substances'' and ''food in conventional food form.'' With the passage of the DSHEA, however, Congress has defined the term ''dietary supplement'' and has modified the act in sections 201(ff) and 411(c)(1) (21 U.S.C. 321(ff) and 350(c)(1)) to make clear that the form of the food is not necessarily determinative of whether it is a dietary supplement or not. Therefore, in this document, FDA will use the more simple terms ''dietary supplement'' and ''conventional food.''

II. FDA Authority

Section 403(r)(2)(A)(i) of the act states that claims that characterize the level of a nutrient may be made only if the claim uses terms that are defined in regulations. In response to this section, the agency is proposing to amend its regulations on nutrient content claims to define the term ''high potency'' as a nutrient content claim for use on labels and in labeling of dietary supplements and the term ''antioxidant'' for use in nutrient content claims for dietary supplements and conventional foods.

FDA has authority to take these actions regarding nutrient content claims under sections 201(n) and 403(a), as well as section 403(r), of the act (21 U.S.C. 321(n) and 343(a)). These sections prohibit labeling that: (1) Is false or misleading in that it fails to reveal facts that are material in light of other representations made in the labeling or that are material with respect to the consequences that may result from use of the food, and (2) uses terms to characterize the level of any nutrient in a food that have not been defined by regulation by FDA.

III. Proposed Rules

A. ''High Potency''

1. Background

In the 1993 nutrient content claims proposal, FDA requested comment on several terms, including ''high potency,'' that are often encountered on labels or in labeling of dietary supplements and that seem to imply that the dietary supplement will contribute to good health (58 FR 33731 at 33748). The agency requested comment on whether there are established meanings for these terms, and, if so, whether they characterize the level of the nutrients in the food. The agency received about 10 comments from trade associations, manufacturers of dietary supplements and conventional foods, academicians, and consumer groups regarding the term ''high potency.''

FDA was persuaded, based on comments that suggested definitions for the term, that ''high potency'' is a claim that characterizes the level of a nutrient or nutrients and, therefore, meets the definition in § 101.13(b) of a nutrient content claim (59 FR 378 at 391). However, given the time constraints under which FDA prepared the final rule, and the range and diversity of the suggested definitions, the agency was not able to adopt a definition of ''high potency'' in the final rule on nutrient content claims for dietary supplements. FDA announced its intention to review the suggestions for a definition of ''high potency'' and, based on information received in the comments, to propose an appropriate definition for this term (59 FR 378 at 391). In this document, the agency is proceeding with its commitment to propose a definition for ''high potency.''

2. Limitation to Dietary Supplements

In the 1994 nutrient content claims final rule, the agency determined that, in many respects, the regulations issued in the 1993 nutrient content claims final rule (58 FR 2302) are directly applicable to dietary supplements (59 FR 378 at 380). However, FDA acknowledged that dietary supplements differ in several respects from conventional foods in their history of use and in their perceived function in the diet (59 FR 378 at 380). This fact and the fact that certain dietary supplements are likely to contain much higher levels of nutrients than conventional foods led FDA to conclude that nutrient content claims that are specific for dietary supplements may be appropriate (59 FR 378 at 380). Comments to the nutrient content claims proposal for dietary supplements stated that the term ''high potency'' seems more appropriate for dietary supplements than for conventional foods (59 FR 378 at 390).

In considering the coverage of this term, FDA has relied, in part, on the National Academy of Sciences' (NAS) Institute of Medicine's (IOM) recommendations found in ''Nutrition Labeling, Issues and Directions for the 1990's'' (Ref. 1). In discussing claims, the IOM suggested that the terms that should be defined are those that are most commonly used (Ref. 1, p. 296). FDA has no evidence that the term ''high potency'' is used with any frequency on conventional foods, that the term was used on conventional foods before the enactment of the 1990 amendments, or that consumers expect or would understand it in association with conventional foods. In contrast, the term ''high potency'' was in widespread use on the labels of dietary supplements before the enactment of the 1990 amendments, continues to be used on dietary supplements, and appears to convey information to the consumer about the level of the nutrients in dietary supplements.

Lacking a clear history of use, or any other indication of the usefulness, of the term ''high potency'' on conventional foods, the agency tentatively concludes that this term should be limited to use on dietary supplements. Accordingly, FDA is proposing to amend part 101 (21 CFR part 101) by adding new § 101.13(b)(6), which states that the term ''high potency'' may be used only on dietary supplements.

FDA recognizes that defining a nutrient content claim exclusively for use on labels and in labeling of dietary supplements is a departure from previous practice. However, the agency tentatively concludes that limiting this claim to dietary supplements is the appropriate course for the reasons stated above. Comment is requested on this tentative conclusion.

3. Definition of ''High Potency'' as a Nutrient Content Claim

a. *Describing a nutrient.* FDA received several comments that presented a wide range of views on how ''high potency'' should be defined. One comment to the proposed rule on nutrient content claims suggested that the term ''high potency'' have the same definition as ''high'' (i.e., 20 percent or more of the RDI), but did not provide any elaboration on why this suggested definition is appropriate. Other comments asserted that this term could be used to establish an hierarchy of absolute claims (i.e., ''good source,'' ''high,'' and ''high potency'') to describe dietary supplements. This hierarchy, the comments suggested, will enable consumers to use the claims to quickly differentiate between varying nutrient levels in dietary supplements.

A few comments suggested that the term be defined to mean that the product contains 200 percent of the RDI. These comments argued that while a multivitamin supplement at 100 percent of the RDI might be ''high potency'' compared to a conventional food, it is not ''high potency'' when compared to other dietary supplements. These comments suggested that defining ''high potency'' as twice the RDI or more would more accurately reflect the level of nutrients found in dietary supplements. One of these comments stated that, in addition to requiring that single nutrient supplements be twice the RDI for that nutrient, FDA should require that the principal display panel disclose what multiple of the RDI the supplement contains. For example, the comment suggested that the principal display panel of a 250 milligram (mg)