vitamins or minerals (e.g., ''more fiber,'' ''high protein'') could not be made on dietary supplements of vitamins or minerals (59 FR 378 at 387). This limitation was carried through in the final rule for nutrient content claims for dietary supplements in § 101.54(b)(1), (c)(1), and (e)(1) that addressed ''high,'' ''good source,'' and ''more'' claims, respectively, for dietary supplements.

For example, § 101.54(b)(1) as amended by the nutrient content claims for dietary supplements final rule (59 FR 378 at 394) reads:

> The terms ''high,'' ''rich in,'' or ''excellent source of'' may be used on the label and in the labeling of foods except meal products as defined in § 101.13(l), main dish products as defined in § 101.13(m), and *dietary supplements of vitamins or minerals to characterize the level of any substance that is not a vitamin or mineral,* provided that the food contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

(emphasis added).

Similar restrictions were added to § 101.54(c)(1) and (e)(1) by the 1994 nutrient content claims for dietary supplements final rule.

In response to section 7(d) of the DSHEA, FDA is proposing to amend § 101.54(b)(1) for ''high'' claims, § 101.54(c)(1) for ''good source'' claims, and § 101.54(e)(1) for ''more,'' ''fortified,'' ''enriched,'' and ''added'' claims to remove these restrictions on claims on dietary supplements that characterize the levels of substances that are not vitamins and minerals. These restrictions are no longer required under the act.

III. Analysis of Impacts

FDA has examined the impacts of the proposed rule under 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 that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. In accordance with the Regulatory Flexibility Act, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The proposed rule does not significantly change the way in which claims are made with three exceptions: (1) Percentage claims for dietary supplements that do not have RDI's or DRV's are no longer prohibited; (2) dietary supplements of vitamins and minerals may now highlight an ingredient that is not a vitamin or mineral; and (3) labels or labeling of dietary supplements may include statements of nutritional support so long as those statements include an appropriate disclaimer, and the manufacturer has substantiation that the statement is truthful and not misleading. With regards to these actions, costs of redesigning labels will be incurred only by those firms wishing to take advantage of the DSHEA. With respect to the third, firms who wish to make nutritional support statements will incur the additional cost of redesigning labels to include the disclaimer. When the label or labeling contains more than one nutritional support statement, the cost of the disclaimer will depend on whether the disclaimer must be made on each label panel, page, or piece of labeling that contains a statement of nutritional support, or whether the disclaimer need only appear once.

FDA is unable to quantify the benefits from this proposed rule. It may be that some consumers will benefit from the additional information about dietary ingredients that will become available. However, because statements of nutritional support may now be made for some dietary ingredients without any publicly available information to demonstrate that the dietary ingredient is safe, or that it will have its claimed effect, it is uncertain whether this proposed rule will in fact provide any significant benefits to consumers. FDA requests comment on this issue.

IV. 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.

V. 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 amend its regulations establishing requirements for the use of nutrient content claims and health claims for dietary supplements and to specify how the disclaimer required by section 403(r)(6)(C) of the act is to be presented on the labels or labeling or dietary supplements imposes any paperwork burden.

VI. Effective Date

FDA is proposing to make this regulation effective on January 1, 1997. This is consistent with section 7(e) of the DSHEA, which states that dietary supplements must be labeled in accordance with the amendments of that section after December 31, 1996.

VII. 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.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Office of Food Labeling, Center for Food Safety and Applied Nutrition, Food and Drug Administration, ''Food Labeling, Questions and Answers,'' August, 1993.

2. Wilkening, Virginia L., Memo to the Record, June 30, 1995.

3. Macro International Inc., ''Iron Supplement Warning Label Focus Group Report,'' U.S. Department of Health and Human Services, Food and Drug Administration, April 14, 1995.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under