

TABLE 13.—SUMMARY OF ANNUAL BENEFITS

Benefits	Mean (in millions)
Fewer illnesses (from table 8) .....	\$39
Fewer illnesses (from table 10) .....	66
Fewer product recalls (from table 9) .....	3
Reduced consumer search (from table 12) .....	109
Total benefits .....	218

## 7. Costs

The same changes in practices that produce benefits also have costs, the opportunity costs of not doing what consumers and manufacturers are now doing. The proposed regulation would require dietary supplement establishments to adopt some new practices in order to manufacture, package, and hold their products. The costs incurred for those who choose to comply will be for personnel, grounds and physical plant, equipment and instrumentation controls, quality control and laboratory operations, production and process controls, handling consumer complaints, and holding. In some cases, establishments would need to make capital improvements to the physical plant, add or replace equipment or controls, perform additional maintenance, keep records, carry out tests, or execute a variety of additional tasks that they may not have previously performed. We estimated the additional costs of production associated with the proposed rule and the leading regulatory options, using the survey (Ref. E2) to estimate baseline manufacturing practices.

a. *Description of the costs.* To estimate costs for the dietary supplement industry, we initially divided the industry into four product categories and three size categories. Because the survey showed that there were only a few establishments in some categories, we consolidated the size and product into three size categories. The size categories were:

- Very small (fewer than 20 employees).
- Small (20 to 499 employees).
- Large (500 or more).

Although this consolidation glosses over the important differences across products, the purpose is to estimate the broad average costs of the rule.

For each category, we constructed a cost model that included every provision of the CGMP regulations that

the proposed rule requires or recommends. We then attached a cost to each provision that had an activity associated with it. Most provisions did not have costs attached to them, mainly because they were either descriptive or the costs were included elsewhere. For the rule as a whole, we estimated the marginal, or additional costs for over 70 provisions of the proposed rule.

We expressed the cost as cost per unit, with the unit being either the establishment, the number of employees, or the annual number of batches produced. The costs of this proposed rule included the following general activities: Sanitation, production and process controls, holding and distributing, and consumer complaints.

b. *Costs of general activities.* i. *Sanitation.* Sanitation includes both one-time capital improvements and ongoing efforts. Some provisions of the proposed regulation may require establishments to perform one-time capital improvements to their physical plant facilities.

The proposed regulation would also require, if not already in place, physical plant owners to install new or additional plumbing systems to carry additional water or sewage, additional toilet or hand washing facilities, additional facilities for trash disposal, or new signs to instruct employees. The proposed regulations might also require establishments to add space in order to keep equipment and materials farther apart, which will help to prevent contamination or mixups. Other possible capital expenditures (among many other possible requirements) include:

- Replacing floors, walls, or ceilings with smooth, hard surfaces;
- Changing fixtures, ducts, or pipes that might be a source of contamination by dripping or condensation;
- Adopting ventilation control systems including filters, fans, or other air-blowing equipment to prevent odors or vapors;
- Additional lighting to ensure that equipment, contact surfaces, or other areas where supplements are examined, processed, or held can be adequately seen.

Sanitation also requires that equipment utensils must be of suitable design, construction, and workmanship to enable them to be adequately cleaned and maintained. To meet this requirement, some establishments may need to provide additional maintenance or additional cleaning and sanitation for their equipment and utensils. Also, freezers and cold storage compartments used to slow or arrest the growth of

microorganisms must be fitted with thermometers to accurately show the temperature within the compartments. Instruments and devices used in manufacturing must be accurate, adequately maintained, and adequate in number. To meet this requirement establishments might have to purchase new equipment, replace old equipment, or provide additional maintenance to existing equipment.

ii. *Production and process controls.* Production and process controls are the main preventive mechanism to ensure the identity, purity, quality, strength, and composition in the proposed rule. Establishments must implement a system of production and process controls that covers all stages of processing, from the receipt and acceptance of components, dietary ingredients, dietary supplements, packaging, and labels through the release for distribution and holding of the dietary ingredients and dietary supplements. Establishments must identify points, steps, or stages in the manufacturing process where control is necessary to prevent adulteration. Establishments must also establish specifications for the identity, quality, purity, strength, and composition of components, dietary ingredients, or dietary supplements. Establishments must monitor the points, steps, or stages in the batch production, as specified in the master manufacturing record, where control is necessary to prevent adulteration. Establishments must establish specifications for packaging to ensure that containers or closures that come into contact with dietary ingredients or dietary supplements are not reactive or absorptive and are composed of substances that are safe for use in or on food.

Establishments that have not already done so must establish a quality control unit with one or more individuals that have with the authority and responsibility to review the results of monitoring, make decisions on the disposition of materials, and identify whether actions taken to correct any deviations are appropriate. The quality control operation must ensure that components, dietary ingredients, and dietary supplements conform to specifications.

iii. *Holding and distributing.* Establishments must hold and distribute dietary ingredients and dietary supplements under appropriate conditions of temperature, humidity, and light so that the identity, quality, purity, strength, and composition of the dietary ingredients and dietary supplements are not affected. Establishments must also identify and