polyunsaturated fat, monounsaturated fat, and cholesterol in the nutrition label of foods, other than infant formula, represented or purported to be for children less than 2 years of age.

Proposed § 101.36(i)(2) describes special labeling provisions for small and intermediate-sized containers. Special labeling provisions are provided for these containers in current § 101.36(g) which cross references § 101.9(j)(13). Section 101.9(j)(13)(i) allows small packages with less than 12 square inches of space available to bear labeling to supply an address or telephone number for the consumer's use in obtaining nutrition information in lieu of nutrition labeling when no claims or other nutrition information are present on the label or in labeling or advertising, or, if they are present, to provide the required nutrition information in 6 point type or in all upper case type of 1/16 inches minimum height. Section 101.9(j)(13)(ii) allows packages with 40 or less square inches of space available to bear labeling to present the nutrition label in a tabular format when the package shape and size cannot accommodate a standard vertical display and in a linear display if the label will not accommodate a tabular display; to use specified abbreviations; to shorten the required footnotes; and to place the required nutrition information on any label panel.

In addition to cross referencing these special labeling provisions, current § 101.36(c)(6) provides for smaller type size requirements for dietary supplements in small and intermediate-sized containers. That provision allows labels of dietary supplements in packages with less than 12 square inches of total surface area available to bear labeling to use a type size no smaller than 4.5 point in the nutrition label, in packages with 12 to 40 square inches of total surface area available to bear labeling to use a type size no smaller than 6 point, and in packages with more than 40 square inches of total surface area available to bear labeling to use type size no smaller than 8 point, except that these larger packages can use 6 point type for column headings, footnotes, and information on beta-carotene, when present.

In proposed § 101.36(i)(2), FDA is continuing to cross reference the special provisions in § 101.9(j)(13) and to allow the use of 4.5 point type on packages with less than 12 square inches of available label space and the use of 6 point type on packages with 12 to 40 square inches of available label space. However, in response to a citizen petition (Docket No. 94P–0110/CP1) (Ref. 11) from a trade association, the agency is proposing to provide additional flexibility for multi-ingredient dietary supplements in packages with less than 20 square inches of available label space. The petition stated that the majority of dietary supplement products on the market have labels that are 12 to 20 square inches in size, and that, while 6 point type in the nutrition label is feasible on single-nutrient products with this size label, there is insufficient space for all the required information on multinutrient products. The petitioner submitted sample labels in support of their position.

FDA is persuaded by this citizen petition that it is infeasible to use 6 point type on many products containing multiple dietary ingredients in packages with less than 20 square inches of space available to bear labeling. However, the agency tentatively finds that 6 point type is feasible on products with a limited number of dietary ingredients based on the following calculations. The agency calculates that a listing of 8 dietary ingredients in 6 point type plus one point leading between each name would take less than 1 inch of vertical space. Adding another inch to this for the title, headings, bars, and footnote would result in a nutrition label for a product declaring up to 8 dietary ingredients of no more, and possibly less, than 2 inches in height. Assuming a 1½ inch width, such a nutrition label would take no more than 3 square inches of surface area.

In the preamble to the final rule implementing the 1990 amendments, FDA based decisions on small package sizes on the assumption that not more than 30 percent of the total surface area of a package should be required to be devoted to FDA-required information that is not on the principal display panel (58 FR 2079 at 2155). On a package with 12 square inches of available label space, 30 percent of the total surface area is 3.6 square inches. Inasmuch as the ingredient list can be included in the nutrition label and based on the above calculations, the agency tentatively concludes that it is reasonable to require that 6 point type be used on a package with 12 to 20 square inches of space available to bear labeling when 8 or fewer dietary ingredients are listed. However, when a dietary supplement is in a package that has from 12 to 20 square inches of surface area available to bear labeling, and the nutrition label lists more than 8 dietary ingredients, the use of 6 point type would likely mean that more than 30 percent of the total surface area of the package would have to be devoted to FDA required information. Therefore, FDA is proposing in § 101.36(i)(2)(ii) to provide for the use of a smaller type size (i.e., a minimum of 4.5 point type) in such circumstances.

It should be noted that the dimensions used by the agency are inclusive of ''space available to bear labeling,'' not merely the dimensions of the current label. When there is space on the container to enlarge the current label (i.e., unused surface area available to bear labeling), and the current label is not large enough to provide the required information in accordance with format and type size specifications, FDA considers it is reasonable to expect that the manufacturer, packer, or distributor will increase the size of the label.

This action (i.e., proposing to allow only those products with more than eight dietary ingredients to use the smaller type size) is supported by the petitioner referred to above (Ref. 11), who stated in followup correspondence that, in a survey of its membership, ''responding companies agreed that eight or ten would be an appropriate cutoff number, triggering the smaller type size for multinutrient products,'' and that the responding companies believed that the cutoff should be set at eight nutrients (Ref. 12).

The aforementioned citizen petition (Ref. 11) also requested that § 101.2(c) be amended to allow the type size requirements in § 101.2 (c)(1) through (c)(3) to apply to the labeling of dietary supplements of vitamins and minerals. Current § 101.36 and proposed § 101.36 include type size requirements for varying sizes of packages of dietary supplements. Therefore, the agency is denying the request to have the type size requirements in § 101.2(c) pertain to the nutrition labeling of dietary supplements.

The agency notes that § 101.2 (c)(1) through (c)(3) were added to the regulations in 1974 (39 FR 15268), in part, in an effort to encourage manufacturers, packers, and distributors to include nutrition labeling on conventional foods. However, because the final rule on nutrition labeling (58 FR 2079) includes type size requirements, the agency believes there is no longer a need for § 101.2 (c)(1) through (c)(3) to address the type size of information in the nutrition label. The agency plans to amend § 101.2 (c)(1) through (c)(3) accordingly in a later document dealing with the labeling of conventional foods, as well as dietary supplements, so that the rulemaking will be seen by the greatest number of persons who may be affected by such action.