A. Costs

Categories of costs for relabeling include administrative, analytical, printing, inventory disposal, and reformulation. The administrative costs associated with a labeling regulation result from the incremental administrative labor expended in order to comply with it. The administrative activities that FDA anticipates will be undertaken in response to a change in regulation include: Identifying the underlying policy of the regulation, interpreting that policy relative to a firm's products, determining the scope and coverage related to product labels, establishing a corporate position, formulating a method for compliance, and managing the compliance method. Longer compliance periods decrease administrative costs because firm executives often delegate downward decisions that are less immediate. Many firms estimate that administrative effort would be twice as high for a 6-month compliance period as for a 12- month compliance period (Ref. 17). FDA is proposing that any final rule that may issue based upon this proposal become effective January 1, 1997. This effective date leads to a compliance period of approximately 1 year. FDA estimates that for a 1-year compliance period, manufacturers of dietary supplements will incur administrative costs of $425 per firm for each of between 150 and 600 firms, or a total of between approximately $65,000 and $300,000.

FDA requests comments on whether dietary supplement products will undergo analytical testing as a result of these regulations if implemented as proposed. Dietary supplement products need only list those nutrients present in significant amounts. The agency assumes that manufacturers of vitamin and mineral supplements are already aware of the nutritional content of their products, and that those products will not undergo any additional testing. However, it is possible that herbal and other botanical products may undergo additional testing for their nutritional content. The agency estimates that between 4,000 and 20,000 products may undergo testing once every 5 years for a total discounted analytical cost over the next 20 years of between $8.3 and $41 million (7 percent discount rate).

However, many herbs do not contain significant amounts of the nutrients that must be listed in the nutrition label, and this fact may be determinable from reference works without testing. Thus, some herbal and botanical products may not require nutrient testing at all. FDA requests comments on this issue.

FDA estimates that printing/redesign costs for dietary supplement manufacturers would be approximately $1,000 per label for each of 75,000 labels with a 6-month compliance period, or a total of $75 million. However, the length of the compliance period determines a firm's ability to combine planned label changes with mandated changes. Therefore, incremental labeling and redesign activities are less costly with lengthier compliance periods. With the proposed compliance period of 1 year, printing and redesign costs would be approximately half that of a 6-month compliance period, or approximately $37.5 million.

FDA estimates the cost of inventory disposal associated with a 1-year compliance period to be approximately $13 million. However, manufacturers of these products have been aware of the potential for regulated labeling changes due to recent regulatory and legal activities. FDA assumes that the majority of these manufacturers have been taking the necessary steps to reduce their label inventories since January of 1994, the date of publication of FDA's previous regulations regarding the labeling of dietary supplements. Therefore, the cost of inventory disposal is more accurately calculated on a compliance period of 2 years, or approximately $6.5 million.

FDA has examined the impact of the proposed regulations on dietary supplement manufacturers and has determined that administrative costs would be between $65,000 and $300,000, discounted analytical testing costs would be between $8.3 and $41 million over the next 20 years (7 percent discount rate), printing and redesign costs would be $37.5 million, and inventory disposal costs would be $6.5 million. Therefore, total discounted costs are estimated to be between $52 and $85 million.

B. Benefits

According to Congress as stated in the DSHEA, almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition. Although almost all dietary supplements of vitamins and minerals currently contain substantial nutrition information, many other dietary supplements do not typically provide such information. Moreover, the information that is presented is not presented in any particular order or following any particular format.

This proposed regulation will benefit consumers by ensuring that adequate and complete nutrition information is provided accurately and consistently in order to aid consumers in their dietary choices. As consumers are given more informative labeling in an improved format, uncertainty and ignorance concerning the ingredient and nutrient content of the products they consume will decrease, and some consumers may select more nutritious, healthier products. Moreover, since FDA began its food labeling initiative in 1989, a theme that has been consistently sounded is that consumers will benefit from nutrition labeling that is presented in a consistent manner, not only within a particular product class but also across all foods. Such a consistent manner will not only help to make the information presented more comprehensible but will facilitate comparisons among food products. This proposed rule, if adopted, will help to ensure that dietary supplements are nutrition labeled in a manner that is as consistent as possible with other foods, yet, with such features as the listing of substances for which no daily reference amount has been established, in a manner that is fully tailored to the special nature of those products.

All told, this action, if adopted, will benefit consumers by ensuring that nutrition labeling is provided on dietary supplements in a manner that will help consumers to follow healthy dietary practices.

C. Regulatory Flexibility

According to the Regulatory Flexibility Act, the definition of small business is a business independently owned and operated and not dominant in its field. The Small Business Administration (SBA) has set size standards for most business categories through use of four-digit Standard Industrial Classification codes. For most food processing industries, a business is considered small if it has fewer than 500 employees. For dietary supplements, a business is considered small if it has fewer than 750 employees. FDA estimates that the majority of manufacturers of dietary supplements meet the SBA definition of a small business.

The agency has published an exemption from mandatory nutrition labeling for small businesses in § 101.9(j)(1) (incorporated in this proposed rule in § 101.36(h)(1)) and has proposed an exemption for low-volume food products of small businesses in § 101.9(j)(18) (59 FR 11872, March 14, 1994) (incorporated in this proposed rule in § 101.36(h)(2)). As of the date this subject rulemaking is proposed to become effective, January 1, 1997,