

consumers in the United States. FDA has determined that the data security and data integrity requirements of the prior notice data are on par with entry data currently submitted through ABI/ACS to OASIS. Prior notice data submitted through ABI/ACS will have the same security and access controls as entry data currently received through ABI/ACS. Adequate and effective security controls will be placed on the FDA PN System Interface through user account management and authentication processes, and password controls, to ensure data security and integrity.

A number of statutes, regulations, and policies address protection of sensitive information from unauthorized disclosure. Some that are relevant to prior notice include the Clinger-Cohen Act of 1996, the Computer Security Act of 1987, the Trade Secrets Act, 21 CFR 20.61 (Trade Secrets and Commercial or Financial Information Which Is Privileged or Confidential), OMB Circular A-130 (Management of Federal Information Resources), and FDA Staff Manual Guide 3250.15 (Information Technology Security, Data Security—Data Confidentiality). For example, Appendix III to OMB Circular No. A-130 establishes a minimum set of controls to be included in an agency's information security program and requires security controls to be commensurate with the risk and magnitude of the harm resulting from the loss, misuse, or unauthorized access to or modification of information.

3a. Prior Notice Form

(Comments) Several comments suggest changes to the proposed form. Most of these recommend changes in the order of items in the form.

(Response) The draft form that was provided as an attachment to the proposed rule was intended only to provide a graphic summary of the information to be collected by the FDA PN System Interface (68 FR 5334). The form was an illustration, intended to help potential users to visualize the data requirements and to better analyze their relationship and impact. FDA did not intend the draft form to be a sample of the screens that will be available to the user on the proposed FDA PN System Interface. Nor was it intended to be a draft paper form, since paper-based submission will not be acceptable, except as a contingency if the system is not operating.

The actual screens of the FDA PN System Interface are based on standard Web design principles, with primary attention to support of anticipated data entry. The screens will incorporate extensive use of "pull-down" lists to

assist users in entering their data. For example, transmitters will use a predefined pull-down list of International Standards Organization (ISO) codes for countries to enter the country from which the article is shipped. Screen design places critical data entry items at the beginning of the submission process and uses those items to drive later processes. Data entry processing will also include robust and user-friendly data validation to ensure that transmitters enter data correctly and do not fail prior notice because of inadvertent errors in their data entry screens. Additional description of the FDA PN System Interface is included in the discussion of the interim final rule at the end of this section.

3b. Form Processing

(Comments) Several comments make suggestions about the way the form should be processed, requesting self-populating fields, the ability to change information without redoing the whole form, confirmation after submission, and other features that would make submission easier.

(Response) As noted previously, FDA did not intend the draft form in the proposed regulation to suggest processing sequences. Submitters or transmitters using the ABI/ACS interface to submit prior notice data to the FDA will be able to make full use of the capabilities of their particular ABI software's automation features. The FDA PN System Interface will permit initial partial data entry and will allow the user to save the information entered until all data are available for submission. The FDA PN System Interface is designed to accept "header" information that will permit repeated information to be automatically entered. This "header" would contain information consistent across several articles of food within the same submission, *e.g.*, date and time of arrival for several articles of food in one shipment. This will reduce the amount of data entry and potentially reduce typing and transcription errors. FDA has developed the FDA PN System Interface to allow submitters to automatically repeat information already entered in the submission where appropriate (*e.g.*, all information is the same except for the identity of the article or the manufacturer).

The order of information required in prior notice is displayed to best support user input. For example, the first information required is the identification of the submitter and transmitter, if applicable. The next information is the common information that may apply to all articles of food for

which prior notice is being submitted at the same time, such as the manufacturer, shipper, carrier, etc. For example, when a manufacturer is identified for the first article of food, the submitter will be able to indicate, using a check box, that the manufacturer is the same for all articles of food in the shipment.

3c. Clarification of Fields

(Comments) A few comments ask for clarification on the meaning of specific fields.

(Response) Elsewhere in this rule FDA sets out the information that must be submitted in a prior notice (see § 1.281). In addition, online help will be available, which will include descriptive information on data fields, and their relationship to other required information and references to the requirements. FDA will also provide a help desk with staff who will answer questions that are not specifically answered by the online help. Information on how to contact the help desk will be available on both the FDA PN System Interface at <http://www.access.fda.gov> and the FDA Web site at <http://www.fda.gov>—see "prior notice."

4. Existing System Adequate

(Comments) Several comments suggest that the regulations proposed were unnecessary and that FDA already had the data required, so prior notice would not provide any additional security. These comments conclude that the proposed regulation is therefore functionally redundant.

(Response) Congress mandated prior notice when it enacted the Bioterrorism Act. FDA disagrees with the assertion that prior notice will not provide any additional security because similar information about food is already available. Current systems do not provide all of the information required by the Bioterrorism Act. Nor do they ensure that FDA is provided with the required information before arrival, as required by Congress when it passed the Bioterrorism Act.

5–11. Description of the Prior Notice Submission Systems

Prior notice submission and electronic review will be accomplished through several new or enhanced components of FDA's and CBP's existing electronic systems.

a. *ABI/ACS interface.* The existing ABI/ACS interface, which sends data from customs brokers or self-filers through ACS to OASIS, will be enhanced to support the prior notice requirement. For customs brokers or