairlines are required in the nutrition labeling of foods in conventional food form as specified in Sec. 101.9(d)(1)(v). The agency intended that Sec. 101.36 contain a similar provision. However, it inadvertently failed to specifically provide for hairlines in the proposed rule, although it included hairlines in the samples labels presented in proposed Sec. 101.36(c)(9) and urged that the graphic specifications set forth in Appendix B to part 101 be followed. These graphic specifications describe the use of hairlines under C-2. Accordingly, the agency concludes that it is appropriate to modify Sec. 101.36(c) to require hairlines in Sec. 101.36(c)(7) and to redesignate paragraphs (c)(7) and (c)(8) as paragraphs (c)(8) and (c)(9), respectively, to reflect this modification. New Sec. 101.36(c)(7) states: ``A hairline rule that is centered between the lines of text shall separate each nutrient and its corresponding percent Daily Value required in paragraph (b)(4) of this section from the nutrient and percent Daily Value above and below it, as shown in paragraph (c)(9) of this section, and shall separate 'Amount Per Serving' from the calorie statement, when the listing of calories is required.''

With respect to Appendix B, the comment is correct in stating that Appendix B contains several nonrequired elements, such as Helvetica typeface, a specified type size for the title ``Nutrition Facts,'' and a specific thickness for the separating bars on the nutrition label. The required graphic elements are specified in Sec. 101.36(b) and (c).

37. A couple of comments objected to the bar at the bottom of the nutrition label and requested that this requirement be deleted. They stated that it is unnecessary and may interfere with the scanning of the UPC symbol. Another comment requested that Sec. 101.36(c) be revised to require a bar following the final vitamin or mineral listed. Other comments supported the proposal.

In Sec. 101.36(b)(3)(ii), FDA proposed to require a bar at the bottom of the nutrition label of dietary supplements of vitamins and minerals to help ensure that the nutrition label on these types of foods has the same readily identifiable image, or ``look,'' as the nutrition label on foods in conventional food form (58 FR 33715 at 33719). Comments to the agency's proposed rule on the format for nutrition labeling (57 FR 32058, July 20, 1992) had argued that a consistent look to the required nutrition information on food packages will help consumers find the information on the package and to recognize it for what it is--a profile of the nutrient content of the food. These comments convinced FDA that the specific format elements mandated provide a visually integrated image that will give the nutrition label a uniform appearance across the various types of packages in the market and will enhance consumer use of the information. Nothing in the comments on proposed Sec. 101.36 provide the basis for a different conclusion. FDA finds that contrary to the comments' assertion, this bar contributes directly to the consistent look of the nutrition label. To avoid any possible interference of the bar at the bottom of the nutrition label with the scanning of the UPC symbol, manufacturers may design the package layout so that the UPC symbol is not adjacent to the nutrition label. Accordingly, the agency is not modifying Sec. 101.36(b)(3)(ii) in response to these comments.

38. One comment requested that bars be required after ``Serving Size'' and ``Amount Per Serving.''

The agency points out that Sec. 101.36(b)(3) requires that the heading ``Amount Per Serving'' be separated from other information on the label by a bar above and beneath it. Thus, the upper bar will be beneath the declaration of ``Servings Per Container'' or, when ``Servings Per Container'' is not required, of ``Serving Size.'' The lower bar would separate the declaration ``Amount Per Serving'' from the heading ``Percent Daily Value.'' The agency notes that this bar should follow information on calories, when that information is declared (i.e., when the dietary supplement of vitamins and minerals contains 5 or more calories), to be consistent with the labeling of foods in conventional food form (Sec. 101.9(d)(6)). However, the agency inadvertently failed to specify in the proposed rule where this bar should be placed. As discussed in the nutrition labeling proposal for dietary supplements (58 FR 33715 at 33716), the agency intended that the nutrition labeling on vitamin and mineral supplements be presented in a manner as similar as possible to the nutrition labeling of foods in conventional food form. Therefore, FDA finds that it is the logical outgrowth of the proposal to specify in this final rule where the bar following ``Amount Per Serving'' should be placed when information on calories is declared in a nutrition label for a dietary supplement of vitamins or minerals. Accordingly, the agency is modifying Sec. 101.36(b)(3) to state: ``The heading 'Amount Per Serving' shall be separated from other information on the label by a bar above and beneath it, except when calories are listed, the bar shall be placed beneath the calorie declaration.''

E. Compliance and Exemption Issues

39. At least three comments requested that dietary supplements be able to indicate compliance with United States Pharmacopeia (USP) requirements. One of these comments requested that a new paragraph, Sec. 101.36(d)(3), be added that would provide that the label could

bear a box entitled ``Nutrition Facts'' that would contain nutrition information for USP recognized substances that are the source of vitamins and minerals. Immediately below that box, the label would bear another section entitled, ``Other Ingredients'' that would list all additional ingredients present in more than insignificant amounts, followed by a listing of all other added substances incorporated in the product as excipients. The comment stated that by listing all other ingredients present, consistency with section 411(b)(2)(A)(i) of the act would be achieved. Alternatively, this comment requested that the following sentence be added after the first sentence of Sec. 101.36(d)(2): ``Such allowances will also be considered where a firm produces an article that purports to comply with the requirements of the official USP and seeks to label it in accordance with the requirements of the Pharmacopeia.'' The comment stated that this new sentence would allow firms to comply with USP labeling requirements with FDA's permission. Additionally, this comment requested that the name of products that meet USP quality standards be followed by the letters ``USP.''

Both of the comment's suggested changes in Sec. 101.36(d) would allow for two very different forms of nutrition labeling on dietary supplements of vitamins and minerals, depending upon whether a manufacturer chose to follow FDA's requirements, which are generally consistent with Sec. 101.9, or USP's, which would list only USP recognized nutrients in the top box. A manufacturer's decision to follow the USP approach would result in a nutrition label that was inconsistent with labels of other dietary supplements of vitamins and minerals, with dietary supplements of herbs and other similar nutritional substances, and with foods in conventional food form. The comment also appears to request that the determination of whether or not a nutrient should be listed in the nutrition label should be based upon its USP status.

FDA finds that it would not be consistent with section 2(b)(1)(A) of the 1990 amendments to provide the flexibility sought by these comments. As discussed in response to earlier comments, the agency decided in the mandatory nutrition labeling final rule that if the nutrition label was to be readily observable and comprehensible, it must be presented in as consistent a manner as possible from label to label. Thus, it was the agency's determination that, whenever possible, nutrition labeling requirements should ensure a distinctive look and order of nutrients to facilitate consumer recognition and understanding of the label and to encourage use of the information. Allowing two different nutrition labeling schemes would make it likely that some consumers would fail to recognize the nutrition information or would be too confused to be able to use it fully. FDA has made the same decision with respect to dietary supplements and thus is not providing the flexibility requested.

However, in regard to the request that the name of ingredients of USP quality be allowed to indicate USP status, the agency advises that although statements appearing outside of the nutrition label are beyond the scope of this final rule, it would not object to the use of truthful and nonmisleading statements regarding USP status elsewhere on product labels. Further, FDA would not object to the use of the USP symbol in the ingredient list to identify those ingredients that are USP grade. The agency advises that it will not consider the USP symbol, when used in this way, to constitute intervening material in the ingredient list.

40. One comment requested that FDA recognize USP methodology. This comment stated that Sec. 101.36(d)(1) requires that dietary supplements comply with Sec. 101.9(g)(2), which specifies Association of Official Analytical Chemists (AOAC) test methodology for nutrient analysis.

The agency wishes to clarify that Sec. 101.9(g)(2) states that when FDA determines compliance, it will analyze composite samples by appropriate methods as given in the ``Official Methods of Analysis of the AOAC International,'' 15th edition, or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures. Manufacturers, however, are free to use whatever methodology they believe will give results consistent with methods used by FDA. Therefore, the requested change is unnecessary.

41. One comment requested that the compliance criteria be revised to allow the actual content of any vitamin or mineral in a dietary supplement to be 90 percent, instead of at least 100 percent, of the declared value. This comment stated that the proposed rule (i.e., Sec. 101.36(d)(1), which refers to Sec. 101.9(g)(1) through (g)(2)) requires that products that contain added vitamins and minerals provide at least the amount declared for each nutrient. The comment stated that consideration should be given to the fact that many dietary supplements, while formulated to contain at least 100 percent of the declared amount, are designed to retain only at least 90 percent of their declared amount over the shelf life declared on these products. The comment attributed this practice to the fact that USP monographs for several nutritional products require a minimum nutrient content of 90 percent of the label declaration.

The agency is not persuaded by this comment. As previously discussed in response to a similar comment in the mandatory nutrition labeling final rule (58 FR 2079 at 2171), dietary supplements of vitamins and minerals are fabricated products. The comments provided no convincing reason for why they should not be held to the same standards as foods in conventional food form that are fortified or enriched. The agency has informed USP that anything less than 100 percent of the value declared on the label for vitamin and mineral products is not acceptable to FDA, and that the only permissible deviation from this requirement would be a deviation that is attributable to the

variability of the analytical method (Ref. 8).

The agency notes that, contrary to the statement in the comments, the General Notices of the USP state that a dosage should be formulated to provide 100 percent of the labeled amount (Ref. 9). The limits in the USP monographs allow for overages of ingredients known to decrease with time, for analytical error, for manufacturing and compounding variations, and for deterioration to an extent considered insignificant under practical conditions (Ref. 9).

42. One comment pertained to small businesses. The comment stated that ``burdening the manufacturer with the cost of the nutrition labeling requirements (listing that a vitamin supplement contains no fat, no protein, no carbohydrate, etc.) would be a useless exercise, especially in the case of the marketing of a single ingredient substance.'' The comment requested that Sec. 101.36(f)(1) of the proposed rule be revised to either delete the nutrition labeling requirement for small businesses or to allow the nutrition label to declare only those nutrients actually present in the supplement.

The agency believes that this comment misunderstood the proposed rule. As the comment requested, the agency requires nutrition labeling ``only with respect to those substances actually contained in the supplement.'' Manufacturers are not burdened with the cost of declaring that a vitamin supplement contains no fat, no protein, or no carbohydrate if they do not. Only nutrients present in significant amounts are required to be declared under Sec. 101.36(b)(3). Therefore, the agency is not changing the regulation in response to this comment.

FDA notes that Congress recently passed, and the President signed on August 13, 1993, the Nutrition Labeling and Education Act Amendments of 1993 (Pub. L. 103-80) that modified the treatment of small businesses. As a result of this change, the exemption from nutrition labeling requirements for small businesses that are food manufacturers will be based on the number of employees in a firm and the number of units of each product sold. FDA expects to publish a proposal to amend Secs. 101.9 and 101.36 to reflect the new law.

F. Misbranding

43. One comment stated that Sec. 101.9(k)(1) through (k)(6) should not apply to dietary supplements. The comment stated that Sec. 101.9(k)(1) is overbroad such that it suppresses truthful, nonmisleading speech about the beneficial properties of a nutrient supplement product that may, by virtue of the supplement's inherent properties, not only be a food but also aid in the prevention, cure, mitigation, or treatment of any disease. This comment did not focus on why Sec. 101.9(k)(2) through (k)(6) should not apply to dietary supplements. Other comments specifically mentioned that the first sentence of Sec. 101.9(k)(5) is vague, confusing, and contradictory. This sentence provides that a food shall be deemed to be misbranded if its label or labeling represents, suggests, or implies that the food has dietary properties when such properties are of no significant value or need in human nutrition. These comments suggested that this sentence be revised to read: ``A food shall be deemed to be misbranded if its label claims or represents that the food has a significant value or need in human nutrition when the scientific evidence for the claim does not exist.'' These comments argued that this change is necessary because ``significant value or need in human nutrition'' is a matter of consumer perception. They said that to a small child, the need for eating spinach is very low, but to the mother the need for spinach is very high. Other comments specifically agreed that Sec. 101.9(k) should apply to dietary supplements of vitamins and minerals.

The agency does not agree with the comment that Sec. 101.9(k)(1) through (k)(6) should not apply to dietary supplements, or that Sec. 101.9(k)(1) suppresses truthful, nonmisleading speech. The comment did not provide any basis for the agency to conclude that this provision is not applicable to dietary supplements, or that it suppresses truthful, nonmisleading speech.

In the final rule on nutrition labeling of January 6, 1993 (58 FR 2079 at 2167), the agency pointed out that the provisions of Sec. 101.9(i) (redesignated as (k)) had long been in effect at the time Congress drafted the 1990 amendments. While Congress did enact provisions under the 1990 amendments that allow for health claims on foods, nothing in the act or in the legislative history of the act suggest that Congress intended that Sec. 101.9(i) should be changed.

Nor did the comments present any persuasive arguments that Sec. 101.9(k)(5) of the proposed rule should be amended. The agency does not agree that whether or not a significant value or need in human nutrition has been established is a matter of consumer perception. The agency notes that the phrase ``significant value or need in human nutrition'' was promulgated and published in the Federal Register of January 19, 1973 (38 FR 2125). In that final rule (38 FR 2125 at 2128), the agency explained that over the years there have been a number of ingredients of products marketed as nutrients and nutritional supplements that have not been shown to be essential in human nutrition, such as rutin, other bioflavonoids, para-aminobenzoic acid, and inositol. The agency stated that calling attention to these ingredients in a manner that implies some nutritional benefit is misleading. The agency concludes that the language of Sec. 101.9(k)(5) remains clear and does not need clarification.

Therefore, the agency is making no change in Sec. 101.9(b) in response to these comments.

IV. Other Provisions

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. Economic Impact

In its dietary supplement labeling proposals of June 18, 1993, FDA stated that the proposed rules on the labeling of dietary supplements, taken as a whole, would have associated costs of approximately $20 million. Thus, the agency concluded that the proposed rules do not constitute a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act (Pub. L. 96-354), FDA explored whether the proposed rules may have a significant impact on small businesses and tentatively concluded that they do not.

FDA has evaluated the many comments that it received in response to its economic impact analysis. Because the issues raised in the comments relate to all three proposals, FDA has combined its discussion of these comments and presented them in the final rule regarding a delay in the date of application, which is published elsewhere in this issue of the Federal Register.

FDA has examined the economic implications of the final rules amending 21 CFR as required by Executive Order 12866 and the Regulatory Flexibility Act. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The Regulatory Flexibility Act requires that the agency analyze options for regulatory relief for small businesses. FDA has concluded, based on its review of the available data and comments, that these final rules are not significant as defined by Executive Order 12866. Further, in accordance with the Regulatory Flexibility Act, the agency certifies that these final rules will not have a significant impact on a substantial number of small businesses.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. References

The following references have been placed on file 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. Food and Nutrition Board, Division of Biology and Agriculture, National Research Council, ``Recommended Dietary Allowances, 7th ed., 1968,'' publication 1694, Printing and Publishing Office, NAS, Washington, DC, 1968.

2. Subcommittee on the 10th edition of the Recommended Dietary Allowances, Food and Nutrition Board, Commission on Life Sciences, National Research Council, ``Recommended Dietary Allowances, 10th edition,'' NAS, Washington, DC, National Academy Press, 1989.

3. Levy, A., S. B. Fein, and R. E. Schucker, ``More Effective Nutrition Label Formats Are Not Necessarily More Preferred,'' Journal of the American Dietetic Association, 92:1230-1234, 1992.

4. Gardner, T. S., and E. T. Guarino, Grocery Manufacturers of America, Inc., Letters to Dockets Management Branch, June 3, 1992.

5. Levy, A. S., S. B. Fein, and R. E. Schucker, ``Evaluation of Nutrition Label Formats: FDA Study 2,'' Center for Food Safety and Applied Nutrition, FDA, Washington, DC, March, 1992.

6. FDA opinion letter, Taylor M. Quinn, Office of Compliance, Bureau of Foods, to Stanley Skelskie, March 30, 1979.

7. FDA opinion letter, Taylor M. Quinn, Office of Compliance, Bureau of Foods, to Stanley Skelskie, January 25, 1980.

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

9. U.S. Pharmacopeial Convention, Inc., ``USP XXII, NF XVII, The United States Pharmacopeia,'' The National Formulary, General Notices and Requirements Applying to Standards, Tests, Assays, and Other Specifications of the United States Pharmacopeia, pp. 1-3, January 1, 1990.

10. Committee on Dietary Allowances, Food and Nutrition Board, Assembly of Life Sciences, National Research Council, ``Recommended Dietary Allowances, 9th revised ed., 1980,'' Washington, DC, National Academy Press, 1980.

List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements,

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 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 101.9, effective May 8, 1994, is amended by revising paragraphs (d)(3)(ii), (h)(2), and (j)(6) to read as follows:

Sec. 101.9 Nutrition labeling of food.

* * * * *

(d) * * *

(3) * * *

(ii) ``Servings Per Container'': The number of servings per container, except that this statement is not required on single serving containers as defined in paragraph (b)(6) of this section or on other food containers when this information is stated in the net quantity of contents declaration.

* * * * *

(h) * * *

(2) If a product consists of two or more separately packaged foods that are intended to be eaten individually and that are enclosed in an outer container (e.g., variety packs of cereals or snack foods), the nutrition information shall:

(i) Be specified per serving for each food in a location that is clearly visible to the consumer at the point of purchase; and

(ii) Be presented in separate nutrition labels or in one aggregate nutrition label with separate columns for the quantitative amount by weight and the percent Daily Value for each food.

* * * * *

(j) * * *

(6) Dietary supplements of vitamins or minerals that have an RDI as established in paragraph (c)(8)(iv) of this section or a DRV as established in paragraph (c)(9) of this section shall be labeled in compliance with Sec. 101.36, except that dietary supplements of vitamins or minerals in food in conventional form (e.g., breakfast cereals), of herbs, and of other similar nutritional substances shall conform to the labeling of this section.

* * * * *

3. Section 101.12, effective May 8, 1994, is amended in paragraph (b), Table 2, by alphabetically adding a new entry under the subheading ``Miscellaneous category'' to read as follows:

Sec. 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 not in conventional food form.....	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, teaspoonful, 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 1977-1978 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; dry, 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 Sec. 101.9(b) using the reference amount determined according to Sec. 101.12(c).

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

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

(a) The label of a dietary supplement of a vitamin or mineral that has a Reference Daily Intake (RDI) as established in Sec. 101.9(c)(8)(iv) or a Daily Reference Value (DRV) as established in Sec. 101.9(c)(9), shall bear nutrition labeling in accordance with this regulation, as illustrated in paragraph (c)(9) of this section, unless an exemption is provided for the product in paragraph (f) of this section. Dietary supplements of herbs or other similar nutritional substances shall bear nutrition labeling in accordance with Sec. 101.9.

(b) The declaration of nutrition information on the label and in labeling shall contain the following information, using the headings and format specified, under the heading of ``Nutrition Facts''. The nutrition information shall be enclosed in a box by use of lines, shall be all black or one color type, and shall be printed on a white or other neutral contrasting background whenever practical.

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

(2) 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.

(3) A listing of all nutrients required in Sec. 101.9(c) that are present in the dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in Sec. 101.9(c). Those nutrients that are not present, or that are present in amounts that would be declared as zero, shall not be declared. In addition, potassium, vitamin K, chloride, chromium, fluoride, manganese, molybdenum, and selenium shall be declared, except when present in quantitative amounts by weight that allow a declaration of zero. The name of each nutrient listed shall be immediately followed by the quantitative amount by weight of the nutrient. Nutrient names and quantitative amounts shall be presented in a column under the heading of ``Amount Per Serving'' and aligned on the left side of the nutrition label. The heading ``Amount Per Serving'' shall be separated from other information on the label by a bar above and beneath it, except that when calories are listed, the bar shall be placed beneath the calorie declaration. When the serving size of the product is one unit (e.g., one tablet), 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.'' Other appropriate terms, such as capsule, packet, or teaspoonful, may be used in place of the term ``Serving.''

(i) These amounts shall be expressed in the increments specified in Sec. 101.9(c), except that the amounts of vitamins and minerals, excluding sodium and potassium, declared on the nutrition label shall be the actual amount of the vitamin or mineral included in the dietary supplement, using the units of measure and the levels of significance given in Sec. 101.9(c). In declaring the amounts of vitamins and minerals, 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 copper is given in whole milligrams (mg), but the quantitative amount may be declared in tenths of a mg). Amounts for chloride, fluoride, and manganese shall be expressed in mg, and, amounts for chromium, molybdenum, selenium, and vitamin K shall be expressed in micrograms. These values shall be expressed in whole numbers, except that tenths may be used for fluoride.

(ii) Nutrients that are present shall be listed in the order specified in Sec. 101.9(c); except that, when present, vitamin K shall follow vitamin E; calcium and iron shall follow pantothenic acid; selenium shall follow zinc; and manganese, fluoride, chromium, molybdenum, chloride, sodium, and potassium shall follow copper. This results in the following order for vitamins and minerals: Vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, biotin, pantothenic acid, calcium, iron, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, fluoride, chromium, molybdenum, chloride, sodium, and potassium. A bar shall separate the last nutrient to be listed from the bottom of the nutrition label, as shown in the sample labels in paragraph (c)(9) of this section.

(iii) If the product contains two or more separately packaged dietary supplements of vitamins and minerals (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 may be presented as specified in this paragraph in individual nutrition labels or in one aggregate nutrition label with separate columns declaring the quantitative amounts for each package as illustrated in paragraph (c)(9)(iii) of this section.

(iv) The percent of vitamin A that is present as beta-carotene may be declared, to the nearest whole percent, immediately adjacent to or beneath the nutrient name (e.g., ``Vitamin A 5000 IU (90 percent as beta-carotene)''), except that the declaration is required when a claim is made about 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 5000 IU (90 percent (4500 IU) as beta-carotene)'').

(v) The following synonyms may be added in parenthesis immediately following the name of these nutrients: Vitamin C (ascorbic acid), thiamin (vitamin B1), riboflavin (vitamin B2), folate (folacin), and calories (energy). Energy content per serving may be expressed in kilojoules units, added in parentheses immediately following the statement of caloric content.

(vi) All nutrients shall be displayed with uniform type size, style, color, and prominence.

(4) A listing of the percent of the Daily Value (i.e., the percent of the RDI as established in Sec. 101.9(c)(8)(iv) or DRV as established in Sec. 101.9(c)(9)), where appropriate, of all nutrients listed in the nutrition label, except that the percent for protein may be omitted as provided in Sec. 101.9(c)(7) and no percent shall be given for sugars, vitamin K, chloride, chromium, fluoride, manganese, molybdenum, selenium. This information shall be presented in one column aligned under the heading of``% Daily Value'' and to the right of the column of nutrient names and 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'' or placed beneath this heading and the bar underneath it, except that ``% Daily Value'' shall be placed beneath this bar when calorie information is required to be declared. Calorie information shall be placed beneath ``Amount Per Serving'' and above the bar.

(i) The percent of Daily Value shall be calculated by dividing either the amount declared on the label for each nutrient or the actual amount of each nutrient (i.e., before rounding) by the RDI or DRV for the specified nutrient and multiplying by 100, except that the percent for protein shall be calculated as specified in Sec. 101.9(c)(7)(ii). The numerical value shall be followed by the symbol for percent (i.e., %).

(ii) The percentages based on RDI's and on DRV's shall be expressed to the nearest whole percent, except that ``Less than 1%'' may be used in place of ``0%'' when the declaration of the quantitative amount by weight is a value greater than zero.

(iii) The percent of Daily Value for vitamins and minerals shall be based on RDI 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 (c)(9)(ii) of this section.

(iv) If the product contains two or more separately packaged dietary supplements of vitamins and minerals (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 percent of Daily Value may be presented as specified in paragraph (b)(4) of this section in individual nutrition labels or in one aggregate nutrition label with separate columns declaring the percent of Daily Value for each package as illustrated in paragraph (c)(9)(iii) of this section.

(v) If the percent of Daily Value is declared for total fat, saturated fat, total carbohydrate, dietary fiber, or protein, the value shall be followed by an asterisk that refers to another asterisk at the bottom of the nutrition label that states ``Percent Daily Values are based on a 2,000 calorie diet.''

(vi) When no percent is given for sugars, vitamin K, chloride, chromium, fluoride, manganese, molybdenum, or selenium, an asterisk shall be placed in the ``% Daily Value'' column that shall refer to another asterisk that is placed at the bottom of the nutrition label that is followed by the statement ``Daily Value not established.''

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

(1) The title of ``Nutrition 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 highlighted (reverse printing is not permitted as a form of highlighting) to distinguish them from other information.

(2) All information within the nutrition label shall utilize a single easy-to-read type style.

(3) All information within the nutrition label shall utilize upper and lower case 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.

(4) All information within the nutrition label shall have at least one point leading (i.e., space between two lines of text).

(5) Letters should never touch.

(6) All information within the nutrition label on packages that have a total surface area available to bear labeling of less than 12 square inches shall have type size no smaller than 4.5 point; packages that have from 12 to 40 square inches of surface area available to bear labeling shall have type size no smaller than 6 point; and packages with more than 40 square inches of surface area available to bear labeling shall have type size no smaller than 8 point, except that on packages with more than 40 square inches of available surface area, type size no smaller than 6 point may be used for the listing of information on beta-carotene, as specified in paragraph (b)(3)(iv) of this section, for the headings required by paragraphs (b)(3) and (b)(4) of this section (i.e., ``Amount Per Serving'' and ``% Daily Value''), and for the footnote required by paragraph (b)(4)(v) of this section.

(7) A hairline rule that is centered between the lines of text shall separate each nutrient and its corresponding percent Daily Value required in paragraph (b)(4) of this section from the nutrient and percent Daily Value above and beneath it, as shown in paragraph (c)(9) of this section, and shall separate ``Amount Per Serving'' from the calorie statement, when the listing of calories is required.

(8) 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.

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

(i) Multiple vitamin.

TR04JA94.000

(ii) Multiple vitamin for children and adults.

TR04JA94.001

(iii) Multiple vitamins in packets.

TR04JA94.002

(10) If space is not adequate to list the required information as shown in the sample labels in paragraph (c)(9) 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 nutrients and percent of Daily Value information given to the left. The following sample label illustrates this display:

TR04JA94.003

(d)(1) Compliance with this section shall be determined in accordance with Sec. 101.9(g)(1) through (g)(8).

(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 Sec. 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.

(e) Except as provided in paragraph (g) of this section, the location of nutrition information on a label shall be in compliance with Sec. 101.2.

(f)(1) Dietary supplements of vitamins or minerals are exempt from this section when they are offered for sale by a manufacturer, packer, or distributor who has annual gross sales made or business done in sales to consumers that is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers of not more than $50,000, Provided, That the food bears no nutrition claims or other nutrition information on a label or labeling or in advertising.

(2) For purposes of the paragraph, calculation of the amount of sales shall be based on the most recent 2-year average of business activity. Where firms have been in business less than 2 years, reasonable estimates must indicate that annual sales will not exceed the amounts specified. For foreign firms that ship foods into the United States, the business activities to be included shall be the total amount of food sales, as well as other sales to consumers, by the

firm in the United States.

(g) Dietary supplements of vitamins and mineral shall be subject to the special labeling conditions specified in Sec. 101.9(j)(5)(i) and (j)(5)(ii) for food, other than infant formula, represented or purported to be specifically for infants and children less than 2 years of age and 4 years of age, respectively; in Sec. 101.9(j)(9) for food products shipped in bulk form that are not for distribution to consumers; in Sec. 101.9(j)(13) for foods in small or intermediate-sized packages; in Sec. 101.9(j)(15) for foods in multiunit food containers; and, in Sec. 101.9(j)(16) for foods sold in bulk containers.

(h) Dietary supplements of vitamins and minerals shall be subject to the misbranding provisions of Sec. 101.9(k).

Dated: December 23, 1993.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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