

interface currently exists between AMS and the existing interface with OASIS through the ABI/ACS entry processes, which means FDA does not have any access to AMS data. However, section 801(m) of the FD&C Act requires that prior notice be submitted to FDA. Given the implementation date of December 12, 2003, CBP and FDA concluded that it was not practical to attempt to modify AMS to accommodate the new prior notice requirements when we could enhance the existing ABI/ACS–OASIS interface.

#### 2a. Viability of a Web-Based System

(Comments) A common concern expressed by commenters is the viability of the FDA PN System Interface for the volume of data traffic and the time-sensitive nature of prior notice information. Multiple comments address system availability, the time needed to enter and process the data, and the need for confirmation.

(Response) FDA agrees that implementation of a new FDA PN System Interface as the primary means of data submission for 25,000 plus transactions a day would be challenging, particularly considering the effect on the food industry if the system were not responsive. That concern has been substantially addressed as a result of the commitment by CBP and FDA to work together to enhance the existing ABI/ACS–OASIS interface to accommodate the prior notice requirements. The decision includes the development of a new ABI/ACS “transaction type” that will accommodate prior notices for IT entries, T&E entries, and food shipped directly to an FTZ. This new feature further reduces the number and type of transactions that must be submitted through the FDA PN System Interface.

FDA anticipates that less than 10 percent of the total submissions will be submitted through the FDA PN System Interface. The FDA PN System Interface will be available 24 hours a day, 7 days a week. FDA has taken steps to ensure that the FDA PN System Interface can provide adequate response times to support data entry and return of confirmation by reply messaging.

#### 2b. Contingency System

(Comments) FDA received several comments on the need for a contingency plan or backup plan in case of FDA Web system failure. The severity of the consequences if FDA were to fail to receive a prior notice, and the common experience with Web system failures, was of great concern to many of the system’s potential users. Many suggestions were made for contingency

plans, *e.g.*, information on what FDA plans to do if the automated system is unavailable.

(Response) FDA agrees that plans for contingencies are needed, even with the reduced volume of traffic on the FDA PN System Interface and the existence of two modes of submission. FDA does not plan to exempt any specific categories of food articles from prior notice if systems are not performing; FDA and CBP are working together to develop contingency plans for when the system(s) are not working. The interim final rule, § 1.279(b) through (d), sets out how we will handle prior notice in four “down-time” situations: The customs broker’s or self-filer’s access to ABI/ACS is not working; the ABI/ACS interface is not working; the FDA PN System Interface is not working; and OASIS is not working. In all these situations, an alternative form of prior notice information is required. If access to ABI/ACS is not available, prior notice must be submitted via the FDA PN System Interface. If FDA determines that FDA PN System Interface is not working, prior notice must be submitted manually by those who do not use ABI/ACS. If FDA determines that OASIS is not working, all prior notices must be submitted manually. FDA will issue notification through notices on the FDA Web site at <http://www.fda.gov>, at <http://www.access.fda.gov>, and through messages in ABI/ACS. Once FDA issues this notification, prior notice information must be submitted to FDA by e-mail or by fax.

Manual submissions must be submitted by e-mail or fax. Because all review is being done in a centralized location, we will not accept manual submissions in person. The FDA Web site at <http://www.fda.gov> will have a list of the information required for prior notice submission and the fax number(s) and e-mail address(es) where prior notice can be sent. The list of the information required can be printed. It can also be downloaded to the submitter’s or transmitter’s word processing system and used as a basis for submitting prior notice information to FDA. Because the FDA PN System Interface at <http://www.access.fda.gov> and FDA’s Web site at <http://www.fda.gov> are located on independent platforms, this information will be available even when the FDA PN System Interface is not working. This fax number and the e-mail address will not be activated to accept prior notice information unless FDA determines that the FDA PN System Interface or OASIS is not working. Additional information about the down-time, *i.e.*, confirmation that the FDA PN System Interface or

OASIS is down and estimated down-time will be posted at <http://www.fda.gov>—see “prior notice” and will be available from the help desk.

#### 2c. Alternate Methods

(Comments) Several comments suggest more than one path for submission of prior notice information. Some comments ask that FDA allow for manual submission, either as a backup, or as an alternate path. Others suggest that some types of “safe” products be allowed to bypass prior notice if the system were not performing. Still others suggest that the potential for catastrophic system failure requires FDA to implement 2 interfaces for prior notice data, often implying that ACS was an appropriate alternative system.

(Response) FDA does not agree that a process for manual transmission is needed, except on a contingency basis. FDA believes that, in 2003, persons engaged in international commerce have, or can get, access to the Internet. If the Internet is not accessible by the submitter, he or she can use a customs broker to submit prior notice through ABI/ACS or another person to transmit prior notice through the FDA PN System Interface. As the primary mode of submission, manual transmission would not give adequate time for FDA personnel to receive, review, and respond, unless the timeframes for prior notice in the interim final rule were greatly extended. Thus, manual transmission will be used only as a contingency alternative. FDA also notes that the data quality of manual systems is usually less than satisfactory, because no automated data validation takes place during data entry. The U.S. Government has a strong commitment to reducing paper-based processes and moving toward e-commerce for all business transactions. Accordingly, under the interim final rule, paper-based submissions will not be allowed, except as set forth in § 1.280(c) and (d), by e-mail and fax. However, FDA and CBP do not expect system failures to be a common occurrence.

#### 2d. Security of System

(Comments) Several comments question the security of the system and suggested that the system must have extraordinarily stringent security protocols in place to protect sensitive commercial information and prevent potential terrorists from obtaining information capable of providing cover.

(Response) FDA agrees the information must be secure. Any fraudulent or inadvertent changes in data could affect FDA response and thus affect the health and welfare of