product alternative)'' * * *) may be made on the label or in labeling of dietary supplements without a regulation that specifically defines such a statement. * * *

Because this provision allows for an exemption to the nutrient content claims rules and is somewhat similar to the exemption in § 101.13(q)(3) for percentage statements for vitamins and minerals, the agency is placing the new paragraph in § 101.13(q)(3) by redesignating current § 101.13(q)(3) as § 101.13(q)(3)(i) and adding new § 101.13(q)(3)(ii).

The agency believes that percentage statements on the label or in labeling of a dietary supplement 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, such as ''100 percent of the allicin in a bulb of garlic'' and ''twice the allicin as (name of product alternative),'' 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 both foods being compared and a meaningful difference between the two foods being contrasted. However, because many dietary ingredients, which are the subject of clause (F), do not have established reference amounts for daily consumption, there is not a single, consistent way to describe the amount or difference that would be considered meaningful for the broad spectrum of these dietary ingredients. Therefore, firms will need to determine on a case-by-case basis whether the stated amount of a dietary ingredient for which an RDI or DRV has not been established, and the difference between the amount of such a dietary ingredient in two products, is meaningful. In making such a determination, published literature on the dietary ingredient, knowledge of the functional properties of the dietary ingredient, and any additional information available to the manufacturer, packer, or distributor should be taken into account.

It should be noted that while FDA is proposing in § 101.13(q)(3)(ii) to provide for statements that characterize the percentage level of dietary ingredients for which no RDI or DRV has been established, the proposed regulations do not provide for use of the defined terms, such as ''more,'' ''good source,'' ''high,'' and ''as much as.'' For example, the statement ''300 percent of the bioflavonoids in a large grapefruit'' is permissible, but a claim such as ''high in bioflavonoids'' is not. As discussed in the nutrient content claims for dietary supplements proposal and final rule, FDA has concluded that if the defined term (i.e., the nutrient content claim) is to have any meaning, there must be a level that can be used as a reference in determining whether the claim is valid and appropriate. The RDI's and DRV's provide such levels. Thus, FDA has limited the use of ''good source,'' ''high,'' and other defined terms to use with nutrients for which RDI's or DRV's have been established.

By way of exception, ''contains'' and ''provides'' are listed in § 101.54(c)(1) (21 CFR 101.54(c)(1)) as synonyms for ''good source'' (e.g., ''Contains vitamin C'' is considered synonymous with ''good source of vitamin C'') and are therefore dependent on the establishment of an RDI or DRV for the nutrient to qualify for the claim. However, the agency has stated that these words may be used with nutrients that do not have RDI's or DRV's when specific amounts are given for the nutrient (Ref. 1, p. 37, C24). Accordingly, the agency has no objection to statements such as ''Contains 4 grams of omega-3 fatty acids per serving'' being made for dietary ingredients for which RDI's and DRV's have not been established provided the specific amount of the nutrient is stated.

It should be noted that section 403(r)(2)(F) of the act applies only to dietary supplements. Congress did not provide this exemption for conventional foods. Therefore, except for the statements discussed in the preceding paragraph that come under § 101.13(i)(3), statements that characterize the level of a dietary ingredient without an established RDI or DRV will continue to be prohibited on conventional foods.

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) for referral statements (i.e., ''See *[location]* for nutrition information'') or from other requirements for nutrient content claims. Accordingly, FDA is proposing to require in § 101.13(q)(3)(ii) that a referral statement (or disclosure statement when fat, saturated fat, cholesterol, or sodium exceed specified limits) accompany the claim in accordance with § 101.13 (g) or (h).

In addition, the agency tentatively concludes that when percentage statements are made comparing or contrasting the amount of a dietary ingredient for which an RDI or DRV has not been established in a dietary supplement to that in a reference food, information on the identity of the reference food and on the quantitative amount of the dietary ingredient in both foods are material facts. Consumers need this information to evaluate and understand the claim being made, and the claim would be misleading under sections 403(a) and 201(n) of the act without it (see 56 FR 60421 at 60446, and 58 FR 2302 at 2365). This situation is analogous to that encountered with relative claims for nutrients, where there is a requirement in § 101.13(j)(2)(iv) for quantitative information comparing the amount of the subject nutrient in the product with that in the reference food. Inclusion of this information is particularly important because, while the nutrition label on dietary supplements will include information about the amount of dietary ingredients for which RDI's and DRV's have not been established that are present in the food (see proposed § 101.36(b)(3) 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), the nutrition label on conventional foods will not (except for nutrients provided for in § 101.9(c) such as sugars and polyunsaturated fat that do not have RDI's and DRV's established). Accordingly, when conventional foods are used as the reference food, information about the amount of a dietary ingredient for which there is no RDI or DRV that is present in the food is likely to only be available when it is provided as accompanying information, in accordance with § 101.13(j)(2)(iv).

For these reasons, FDA is proposing in § 101.13(q)(3)(ii) to require that whenever statements characterizing the percentage level of a dietary ingredient for which there is no RDI or DRV are made in comparison to the amount in a reference food, the reference food be clearly identified, and information on the actual amount of the dietary ingredient in both foods be provided in accordance with § 101.13(j)(2)(iv). Section 101.13(j)(2)(iv)(B) requires that this quantitative information be placed adjacent to the most prominent claim or to the nutrition label, except that when the nutrition label is on the information panel, the quantitative information may be placed elsewhere on that panel in accordance with § 101.2 (21 CFR 101.2) (see 60 FR 17202, April 5, 1995).