

TABLE 17.—ESTIMATED TOTAL COSTS  
[In millions]

	1st Year	2nd Year	3rd Year	4th Year and after
Very small establishments .....	0	0	\$46	\$28
Small establishments .....	0	\$76	47	47
Large establishments .....	5	3	3	3
Warehouses .....	12	9	9	9
Total .....	17	88	105	87

## 8. Summary of Benefits and Costs

We estimated that, once it is fully implemented, the measured annual benefits from the proposed rule would be \$218 million; measured annual costs would be about \$86 million. Additional but unmeasured benefits should also be recognized when comparing the total costs and benefits. Table 18 of this document compares the benefits and costs of the proposed rule to the benefits and costs of the leading regulatory options. Because the phase in period, complicates the comparison for the early years, we limit the comparison to annual benefits once all establishments are covered.

TABLE 18.—ANNUAL BENEFITS AND COSTS OF REGULATORY OPTIONS  
[In millions]

Regulatory option	Annual benefits	Annual costs
Proposed rule ...	\$218	\$86
Fewer requirements for vitamins and minerals .....	109	69
Stricter CGMP ..	218	178
HACCP only .....	42	38
Testing only (unable to estimate) .....	.....	32
High risk products only (unable to estimate) .....	.....	( <sup>1</sup> )

<sup>1</sup> Less than \$86 million.

*Uncertainties in the analysis.* In this section, we list all of the significant assumptions in the analysis, which if varied, could significantly change the estimates of costs and benefits. Such changes could have importance for the construction of any potential final rule. Therefore, we ask that comments address these aspects of the analysis and, where possible, provide FDA with better data to reduce the uncertainty. We estimated the benefits using indirect methods, which required several key assumptions that are critical for our estimates. With the exception of the

recall benefit, which is based directly on FDA recall records, each component of the estimated benefits involves assumptions that reflect our uncertainty.

Our basic assumption is that manufacturers lack market-based incentives to prevent hidden product quality defects. Our survey (Ref. E2) indicated that many firms do not have reliable quality control mechanisms in place. The survey was a one-time look at the manufacturing practices during the time of the survey. If the trend in the market is toward the adoption of the controls that we are proposing here in the absence of regulation, then both the cost and benefits of the rule will be less than we estimate. If the market-based trend is toward fewer controls, then both the cost and benefits of the regulation will be greater. Other key assumptions are listed below:

The assumptions for the health benefits from reducing the number of sporadic illnesses model are:

1. The baseline health of consumers is normal, not perfect. To estimate the change in health status from consuming defective products, we assumed that the baseline health of consumers is normal, which does not mean that we assumed that consumers have perfect health. We recognize that consumers will already have "background" health problems, by which we mean that many will have health problems unrelated to the consumption of defective products. Our assumption is that only the change in health status is relevant for our analysis. If an immune-compromised consumer is made ill by a defective product, *e.g.*, gets lead poisoning, the consumer might in fact have more difficulty recovering than an otherwise healthy person. However, we assume that the change in productivity, functional state, pain and suffering, and medical costs will be the same, regardless of prior health status. Accounting for confounding factors would have the effect of making health problems worse than we estimate, not better, so our estimate may be understating the true health benefits.

2. The average value of a QALY is \$630 per day. That value, \$630 per day,

is in turn based on: (1) The value of a statistical life of \$5 million; (2) the expected remaining life of consumers of 21.84 years (average), discounted from 36 years; and, (3) the social rate of time preference of 3 percent. The estimate is derived from workers in somewhat risky occupations who demand a wage premium for their additional risk of fatality. If our estimate of the value of a statistical life of workers does not represent the value of a statistical life of consumers of dietary supplements, then our benefits estimate will be different from the true health benefits of the rule. If consumers value their life differently than workers or if consumers place different values for different kinds of hazard-related deaths than do workers for job-related safety hazards, then we will have incorrect estimates for the true health benefits. If we discount life expectancy by 7 percent instead of 3 percent, the benefits would be much higher.

3. There is one illness for each recall. We assumed that for each class 1 and 2 recalled product there was only one illness that was reported to the public health authority. For instance, if a product was recalled because the defective product contained lead, we assume that a person was made ill from lead poisoning and that was how the recalled product was discovered. If there were more illnesses per recall than one, then our estimates of benefits will be low. If fewer than one illness per recall occurred (or is likely to occur in the future), then our estimate of health benefits will be more than the actual health benefits.

4. The assumed frequency of actual illnesses is 100 times the frequency of reported illnesses. This assumption is based on Ref. E16. We recognize that the factor of 100, although it has empirical support, might be wrong and that there is likely to be considerable uncertainty about this point estimate. It is widely believed in the public health community that most illnesses are underreported to public health authorities, particularly in passive reporting systems, such as the case with