

TABLE 18.—NUMBER OF FOREIGN FACILITIES COVERED UNDER OPTION 3

Foreign holders and packagers	100,027
Foreign manufacturers/processors	125,450
Stops exporting	16%
Total facilities	205,405

TABLE 19.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES UNDER OPTION 3

Speaks English	16%
Has Internet access	31%
Has U.S. agent	10%
Cost of U.S. agent (annual)	\$1,000
Hourly wage rate	\$25

TABLE 19.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES UNDER OPTION 3—Continued

Time to find agent (hours)	5
Additional time language (hours)	5
Additional time Internet (hours)	5
First year agent cost	\$67,340,000
Agent fee (annual cost)	\$194,868,000
Administrative time (hours)	1
Additional time language (hours)	5
Additional time Internet (hours)	5
First year administrative costs	\$44,418,929

TABLE 19.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES UNDER OPTION 3—Continued

Time to fill out form (hours)	1
Additional time language (hours)	1
Additional time Internet (hours)	1
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	20%
First year form cost	\$12,992,000
Total first year costs	\$319,619,000
Total annual costs	\$228,370,000

TABLE 20.—COSTS INCURRED BY FDA UNDER OPTION 3

FDA Costs	2003	2004	2005	2006	2007
Development/modification/enhancement	\$8,200,000	\$3,000,000	\$3,300,000	\$2,300,000	\$2,300,000
Maintenance/steady state	\$1,560,000	\$3,500,000	\$4,300,000	\$4,300,000	\$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	\$110,588	\$110,588	\$110,588	\$110,588	\$110,588
Cost per paper submission	\$10	\$10	\$10	\$10	\$10
Number of domestic paper submissions	31,217	12,487	12,487	12,487	12,487
Number of foreign paper submissions	22,677	9,071	9,071	9,071	9,071
Total number of domestic registrations in database	107,646	107,646	107,646	107,646	107,646
Total number of foreign registrations in database	205,405	205,405	205,405	205,405	205,405
Mailings to domestic facilities	\$1	\$1	\$1	\$1	\$1
Mailings to foreign facilities	\$1	\$1	\$1	\$1	\$1
Error rate for paper submissions	10%	10%	10%	10%	10%
Number of errors	5,389	2,156	2,156	2,156	2,156
Cost per error	\$15	\$15	\$15	\$15	\$15
Total costs	\$10,907,000	\$7,243,000	\$8,343,000	\$7,122,000	\$7,122,000
Discounted total costs	\$10,907,000	\$6,769,000	\$7,287,000	\$5,814,000	\$5,433,000