DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 95N–0282]

Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its nutrient content claims regulations to change the terminology used to describe dietary supplements; provide for the use of statements that characterize the percentage level of dietary ingredients that do not have Reference Daily Intakes (RDI's) or Daily Reference Values (DRV's); and withdraw the provision that dietary supplements of vitamins and minerals may not give prominence to any ingredient that is not a vitamin or a mineral on its label or in labeling. The agency is also amending its regulations to specify how (i.e., text, placement, and type size) the disclaimer that must be contained in statements made in accordance with the Federal Food, Drug, and Cosmetic Act (the act) is to be presented. Additionally, FDA is removing the definition of ''dietary supplements,'' and revising the terminology used to describe these products in the regulations on health claims for food products. FDA is taking this action to implement, in part, the Dietary Supplement Health and Education Act of 1994 (the DSHEA).

EFFECTIVE DATE: March 23, 1999.

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SUPPLEMENTARY INFORMATION:

I. Background

On October 25, 1994, the President signed into law the DSHEA (Pub. L. 103–417). The DSHEA, among other things, defined ''dietary supplement'' by adding section 201(ff) to the act (21 U.S.C. 321(ff)); made provision for statements that characterize the percentage level of dietary ingredients that do not have RDI's or DRV's by adding section 403(r)(2)(F) to the act (21 U.S.C. 343(r)(2)(F)); and amended sections 411(b)(2) and (c)(1) of the act (21 U.S.C. 350(b)(2) and (c)(1)) on the labeling of products that contain vitamins and minerals. In addition, the DSHEA added section 403(r)(6) to the act, which states that statements may be made for dietary supplements if:

> [t]he statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient * * *

(section 403(r)(6)(A) of the act), and if certain other conditions are met. The manufacturer of the dietary supplement must have substantiation that the statement is truthful and not misleading (section 403(r)(6)(B)), and the statement must prominently contain the following:

> This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Section 403(r)(6)(C) of the act.

In the **Federal Register** of December 28, 1995, FDA published a proposed rule entitled ''Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements'' (60 FR 67176)(hereinafter referred to as ''the dietary supplement proposal''), in which the agency proposed to conform its regulations on nutrient content claims and health claims to the DSHEA. The proposed rule addressed how the statements provided for in section 403(r)(6) of the act (referred to as ''statements of nutritional support'' in the dietary supplement proposal) are to be presented on the label or in labeling of a dietary supplement. In addition, the proposal sought to provide for the use of statements that characterize the percentage level of dietary ingredients that do not have RDI's or DRV's on the labels and in the labeling of dietary supplements.

The agency received approximately 30 letters in response to the proposed rule. Each letter contained one or more comments. Several comments supported the proposal generally or supported aspects of the proposal. Other comments addressed issues outside the scope of the proposal (e.g., monitoring of adverse events, definition of fiber) and will not be discussed here. Several comments suggested modifications or revisions of various aspects of the proposal. A summary of these comments, and a discussion of the agency's conclusions, follow.

II. Revised Regulations

A. Coverage

1. A couple of comments maintained that there is no statutory basis for the issuance of FDA's dietary supplement proposal. These comments argued that the Nutrition Labeling and Education Act of 1990 (hereinafter referred to as ''the 1990 amendments'') limits the reach of ''nutrient content claims'' to claims regarding nutrients of the type required under section 403(q)(1) and (q)(2) of the act, that is, according to these comments, the nutrients that are to be declared in nutrition labeling. One comment maintained that the existence of the alternative language in section 403(r)(5)(D) of the act suggests that Congress was aware of the difference between ''nutrients'' and ''other similar nutritional substances,'' and that it intentionally utilized different language for nutrient content claims and health claims. Similarly, another comment stated that there is no justification for FDA to conclude that the phrase ''other similar nutritional substances'' is applicable to nutrient content claims.

The agency has addressed the question of the application of the nutrient content claims provisions to nutrients without RDI's or DRV's (59 FR 378, January 4, 1994; and 60 FR 67176, December 28, 1995). In the dietary supplement proposal (60 FR 67176), the agency stated:

> Section 403(r)(1)(A) of the act states that a food intended for human consumption is misbranded if it bears a claim that expressly or by implication ''characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food * * *.'' The statute uses the same language in section 403(r)(1)(B) to describe the substances that could be the subject of a health claim. A health claim is a claim that ''characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health-related condition * * *.'' Under section 403(r)(1)(B), a health claim may be made in accordance with section 403(r)(5)(D) as well as section 403(r)(3). Thus, because a statute must be read as a whole, the language in both sections 403(r)(1)(A) and (r)(1)(B) of the act that describes the substances that may be the subject of a nutrient content or of a health claim must be read in conjunction with section 403(r)(5)(D), which addresses health claims for vitamins, minerals, herbs, or other similar nutritional substances that are components of dietary supplements. Thus, the ''nutrients of the type required by paragraph (q)(1) or (q)(2)'' that are the subject of sections 403(r)(1)(A) and (r)(1)(B) of the act include vitamins, minerals, herbs, and other similar nutritional substances.

The agency also noted in the dietary supplement proposal (60 FR 67176) that the legislative history of ''other

nutritional substances'' reveals that its coverage is broad and could, in appropriate circumstances, include dietary ingredients without RDI's or DRV's (136 Congressional Record S16609 (October 24, 1990)). In a discussion between Senators Metzenbaum and Symms before the passage of the 1990 amendments, Senator Symms stated:

* * * What follows is a list of a few of the items and foods that I believe would fall under the ''other similar nutritional substances'' category established by this bill:

Primrose oil, black currant seed oil, coldpressed flax seed oil, ''Barleygreen'' and similar nutritional powdered drink mixes, Coenzyme Q 10, enzymes such as bromelain and quercetin, amino acids, pollens, propolis, royal jelly, garlic, orotates, calcium-EAP (colamine phosphate), glandulars, hydrogen peroxide (H_2O_2), nutritional antioxidants such a superoxide dismutase (SOD), and herbal tinctures.

Based on this colloquy, the agency interprets the list of dietary ingredients that fall under the definition of ''dietary supplement'' in section 201(ff) of the act as an explication of ''other similar nutritional substances.'' The comments to this rulemaking ignored the identity of language between 403(r)(1)(A) and 403(r)(1)(B) of the act and that the 403(r)(5)(D) language (i.e., ''other similar nutritional substances'') is subsumed under the ''nutrients of the type'' language that appears in 403(r)(1)(B) as well as in 430(r)(1)(A) of the act.

The comments to this rulemaking did not provide any information to persuade the agency to modify its tentative conclusions. The comments construed the language in section 403(1)(A) and (1)(B) of the act too narrowly. As the discussion from the proposal quoted above makes clear, the structure of the law itself compels FDA's conclusion with respect to the coverage of the language in question. Nor is there anything in the DSHEA that would suggest a different result with regard to the coverage of these provisions. FDA therefore rejects the comments that disagreed with the proposal on the coverage of the nutrient content claim provisions.

2. Several comments from the conventional food industry expressed concern that the statutory requirements for claims on dietary supplements can result in claims that give the misleading impression that dietary supplements provide more health benefits than conventional foods, as well as the erroneous impression that the presence of a dietary ingredient in a supplement is superior to the same ingredient provided in a matrix of conventional food by allowing dietary supplements to make claims that foods cannot. To illustrate these points, one comment stated that powdered, dehydrated cranberries sold in capsule form could bear a claim stating that they are beneficial for urinary tract health, while cranberry juice cocktail may not. The comment argued that such a claim is denied cranberry juice despite the fact that it has been demonstrated in clinical trials to prevent recurrence of urinary tract infections in women.

Other comments stated that the percentage claim provisions are an example of inequality in the regulatory treatment of conventional foods and dietary supplements. One comment stated that under the proposal, comparative percentage claims (e.g. ''as much as,'' ''twice the amount of * * *,'' ''500 percent of * * *'') for dietary ingredients that do not have RDI's or DRV's are forbidden to conventional food marketers, because the 1990 amendments prohibit claims that ''characterize'' the level of these dietary ingredients unless such claims have been defined by the agency in a regulation, but not to dietary supplement marketers. The comment argued that this situation is inequitable and internally inconsistent because it permits dietary supplement marketers to make, by circuitous language, claims that they cannot make directly. As an example, the comment stated that the effect of the agency's proposal is to lay down for dietary supplement marketers the following two rules: (1) You cannot claim that your product has ''more'' of a dietary ingredient than ''x'' product; but (2) you can claim that your product has ''twice as much'' of a dietary ingredient as ''x'' product. The comment argued that virtually every consumer will understand the latter claim to communicate the impermissible message contained in the former claim.

Another comment from a trade association for conventional food manufacturers stated that accurate statements describing the quantity of a dietary ingredient for which there is no RDI or DRV would be more appropriate than percentage claims. The comment stated that should FDA allow quantitative declarations for dietary ingredients without RDI's or DRV's, equity and fairness require that such statements also be allowed on conventional foods. The comment stated that such quantitative statements will be meaningful to consumers, and that conventional foods will be placed at a competitive disadvantage if prohibited from using these statements.

One comment stated that labeling claims for which there is no scientific basis are not in the public interest. The comment maintained that such statements undermine the public's confidence in the government's ability to protect consumers from products that may pose health risks. Further, the comment stated that the proposed regulations will undermine the credibility of FDA's regulations on nutrient content and health claims for foods.

On the other hand, a comment from a trade association for dietary supplement manufacturers stated that dietary supplements should be treated differently than conventional foods because the supplement industry thrives on open competition and does not seek government regulation to limit competition. The comment also stated that the dietary supplement industry wants to be able to make content claims for its products without FDA's approval because consumers are protected under the agency's general misbranding authority.

FDA acknowledges that there are some differences between dietary supplements and conventional foods with respect to the types of claims that can be made on their product labels, and that the content claims that can be made on both types of products without FDA authorization are limited. These differences and limitations, however, are created by the statute itself. FDA has no authority to modify the regulatory regime that is established by the act.

Section 201(g)(1)(B) of the act states that the term ''drug'' means articles intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease. FDA points out that the claim that cranberry juice cocktail prevents the recurrence of urinary tract infections mentioned by one of the comments is a claim that brings the product within the ''drug'' definition whether it appears on a conventional food or on a dietary supplement because it is a claim that the product will prevent disease. However, a claim that cranberry products help to maintain urinary tract health may be permissible on both cranberry products in conventional food form and dietary supplement form if it is truthful, not misleading, and derives from the nutritional value of cranberries. If the effect derives from the nutritive value of cranberries, the claim would describe an effect of a food on the structure or function of the body and thus fall under one exception to the definition for the term ''drug'' found in 201(g)(1)(C) of the act. The claim is not a health claim because no disease is mentioned explicitly or implicitly (see section 403(r)(1)(B) of the act).

Only if the claimed benefit did not derive from the nutritional value of cranberries would it be true that the

claim could appear on a dietary supplement but not a conventional food. This result is dictated by section 403(r)(6) of the DSHEA.

With regard to percentage claims, section 7(c) of the DSHEA amends section 403(r)(2) of the act by adding clause (F) which reads:

Subclause (i) clause (A) does not apply to a statement in the labeling of a dietary supplement that characterizes the percentage level of a dietary ingredient for which the Secretary has not established a reference daily intake, daily recommended value, or other recommendation for daily consumption.

This new provision refers to section 403(r)(2)(A)(i) of the act, which states that nutrient content claims may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary. The effect of section 403(r)(2)(F) of the act is to permit, on dietary supplement labels or in dietary supplement labeling, the use of statements that have not been defined by FDA but that, nonetheless, characterize the percentage level of a dietary ingredient for which an RDI or DRV has not been established.

In the dietary supplement proposal (60 FR 67176), the agency interpreted section 403(r)(2)(F) of the act as permitting percentage claims for substances for which an RDI or DRV has not been established on labels or labeling of dietary supplements but not on conventional foods. Significantly, while comments objected to FDA doing so, no comments argued that the agency had misinterpreted this aspect of section 403(r)(2)(F). The limited legislative history does not make clear why Congress chose to differentiate between these two types of food in this way.

However, the structure of the DSHEA suggests that Congress recognized that dietary supplements are not necessarily like other foods. Where other foods are consumed for taste, aroma, or nutritive value, some dietary supplements are consumed for none of these reasons. Congress apparently concluded that the labeling of dietary supplements should be able to accommodate this fact. Thus, Congress provided for the inclusion in the nutrition label of dietary ingredients for which no daily consumption recommendations have been established, as well as for the use of percentage claims about such ingredients. Congress did not make similar provision for such ingredients in conventional foods, presumably because it saw no reason to distract consumers from the traditional reasons why they choose particular conventional foods.

In the percentage claims provisions in § 101.13(q)(3)(ii) (21 CFR 101.13(q)(3)(ii)), the agency sought to interpret section 403(r)(2)(F) of the act in a flexible manner. Giving section 403(r)(2)(F) of the act a significantly broader or different application must be accomplished through the legislative process. For now, however, it remains the case that, except for the provisions for amount or percentage statements under § 101.13(i)(3), statements that characterize the level of a dietary ingredient without an established RDI or DRV will misbrand a conventional food.

It is important to note that the use of defined nutrient content claims, such as ''more'' and ''high,'' remains limited, for both conventional foods and dietary supplements, to those dietary ingredients that have RDI's or DRV's. Consumer research shows that the defined nutrient content claims are widely recognized and used by consumers, and that consumers understand that the defined claims have specific meanings (Ref. 1). The agency is not convinced that consumers will automatically associate comparative percentage statements on dietary supplements with these defined nutrient content claims. Consumer research shows that public confidence in the food label is high (Ref. 2), and FDA has no reason to believe that the comparative percentage claims provisions for dietary supplements will undermine public confidence in the agency's regulations.

Moreover, as the agency has previously stated (60 FR 67175 at 67177), FDA is not without recourse to curtail percentage claims that are misleading on the labels and in the labeling of dietary supplements. Percentage statements on the label or in labeling of dietary supplements that characterize the percentage level of a dietary ingredient for which there is no established RDI or DRV in relation to an equivalent or increased/decreased amount of the dietary ingredient in another food, would be misleading under sections 403(a) and 201(n) of the act if there is not a meaningful amount of the dietary ingredient in either of the foods being compared, or if there is not a meaningful difference in the level of the dietary ingredient between the two foods.

The agency recognizes that it cannot provide a completely satisfying resolution for the differences in the types of percentage claims that can be made on the labels and in labeling of dietary supplements as opposed to conventional foods. FDA is committed, however, to as much parity between dietary supplements and conventional foods as is possible within the statute. The agency rejects the comment that dietary supplements should be treated differently than conventional foods because differences in treatment are in the interest of a free market in dietary supplements. The agency has an obligation to implement the law that Congress has enacted in a fair and equitable manner. FDA is doing exactly that in its regulation of content claims for dietary supplements as well as for conventional foods.

3. One comment from a food manufacturer interpreted the proposal to mean that food companies may no longer make percentage statements about ingredients contained in their products (e.g., ''70% milk,'' ''twice as much milk as the leading brand'') because FDA has not adopted RDI's or DRV's for these ingredients. The manufacturer argued that there is nothing in any statute or regulation that prohibits a food manufacturer from stating that its product contains a particular ingredient, or from comparing the amount of the ingredient to the amount present in another food.

FDA concludes that this comment misconstrues the statute. The agency proposed to implement section 403(r)(2)(F) of the act, which, as stated above, applies only to claims in the labeling of a dietary supplement that characterize the percentage of a dietary ingredient for which FDA has not established an RDI or DRV (e.g., omega-3 fatty acids, amino acids, phytochemicals). This provision has no application to conventional foods.

As for the milk claims that the comment cites, the agency advises that it has no intention of limiting percentage statements on conventional foods that clearly describe ingredients in a manner that relates to their organoleptic properties or that presents them as adding value to the product. Manufacturers of conventional foods may continue to state that products contain particular ingredients and to compare the amounts of such ingredients to the amounts present in other foods (see 21 CFR 101.65(b)(3)). However, the agency will continue to evaluate the context in which claims such as ''70% milk'' and ''twice as much milk as a leading brand'' are made to determine whether they fall under the nutrient content claims regime. Such claims can be, in some cases, implied nutrient content claims about the level of calcium in the product that bears the claim. If such statements are found to be implied nutrient content claims for calcium by the agency, they may be used as long as they meet the criteria for the claim (see 21 CFR 101.54). If they are not implied claims, nothing in the regulations precludes the use of such

statements so long as they are truthful and nonmisleading.

4. One comment argued that the new definition of ''dietary supplement'' is ambiguous and would include products marketed in ''traditional food form.'' The comment requested that the agency clarify whether conventional food products that contain high levels of nutrients, such as breakfast cereals and fruits and vegetables can be marketed as supplements.

The distinction between dietary supplements and conventional foods becomes more apparent when the act is read carefully. The DSHEA added section 201(ff)(2) which provides that a ''dietary supplement'' is a product that is not represented for use as a conventional food. It also struck the provision that excluded products that simulate conventional foods from the coverage of section 411 of the act (see section 3(c)(2) of the DSHEA). Thus, under the act, as amended by the DSHEA, a dietary supplement may be ''in conventional food form.'' In other words, a dietary supplement may be a product with physical attributes (e.g., product size, shape, taste, packaging) that are essentially the same as a conventional food, so long as it is not represented for use as a conventional food.

Thus, whether a product is a dietary supplement or a conventional food will depend on how it is labeled. To be a dietary supplement, a product must bear the term ''dietary supplement'' as part of its common or usual name. This term may be modified to include the name of the dietary ingredient (e.g, ''vitamin C supplement'') or an appropriately descriptive term (e.g., ''multivitamin supplement''). (See comment number 1 in the companion document entitled ''Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements'' published elsewhere in this issue of the **Federal Register** for further discussion of this issue.) All other food products, that is, those that are not identified as dietary supplements, will be subject to regulation as conventional foods.

While use of the term ''dietary supplement'' in the statement of identity is a necessary condition for a product to be represented as a dietary supplement, it may not be enough to establish that the food is appropriately regulated as one. If the food is represented as a dietary supplement and is only intended to increase the dietary intake of specific substances (e.g., vitamins), then the product would likely be subject to regulation as a dietary supplement (section 201(ff)(1) of the act). It would not be subject to regulation as a dietary supplement, however, if it bears a statement that associates it with a conventional food. For example, a product in bar form that is labeled as a dietary supplement but that also bears label statements that represent it as a snack food or as a substitute for a candy bar would be subject to regulation as a conventional food. Similarly, a breakfast cereal-type product could characterize itself as a dietary supplement if it did not represent itself as a breakfast food or use the term ''cereal'' as a statement of identity. Either of the latter two scenarios would represent the product as a conventional food.

This result is compelled by section 201(ff)(1) of the act, which states that a dietary supplement is intended to supplement the diet. Claims that represent the product as being a snack food or a breakfast cereal would evidence that the product is intended to do more than supplement the diet and thus would subject it to the regime that applies to foods other than dietary supplements.

B. Quantitative Amounts for Percentage Claims

5. A comment from a manufacturer of a dietary supplement stated that percentage claims such as ''40 percent omega-3 fatty acids'' do not give the consumer any meaningful information because the consumer will not know whether the claim means that 40 percent of the product is omega-3 fatty acids, or that the product contains an ingredient that is composed of 40 percent omega-3 fatty acids, or even that the product contains 40 percent of the omega-3 fatty acids as compared to another brand or another food. The comment stated that the only way to make this information useful and nonmisleading is to require that the percentage level be immediately accompanied by a statement of the quantity of the dietary ingredient per serving of the product.

The comment also stated that there are inherent problems in comparing a manufactured or synthetic dietary ingredient with a dietary ingredient in its natural source because natural sources are subject to wide variability in composition. For example, the comment maintained that there would be no way to accurately quantify the actual amount that comprises ''100 percent of the dietary ingredient 'X' in a bulb of garlic.'' The comment stated that this example is meaningless and would mislead consumers. The comment suggested that to provide any meaningful comparative information to consumers, there must be some generally recognized quantitative amount of the dietary ingredient in the reference substance. The comment also suggested that in the absence of a scientifically accepted standard for measuring the dietary ingredient in a natural source, FDA should clarify that when there is a comparison of an added, or a synthetic, dietary ingredient to a natural source (e.g., garlic bulb, fish liver oil), the natural source is the ''reference food,'' which is subject to the requirement for clear identification. The comment suggested that the actual amounts of the dietary ingredient in the labeled and reference foods be declared.

The agency is persuaded that percentage claims will provide more useful information to the consumer, and that the potential for misleading claims will be limited, if quantitative information is provided along with the percentage information. This information will facilitate comparisons of the amounts of dietary ingredients in products that bear percentage claims, which, in turn, will assist consumers in selecting products with the amount of the dietary ingredient that they are seeking and will allow consumers to make comparisons of the content of specific dietary ingredients across products.

Accordingly, FDA is revising § 101.13(q)(3)(ii) by adding § 101.13(q)(3)(ii)(A) to state that, for dietary supplements, whenever a statement is made that characterizes the percentage level of a dietary ingredient for which there is no RDI or DRV, the actual amount of the dietary ingredient in a serving of the product shall also be declared (e.g., ''40 percent omega-3 fatty acids, 10 mg per capsule'').

In addition, FDA is adding § 101.13(q)(3)(ii)(B), which states that, for dietary supplements, where a statement that characterizes the percentage level for a dietary ingredient for which there is no RDI or DRV is used to compare the amount of the ingredient in the food that bears the claim to the amount in a reference food, the amount of the dietary ingredient in the food must be declared and the amount of the dietary ingredient in the reference food to which the product is being compared must also be declared. Moreover, the reference food must be clearly identified (e.g., ''twice the omega-3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (40 mg)'').

While FDA acknowledges that there may be variability in the content of certain dietary ingredients in natural source products (e.g., garlic) based on a variety of conditions (e.g., soil, cultivars, climate), FDA is not persuaded that the inherent variability

in the content of a dietary ingredient is a barrier to the declaration of the quantitative amount of the dietary ingredient on the product label. Variability in nutrient content is a factor that the agency takes into consideration in evaluating label statements for all foods, not just dietary supplements. Implicit in the compliance sampling provisions in 21 CFR 101.9(g) is the concept that there will be variation in naturally-occurring nutrients present in subsamples of a product. Variability is taken into consideration in the development of data bases and food composition tables. FDA expects that, as more analyses are performed in support of label values for naturally-occurring dietary ingredients that have and do not have RDI's or DRV's, guidance on sampling strategies, weighing procedures, and statistical treatment to account for variation among samples will improve. Because of potential variation in the dietary ingredient content, firms may label the dietary ingredient values on products conservatively, so that the products declaring such values have a high probability of passing the FDA compliance evaluation. Statistical procedures for doing so are discussed in ''FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases.'' At the same time, consumers have the right to expect, with a reasonable probability, that label values honestly and reasonably represent the content in the products they purchase.

6. A couple of comments noted that in many instances there are no validated methods to analyze for a variety of dietary ingredients, particularly herbal ingredients. The comments pointed out that the accuracy of label claims will be impossible to verify because of the lack of accepted quantitative analytical methods or standards.

FDA recognizes that analytical methods are needed for a variety of dietary ingredients. The agency encourages the dietary supplement industry to participate in developing and in validating analytical methods for dietary ingredients for which there are not generally accepted methods. The lack of methodology to assess the validity of label claims is of concern because it increases the possibility of consumer fraud. However, FDA has every expectation that dietary supplement manufacturers will make claims in a responsible manner. This is the premise on which section 403(r)(6) of the act (see section 403(r)(6)(B)) was apparently based. Therefore, FDA expects that firms will not make claims unless they are in possession of evidence that establishes the validity of their claims.

7. Several comments suggested that all examples discussing the amount of allicin in garlic (e.g., ''100 percent of the allicin in a bulb of garlic'') be dropped because there is no allicin in a bulb of garlic or in dietary supplements of garlic. One comment stated that allicin is produced as a result of an enzymatic reaction of alliin with the enzyme alliinase (which are both components of raw garlic), and that this reaction occurs only when the garlic clove is ruptured by crushing, cutting, or some other manner. The comment stated that allicin is associated with garlic only during the process of decomposition, and that it has a half-life of less than 24 hours at room temperature. The comment stated that it is helpful to have some examples that illustrate the distinction between ''ingredient'' and ''dietary ingredient.''

The agency used the allicin and garlic examples only to illustrate distinctions in label statements about dietary ingredients and ingredients. Based on the comments, the agency concludes that the examples, which were taken from statements by representatives of the dietary supplement industry, were not the best choices to illustrate this distinction. Questions regarding the presence or absence of allicin are beyond the scope of this rulemaking. Accordingly, the agency will remove all examples referring to garlic and allicin from § 101.13(q).

The agency agrees that examples that show the difference between a dietary ingredient and an ingredient are helpful. Calcium, iron, and omega-3 fatty acids are examples of dietary ingredients, while calcium carbonate, ferrous sulfate, and cod liver oil respectively, are examples of ingredients.

8. One comment requested that the agency drop the proposed requirements for referral statements, disclosure statements, and accompanying information for percentage claims on dietary supplements.

The comment did not provide any explanation to support its request, and therefore, the agency has no basis upon which to change its position on these requirements. While section 403(r)(2)(F) of the act states that section 403(r)(2)(A)(i) does not apply to statements on the labels of dietary supplements that characterize the percent level of dietary ingredients, there is nothing in the DSHEA that exempts such statements from the requirement in section 403(r)(2)(B) of the act for referral statements (i.e., ''See *[location]* for nutrition information'') or from other requirements for nutrient content claims. Therefore, FDA has made no change in response to this comment.

C. Disclaimer

9. Several comments requested that FDA clarify that the disclaimer for statements made under section 403(r)(6) of the act is required only when the manufacturer wishes to take advantage of the provisions for exemption from the drug definition. Other comments requested that the agency clarify that section 6 of the DSHEA (which added section 403(r)(6) to the act) does not apply to recognized nutrients with RDI's or DRV's. Other comments requested that the agency clarify the type of claims that may be made, the form and amount of substantiation that FDA will require, and to whom and in what form the 30-day notification must be made.

Section 403(r)(6) of the act sets out the circumstances in which certain types of statements can be made about all of the substances listed in section 201(ff) of the act in the label or labeling of dietary supplements. FDA is no longer referring to these statements as ''statements of nutritional support,'' even though this phrase is used in the title of section 6 of the DSHEA, because many of the substances that can be the subject of this type of claim do not have nutritional value. Thus, the term ''statement of nutritional support'' is not accurate in all instances.

The agency agrees that the disclaimer provided for in section 403(r)(6) of the act is required only when the manufacturer wishes to take advantage of the exception from the drug definition that is provided for in section 201(g)(1) of the act for products that comply with section 403(r)(6). Section 201(g)(1)(C) of the act recognizes that common sense foods, that is, products with nutritional value, affect the structure or function of the body because of their nutritional value. Thus, the types of claims described in section 403(r)(6)(A) of the act can be made to describe the nutritive value of a product without fear of action against the product as a drug (e.g., ''calcium builds strong bones and teeth'') so long as the claims are not false or misleading. The claim would simply describe the nutritive value of the substance in question. However, a dietary supplement manufacturer may still choose to comply with section 403(r)(6) of the act in making a claim about a substance with nutritive value if the manufacturer chooses to take advantage of the protection provided by that section and the last sentence of section of section 201(g)(1) of the act. Products without nutritive value, however, would be subject to regulatory action as drugs

under section 201(g)(1)(C) of the act if they make any of the claims listed in section 403(r)(6)(A) of the act without compliance with all of the provisions of section 403(r)(6).

Questions regarding substantiation and notification requirements for statements provided for under section 403(r)(6) of the act are outside the scope of this rulemaking. The agency advises that it published a proposed rule on notification procedures for such statements in the **Federal Register** on September 27, 1996 (61 FR 50771). The agency's tentative conclusions with respect to notification procedures are discussed in that proposal.

The agency concludes that it is desirable to streamline its regulations by covering all provisions addressing statements provided for under section 403(r)(6) of the act in one section. For consistency with the proposed regulation on notification procedures, the agency is changing the title and the section number from ''§ 101.94 *Statements of nutritional support; disclaimer*'' to ''§ 101.93 *Notification procedures for certain types of statements on dietary supplements*.'' Additionally, the agency is redesignating proposed § 101.94(a), (b), (c), and (d) as § 101.93 (b), (c), (d), and (e) and reserving § 101.93(a) in anticipation of the final rule on notification procedures.

10. One comment requested that the agency eliminate a reference to ''the exemption to section 201(g)(1)(C) of the act'' from proposed § 101.94(a) (redesignated as § 101.93(b)) because there are two exceptions to 201(g)(1)(C) of the act. The comment stated that the first exemption is the exception for ''food'' in section 201(g)(1)(C) of the act. The comment stated that the second exemption is the one that was added by the DSHEA. The comment stated that the DSHEA provides that those dietary ingredients that are not covered by the first exception from the drug definition (i.e., for food) are covered by the mechanism in section 403(r)(6) of the act that permits claims to be made concerning the role of other dietary ingredients in the body while avoiding classification as a ''drug.''

FDA acknowledges that there are now two exceptions to section 201(g)(1)(C) of the act. Accordingly, the agency is clarifying that § 101.93(b) refers to the second exception, that is, for dietary supplements that are labeled in compliance with section 403(r)(6) of the act. FDA is revising § 101.93(b) to reflect the comment's point that there are now two exceptions to section 201(g)(1)(C) of the act.

However, FDA disagrees with the comment in two respects. First, the comment seems to imply that all dietary supplements are covered per se by the exception, which is not the case. Dietary supplements have to comply with section 403(r)(6) of the act to be subject to the exception (unless, of course, as stated above, they are subject to the other exception for ''food'' as that term has been interpreted by the courts, see *Nutrilab Inc.* v. *Schweiker*, 713 F.2d. 335, 338 (7th Cr. 1983)). In addition, paragraph (a) of the conforming amendments found in section 10 of the DSHEA states that a product that bears a statement made in accordance with section 403(r)(6) of the act is not a drug under section 201(g)(1)(C) of the act ''solely because the label or the labeling contains such a statement.'' Thus, the dietary supplement may be found to be a drug based on some evidence of intended use other than the statement made in accordance with section 403(r)(6) of the act.

11. Several comments supported the proposal to place the disclaimer adjacent to the statement provided for under section 403(r)(6) of the act where there is a single statement. Other comments disagreed with this aspect of the proposal. The latter comments stated that it is sufficient to tie the statement to the disclaimer through the use of asterisks. These comments maintained that dietary supplement packages tend to be small, that space is at a premium on dietary supplement labels, and that consumers are sufficiently accustomed to the asterisk to locate the disclaimer elsewhere on the label.

Similarly, other comments supported the proposal that the disclaimer be placed on the same panel or page where there are multiple statements. Other comments objected to this placement and stated that the repetition of the disclaimer on every panel or page on which a statement appears is redundant and unnecessary. To justify the placement of the disclaimer on an alternate panel, one comment stated that safety claims are often found on separate label panels, and that there is no evidence that separating a message on different parts of a label leads to a lack of consumer understanding of the safety information on these products. Other comments stated that the agency's proposed approach is not required by statute, places an undue burden on dietary supplement manufacturers and distributors, and would inhibit, rather than aid, consumer understanding of information on the labeling of these products. These comments also maintained that there is typically insufficient space to repeat the disclaimer on every panel or page.

One comment urged the agency to use a single ''global'' disclaimer for all claims made on a dietary supplement label and claimed that if the agency did so, no asterisks or symbols would be necessary.

A variety of locations were suggested for the placement of the disclaimer. A couple of comments suggested that the disclaimer be placed under, or adjacent to, the nutrition label. Other comments suggested that the disclaimer be placed on the panel to the left of the principal display panel. Another comment suggested that the disclaimer be placed next to the most prominent claim.

FDA has evaluated the comments and concludes that the placement of the disclaimer on a panel other than where the statement is made would not meet the statutory requirement for the placement of the disclaimer. Section 403(r)(6)(C) of the act requires that the statement ''contain'' the disclaimer, prominently displayed in boldface type. A literal reading of section 403(r)(6)(C) of the act suggests that each statement must contain the disclaimer in its entirety.

In the case of multiple statements, the agency sought to minimize the burdens imposed by the act by proposing that when the statements provided for in section 403(r)(6) of the act are tied to the disclaimer by means of an asterisk or other symbol, the statutory requirement that the statement contain the disclaimer would be met because the two discrete pieces would be linked together.

Based on its experience with asterisks within the nutrition label, the agency concludes that consumers are accustomed to using asterisks on labels to associate two discrete pieces of important information when they are in the same field of vision (Ref. 3). For this reason, the agency is persuaded that the use of an asterisk or other symbol that links the statement to the disclaimer meets the statutory requirement for single statements. Ideally, the disclaimer should be placed immediately adjacent to each statement, but the agency is convinced that the use of asterisks or other symbols will adequately serve the same purpose while providing flexibility to the manufacturers. The agency is revising proposed § 101.94(c) (redesignated as § 101.93(d)) to reflect this judgement.

The agency rejects the comments that stated that repetition of the disclaimer on every panel or page where a statement made in accordance with section 403(r)(6) of the act appears is unnecessary. The agency concludes that

to meet the statutory requirement that the disclaimer be ''contained'' within the statement, the disclaimer must be within the same field of vision as the statement itself. Because the agency concludes that the placement of the disclaimer anywhere on the same page or panel of labeling is equivalent to meeting the requirement of being ''contained,'' each of the suggestions for the placement of a single disclaimer on a product label (e.g., under the nutrition label, adjacent to the most prominent claim) would not provide an acceptable alternative.

The agency points out that the requirements for the disclaimer also extend to labeling: There are potentially many vehicles (e.g., placards, pamphlets, catalogs, books) that would have to bear the disclaimer. The agency is concerned that the disclaimer be prominent in these forms of labeling. Even with the flexibility of the use of an asterisk to tie the claim and the disclaimer to a single statement, the disclaimer could be obscured in pages of text of a package insert, pamphlet, or book if it did not appear on the same page or panel (i.e., in the same field of vision) as the statement itself. Because of the variety of possibilities for the presentation of the disclaimer, the agency concludes that for labeling, as for labels, it is important to retain the provision that the disclaimer appear within the same field of vision, that is, on each package panel or page where a statement is made, under section 403(r)(6) of the act.

The use of the statements provided for in section 403(r)(6) of the act is entirely voluntary, and the agency is not persuaded that the use of the disclaimer would be unduly burdensome to manufacturers that choose to use such statements.

The agency rejects the concept of a ''global'' disclaimer because its application would be undefined and thus could create misleading or false impressions. For example, some products may bear a variety of claims, including nutrient content and health claims, which are authorized by the agency. In this case, the use of a ''global'' disclaimer could create the impression that these claims had not been evaluated by FDA, which would be false.

Accordingly, the agency is revising proposed § 101.94(c) (redesignated as § 101.93(d)) to state that a symbol (e.g., an asterisk) can be used to link a single statement to the disclaimer. On product labels and in labeling for single and multiple statements, the disclaimer shall appear on each panel or page where there is a statement.

12. A couple of comments supported the placement of the disclaimer within a box. These comments stated that placement of the statement within a box should help ensure that consumers will read the disclaimer and will give adequate prominence to the statutory statement. Other comments disagreed with the placement of the disclaimer within a box. Several comments stated that the DSHEA makes no reference to a box. A couple of comments stated that warnings are typically set out in boxes in labeling, and the disclaimer is not intended to be a warning. Another comment objected to boldface type.

One comment referred to the definition of prominence in section 403(f) of the act and stated that all this section requires is that the information be placed such that consumers are likely to read it under customary conditions of purchase and use. One comment stated that it should be left to the discretion of the manufacturer to ensure that the disclaimer is prominently featured, through some combination of boldface type, color, a box, or other design features.

The agency is not aware of any research that specifically examines whether consumers associate boxed information with warning information. No evidence was included in the comments to persuade the agency that boxed information is viewed by consumers as a warning. Manufacturers may voluntarily enhance the disclaimer by a variety of other graphic measures. However, section 403(r)(6)(C) of the act requires that the disclaimer be in boldface type. Graphic devices such as boxing are used to draw attention to important information. For example, the nutrition label is placed in a box. Thus, the relevant question is whether the information is important enough to be boxed, not whether it will be seen as a warning.

Congress has made the judgment that the disclaimer is important information by requiring that the statement be in boldface type. Because the statue explicitly requires boldface type, FDA is not persuaded that the standard for prominence in 403(f) of that act is sufficient to meet the standard for prominence for the disclaimer intended by the Congress. FDA is providing that the statement may be physically separated from the statements made under section 403(r)(6) of the act. To ensure that the disclaimer gets the prominence that Congress intended, FDA is requiring that it be put in a box if it is separated from the statement made under section 403(r)(6) of the act. Therefore, the agency is is retaining the requirement in § 101.94(c)(2) (redesignated as § 101.93(d)) that the disclaimer be set off in a box where it is not adjacent to the statement.

13. One comment requested that the type size requirement be revised to meet the requirements in § 101.2 (21 CFR 101.2) which provide one-sixteenth of an inch as a general minimum type size. The comment maintained that inasmuch as FDA has determined that the requirements in § 101.2 are adequate to satisfy section 403(f) of the act, the requirements of § 101.2 are also appropriate in implementing the disclaimer provisions specified in section 403(r)(6) of the act. In addition, the comment urged the agency to clarify that the type size options for special package sizes are available to dietary supplements which often come in small packages.

Based on the plain language of section 403(r)(6)(C) of the act, the agency concludes that it was Congress' intent that the disclaimer be prominent and not obscured on the label or in labeling. For that reason, the agency proposed that the typesize for the disclaimer be no smaller than the larger of one-half the type size of the largest statement provided for in section 403(r)(6) of the act, but in no case no smaller than one-sixteenth of an inch. FDA tentatively concluded that in this manner, prominence could be assured because the disclaimer would be proportional to the section 403(r)(6) of the act statement or, at minimum, one-sixteenth of an inch (60 FR 67176 at 6781).

Because FDA is retaining the provisions that the disclaimer be on the same panel or page as the statement, and that the disclaimer be boxed when it is not adjacent to the statement, the agency concludes that the disclaimer can be readily located and, thus, that the statutory requirement for prominence is largely met. Readability is a clear attribute of prominence, and based on its experience with food labeling, one-sixteenth of an inch is generally readable (Ref. 3). Section 403(r)(6)(C) of the act requires that the disclaimer be in boldface type, which should also facilitate readability. Therefore, FDA has no objection to a minimum typesize of one-sixteenth of an inch for the disclaimer. Accordingly, the agency is revising proposed § 101.94(d) (redesignated as § 101.93(e)) to specify that one-sixteenth inch is the minimum typesize for the disclaimer.

Statements provided for in section 403(r)(6) of the act are entirely voluntary. All required information must first be considered in designing labels. Moreover, the firm must consider that the disclaimer must be prominent as required by the statute. Therefore,

there will be instances in which statements under section 403(r)(6) of the act should not be used on a label or in labeling because it is not feasible to accommodate both the required information and the statutory requirement for prominence for the disclaimer.

Inasmuch as the purpose of § 101.2(c)(1) through (c)(3) was to encourage voluntary declaration of nutrition information and complete ingredient listing on all foods before the provision of this information was made mandatory by the 1990 amendments, FDA gave notice of its intention to revoke the exemptions in § 101.2(c)(1), (c)(2), and (c)(3) in its December 1995 proposal entitled ''Food Labeling: Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements'' (60 FR 67194 at 67208) and proposed to do so in the **Federal Register** of June 12, 1996 (61 FR 29708). These provisions are now obsolete. Therefore, FDA is not accepting the recommendation of these comments, and the request to include the options for small package size listed under § 101.2(c) is denied.

III. Effective Date

14. Several comments recommended an effective date of 18 months following the publication of the final rule. One comment stated that the dietary supplement industry is unique because of the number of dietary supplement products sold that are ''private label,'' that is manufactured for or distributed by the company named on the label (the brand owner). The comment noted that many products in the ''private label'' category are store brands. The comment stated that these facts mean that many manufacturers must prepare a wide variety of labels for the same product. The comment used the example of one company producing private label merchandise that may have over 10,000 labels that will need to be conformed to the new regulations, and that for such store brand private label products, the time it would take to deplete the inventory of labels is well over 18 months. The comment noted that the period to use labels that state ''manufactured for'' and ''distributed by'' could be easily as long.

FDA is persuaded by the majority of the comments that it is appropriate to have the effective date of this final rule be 18 months from the date of its publication, consistent with the time period allowed for the labels of conventional foods to comply with the 1990 amendments. FDA is addressing the issues raised by these comments in greater detail in the final rule entitled ''Food Labeling: Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements'' published elsewhere in this issue of the **Federal Register**.

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. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (60 FR 67176). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact of the human environment and that an environmental impact statement is not required.

VI. Paperwork Reduction Act

In the dietary supplement proposal, FDA stated its tentative conclusion that the proposed rule contains no reporting, recordkeeping, labeling, or other third party disclosure requirements and asked for comments on whether the proposed rule imposed any paperwork burden. No comments were received addressing the question of paperwork burden. FDA concludes that the labeling requirement in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VII. Analysis of Impacts

FDA has examined the economic implications of the final rule as required by Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approach that maximizes net benefits (including potential economic, environmental, public health and safety effects; and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. If a rule has a significant impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze options that would minimize the economic impact of that rule on small entities. FDA finds that this final rule is not a significant rule as defined by Executive Order 12866, and finds under the Regulatory Flexibility Act, that the final rule will not have a significant impact on a substantial number of small entities. Similarly, it has been determined that this rule is not a major rule for the purpose of congressional review (Pub. L. 104–121).

The final rule does not significantly change the way in which claims are made with three exceptions: (1) Percentage claims for dietary supplements that do not have RDI's or DRV's are no longer prohibited; (2) dietary supplements of vitamins and minerals may now highlight an ingredient that is not a vitamin or mineral; and (3) labels or labeling of dietary supplements may include the types of statements listed in 403(r)(6) of the act so long as those statements are made in accordance with requirements of that section. With regards to these actions, costs of redesigning labels will be incurred only by those firms wishing to take advantage of the DSHEA. With respect to the third, firms who wish to make the statements provided for in section 403(r)(6) of the act will incur the additional cost of redesigning labels to include the disclaimer.

FDA is unable to quantify the benefits from this final rule. Some consumers will benefit from the additional information about dietary ingredients that will become available. However, because statements may now be made under section 403(r)(6) of the act for some dietary ingredients without any information being submitted to FDA to demonstrate that the dietary ingredient is safe, or that it will have its claimed effect, it is uncertain whether this final rule will have any significant health benefits.

This rule provides small entities with the opportunity to use certain claims that were previously prohibited. Small entities will incur the cost of redesigning labels to include claims only if making the claim will be profitable to the firm. In the proposed rule (60 FR 67176), FDA certified that this rule will not have a significant impact on a substantial number of small entities. FDA received no objections to that certification.

VIII. References

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

1. The Research Department, Food Marketing Institute, ''Trends in the United States: Consumer Attitudes & the Supermarket,'' 1996.

2. Levy, A. S., and B. M. Derby, ''The Impact of the NLEA on Consumer: Recent Findings from FDA's Food Label and Nutrition Tracking System. Executive Summary, January 23, 1996.

3. Levy, A. S., memorandum to Camille Brewer: Likely Effectiveness of Proposed Format Requirements for Disclaimer Statement on Dietary Supplement Products, January 16, 1997.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 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 101.13 is amended by revising paragraph (a), the introductory text of paragraph (b), and redesignating paragraph (q)(3) as paragraph (q)(3)(i), and adding new paragraph (q)(3)(ii) to read as follows:

§ 101.13 Nutrient content claims—general principles.

(a) This section and the regulations in subpart D of this part apply to foods that are intended for human consumption and that are offered for sale, including conventional foods and dietary supplements.

(b) A claim that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.36 (that is, a nutrient content claim) may not be made on the label or in labeling of foods unless the claim is made in accordance with this regulation and with the applicable regulations in subpart D of this part or in part 105 or part 107 of this chapter.

* * * * *

(q) * * *

(3) * * *

(ii) Percentage claims for dietary supplements. Under section 403(r)(2)(F) of the act, a statement that characterizes the percentage level of a dietary ingredient for which a reference daily intake (RDI) or daily reference value (DRV) has not been established may be made on the label or in labeling of dietary supplements without a regulation that specifically defines such a statement. All such claims shall be accompanied by a referral or disclosure statement in accordance with paragraphs (g) or (h) of this section.

(A) *Simple percentage claims.* Whenever a statement is made that characterizes the percentage level of a dietary ingredient for which there is no RDI or DRV, the statement of the actual amount of the dietary ingredient per serving shall be declared next to the percentage statement (e.g., ''40 percent omega-3 fatty acids, 10 mg per capsule'').

(B) *Comparative percentage claims.* Whenever a statement is made that characterizes the percentage level of a dietary ingredient for which there is no RDI or DRV and the statement draws a comparison to the amount of the dietary ingredient in a reference food, the reference food shall be clearly identified, the amount of that food shall be identified, and the information on the actual amount of the dietary ingredient in both foods shall be declared in accordance with paragraph (j)(2)(iv) of this section (e.g., ''twice the omega-3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (40 mg)'').

* * * * *

3. Section 101.14 is amended by removing paragraph (a)(4), by redesignating paragraphs (a)(5) and (a)(6) as paragraphs (a)(4) and (a)(5), respectively; and by revising paragraphs (b)(3)(i) and (d)(3) to read as follows:

§ 101.14 Health claims: general requirements.

* * * * *

(b) * * *

(3) * * *

(i) The substance must, regardless of whether the food is a conventional food or a dietary supplement, contribute taste, aroma, or nutritive value, or any other technical effect listed in § 170.3(o) of this chapter, to the food and must retain that attribute when consumed at levels that are necessary to justify a claim; and

* * * * *

(d) * * *

(3) Nutrition labeling shall be provided in the label or labeling of any food for which a health claim is made in accordance with § 101.9; for restaurant foods, in accordance with § 101.10; or for dietary supplements, in accordance with § 101.36.

* * * * *

4. Section 101.54 is amended by revising paragraphs (b)(1), (c)(1), and the introductory text of paragraph (e)(1) to read as follows:

§ 101.54 Nutrient content claims for ''good source,'' ''high,'' and ''more.''

* * * * *

(b) ''*High*'' *claims.* (1) The terms ''high,'' ''rich in,'' or ''excellent source of'' may be used on the label and in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that the food contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

* * * * *

(c) ''*Good Source*'' *claims.* (1) The terms ''good source,'' ''contains,'' or ''provides'' may be used on the label and in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that the food contains 10 to 19 percent of the RDI or the DRV per reference amount customarily consumed.

* * * * *

(e) ''*More*'' *claims.* (1) A relative claim using the terms ''more,'' ''fortified,'' ''enriched,'' and ''added'' may be used on the label or in labeling of foods to describe the level of protein, vitamins, minerals, dietary fiber, or potassium, except as limited by § 101.13(j)(1)(i) and except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

* * * * *

5. New § 101.93 is amended by adding paragraphs (b) through (e) to read as follows:

§ 101.93 Notification procedures for certain types of statements on dietary supplements.

(a) * * *

(b) *Disclaimer.* The requirements in this section apply to the label or labeling of dietary supplements where the dietary supplement bears a statement that is provided for by section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), and the manufacturer, packer, or distributor wishes to take advantage of the exemption to section 201(g)(1)(C) of the act that is provided by compliance with section 403(r)(6) of the act.

(c) *Text for disclaimer.* (1) Where there is one statement, the disclaimer shall be placed in accordance with

paragraph (d) of this section and shall state:

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(2) Where there is more than one such statement on the label or in the labeling, each statement shall bear the disclaimer in accordance with paragraph (c)(1) of this section, or a plural disclaimer may be placed in accordance with paragraph (d) of this section and shall state:

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(d) *Placement.* The disclaimer shall be placed adjacent to the statement with no intervening material or linked to the statement with a symbol (e.g., an asterisk) at the end of each such statement that refers to the same symbol placed adjacent to the disclaimer specified in paragraphs (c)(1) or (c)(2) of this section. On product labels and in labeling (e.g., pamphlets, catalogs), the disclaimer shall appear on each panel or page where there such is a statement. The disclaimer shall be set off in a box where it is not adjacent to the statement in question.

(e) *Typesize.* The disclaimer in paragraph (c) of this section shall appear in boldface type in letters of a typesize no smaller than one-sixteenth inch.

Dated: September 11, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–24730 Filed 9–22–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 95N–0245, 95N–0282, and 95N–0347]

RIN 0905–AD96

Food Labeling; Nutrient Content Claims: Definition for ''High Potency'' and Definition of ''Antioxidant'' for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to: Define the term ''high potency'' as a nutrient content claim; define nutrient content claims using the term ''antioxidant'' (e.g., ''good source of antioxidants,'' ''high in antioxidants,'' ''more antioxidants''); and to correct an omission pertaining to the use of ''sugar free'' claims on dietary supplements. FDA is taking these actions to provide for the use of additional nutrient content claims on labels or in labeling in accordance with provisions of the Nutrition Labeling and Education Act of 1990.

EFFECTIVE DATE: March 23, 1999.

FOR FURTHER INFORMATION CONTACT: Camille E. Brewer, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5483.

I. Background

On June 18, 1993 (58 FR 33731), FDA published a proposal entitled ''Food Labeling; Requirements for Nutrient Content Claims for Dietary Supplements of Vitamins, Minerals, Herbs, and Other Similar Nutritional Substances'' (hereinafter referred to as the 1993 nutrient content claims proposal). In that proposal FDA requested comment on several terms, including ''high potency'' that are often encountered on labels or in labeling of dietary supplements and that seem to imply that the dietary supplement will contribute to good health (58 FR 33731 at 33748). The agency requested comment on whether there were established meanings for these terms, and, if so, whether they characterized the level of the nutrients in the food and thus should be considered to be nutrient content claims. In 1994, in its final rule in the nutrient content claims proceeding (hereinafter referred to as the 1994 nutrient content claims final rule), based on the comments that it received, FDA determined that ''high potency'' is a claim that characterizes the level of a nutrient or nutrients and, therefore, meets the definition of a nutrient content claim in § 101.13(b) (21 CFR 101.13(b)) (59 FR 378 at 391, January 4, 1994).

One comment to the 1993 nutrient content claims proposal stated that FDA failed to address whether certain claims regarding antioxidants were within the scope of the proposed regulation. In the 1994 nutrient content claims final rule, the agency stated that while such claims were not explicitly discussed in the 1993 nutrient content claims proposal, they also are nutrient content claims (59 FR 378 at 389).

However, given the time constraints under which FDA prepared the 1994 nutrient content claims final rule, the agency was not able to adopt a definition either for ''high potency'' or for nutrient content claims for antioxidants. FDA announced its intention to review the suggestions for a definition of ''high potency'' and ''antioxidant'' claims and, based on information received in the comments, to propose an appropriate definition for these terms (59 FR 378 at 391). In the **Federal Register** of December 28, 1995 (60 FR 67184), the agency published a proposed rule entitled ''Nutrient Content Claims: Definition for 'High Potency' Claim for Dietary Supplements and Definition of 'Antioxidant' for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods'' (hereinafter referred to as the high potency/antioxidant proposal).

The agency received approximately 70 comments in response to the high potency/antioxidant proposal. A number of comments supported the proposal, while others disagreed with various aspects of the proposal. A few comments addressed issues that are outside the scope of this rulemaking. A summary of the comments, the agency's responses to the comments, and a discussion of the agency's conclusions follow.

II. High Potency

In the high potency/antioxidant proposal, FDA proposed that the term ''high potency'' may be used on the labels or in the labeling of dietary supplements to describe a nutrient that is present at 100 percent or more of the Reference Daily Intake (RDI) for vitamins and minerals, or of the Daily Reference Value (DRV) for protein and dietary fiber, per reference amount customarily consumed. To describe multinutrient products as ''high potency,'' FDA proposed that at least two-thirds of the nutrients in a product must be present at 100 percent of the RDI for vitamins and minerals or of the DRV for protein and dietary fiber per reference amount customarily consumed.

A. ''High Potency'' as a Nutrient Content Claim

1. The majority of the comments agreed that ''high potency'' is a nutrient content claim. These comments stated that the agency's definition has a basis in the labeling practices of the dietary supplement industry, and that consumers are already familiar with this definition. Some comments stated that the term ''high potency'' is commonly understood to describe the level of a nutrient or nutrients in a product, particularly on dietary supplements of vitamins and minerals.

On the other hand, a few comments stated that ''high potency'' is not a