

In particular, comments said that firms will need to teach their suppliers, manufacturers/processors, customers, drivers, warehouses, growers, carriers, and shippers about the prior notice requirements regardless of whether each of the parties has filing responsibilities. FDA agrees. This new collection will necessitate some additional coordination of information among the parties involved in importing the article of food into the United States.

FDA assumes it takes about 2 business days (16 hours) for an administrative employee of the prior notice-submitting firm to coordinate with others to set up the new business practices required to receive the information needed for prior notice. We assume this set-up time will be sufficient to coordinate information for existing importing accounts. Table 4 of this document reports the costs of this information gathering and coordinating activity.

Because we expect some importing firms to enter and leave the industry every year, so do we expect importing firms to experience a turnover rate for their import accounts. FDA assumes that the turnover rate on these types of accounts is similar to the entry and exit rate of firms. We therefore assume that 10 percent of the firms' accounts each year are new accounts for which prior notice coordination of information is needed. This cost is also presented in table 4 of this document.

TABLE 4.—INFORMATION GATHERING AND COORDINATION FOR PRIOR NOTICE

Number of firms submitting notices	77,427
Administrative worker wage rate (doubled to include overhead)	\$25.10
Time to coordinate existing accounts	16 hours
First year cost of coordination of information on current accounts	\$31,094,683
Annual cost of coordination of information on new accounts	\$3,109,468

ii. *FDA costs. Information Technology.* We assume that FDA's information technology (IT) costs for this option and each option hereafter are the costs of interfacing with ABI/ACS to receive prior notice through OASIS for most FDA-regulated food subject to this interim final rule. FDA is developing an FDA PN System Interface to receive prior notice information for import entries that cannot be accommodated through ABI/ACS, mainly mail and baggage entries, and prior notices for food refused under section 801(m) of the FD&C Act.

FDA has allocated \$12.5 million for the development of the FDA prior notice system for fiscal year 2003. This total is broken down into \$7,400,000 for infrastructure design, procurement, setup, operations, and maintenance of computer system hardware and system and database software and licensing, plus \$5,100,000 for contractor services for the design, development, testing, and implementation of the FDA PN System Interface and the extensive enhancements required by OASIS to support prior notice. These costs are summarized in table 5 of this document.

Also included in table 5 are the costs CBP has incurred to accommodate prior notice. CBP costs include modifying ABI/ACS, training, and outreach. In the next few years, CBP plans to have its new system, ACE (Automated Commercial Environment), operational. The ACE system will replace the current ABI/ACS as well as combine other CBP entry functions and transactions. Prior Notice submission will be compatible with ACE. It is quite likely that importers will benefit from the enhanced functions of the new ACE system.

TABLE 5.—FDA PRIOR NOTICE SYSTEM COSTS

Infrastructure design and implementation	\$7,400,000
Contractor services	\$5,100,000
FDA system interface costs	\$12,500,000
CBP ABI/ACS system modification costs	\$500,000
Total prior notice system costs	\$13,000,000

Human Resources. The implementation of prior notice does not specifically call for the hiring of additional FDA border or inspectional staff. However, even before the passage of the Bioterrorism Act, FDA hired 300 additional consumer safety officers to help with the inspection of articles of food. And with the implementation of the prior notice interim final rule, it is quite likely that FDA will need to concentrate even more of its human resources on enforcement activities. Currently, FDA is working on a memorandum of understanding with CBP that would allow FDA to commission CBP's help as needed for inspections and enforcement activities related to the prior notice rule. *Destruction of Foods.* FDA will be responsible for the destruction of

articles of food that come into the United States via international mail and whose prior notices are considered inadequate or refused. FDA does not have an estimate of these destruction costs. We expect these destruction costs to be minimal, however, based on the fact that these will be personal food shipments and that there were relatively few formal mail entries (38,000) for articles of food in the OASIS data for fiscal year 2002. iii. *Current operating practices affected—(1) Food importers currently using BRASS.* In response to comments, FDA and CBP have agreed to allow prior notice information to be filed through ABI/ACS for most articles of food. By allowing prior notice to be submitted through ABI/ACS, FDA has eliminated the duplicative information collection

that would have resulted from the proposed stand-alone FDA Web-based system. While combining agency efforts has eliminated duplicative submission of information for many food importers, the combined system will increase submission requirements for those food importers who use BRASS. BRASS is a CBP program that allows expedited arrival processing for high-volume, repetitive shipments that have been judged by CBP to be low risk. BRASS processing is not compatible with the electronic submission of prior notice information because entry information for BRASS shipments is not filed until entry summary, long after the food has crossed the border. Therefore, those food importers who currently use BRASS and its expedited arrival process