

self-filers providing prior notice as part of their CBP entry through the ABI/ACS interface, the process for submission and response will be similar to the current process for submitting entry information about FDA-regulated products. A customs broker or self-filer will enter and transmit the information currently required in a CBP entry, along with any additional information required in prior notice, using the software that currently supports submission of data through the ABI interface. (Changes will be required to the existing software to support the additional information required in the prior notice.) As it does currently, ACS will validate the submission to ensure that data required by CBP and FDA is entered. The existing validation will be enhanced to include validation of some prior notice information. If errors or deficiencies are found, the transmission will be rejected and the customs broker or self-filer can resubmit after correcting the errors or deficiencies.

Once ACS determines a submission is valid, the prior notice information and other data will be transmitted to OASIS. OASIS will perform additional data checks and validations. Validation is the process by which the data are checked for completeness and self-consistency by the system. It is a rapid process that does not include screening the data for potential public health concerns. That screening occurs after data validation. If the submission is determined to be facially valid, FDA will transmit a message through ACS to the customs broker or self-filer. The message will provide the Prior Notice Confirmation Number (PN Confirmation Number), which verifies that the prior notice has been confirmed by FDA for review.

If errors are found, OASIS will reject the submission and generate a message(s) identifying where the error occurs. No PN confirmation number will be issued. After the customs broker or self-filer is notified of the errors, the customs broker or self-filer can correct the errors and resubmit the entire entry using the same entry number through the existing CP transaction process (which is the existing transaction for brokers or self-filers to resubmit FDA-specific data through ACS). This process only allows FDA-specific data to be corrected for resubmission, and not CBP-specific data.

A new ABI/ACS-OASIS interface, modeled after the existing process, will be available to submit prior notice for an article of food entering the United States as an IT or T&E entry, or an FTZ admission. This new transaction will not require all of the information currently submitted to CBP at the time

a consumption entry is filed, but will require complete prior notice information. Processing of these prior notices will be similar to that described for consumption entries. However, prior notice will be submitted by a new transaction type that will require only the information needed for prior notice and to support messages to CBP regarding the adequacy of the prior notice.

If CBP entry is later filed, the PN Confirmation Number for the article must be entered as an affirmation of compliance for OASIS purposes as evidence that prior notice for the product was submitted and confirmed before arrival. Depending on the capabilities of a customs broker's or self-filer's software, a copy of the ABI Cargo Release Summary will also show that the prior notice has been received, though not necessarily confirmed, by FDA.

The following list identifies the types of entries, with accompanying CBP description, for which prior notice may be submitted through ABI/ACS at the submitter's option:

"Consumption entries"—products entered for use or consumption in the United States;

"Warehouse entries"—products subject to duty but for which payment of duties is deferred. Merchandise entered into a warehouse may be stored, repacked, cleaned, manufactured, smelted, refined, or sold for export. Food must remain in the warehouse until withdrawn for consumption in the United States (and any applicable duty paid);

"IT entries"—in-bond transportation entries for merchandise that arrives at a Customs port of entry but is transported without appraisement to another Customs port of entry where it may be entered for consumption or warehouse, admitted into a FTZ or may be the subject of another transportation entry;

"T&E" entries"—in-bond transportation entries for merchandise which arrives at a Customs port of entry and is to be transported without appraisement through the Customs territory and then exported; and

"FTZ admissions"—are for merchandise to be used in manufacturing or exhibition or to be manipulated in a FTZ. Merchandise admitted into the zone is not subject to the payment of duties. Merchandise may be withdrawn from the zone for consumption, warehousing, or exportation. There are various categories of merchandise in a zone.

b. *FDA PN System Interface.* The new FDA PN System Interface will be available for international mail and

other transactions that are not accepted by ABI/ACS, food refused under section 801(m) of the FD&C Act, and those who choose not to submit prior notice through ABI/ACS. The FDA PN System Interface is available at <http://www.access.fda.gov>. FDA expects that less than 10 percent of transactions will be routinely submitted through the FDA PN System Interface. We estimated the number of informal entries that are not currently captured by ABI/ACS and international mail submissions based on discussions with CBP.

The FDA PN System Interface will allow the user to view and print a prior notice confirmation, including a PN Confirmation Number, the time the prior notice was confirmed, and a record of the information received and validated by FDA.

To submit prior notice information electronically by the FDA PN System Interface, the transmitter must establish a prior notice account. FDA's Unified Registration and Listing System (FURLS) at <http://www.access.fda.gov> will manage the issuance of user accounts for both food facility registrations and prior notice submissions. FURLS will be available 24 hours a day, 7 days a week, and will provide end-users access to the systems. After successfully logging in using the account password, FURLS will pass the user account credentials to the FDA PN System Interface. If the transmitter has not established a prior notice account, the transmitter will be directed to establish a prior notice account the first time he or she accesses the FDA PN System Interface. Subaccounts can also be created, at the discretion of the primary account, to allow more than one person associated with a prior notice to access the prior notice information.

A submitter or transmitter who elects to use the FDA PN System Interface will enter information online, using a series of screens designed to lead the submitter through the prior notice submission process. Data will be subject to the same validation criteria used in the ABI/ACS-OASIS interface, but the validation will be performed on-line, in real time. When the prior notice submission has been validated, the transmitter will receive a message showing that the prior notice has been received by FDA for review and accepted as facially complete. This message will include a unique PN Confirmation Number as well as the date and time of the submission and confirmation. The message will confirm that the prior notice is facially complete and has been received by the FDA for review. Capability will also be provided