

would be hard pressed to continue to operate. Therefore, some of these establishments, for example, such as those that produce other products (foods or pharmaceuticals) or are part of firms with more than one establishment, may decide it is too costly and either change product lines or go out of business. If we assume that one half of these firms have sales revenues from other products and locations and remove them from the at-risk group, we are left with approximately 350 very small and small establishments with less than \$500,000 in revenue. It is possible that a large number of these 350 very small and small establishments would be unable to absorb the compliance costs and will close.

3. Regulatory Options

a. *Exemptions for small entities.* The burden on small establishments would be reduced if they were exempt from some provisions of the proposed rule. Most entities affected by this proposed rule, however, are small. Exempting small establishments from some or all of its provisions would be likely to reduce benefits.

b. *Longer compliance periods.* Lengthening the compliance period would provide regulatory relief for small entities. A longer compliance period for small entities would allow additional time for setting up recordkeeping, making capital improvements to the physical plant, purchasing new or replacement equipment, and other one-time expenditures. It would also delay the impact of the annual costs of compliance. We have given very small and small firms an additional 2 years for compliance. The proposed rule, then, would be phased-in over 3 years, with large firms complying after 1 year, and both very small and small firms after 3 years. After 3 years, the annual costs would be incurred. The cost savings of delay may well be larger than simply the present value of the delay because very small and small firms may also be able to reduce their compliance costs by taking advantage of increases in industry knowledge and experience in implementing CGMP regulations. A summary of the compliance costs is shown in table 22 of this document.

Although lengthening the compliance period would provide some regulatory relief to small entities, relief for these provisions would also delay the full realization of the benefits of the proposed rule.

4. Description of Recordkeeping and Reporting

The Regulatory Flexibility Act requires a description of the recordkeeping and recording required for compliance with this proposed rule. This proposed rule would require the preparation of records. As described in the Preliminary Regulatory Impact Analysis, records must be written or electronic documents must be kept that demonstrate that specific action or actions occurred in the manufacturing process in compliance with the proposed regulations. Records that would be required in this proposed rule would demonstrate, that corrective actions were taken, that equipment, instruments, and controls used in laboratory operations and quality control were installed properly, and calibrated; that maintenance programs were followed; and that the results of any testing meet the necessary specifications.

The compliance cost of recordkeeping is the sum of both the initial design and printing of the recordkeeping documents and the recurring costs of maintaining the records. The cost of training personnel to use the new documents is a recurring cost depending on how frequently documents are modified, how often personnel turn over, and how complicated the tasks are that are being recorded. The recurring costs are measured by the workers' wage rate multiplied by the expected labor hours necessary to perform a written or electronic record and the time necessary for management to review the records to see that actions are documented accurately. In addition, electronic records necessitate recurring time spent ensuring that the equipment is serviced and maintained properly.

5. Summary

The proposed CGMP regulations would have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires cost-benefit and other analyses for rules that would cost more than \$100 million in a single year. The current inflation-adjusted statutory threshold is \$112 million. The proposed rule qualifies as a significant rule under the statute because there is a significant possibility that the cost of the rule will be above the threshold. Most of the requirements of the Unfunded Mandates are fulfilled in the Executive Order 12866 analysis. The requirements under the Unfunded

Mandates Act of 1995 include assessing the rule's effects on future costs; productivity; particular regions, communities, or industrial sectors; economic growth; full employment; job creation; and exports.

Future Costs

The future costs from the rule include the recurring costs, which reach their long-term value in the third year after the proposed rule would become final. These costs would be incurred by the establishments that manufacture, process, pack, transport, distribute, receive, hold, or import dietary ingredients or dietary products. Recurring costs from the regulatory requirements would be incurred in each future year. Table 18 of this document summarizes the annual future recurring costs.

Particular Regions, Communities, or Industrial Sectors

The costs of the rule will be shared among manufacturers, processors, packagers, transporters, receivers, holders, and importers of dietary ingredients or dietary products as well as domestic consumers. The higher costs incurred by domestic suppliers of dietary supplement products as a result of these regulations will mostly be passed on to consumers in the form of higher prices. Since consumer demand for dietary supplements is price elastic, most of the higher costs incurred by suppliers will be passed on to consumers. Consequently, higher dietary supplement prices will reduce real incomes for many consumers. However, the reduction in real incomes is thought to be more than offset by the benefits from these regulations. These benefits are measured as an improved ability by the FDA to respond to and contain threats of serious adverse health consequences from accidental contamination of dietary supplements.

National Productivity, Economic Growth, Job Creation, and Full Employment

Although this proposed regulation is significant, we do not expect it to substantially affect national productivity, growth, jobs, or full employment. The total costs will be small relative to the economy, and will be offset by benefits. The improved ability to respond to, and contain, serious adverse health consequences means less illness and fewer sick days taken by employees, and lower adjustment costs by firms that would otherwise need to hire replacement employees.