is found to contain more than 20 percent in excess of the amount declared for one of these nutrients. FDA is not aware of any other dietary ingredient that should be singled out in this way. The agency requests comments on the proposed criteria for other dietary ingredients.

In recognition of the fact that the exemptive provisions referenced in proposed § 101.36(f)(1) may not include all situations in which nutrition information is technologically infeasible or impracticable on a particular package, the agency is proposing in § 101.36(f)(2) to carry forward current § 101.36(d)(2), which provides the opportunity in such a situation for firms to write to the Office of Food Labeling, FDA, to request additional exemptions or alternative means of compliance. This provision is identical to that in § 101.9(g)(9) for conventional foods. In such a situation, the firm should state why it is technologically infeasible or impracticable for the specified products to comply with the nutrition labeling regulations, identify alternative means of compliance that would be used to provide nutrition information for the product (e.g., specify type size variations needed), and explain why this mode of compliance would be consistent with the intent of the 1990 amendments and the DSHEA.

With respect to analytical procedures for compliance programs, § 101.9(g)(2) states that FDA will use methods as given in the ''Official Methods of Analysis of the AOAC [Association of Official Analytical Chemists] International'' unless no AOAC method is available or appropriate, in which case other reliable and appropriate analytical procedures will be used. AOAC methods and other reliable analytical methods exist for most vitamins and minerals used as, or as a component of, dietary supplements. However, AOAC methods do not exist for most other dietary ingredients, including many botanicals. Accordingly, the agency is interested in identifying a variety of analytical procedures and sources of information that can be used for other dietary ingredients. FDA requests comments on appropriate analytical procedures or other alternative approaches for determining whether the dietary supplement provides the quantity of dietary ingredient listed in the nutrition label for the supplement. Additionally, FDA is requesting information on organizations that establish such procedures.

The agency is proposing in § 101.36(g) to require that the location of nutrition information on a label be in compliance with § 101.2, except as provided in proposed paragraphs (i)(2) and (i)(5) of § 101.36. Proposed (i)(2) states that dietary supplements are subject to the special labeling provisions specified in § 101.9(j)(13) for foods in small or intermediate-sized packages. Section 101.9(j)(13)(ii)(D) provides that foods in packages that have a total surface area available to bear labeling of 40 or less square inches may present the required nutrition information on any label panel. In addition, proposed (i)(5) states that dietary supplements are subject to the special labeling provision specified in § 101.9(j)(17) 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 (see 50 FR 17202, April 5, 1995). Section 101.9(j)(17) allows the nutrition label on such packages to be moved to any other label panel that is readily seen by consumers. However, because of the requirement in section 403(q)(5)(F)(iv) of the act that the ingredient list immediately follow the nutrition label, proposed § 101.36(i)(5) states that the ingredient list shall continue to be located 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 as specified in § 101.4(g), which FDA has proposed to adopt in this document.

J. Exemptions and Special Labeling Provisions

FDA is proposing in § 101.36(h)(1) and (h)(2) to provide for small business exemptions in accordance with the 1990 amendments and the Nutrition Labeling and Education Act Amendments of 1993 (the 1993 amendments) (Pub. L. 103–80), which (1) stated that, after May 8, 1995, section 403(q)(5)(D) of the act, which provides an exemption based on total gross annual sales, shall apply to food from retailers only, and (2) established a new exemption for low-volume food products from manufacturers, packers, distributors, and retailers that are small businesses. A proposed rule to implement this change in § 101.9(j) and current § 101.36(f) was published on March 14, 1994 (59 FR 11872). A final rule has not yet been published.

To streamline the regulations and be consistent with the manner in which other exemptions and special labeling provisions are listed in current § 101.36(f) and (g) (proposed § 101.36(h) and (i)), FDA is proposing in § 101.36(h)(1) and (2) to cross reference the small business exemption in § 101.9(j)(1) and the exemption for low-volume food products of small businesses in proposed § 101.9(j)(18), respectively, rather than to independently codify those exemptions under § 101.36.

Proposed § 101.36(h)(3) incorporates the exemption in § 101.9(j)(9) for foods shipped in bulk form that are not for distribution to consumers in such form and that are for use solely in the manufacture of other foods or that are to be processed, labeled, or repacked at a site other than where originally processed or packed. This exemption was incorrectly listed in current § 101.36(g) and identified as a special labeling condition. Inasmuch as nutrition labeling is not required on products shipped in bulk form that are not intended to be seen by consumers (section 403(q)(5)(A)(v)) of the act, it is being redesignated as an exemption under proposed § 101.36(h)(3).

Special labeling provisions (or conditions) are provided for specific situations in which the product is not exempt from nutrition labeling requirements, but deviations from the general nutrition labeling requirements are necessary for a variety of reasons. For example, proposed § 101.36(i)(1), which was carried forward from current § 101.36(g), references § 101.9(j)(5)(i) which describes a special labeling provision that pertains to the nutrition labeling of foods represented or purported to be for children less the 2 years of age. In the nutrition labeling of these foods, other than infant formula, the listing of calories from fat, calories from saturated fat, saturated fat, polysaturated fat, monounsaturated fat, and cholesterol is prohibited. FDA included this special labeling provision in its regulations to discourage the inappropriate application of adult dietary guidelines to infants and toddlers (55 FR 29487 at 29506, July 19, 1990, as modified in 58 FR 2079 at 2150). While current § 101.36(g) also cross references § 101.9(j)(5)(ii), which addresses broader issues of the format of nutrition labeling on foods intended for children less than 4 years of ages, these format issues are addressed elsewhere in this proposed regulation (e.g., the exclusion of percent Daily Value in proposed § 101.36(b)(2)(iii)(F) for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber because DRV's have not been established for this age group). Accordingly, proposed § 101.36(i)(1) references only that portion of § 101.9(j)(5)(i) that prohibits the inclusion of calories from fat, calories from saturated fat, saturated fat,