Location Requirements. The agency recognizes that in some cases individual dietary ingredients may conform to compendial specifications even though the entire product does not. Thus, the agency is proposing in § 101.36(d)(3) to allow individual dietary ingredients to be so represented.

If such a representation is made, and the ingredient does not comply with the specifications of the official compendium, the supplement would be misbranded under 403(a) of the act. The agency notes that section 403(s)(2)(D) of the act provides that a dietary supplement is misbranded if it is represented as complying with an official compendium and fails to do so. Proposed § 101.36(d)(3) applies to representations about a particular ingredient and not the entire supplement, as does section 403(s)(2)(D) of the act.

H. Format Requirements

As stated above, the agency continues to believe that consistency in the presentation of nutrition information on all foods will help consumers observe and comprehend such information, as required by section 2(b)(1)(A) of the 1990 amendments. Accordingly, FDA is proposing in § 101.36(e) that the information required in proposed § 101.36 (b) and (c) be presented in a manner that is similar to the requirements listed in § 101.9(d) for conventional foods, as well as those in current § 101.36 for dietary supplements of vitamins and minerals. In this rulemaking, the agency is proposing to alter slightly the organization in current § 101.36 to combine all format requirements in proposed § 101.36(e), all exemptions in § 101.36(h), and all special labeling provisions (such as those for small or intermediate-sized containers) in § 101.36(i), respectively.

Despite the desire for consistency in the appearance of nutrition information on dietary supplements and conventional foods, the requirements adopted in the DSHEA, such as the listing of the names and amounts of other dietary ingredients and the optional listing of source information, necessitate that there be some differences in format. Accordingly, to signal to consumers that nutrition labeling on dietary supplements differs in several significant respects from that on conventional foods, FDA is proposing in § 101.36(e)(1) that the title for the nutrition information on packages of dietary supplements be ''Supplement Facts.'' The agency tentatively concludes that the title ''Supplement Facts'' and the proposed format structure are sufficiently similar to the title ''Nutrition Facts'' and the format requirements used in nutrition labeling of conventional foods for the consumer to immediately recognize that the information in the two boxes is related. However, by the use of a different name, the consumer can be taught to recognize the basic structural differences in nutrition information on the two different types of food products. For example, the nutrition information on dietary supplements will have the quantitative amounts by weight located in a separate column; may include source ingredients; and may not have a ''% Daily Value'' column if no dietary ingredients having RDI's or DRV's are present in the product. Comments are requested on the appropriateness of the title ''Supplement Facts.''

FDA is proposing in § 101.36 (e)(1) through (e)(3) to maintain the graphic requirements in current § 101.36(b) and (c)(1) through (c)(5). These sections require the use of the largest type size within the nutrition label for the title; bolding of the title and column headings; a hairline box around the nutrition label; a single easy-to-read type style; all black or one color type on a white or other neutral contrasting background, whenever practical; upper and lower case letters, except on very small packages; at least one point leading; and letters that do not touch. The agency is retaining these requirements because they are responsible, in large measure, for the appearance of the nutrition label and are designed to maximize the legibility of the label.

The agency is addressing type size requirements in proposed § 101.36(e)(4). Current § 101.36(c)(6) requires that: (1) packages with less than 12 square inches of total surface area available to bear labeling (i.e., small-sized packages) use a type size no smaller than 4.5 point for the nutrition label, (2) packages with 12 to 40 square inches of total surface area available to bear labeling (i.e., intermediate-sized packages) use a type size no smaller than 6 point, and (3) packages with more than 40 square inches of total surface area available to bear labeling use type size no smaller than 8 point, except that these larger packages could use 6 point type for column headings, footnotes, and information on beta-carotene, when present. Because the DSHEA does not necessitate any changes in type size, the agency is proposing in § 101.36(e)(4) to carry forward the requirement for larger-sized packages of 8 point type with 6 point type for column headings and footnotes. (The agency is not proposing to carry forward 6 point type for the information on beta-carotene because the agency tentatively concludes that the type size for all dietary ingredients should be uniform.) To be more consistent with the organization of § 101.9, FDA is proposing to move the exceptions in type size for small and intermediate-sized packages to § 101.36(i)(2). The agency will discuss these exceptions under section III.J. of this document.

Proposed § 101.36(e)(5) requires a hairline rule between the listing of each dietary ingredient. This requirement is identical to that in current § 101.36(c)(7). Following publication of the 1994 dietary supplement final rule, the agency received comment on this requirement and on the effect that the multiple hairlines could have on the legibility of labels of products with large numbers of dietary ingredients, where labels have severe space constraints, and where the minimum type size (i.e., 4.5 point type) is used. FDA requests comments on the use of hairlines to separate the dietary ingredients listed. Such comments will be particularly helpful if actual sample labels are included as well as suggestions for when relief from such a requirement should be provided, e.g., should hairlines be omitted when more than 8 (or some other number) dietary ingredients that qualify to use 4.5 point type are listed? Comments should set out in detail the basis for their recommendations.

Comments received by the agency since publication of the 1994 dietary supplement final rule suggest that there is some confusion about the relative size of bars used to separate parts of the nutrition label, and whether the bars are required by regulation. It appears that many persons were unable to find the regulatory references to the bars in current § 101.36 (b)(3), (b)(3)(ii), and (b)(4). Therefore, FDA is proposing to focus two paragraphs, § 101.36 (e)(6) and (e)(7), specifically on bars, rather than addressing them as ancillary issues in broader provisions. These paragraphs identify the points in the label format where bars are required and differentiate the thickness of the bars (i.e., ''heavy bars'' versus ''light bars'').

In proposed § 101.36(e)(6), the agency is requiring that a heavy bar be placed beneath the subheading ''Serving Size'' or the subheading ''Servings Per Container'' when it is required, beneath the last dietary ingredient to be listed in proposed § 101.36(b)(2)(i), and beneath the last other dietary ingredient to be listed in proposed § 101.36(b)(3). Also, in proposed § 101.36(e)(7), the agency is proposing that a light bar be placed beneath the headings ''Amount Per Serving'' and ''% Daily Value,'' which