The agency is proposing, however, to amend § 101.2 (b) and (f) to include § 101.36 among the list of sections noted. Section 101.2(b) states that the information required to appear under the sections noted shall appear either on the principal display panel or the information panel unless otherwise specified by regulation. Section 101.2(f) provides that when the label of any package is too small to accommodate all of the information required under the sections noted, FDA may establish by regulation an acceptable alternative method of disseminating such information to the public (e.g., by the use of smaller type size).

FDA is proposing a special labeling provision in proposed § 101.36(i)(2)(iii) for dietary supplements in packages that have a surface area available to bear labeling of 40 or less square inches. Under this provision, when the nutrition label on packages of this size is presented on a label panel other than the principal display or information panels, as allowed in § 101.9(j)(13)(ii)(D), the ingredient information must move in conjunction with the nutrition label. This provision is in response to section 403(q)(5)(F)(iv) of the act as added by the DSHEA, which states that nutrition information shall immediately precede the ingredient information.

In proposed § 101.36(i)(2)(iv), the agency is providing additional flexibility for dietary supplements in packages that have a surface area available to bear labeling of 40 or less square inches. When it is not possible for primary (inner) containers of this size to comply with the type size requirements, the agency is proposing that type as small as needed may be used in the nutrition label as long as the primary container is securely enclosed in outer packaging that bears nutrition labeling in required type size. In the preamble of the 1994 dietary supplement final rule (59 FR 354 at 367), the agency erroneously advised that it considered outer packaging that securely encloses a primary container and that is not intended to be separated from the primary container under conditions of retail sale to be the equivalent of the product label. In these situations, the agency stated that manufacturers did not have to repeat the nutrition information on the primary container, although it encouraged them to do so to give consumers easy access to the information once the container is removed from the outer packaging. These statements were inconsistent with section 201(k) of the act which defines the term ''label'' as ''* * * a display of written, printed, or graphic matter upon the immediate container of any article * * *'' as well as with previous agency policy that requires that other required information appear on the primary container (e.g., statement of identity, quantity of contents, name and place of business of the manufacturer, packer, or distributor). Therefore, nutrition labeling is required to appear on the label of the primary container. However, consistent with FDA's intent in the preamble of the 1994 dietary supplement final rule to allow flexibility, the agency is proposing in § 101.36(i)(2)(iv) that when nutrition labeling is presented in required type size on outer packaging that securely encloses a primary container and is not intended to be separated from the primary container under conditions of retail sale, the nutrition labeling on the primary container may use type size as small as needed to accommodate all of the required information on the label.

FDA is proposing to carry forward the special labeling provisions in current § 101.36(g) for foods in multiunit containers in proposed § 101.36(i)(3) and for foods sold in bulk containers in proposed § 101.36(i)(4).

FDA is proposing to add a special labeling provision in proposed § 101.36(i)(5) for foods in packages that have a total surface area available to bear labeling greater than 40 square inches but whose principal display panel and information panel do not provide sufficient space to accommodate all required label information. This provision cross references § 101.9(j)(17), which was recently added to the regulations (60 FR 17202, April 5, 1995) and allows the nutrition label on such packages to be placed on any alternate panel that can be readily seen by consumers. However, as previously discussed, ingredient information must move in conjunction with the nutrition label. Accordingly, proposed § 101.36(i)(5) includes an exception to § 101.9(j)(17) whereby the ingredient list would continue to be located immediately beneath the nutrition label, or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label as proposed in § 101.4(g).

K. Misbranding Provisions

Current § 101.36(h), redesignated as § 101.36(j) in this proposed rulemaking, cross references the misbranding provisions of § 101.9(k) that were first proposed in the Federal Register of March 30, 1972 (37 FR 6493) and that were issued and published in the Federal Register of January 19, 1973 (38 FR 2125). These provisions were based on findings of fact and conclusions of law resulting from 1968–1970 Special Dietary Hearings (38 FR 2143). Following a comment period, these regulations were modified and published as final regulations in § 1.17 (i)(2) through (i)(6) on March 14, 1973 (38 FR 6961). In the reorganization and republication of Title 21 of the Code of Federal Regulations that appeared in the Federal Register of March 15, 1977 (42 FR 14308), § 1.17(i) was recodified as § 101.9(i).

No changes were made to the original codified language of the subject paragraphs until regulations implementing the 1990 amendments were published on January 6, 1993, at which time FDA redesignated the paragraphs as § 101.9(k) and modified § 101.9(k)(1) to incorporate a reference to the general requirements for health claims in §§ 101.14 and 101.9(k)(5) in response to requests to remove restrictions about the incorporation of substances such as rutin, inositol, and other similar substances to conventional foods or dietary supplements (38 FR 2478 at 2502 and 38 FR 2079 at 2166, respectively).

The current misbranding provisions in § 101.9(k) state that a food will be considered to be misbranded under sections 201(n) and 403(a) of the act if its label or labeling represents, suggests, or implies: (1) That the food, because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom except as provided for in health claim regulations; (2) that a balanced diet of ordinary foods cannot supply adequate amounts of nutrients; (3) that the lack of optimum nutritive quality of a food, by reason of the soil on which the food was grown, is or may be responsible for an inadequacy or deficiency in the quality of the diet; (4) that the storage, transportation, processing, or cooking of a food is or may be responsible for an inadequacy or deficiency in the quality of the diet; (5) that the food has special dietary properties when such properties are of no significant value or need in human nutrition; and (6) that a natural vitamin in a food is superior to an added or synthetic vitamin or to differentiate in any way between vitamins naturally present from those added.

FDA has reviewed these misbranding provisions in light of the DSHEA and current scientific knowledge. As a result of its review, the agency is proposing to delete current § 101.9 (k)(2) and (k)(5). Section 101.9(k)(2) states that a food is misbranded if its label or labeling represents, suggests, or implies that a