§ 101.9(j)(1) (and proposed § 101.36(h)(1)) will only apply to retailers. Proposed § 101.9(j)(18) (and proposed § 101.36(h)(2)) will apply to manufacturers, packers, distributors, or retailers of low volume products, defined as fewer than 200,000 units, produced by firms with fewer than 200 employees. As of May 1997, criteria for meeting the definition of low volume product will be reduced to 100,000 units and 100 employees. FDA does not have information to show how many dietary supplement products would be exempted under this provision. The agency believes that several herbal and botanical products will have unit sales and firm size low enough to meet this definition. Therefore, many of the products produced by businesses defined as small by the SBA will not be subject to the rules if issued as proposed.

The agency requests information regarding the impact of this regulation on small firms. Most of the costs associated with labeling regulations are fixed costs which are typically more burdensome for small firms than for large firms because of the smaller sales base on which to spread costs. Estimates of annual sales for the dietary supplement industry range from $2.9 billion to over $4 billion. The estimated cost of between $52 and $85 million is approximately one to three percent of industry annual sales. In relation to the volume of sales, this amount does not appear to represent a significant cost.

D. Summary

Total discounted costs of this regulation is estimated to be between $52 and $85 million over the next 20 years (7 percent discount rate). These costs include administrative, analytical, printing, and inventory disposal costs. The benefits are improved and more consistent information with which consumers can refine their choices for health or other reasons. FDA is unable to quantify this benefit.

FDA has analyzed the costs and benefits of this proposed rule and has determined that it does not constitute an economically significant rule as defined by Executive Order 12866.

FDA has also analyzed the impacts on small firms according to the Regulatory Flexibility Act and has determined that the proposed rules will probably not have an adverse impact on a substantial number of small businesses. Nonetheless, the agency requests comments on the impact on small businesses and any burden-reducing options.

VII. Environmental Impact

The agency has determined under § 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 environment assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This proposed rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). In particular, the proposed regulations would require that manufacturers and distributors of dietary supplements disclose information on the levels of specific nutrients on the label or in labeling of their products with some exceptions. Additionally, the proposed regulations would require that these firms disclose the quantity of other dietary ingredients in their dietary supplements. Therefore, in accordance with 5 CFR Part 1320, FDA is providing below the title, description, and respondent descriptions for the information collection requirements that will be submitted to OMB along with an estimate of the annual collection of information burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering necessary information, and disclosure of the information.

FDA is soliciting comments to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) evaluate the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology, when appropriate.

Title: Requirements for Nutrition and Ingredient Labeling of Dietary Supplements.

Description: The proposed rule, § 101.36, would require that most dietary supplements provide on their labels and in their labeling information on the quantity of specific nutrients present in them, along with daily value for each, and the quantity of other dietary ingredients. This requirement is being proposed to implement the requirements of the 1990 amendments and the DSHEA.

The DSHEA requires that dietary supplements provide information on their labels as to the level of nutrients and other dietary ingredients present in them. The DSHEA requires that FDA issue regulations to implement these requirements within specific timeframes. Section 101.36(b)(2) specifies the nutrients for which amount must be present on the labels of dietary supplements and § 101.36(b)(3) provides for the listing of the quantity of other dietary ingredients, respectively. Other paragraphs of § 101.36 provide information to assist manufacturers and distributors of dietary supplements to determine the amount of nutrient that their products contain and that should be disclosed on the labels of the products.

Description of Respondents: Persons and businesses, including small businesses.

Title 21	No. of respondents	No. of responses per respondent	Total annual responses	Hours per response	Total annual hours	Total operating maintenance costs
101.36	600	40	24,000	4	96,000	$51,616,000

FDA estimates that each supplier of dietary supplements will revise the labels for each product that is not otherwise exempt to comply with the requirements for nutrition labeling within the first year after publication of a final rule. The agency expects that the number of respondents and corresponding annual burden hours will decrease over succeeding years because it does not believe that firms will modify the composition of each of their products and revise the labeling for each of their products each year. FDA has estimated the total annual operating and