

TABLE 38.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 7—Continued

Manager time for form (hours)	0.25
Form costs	\$6,670,000
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	20%
Annual facility costs	\$3,322,000
Total domestic costs	\$13,212,000

TABLE 39.—NUMBER OF FOREIGN FACILITIES COVERED UNDER OPTION 7

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

TABLE 40.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES

Speaks English	16%
Has Internet access	31%
Has U.S. agent	10%
Cost of U.S. agent (annual)	\$1,000
Hourly wage rate	\$25
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 40.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES—Continued

Time to fill out form (hours)	1
Additional time language (hours)	0
Additional time Internet (hours)	0
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	20%
First year form cost	\$5,135,000
Total first year costs	\$311,762,000
Total annual costs	\$227,585,000

TABLE 41.—COSTS INCURRED BY FDA UNDER OPTION 7

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	58,593	23,437	23,437	23,437	23,437
Number of foreign paper submissions	22,677	9,071	9,071	9,071	9,071
Total number of domestic registrations in database	202,046	202,046	202,046	202,046	202,046
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	5,860	2,345	2,345	2,345	2,345
Cost per error	\$15	\$15	\$15	\$15	\$15
Total costs	\$11,225,000	\$7,376,000	\$8,476,000	\$7,255,000	\$7,255,000
Discounted total costs	\$11,225,000	\$6,893,000	\$7,403,000	\$5,922,000	\$5,535,000