

TABLE 19.—COST DESCRIPTION IN PRESENT VALUE TERMS: OPTION 10—Continued

21 CFR Section	Mean	Low	High
1.337, 1.345, and 1.352 (Additional Records Maintenance)	\$2,952,309,000	\$2,817,570,000	\$3,070,891,000
1.337, 1.345, and 1.352, (Learning for New Firms)	\$13,836,000	\$13,310,000	\$14,328,000
1.361 (Access Preparation for New Firms)	\$7,883,000	\$7,318,000	\$8,418,000
Total ¹	\$3,660,808,000	\$3,478,944,000	\$3,833,452,000

¹ The totals reported at the bottom of each column differ slightly from the results that would be obtained by adding together all of the cells in the column. This is because the computation of the totals reported here is made assuming a joint distribution of the cost components, as described elsewhere in the analysis, rather than by adding together the individually computed component costs.

The annual range and discounted costs for option 10 as well as the marginal savings of option 10 with respect to option 4 are detailed in tables 20 and 21 of this document. 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. That

cost estimate that is greater than 95 percent of all other estimates generated in the model is reported as the high cost estimate.

TABLE 20.—TOTAL ANNUAL COSTS, OPTION 10

	Mean	Low	High	Average Mean Cost per Firm
Year 1	\$234,425,000	\$215,030,000	\$252,196,000	\$383
Year 2	\$507,230,000	\$459,345,000	\$550,801,000	\$828
Year 3 and later years	\$221,130,000	\$212,313,000	\$229,680,000	\$361

TABLE 21.—DISCOUNTED ANNUAL COSTS, PRESENT VALUE, AND MARGINAL SAVINGS: OPTION 10

	Discounted Annual Costs: Option 10	Marginal Savings of Option 10 With Respect to Option 4
Year 1	\$234,425,000	\$166,066,000
Year 2	\$474,047,000	\$191,243,000
Year 3	\$193,144,000	\$99,180,000
Year 4	\$180,508,000	\$92,692,000
Year 5	\$168,699,000	\$86,628,000
Year 6	\$157,663,000	\$80,961,000
: ¹	:	:
:	:	:
Year 15	\$85,758,000	\$44,037,000
:	:	:
:	:	:
Year 30	\$31,083,000	\$15,961,000
:	:	:
:	:	:
Present Value as of Year 1	\$3,660,808,000	\$1,873,357,000

¹ 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.