

All other requirements for the listing of dietary ingredients remain in effect for dietary supplements containing, or consisting solely of, a proprietary blend. For example, under proposed § 101.36(c)(3), the total weight must be specified to the right (beneath the column of amounts described in paragraph (b)(2)(ii) of § 101.36), and the symbol (e.g., asterisk) referring to the statement "Daily Value not established" must be placed in the column under the heading of "% Daily Value," if present, or immediately following the quantitative amount by weight for the proprietary blend.

In addition, the agency is proposing to require that a dietary supplement containing a proprietary blend comply with § 101.36(b)(2) (§ 101.36(c)(1)). If the proprietary blend furnishes more than insignificant amounts of any required (b)(2)-dietary ingredients (i.e., calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, sugars, dietary fiber, protein, vitamin A, vitamin C, calcium, iron, or any other dietary ingredient listed in proposed § 101.36(b)(2)(i) that is added for purposes of supplementation or about which claims are made), that dietary ingredient must be declared, as well as the amount of the ingredient and the percent of the Daily Value that the supplement supplies. While FDA recognizes some ambiguity in the language of section 403 (q)(5)(F)(ii) and (s)(2)(ii)(II) of the act, the agency tentatively concludes that an interpretation of these provisions of the act to mean that amounts of (b)(2)-dietary ingredients need not be listed individually, but rather be included in the total weight of the proprietary blend, would be inconsistent with section 403(q)(5)(F) of the act, which states that dietary supplement products "shall comply with the requirements of subparagraphs (1) and (2)," albeit in a manner which is appropriate for the product. Section 403(q)(1) and (q)(2) of the act require the listing of the individual nutrients determined by the Secretary to assist consumers in maintaining healthy dietary practices. FDA tentatively concludes that it would be contrary to the intent of the 1990 amendments to fail to list nutrients such as calories, total fat, sodium, or vitamin C, when present, in the nutrition labeling of dietary supplements containing proprietary blends.

Inasmuch as FDA is proposing that any (b)(2)-dietary ingredients present in the proprietary blend be listed in accordance with § 101.36(b)(2) (e.g., above the heavy bar separating (b)(2)-dietary ingredients and other dietary ingredients), these (b)(2)-dietary

ingredients in the blend would not need to be listed a second time under the term "Proprietary Blend" and, if not listed, would not be included in the weight specified for such blend.

G. Information on the Source of a Dietary Ingredient and Other Ingredient Labeling Issues

In response to sections 403 (q)(5)(F)(iii) and (q)(5)(F)(iv) of the act, which were added by the DSHEA, FDA is proposing in new § 101.36(d) to allow the source of a dietary ingredient to be declared in the nutrition label. Section 403(q)(5)(F)(iii) of the act states that "the listing of dietary ingredients may include the source of a dietary ingredient," and subclause (iv) states that "the nutrition information shall immediately precede the ingredient information required under subclause (i), except that no ingredient identified pursuant to subclause (i) shall be required to be identified a second time." With respect to subclause (iv), the agency observes that it has received questions regarding the intent of the phrase "except that no ingredient identified pursuant to subclause (i) shall be required to be identified a second time." The agency acknowledges that the meaning of this phrase is not clear and has speculated whether the reference to "subclause (i)" is intended to refer to section 403(i) of the act. Given this ambiguity, the agency is interpreting subclause (iv) to mean that any ingredient listed in the nutrition label need not be listed a second time in the ingredient statement required in § 101.4. For example, under the agency's proposal, if an ingredient such as calcium carbonate is listed as the source of "calcium" in the nutrition information, it would not need to be listed again in the ingredient statement. Accordingly, the agency is proposing to revise § 101.4(a)(1) to provide that any ingredient of a dietary supplement that is listed in the nutrition label in accordance with proposed § 101.36(d) (i.e., inside the box) need not be repeated in the ingredient list.

The agency notes that one of the analyses of the DSHEA that it has received addressed section 403(q)(5)(F)(iv) of the act in detail (Ref. 4). The analysis stated: "The listing [of dietary ingredients] can also include the source ingredient of the dietary ingredient, and the traditional ingredient declaration need not repeat those ingredients (although a technical correction is needed so that the first cross reference in section 403(q)(5)(F)(iv) of the act is to 'subsection (i)' rather than to 'subclause(i)')." Hence, this analysis is

suggesting the first cross reference is to section 403(i) of the act that deals with the ingredient statement that is required in § 101.4. This analysis is consistent with FDA's interpretation that: (1) A source ingredient may be included in the nutrition information, (2) the nutrition information must immediately precede the ingredient statement required in § 101.4, and (3) no ingredient listed in the nutrition label is required to be declared a second time in the ingredient statement.

Accordingly, the agency is proposing in § 101.36(d) that the source of any dietary ingredient (i.e., the ingredient supplying the dietary ingredient) may be added in parentheses immediately following or indented beneath the name of the dietary ingredient, and that the words "as" or "from" must precede the name of the source ingredient, e.g., "calcium (as calcium carbonate)" or "calcium (from oyster shell powder)." By way of exception, the agency is proposing that, if the name of the dietary ingredient (e.g., Siberian ginseng) or its synonym (e.g., ascorbic acid as a synonym for vitamin C) is itself the source ingredient, the listing of the dietary ingredient will fulfill the requirement for the listing of the ingredient. In regard to the use of the words "as" or "from," many dietary supplements in the marketplace currently use such terminology. The agency tentatively concludes that these words will help to convey to consumers the understanding that such compounds are the source of the dietary ingredients.

If this proposal becomes final, when a source is disclosed in parentheses in the nutrition label, or when the name of a dietary ingredient or its synonym (e.g., ascorbic acid) is itself the source ingredient, the ingredient need not be listed in the ingredient statement that is required under section 403(i)(2) of the act. When a source is not identified within the nutrition label, proposed § 101.36(d) provides that it shall be listed in the ingredient statement in accordance with proposed § 101.4(g).

Under proposed § 101.4(g), the ingredient statement on a dietary supplement shall appear outside and immediately below the nutrition label or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label. This provision is in accordance with section 403(q)(5)(F)(iv) of the act, which was added by the DSHEA. It requires that the nutrition information immediately precede the ingredient information. The agency tentatively concludes that when there is insufficient space below the nutrition label, it is appropriate to allow the