

systems. Costs for submitting the data will be different if other registration systems are used. For the costs of accepting duplicate registrations to be lower for facilities, the alternate registration system must include all the data elements required by the FDA registration. The system that initially seemed most likely to match FDA's requirements and most frequently mentioned in comments involved the permit requirements applicable to the alcohol beverage industry under laws enforced by TTB. FDA met with TTB to determine whether it was feasible to use TTB's basic permit system. FDA and TTB determined that TTB's regulations do not apply to all facilities required to register under this interim final rule. For example, the laws administered by TTB do not require foreign alcohol beverage producers to obtain permits, unless they are also engaged in the business of importing alcohol beverages into the U.S. FDA and TTB also determined that several of the required data elements for FDA registration are not mandatory information for alcohol beverage permittees, including some of the emergency contact information required by this interim final rule. Accordingly, even facilities with TTB permits would still have to file immediately a

registration update with FDA to provide missing data elements. FDA concluded that accepting registrations in alternative registration systems would not lower costs for facilities. If accepting registrations does not lower costs for FDA or for facilities, it is not a cost-effective alternative.

FDA assumes that if original data collection is not cost-effective for domestic facilities, it will be less cost-effective for foreign facilities, because foreign facilities will still have to obtain a U.S. agent and submit to FDA the information for their U.S. agent.

f. FDA costs.

FDA costs include creating and maintaining a database, processing paper submissions, and sending an annual mailing to registrants. Developing and maintaining a database includes automatically entering registrations into the database that arrive electronically and sending an electronic receipt and facility registration number back to the registrant. FDA estimates that four full-time equivalent employees (FTEs) will be needed to oversee the database. Additionally, paper submissions (*i.e.* those received by mail, fax, or on CD-ROM) will have to be entered manually. Costs are presented for the first 5 years

of the system in table 9 of this document. Annual costs are discounted at 7 and 3 percent. No comments were received on FDA's cost estimates in the PRIA. However, cost numbers were revised based on new information obtained by FDA.

Tables 10 through 12 provide details of the components of total costs for FDA, domestic facilities, and foreign facilities. For tables 11 and 12, FDA provides the estimate of the costs from the PRIA, and from 4 options; the interim final rule, the interim final rule with longer updates, the interim final rule without product categories, and the interim final rule with no U.S. agent requirement. Details of the costs that have not changed in response to comments may be found in the proposed rule. Tables 13 and 14 summarize the total costs over the first four years and provide a present value for a 20 year horizon for a 7 percent and 3 percent discount rate, respectively. FDA acknowledges uncertainty in these estimates; please see the proposed rule for a fuller discussion of all sources of uncertainty, and the discussion and sensitivity analysis under comment 192 regarding the uncertainty of the U.S. agent estimate.

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Table 10.--FDA Costs

FDA Costs	Year One	Year Two	Year Three	Year Four	Year Five
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	\$97,000	\$97,000	\$97,000	\$97,000	\$97,000
Processing paper submissions	\$2,900,000	\$1,600,000	\$1,600,000	\$1,600,000	\$1,600,000
Mailing costs	\$180,000	\$35,000	\$35,000	\$35,000	\$35,000
New hardware	\$0	\$0	\$0	\$650,000	\$0
Total	\$13,228,000	\$8,523,000	\$9,623,000	\$9,079,000	\$8,429,000
Total discounted at 7%	\$13,228,000	\$7,965,000	\$8,405,000	\$7,411,000	\$6,430,000
Total discounted at 3%	\$13,228,000	\$8,275,000	\$9,071,000	\$8,309,000	\$7,489,000