other than a label, and the manufacturer, packer, or distributor wishes to comply with section 403(r)(6) of the act without having to place the disclaimer immediately after each statement of nutritional support, it can place a symbol (e.g., an asterisk) at the end of each statement of nutritional support that refers to the same symbol placed elsewhere on the same label panel or in the labeling that is followed by the disclaimer.

In a citizen petition dated March 20, 1995 (petition number 95P–0079/CP 1), the Nutritional Health Alliance (NHA) requested, among other things, that FDA issue regulations implementing section 403(r)(6) of the act. With respect to the placement of the disclaimer, NHA suggested that an asterisk follow each statement of nutritional support to refer the consumer to a specific place on the label, such as the information panel, where the disclaimer would appear only once.

Although FDA is proposing to provide most of what this petition seeks, the agency tentatively rejects the last aspect of this suggestion. Splitting the statement of nutritional support from the required disclaimer and allowing the disclaimer to appear on another panel does not establish an obvious relationship between the two pieces of information. The agency is concerned that the placement of the disclaimer on another panel would not reveal material facts in conjunction with the statement of nutritional support that are necessary for consumers to fully understand the significance of the statement. However, the agency will consider establishing provisions for the use of asterisks that refer to the disclaimer in a single specific location (such as the information panel), instead of on each panel bearing a statement of nutritional support, if the comments convince it that such an approach is consistent with the statute and would be useful to consumers. FDA requests any data that bear on the question of the effect that splitting a statement from a disclaimer in this manner will have on the likelihood that consumers will read the disclaimer. Specifically, the agency requests data on whether a consumer will track a symbol from one label panel or page of labeling to another to obtain the information about a statement of nutritional support that follows the symbol.

In addition, the requirement in the act for prominent display means that when the disclaimer does not appear immediately adjacent to a statement of nutritional support, it must be presented on the label or labeling in a manner that renders it as readily observable and as likely to be read as the statement of nutritional support itself. In this regard, the agency's experience with the graphic requirements for the new nutrition label has been that a box around required label information greatly increases the prominence of the information placed inside the box (Ref. 2). Moreover, focus group discussions regarding warning labels show that messages put in a boxed area help consumers to distinguish the message from other information as well as draw attention to it (Ref. 3). Therefore, FDA is proposing in § 101.94(c)(2) to require that a box be drawn around the disclaimer when the disclaimer is not immediately adjacent to the statement of nutritional support.

For example, a side panel of a dietary supplement label may contain paragraphs of text that include more than one statement of nutritional support. Assuming that the manufacturer did not choose to place the disclaimer immediately after each statement of nutritional support, each such statement would be followed by a symbol, and the referenced symbol and disclaimer would be placed in a box on the same panel with the first sentence reading ''*These statements have not been evaluated by the Food and Drug Administration,'' as proposed in section § 101.94(b)(2).

4. Type Size and Style

With respect to the style of type to be used in the disclaimer, the DSHEA specifies that ''boldface type'' shall be used (section 403(r)(6)(C) of the act). FDA has reiterated this provision in proposed § 101.94(d).

With respect to type size requirements, FDA notes that even though section 403(r)(6) of the act does not include specific type size requirements for the accompanying information referred to as the disclaimer, other sections of the act, and the regulations promulgated thereunder, address a variety of requirements for information that is to accompany a claim. Sections 403(r)(2)(A)(iii) through (r)(2)(A)(v) of the act require that statements that disclose the level of fat, saturated fat, or cholesterol, which must be presented in conjunction with certain nutrient content claims, ''have appropriate prominence which shall be no less than one-half the size of the claim.'' The agency tentatively concludes that, for consistency, this requirement should be considered a key element of ''prominent display'' for the disclaimer.

FDA has long held that accompanying information should be in a size reasonably related to that of the information that it modifies. This relative prominence, when codified, has (except in the case of provisions pertaining to nutrient content claim referral and disclosure statements in § 101.13) been one-half the type size of the information modified (see, e.g., §§ 101.22(i)(2) and 102.5(b)(2)(ii)). For nutrient content claims, FDA did establish type size requirements for referral and disclosure statements related to the area of the surface bearing the principal display panel rather than to the type size used for the nutrient content claim. However, nutrient content claims often have very large type size, whereas nutritional support statements will likely not appear in such large type because they are intended to convey more lengthy information. Certainly the statements that would qualify as nutritional support statements under section 403(r)(6) of the act that have appeared in dietary supplement labeling are of much greater length than most nutrient content claims.

Because nutritional support statements are likely to be more lengthy, firms are likely to use relatively small type for them. The agency is concerned that one-half the size of the type commonly used for long statements or paragraphs may be too small for consumers to read easily. Thus, FDA is proposing one-sixteenth of an inch as the minimum type size for the disclaimer in § 101.94(d).

One-sixteenth of an inch is specified in § 101.2(c) as the minimum type size for most other mandatory information on the principal display panel or information panel, e.g., designation of ingredients, name and place of business, and warning and disclaimer statements. Further, one-sixteenth of an inch is the minimum size required in § 101.105(i) for net quantity of contents statements. Consequently, the agency tentatively concludes that a minimum type size of one-sixteenth of an inch for the disclaimer is necessary to ensure that it is prominently displayed in accordance with section 403(r)(6)(C) of the act.

E. Prominence of Ingredients That Are Not Vitamins or Minerals

Section 7(d) of the DSHEA strikes section 411(b)(2)(B) of the act. Before it was removed by the DSHEA, section 411(b)(2)(B) stated that the labeling and advertising of dietary supplements of vitamins and minerals could not give prominence to or emphasize ingredients that are not vitamins, minerals, or represented as a source of vitamins or minerals. Because of this provision, the agency stated that nutrient content claims about ingredients that are not