names among all identical or similar products could be seriously compromised unless the term ''dietary supplement'' is included in the common or usual name of such a supplement. As explained below, the potential for compromising this requirement would be particularly great where dietary supplements are in other than tablet, capsule, powder, softgel, gelcap, or liquid form. Finally, use of this term as part of the statement of identity of dietary supplements will distinguish this potentially broad class of products from other types of food.

New section 201(ff)(2) of the act provides that a ''dietary supplement'' is a product that is not represented for use as a conventional food. At the same time, the DSHEA 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.) As a result of the latter change, however, there may now be dietary supplements for which the presence of the term ''dietary supplement'' constitutes the primary, if not the only, means by which consumers will be able to determine that the food is a dietary supplement. Under such circumstances, it seems imperative that the term ''dietary supplement'' appear in the statement of identity.

For the foregoing reasons, FDA is proposing to add § 101.3(g), which states that products marketed as dietary supplements shall bear the term ''dietary supplement'' as part of their statement of identity, to its regulations.

III. Provisions of Proposed § 101.36

A. Foods Covered by § 101.36

The agency is proposing to revise § 101.36(a) to state that the label of a dietary supplement shall bear nutrition labeling in accordance with § 101.36, unless an exemption is provided for the product in § 101.36(h). Previously, only dietary supplements of vitamins and minerals were subject to the provisions of § 101.36. As stated above, dietary supplements of herbs and other similar nutritional substances were to follow the general nutrition labeling requirements in § 101.9. This separation was in accordance with section 403(q)(5)(F) of the act as passed in the 1990 amendments, which instructed the Secretary to issue nutrition labeling regulations appropriate for dietary supplements of vitamins and minerals.

However, the DSHEA revised 403(q)(5)(F) of the act to provide that it covers all dietary supplements, that is, all products that meet the definition in section 201(ff) of the act. Consequently, the agency is proposing to amend § 101.36(a) to reflect this change.

B. General Requirements

In § 101.36(b), the agency is proposing to require that nutrition information on dietary supplements include the information specified in this section of the regulations, and that it be presented in the format specified in proposed § 101.36(e). These proposed requirements reflect the requirements in section 403(q)(1) of the act and in section 2(b)(1)(A) of the 1990 amendments, which states that the information required under section 403(q) is to ''be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of the total daily diet.''

The agency notes that it has been asked whether current § 101.36(b) is to be interpreted as requiring nutrition labeling in all dietary supplement labeling (i.e., printed material accompanying a product) as well as on the label attached to a product. The agency advises that it does not intend that nutrition labeling appear on all labeling. It generally must appear on the label of dietary supplement products, although there may be circumstances in which it appears in labeling in lieu of the label. When nutrition labeling is presented, however, it must conform to the requirements of § 101.36.

C. Serving Size

Proposed § 101.36 (b)(1)(i) and (b)(1)(ii) on serving size and on servings per container, respectively, differ only slightly from current § 101.36 (b)(1) and (b)(2). In the first sentence of proposed § 101.36(b)(1)(i), the agency is stating that the subheading ''Serving Size'' is to be placed under the heading of ''Supplement Facts.'' The agency is proposing to include the name of the heading (i.e., ''Supplement Facts'') in § 101.36(b)(1)(i) for clarity.

On a related note, the agency points out that it is proposing to change the language in § 101.12(b), Table 2, to read ''Dietary supplements'' instead of ''Dietary supplements not in conventional food form'' in response to the DSHEA. The language in current § 101.12(b) reflected the DS act, which, in its legislative history, made clear that the moratorium it effected applied only to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances not in the form of conventional food. (See 138 Congressional Record S17240 (Joint Statement Senators Kennedy and Hatch) (October 7, 1992).) The DSHEA, however, evidences an intent, for labeling purposes, to treat all dietary supplements in a similar manner. In particular, section 7 of the DSHEA addresses dietary supplement labeling and does not distinguish between dietary supplements that are not in conventional food form and those that are. Therefore, FDA is proposing to amend § 101.12(b), Table 2, to reflect this development.

D. Requirements for Dietary Ingredients Having Recommendations for Daily Consumption

The DSHEA added four subclauses to section 403(q)(5)(F) of the act. Subclause (i) states that the Secretary (and, by delegation, FDA) shall provide by regulation that the nutrition information on dietary supplements first list those dietary ingredients that are present in the product in a significant amount and for which a recommendation for daily consumption has been established by the Secretary, except that a dietary ingredient shall not be required to be listed if it is not present in a significant amount, and shall list any other dietary ingredient present and identified as having no such recommendation. The agency tentatively concludes that by a dietary ingredient ''for which a recommendation for daily consumption has been established by the Secretary,'' the DSHEA is referring to a nutrient having an RDI as established in § 101.9 (c)(7)(iii) and (c)(8)(iv) or a Daily Reference Value (DRV) as established in § 101.9 (c)(7)(iii) and (c)(9).

The requirement in section 403(q)(5)(F)(i) of the act that the dietary ingredients for which there are no RDI's or DRV's be listed in the nutrition label following the listing of dietary ingredients for which RDI's or DRV's have been established necessitates changes in the organization of § 101.36. The agency is therefore consolidating all of the information required in the listing of dietary ingredients for which RDI's or DRV's have been established under proposed § 101.36(b)(2) and the information required in the listing of other dietary ingredients in proposed § 101.36(b)(3). (See section III. E. of this document.)

1. Listing of Dietary Ingredients for Which RDI's and DRV's Have Been Established

With respect to the listing of dietary ingredients for which RDI's and DRV's have been established, the agency tentatively concludes that no major change in the 1994 dietary supplement final rule is needed as a result of the DSHEA. The agency is proposing in § 101.36(b)(2)(i) that the 14 nutrients