balanced diet of ordinary foods cannot supply adequate amounts of nutrients. The agency is deleting this provision based on the acknowledgment by scientific and consensus groups that there are certain situations in which the use of dietary supplements may be needed for persons to obtain adequate nutrient intakes. For example, the National Academy of Sciences has stated in the 10th edition of ''Recommended Dietary Allowances'' that ''In a few cases where deficiency is commonly observed (e.g., iron deficiency in women), food fortification and individual supplementation are appropriate'' (Ref. 13, p. 14). Also, the ''Dietary Guidelines for Americans'' states that supplements may be needed by pregnant or lactating women; other women in their childbearing years; people who are unable to be active and eat little food; and people, especially older people, who take medicines that interact with nutrients (Ref. 14). These conclusions are supported by other documents such as ''Diet and Health, Implications for Reducing Chronic Disease Risk'' (Ref. 15, pp. 509–525) and a task force representing the American Dietetic Association, National Council Against Health Fraud, Inc., Society for Nutrition Education, American Society for Clinical Nutrition, and the American Institute of Nutrition (Ref. 16).

Section 101.9(k)(5) states that a food is misbranded if its label or labeling represents, suggests, or implies that ''the food has dietary properties when such properties are of no significant value or need in human nutrition.'' New section 403(r)(6) of the act, which was added by the DSHEA, provides for statements that, in part, describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or which describe general well-being from consumption of a nutrient or dietary ingredient. There is no requirement in this new section that the subject of the statement be of significant value or need in human nutrition. Therefore, to eliminate any inconsistency between section 403(r)(6) of the act and the agency's regulations, FDA is proposing to delete § 101.9(k)(5). If it adopts the proposed deletion of § 101.9 (k)(2) and (k)(5), the agency will redesignate current § 101.9(k)(3) as (k)(2), § 101.9(k)(4) as (k)(3), and § 101.9(k)(6) as (k)(4).

FDA is not aware of grounds for eliminating the other provisions under § 101.9(k). However, if information is provided in comments to this proposed rule that persuades the agency that the findings of fact and conclusions of law resulting from 1968–1970 special dietary hearings (38 FR 2143) that underlie the other provisions in § 101.9(k) are no longer supportable, FDA will consider deleting the subject provisions in the final rule.

IV. Conforming Amendments

As previously discussed (in section III.J. of this document), FDA is proposing to amend § 101.2 (b) and (f) to include § 101.36 in the lists of sections noted. The agency is also proposing to amend § 101.2(d)(1), which states that all required label information shall appear on the principal display panel or the information panel. This paragraph was recently amended in a document entitled ''Food Labeling; Placement of the Nutrition Label on Food Packages'' (60 FR 17202, April 5, 1995) to exclude from its coverage products that are exempt under § 101.9(j)(13), which allows flexibility in the placement of the nutrition label on packages that have less than 40 square inches of space available to bear labeling, and § 101.9(j)(17), which allows the nutrition label on 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 information to be placed on any alternate panel that can be readily seen by consumers. Inasmuch as proposed § 101.36 (i)(2) and (i)(5) cross reference § 101.9 (j)(13) and (j)(17), respectively, and therefore similarly exclude dietary supplements that meet the criteria in § 101.9 (j)(13) and (j)(17) from coverage of § 101.2(d)(1), FDA is proposing to amend that paragraph to cite § 101.36 (i)(2) and (i)(5) as exceptions.

Section 101.9(j)(6) of the nutrition labeling regulations lists as an exemption: Dietary supplements of vitamins and minerals that have an RDI as established in § 101.9(c)(8)(iv) of this section or a DRV as established in § 101.9(c)(9) of this section shall be labeled in compliance with § 101.36, except that dietary supplements of vitamins and minerals in food in conventional form (e.g., a breakfast cereals), of herbs, and of other similar nutritional substances shall conform to the labeling of this section.

As discussed previously (in section III. of this document), the definition of dietary supplements in new section 201(ff) of the act broadens the coverage of proposed § 101.36 and eliminates differentiation based on the form of the food. Therefore, FDA is proposing to amend § 101.9(j)(6) to exempt all dietary supplements from coverage under § 101.9, noting that such foods must be labeled in compliance with § 101.36.

The agency is also proposing to amend § 101.65(b)(4) to modify the example given of the statement of identity of a dietary supplement of vitamin C to incorporate the term ''dietary supplement'' in accordance with proposed § 101.3(g). The amended paragraph will state:

> A statement of identity for a food in which an ingredient constitutes essentially 100 percent of a food (e.g., ''corn oil,'' ''oat bran,'' ''dietary supplement of vitamin C 60 mg tablet'').

V. Regulatory Review Under Executive Order 12866

This proposed rule has been deemed by the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget to be a significant regulatory action pursuant to Section 3(f)(4) of Executive Order 12866 because it raises novel legal and/or policy issues arising out of a legal mandate, namely the DSHEA, or principles set forth in Executive Order 12866. Accordingly, this proposed rule has been formally reviewed by OIRA pursuant to the provisions of Executive Order 12866.

VI. Economic Impact

FDA has examined the economic implications of the proposed rule as required by Executive Order 12866 and the Regulatory Flexibility Act (Pub. Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The Regulatory Flexibility Act requires analyzing options for regulatory relief for small businesses. FDA finds that this proposed rule is not an economically significant rule as defined by Executive Order 12866. In accordance with the Regulatory Flexibility Act, the agency certifies that the proposed rule will not have a significant impact on a substantial number of small businesses.

There are several different types of products that may be considered to be dietary supplements. These products include, but are not limited to, vitamin and mineral supplements, herbal products, and products that contain other similar nutritional substances. Estimates of the number of such products range from 4,000 to over 25,000 such products. Similarly, estimates of the number of dietary supplement manufacturers range from 150 to 600.