

TABLE 21.—SENSITIVITY OF COSTS
[In millions]

Description	Estimated Annual Costs
The proposed rule	\$86
6 tests per batch (baseline is 3)	119
1 test per batch (baseline is 3)	66
\$100 per test (baseline is \$60)	101
1 consumer complaint per 20 batches (baseline is 1 per 10)	77
1 consumer complaint per 5 batches (baseline is 1 per 10)	104

C. Initial Regulatory Flexibility Analysis

1. Introduction

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. We find that this proposed rule would have a significant economic impact on a substantial number of small entities.

2. Economic Effects on Small Entities

a. *Number of small entities affected.* The proposed regulations would affect many small entities. Our classification of establishment size is based on the Small Business Administration's definition for small, as discussed previously in this document. A small business by this definition is any establishment with fewer than 500 employees. For this analysis, we defined very small establishments as establishments with fewer than 20 employees. Some small and very small establishments produce very large revenues and would probably not incur

a large decline in profitability from the proposed CGMP regulations. We lack precise information about those establishments. Based on the survey, we estimated that 830 establishments, 53 percent of the total establishments, could be classified as very small (under 20 employees) and 564 as small (20 to 499 employees), which is 36 percent of the total establishments.

We estimated that 95 percent of all holders (warehouses and wholesalers) covered by this regulation are small using the Small Business Administration definition. The total number of holders likely to be affected by this regulation is 26,617 (see table 4 of this document), so the total number of holders that are small would be 25,286 ($= 0.95 \times 26,617$).

The small establishments that would be affected by the proposed regulations are those establishments that would have to perform the various required activities, and that would not have done so without the regulations. As in the preliminary regulatory impact analysis (section VII.B of this document), we determined our estimate of baseline (pre-CGMP) manufacturing practices with the survey of the industry (Ref. E2). The survey asked representative respondents to answer a series of

questions, including how many employees they had and what their existing practices were. From the survey, we determined that small establishments do not now follow all of the provisions of the proposed CGMP regulations now. Those that do not follow the proposed requirements will incur a cost to do so.

b. *Costs to small entities.*

Implementation costs vary across establishments based on current practices and the types of products manufactured, packaged, or held. We estimated the range of current practices using the survey of the industry. The cost model divided establishments by size, which allowed us to estimate the distribution of costs per establishment for each size and product class. Table 22 of this document shows the cost per establishment for very small and small establishments. For comparison, we include the estimated average cost per large establishment and the median revenues for each size category. As the table shows, costs per establishment are proportionally higher for very small than for large establishments. The table's most striking result is that costs are highest for small (20 to 499 employees) establishments.

TABLE 22.—COST PER ESTABLISHMENT

	1st year	Annual
Very small—fewer than 20 employees; median revenue under \$1 million	\$62,000	\$38,000
Small—20 to 499 employees; median revenue \$5 to 10 million	99,000	61,000
Large—500 or more employees; median revenue \$20 to \$50 million	83,000	47,000

Small establishments that do not perform a substantial number of the actions required by the proposed CGMP regulations would bear relatively high costs for compliance with the provisions of this proposed rule. As shown in table 22 of this document, we estimated the average annual compliance costs for a very small establishment to be around \$38,000. About one-third of those establishments or about 500 firms have annual sales revenues under \$500,000.

In addition, the average annual compliance cost for a small establishment is around \$61,000. As the survey indicated, about 14 percent of establishments with 20 to 499 employees or about 200 firms have annual sales revenues under \$500,000. For purposes of our analysis, we regard firms with revenues of \$500,000 or less to be low revenue firms. Although the proposed rule would raise product prices, the price increase (which would

largely be determined by changes made by large establishments) would be much smaller than the increase in the average costs of very small producers. The average burden to very small low revenue firms, then, would be at least 8 percent of their annual revenue. The average burden to small low revenue firms would be at least 12 percent of annual revenue. Establishments with above average costs, and even establishments with average costs,