listing of the ingredient in the ingredient statement is followed by an asterisk that refers to a statement below the list of ingredients such as ''adds a negligible amount of sugar,'' and (3) it is labeled ''low calorie'' or ''reduced calorie'' or bears a relative claim of special dietary usefulness, or is labeled ''not a reduced calorie food,'' ''not a low calorie food,'' or ''not for weight control.''

In the 1994 nutrient content claims final rule, FDA added paragraph § 101.60(a)(4) to state that ''calorie free'' and ''low calorie'' claims may not be made on dietary supplement products, except when an equivalent amount of a dietary supplement that the labeled food resembles and for which it substitutes (e.g., another protein supplement), normally exceeds the definition for ''low calorie'' in § 101.60(b)(2). The agency also similarly revised § 101.13(b)(5). This change in §§ 101.13(b)(5) and 101.60(a)(4) had the unintended effect of limiting the use of ''sugar free'' or ''no sugar'' claims on dietary supplements that would otherwise meet the requirements for ''low calorie'' in § 101.60(b)(2) but are not permitted to bear the claim because they do not substitute for a similar dietary supplement that normally exceeds the definition for ''low calorie.''

In the 1994 nutrient content claims final rule, FDA had found that, because the level of sugars in dietary supplements can vary substantially, claims about the sugars content of dietary supplements may be useful in helping consumers make purchasing decisions that will assist them in maintaining healthy dietary practices (59 FR 378 at 382). Thus, the agency concluded that extending the definitions of ''sugar free'' and ''reduced sugar'' to dietary supplements was appropriate irrespective of the calorie level of the dietary supplement. Therefore, FDA did not modify the requirements governing claims for sugars in § 101.60(c) for dietary supplements. In not making a change to § 101.60(c), however, FDA overlooked the impact of new §§ 101.13(b)(5) and 101.60(a)(4).

In order to allow for ''sugar free'' or ''no sugar'' claims on dietary supplements that meet the other criteria for the claim (i.e., contain less than 0.5 g of sugars per reference amount and contain no ingredient that is a sugar or that is generally understood by consumers to contain sugars unless an appropriate statement is added after the ingredient list), the requirement that the product be labeled ''low calorie'' should have been modified for dietary supplements that were prohibited from making ''low calorie'' claims because no other dietary supplement that the labeled food resembles and for which it substitutes exceeded the definition for ''low calorie.'' FDA is proposing to make that change now. No modification is needed for dietary supplements labeled ''reduced calorie'' since that claim was not changed by the final rules on nutrient content claims for dietary supplements or for those dietary supplements that are not low or reduced in calories.

The agency is not aware of any reason why its position in § 101.60(c)(1) that consumers may be expected to regard ''sugar free'' and ''no sugar'' claims as indicative of a product that is low or reduced in calories should be different for dietary supplements than for conventional foods. Therefore, FDA is proposing to revise § 101.60(c)(1)(iii)(A) to excuse only dietary supplements that otherwise meet the definition of ''low calorie'' under § 101.60(b)(2) but that are prohibited by §§ 101.13(b)(5) and 101.60(a)(4) from bearing the claim.

IV. Effective Date

FDA is proposing an effective date of January 1, 1997. This date is consistent with the effective date proposed in two companion proposals published elsewhere in this issue of the Federal Register entitled ''Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements'' and ''Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements.'' This date will allow firms to make all label changes associated with the DSHEA and with the two companion proposals at the same time.

V. Economic Impact

FDA has examined the economic implications of the proposed rule amending 21 CFR as required by Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 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 which 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 a 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.

Many currently marketed foods and dietary supplements use the terms ''high potency'' and ''high in antioxidants'' to describe the level of nutrients in the products. Without definitions for these terms, manufacturers will not be able to continue to use them. This proposed rule will require that any manufacturer currently using the terms ''high potency'' or ''antioxidant'' bear the costs of removing such statements from their labels only if the products do not meet the proposed definition. FDA does not believe that the number of products that would not meet the proposed definition is high.

VI. Paperwork Reduction Act

FDA tentatively concludes that this proposed rule contains no reporting, recordkeeping, labeling, or other third party disclosure requirements; thus there is no ''information collection'' necessitating clearance by the Office of Management and Budget. However, to ensure the accuracy of this tentative conclusion, FDA is asking for comment on whether this proposed rule to define the term ''high potency'' as a nutrient content claim for dietary supplements, to define the term ''antioxidant'' for use in nutrient content claims for dietary supplements, and to correct an omission pertaining to the use of ''sugar free'' claims on dietary supplements imposes any paperwork burden.

VII. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Comments

Interested persons may, on or before March 13, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references have been placed on file in the Dockets Management Branch (address above) and may be seen by interested persons