

TABLE 6.—ACCESS COSTS OPTION 2

	Firm Count	Cost	Average Cost per Firm
Domestic			
Manufacturers	36,948	\$5,564,000	\$151
Wholesalers/Warehouses	76,952	\$11,589,000	\$151
Packaging ¹	69,266	\$10,431,000	\$151
Transporters/Packers	15,171	\$2,285,000	\$151
Retail Grocery and Specialty Food	153,277	\$23,084,000	\$151
Convenience Stores	68,866	\$5,186,000	\$75
Mixed-Type Facilities that Engage in Farming	24,397	\$3,674,000	\$151
Importers	4,029	\$607,000	\$151
Total Domestic	448,905	\$62,420,000	\$139
Foreign			
Final Holders	42,182	\$6,353,000	\$151
Manufacturers	72,770	\$10,959,000	\$151
Other Facility Types	249,429	\$37,564,000	\$151
Total Foreign	364,381	\$54,876,000	\$151

¹ Includes both outer packaging and food contact substances.

Total quantified costs for option 2. Table 7 of this document presents the total quantifiable startup and recurring costs for option 2, and a range of uncertainty based on the uncertain number of exclusive importers and the range of uncertainty in design costs. We calculated the range of uncertainty using the 5th and 95th percentiles of the range of costs, with a uniform distribution of importers and a separate triangular distribution of redesign costs for each facility category and size. Both distributions represent the most amount of information implied by the known characteristics of the uncertain ranges. This procedure allows each component of cost uncertainty to vary independently, but this range cannot be interpreted in probabilistic terms.

Table 7 of this document presents the range of undiscounted annual costs of

future compliance for option 2. Costs incurred in year 1 are learning costs for all existing firms, redesign costs for large and small firms, and access planning costs for large and small firms. Costs incurred in year 2 are redesign and access planning costs for very small firms. Recurring costs are the additional records maintenance costs incurred by all firms and learning costs and records access costs for new firms. The mean, low, and high cost estimates presented here characterize the known and quantifiable uncertainties as they are defined previously. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low cost estimate. The cost estimate that is greater than 95 percent of all other estimates generated in the model is reported as the high cost estimate. Table 8 presents the

discounted annual costs incurred in future years and the present value of total costs incurred for option 2. The computations are made using the mean costs, and assume no increase in real labor cost and a 7 percent real discount rate. Although the recurring costs reported for year 3 and later years are the same in nominal terms (\$341,669,000 reported in Table 7), they are reported in discounted terms for each year in Table 8 to account for the fact that a dollar in 5 years, for example, is worth less than a dollar today. Each cell that contains only the symbol “:” is meant to convey the continuation of the series depicted in the cells that precede it from above. FDA acknowledges considerable nonquantifiable uncertainty in the estimates presented in Table 7 and requests comments.

TABLE 7.—TOTAL ANNUAL COSTS, OPTION 2

	Mean	Low	High	Average Mean Cost per Firm
Year 1	\$412,474,000	\$389,256,000	\$432,307,000	\$415
Year 2	\$737,595,000	\$665,189,000	\$816,183,000	\$741
Year 3 and later years	\$341,669,000	\$327,575,000	\$355,445,000	\$343