and that are offered for sale, including conventional foods and dietary supplements.''

2. Health Claims

Under the general principles governing health claims, § 101.14(a)(4) (21 CFR 101.14(a)(4)) currently states that ''dietary supplement'' means a food, not in conventional food form, that supplies a component to supplement the diet by increasing the total dietary intake of that component. This definition has been superseded by the definition of ''dietary supplement'' found in new section 201(ff) of the act. Further, because section 201(ff)(2)(A) makes it clear that dietary supplements can be in a variety of forms, including conventional food form, FDA is proposing to remove § 101.14(a)(4) and redesignate current § 101.14 (a)(5) and (a)(6) as § 101.14 (a)(4) and (a)(5), respectively.

A similar conforming change is necessary in § 101.14(b)(3)(i) in the preliminary requirements for a substance to be eligible to be the subject of a health claim. This regulation refers to the fact that the food in which a substance is found may be ''in conventional food form or dietary supplement form.''

To bring this section into conformance with section 201(ff) of the act, FDA is proposing to revise § 101.14(b)(3)(i) to read as follows:

> 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 * * *.

Section § 101.14(d)(3) currently states:

> 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 of vitamins or minerals, in accordance with § 101.36. The requirements of the introductory text of paragraph (d)(3) of this section are effective as of May 8, 1993, except:
>
> (i)–(ii) [Reserved]
>
> (iii) For dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances for which the requirements of paragraph (d)(3) of this section will be effective July 5, 1994.

In the Federal Register of March 31, 1994 (59 FR 15050), the effective date was corrected for the nutrient content claims provision to July 1, 1994. Because of the passage of the DSHEA, the agency published a notice in the Federal Register of February 9, 1995 (60 FR 7711), stating that it does not intend to enforce the Nutrient Content Claim regulations for dietary supplements until after December 31, 1996.

As above, the terminology for dietary supplements (i.e., ''dietary supplements of vitamins and minerals'') used in § 101.14(d)(3) is too narrowly drawn in light of new section 201(ff) of the act. In addition, since the effective date is past, there is no longer a need to include it in the regulations. Therefore, FDA is proposing to revise § 101.14(d)(3) to remove ''of vitamins and minerals'' as a qualifier of the types of dietary supplements and to remove the language setting out the effective date in the second sentence of § 101.14(d)(3). These changes also mean that there is no need for paragraphs (d)(3)(i) through (d)(3)(iii). Accordingly, proposed § 101.14(d)(3) reads as follows:

> 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.

C. 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. Thus, section 403(r)(2)(A)(i) of the act limits the type of nutrient content claims that can be made to those terms that are defined and authorized by regulation. The effect of section 403(r)(2)(F) of the act is to permit the use on the labels or in the labeling of dietary supplements of statements that have not been defined by FDA that characterize the percentage level of a dietary ingredient for which an RDI or DRV has not been established.

In the absence of any substantive legislative history on this provision, the agency interprets section 403(r)(2)(F) of the act as authorizing claims on the label or in labeling of a dietary supplement that disclose the percentage level in the dietary supplement of a dietary ingredient for which an RDI and DRV has not been established in a product (e.g., ''40 percent omega-3 fatty acids'') as well as statements that characterize the percentage of such dietary ingredients in relation to an equivalent or increased/decreased amount found in another food product (e.g., ''100 percent of the allicin in a bulb of garlic,'' ''twice the allicin as (product alternative)'' [where ''twice'' is another way of saying 200 percent]).

Section 3(b)(1)(A)(iv) of the 1990 amendments directed the agency to promulgate regulations that permit statements describing the amount and percentage of nutrients in food that are not misleading and that are consistent with the terms defined under section 403(r)(2)(A)(i) of the act. Consequently, FDA provided in § 101.13(i) for statements about the amount or percentage of nutrients when specified criteria are met. While this regulation did not specifically include a provision for the use of such statements with respect to dietary ingredients for which no RDI or DRV had been established, § 101.13(i)(3) allowed for the use of amount or percentage statements that do not implicitly characterize the level of the nutrient in the food (e.g., claims that do not imply whether the amount is high or low based on an established RDI or DRV value), and that are not misleading in any way. In ''Food Labeling, Questions and Answers'' (Ref. 1, p. 36, C23), FDA stated that statements about a nutrient for which there is no established daily value (i.e., no RDI or DRV) could be made under § 101.13(i)(3) as long as the claim specifies only the amount of the nutrient per serving and does not imply that there is a lot or a little of that nutrient in the product. The example ''x grams of omega-3 fatty acids'' was given.

Accordingly, percentage claims such as ''40 percent omega-3 fatty acids'' that do not in any way characterize the level of a nutrient in terms of defined claims such as ''high,'' ''low,'' or ''reduced'' were permitted on dietary supplements as well as conventional foods before the enactment of the DSHEA. To memorialize this fact and to implement the DSHEA by reflecting that labels or labeling of dietary supplements may bear statements that characterize the percentage level of a dietary ingredient for which an RDI or DRV has not been established even though those statements have not been defined by FDA, the agency is proposing to amend § 101.13 by adding new paragraph (q)(3)(ii) to read as follows:

> Under section 403(r)(2)(F) of the act, a statement that characterizes the percentage level of a dietary ingredient for which an RDI or daily reference value (DRV) has not been established (e.g., ''40 percent omega-3 fatty acids,'' ''100 percent of the allicin in a bulb of garlic,'' or ''twice the allicin as (name of