

2. Fax & E-mail Addresses

(Comments) Some comments state that the fax number and e-mail address should be optional.

(Response) FDA agrees, in part, and has eliminated the requirement for telephone and fax numbers and e-mail addresses in many instances. In the interim final rule, the telephone and fax numbers and e-mail addresses (if they exist) are only required for submitters and transmitters so that FDA can communicate with them, if necessary. The prior notice submission must declare if these persons do not have a telephone number, fax number, or e-mail address.

3. Submitter and Transmitter (§ 1.281(a)(1) and (a)(2) Proposed as § 1.288(a))

The proposed rule required the identity of the submitter and the associated submitting firm.

(Comments) Comments addressing the submitter focused primarily on who is authorized to submit prior notice and on the need for registration numbers and fax and e-mail information.

(Response) Comments regarding who may submit, as well as comments regarding registration numbers and telephone, fax, and e-mail information already have been addressed.

As explained in the proposal, the identification of the submitter is needed so that FDA knows who is responsible for the information in the prior notice and can communicate with them when necessary. The information is also necessary to follow up when audits, inspections, or enforcement are necessary.

The FDA PN System Interface will allow the information transmitted for identification of the submitter to be automatically repeated in the same submission if the submitting firm is also any other firm identified in the prior notice, such as the transmitter, importer, owner, ultimate consignee, etc. This ability to automatically repeat information may also be available for transmitters submitting prior notice through ABI/ACS, depending on the features of the ABI software package used by the transmitter.

(Interim final rule) Section 1.281(a)(1) requires submission of the name of the individual submitting the prior notice, *i.e.*, the submitter, and his or her business address, and telephone number, fax number, and e-mail address (if they exist), as well as the name and address of the submitting firm associated with the submitting individual, if it exists.

4. Transmitter (§ 1.281(a)(2))

The proposed rule allowed an agent to provide prior notice.

(Comments) Comments on the use of agents to provide prior notice are discussed under § 1.278.

(Response) Responses to comments on the use of agents are discussed under § 1.278.

(Interim final rule) If the prior notice is transmitted by a person other than the submitter, § 1.281(a)(2) requires the name of the individual transmitting the prior notice, *i.e.*, the transmitter, on behalf of the submitter and his or her business address, telephone number, fax number, and e-mail address, if they exist. The submission must also include the name of the firm associated with the individual transmitting the prior notice information, if it exists. The identification of the transmitter is needed so that FDA may confirm the prior notice, communicate regarding the prior notice after FDA review, and followup when audits, inspections, or enforcement are necessary.

5. CBP Entry Type (§ 1.281(a)(3) Proposed as § 1.288(b))

The proposed rule required the submission of the Customs entry type associated with the article of food being imported or offered for import (proposed § 1.288(b)).

(Comments) Comments state that the CBP entry type is not always available by noon of the day before arrival. They also note that entry type may change depending on quota status, *e.g.*, where a consumption entry was planned but then was changed to a warehouse entry because an entry quota on the product was temporarily filled or closed.

(Response) FDA and CBP believe that the significant shortening of the prior notice timeframe resolves many of the concerns about the availability of the CBP entry type. As discussed in the proposed rule, FDA needs this information for screening to identify the appropriate articles for inspection. It is also needed for communication with FDA and CBP staff at the border. Also, entry type determines which entry identifiers should be used (entry number, in-bond number) to identify the shipment. In addition, the CBP entry type tells us if the article of food is for consumption in the United States or is for export or other uses that, in turn, allows FDA to determine that certain information is not required (*e.g.*, registration numbers).

(Interim final rule) Section 1.281(a)(3) of the interim final rule requires submission of the entry type. Some examples of entry types are listed as

follows: Consumption entries, warehouse entries, and temporary importation bond entries. Each of these types has a designated CBP code. For prior notice submissions made through ABI/ACS, the entry type will consist of the CBP entry code specific for that type of entry, *e.g.*, "01" for a consumption entry, "21" for a warehouse entry, "23" for a temporary importation bond entry, *etc.* These codes are ones customs brokers and self-filers currently provide to CBP at entry. For prior notice submissions made through the FDA PN System Interface, applicable entry types or other admission categories will be provided for selection in a drop-down menu, *e.g.*, consumption, IT, T&E, mail, FTZ, *etc.* Explanations of the different entry types or other admission categories will be available to help the transmitter choose the right one.

6. ACS Entry Line Number or Other Customs Identification Number (§ 1.281(a)(4) Proposed as § 1.288(c))

The proposed rule required the identification of the CBP entry number, the CBP ACS line number and the FDA line number. FDA explained that this information is necessary for screening and identification of the appropriate articles for inspection, as well as for matching the prior notice to the corresponding CBP entry to assess the adequacy of the prior notice when shipments arrive and are presented for review.

(Comments) Comments state that the CBP entry number is available only from a customs broker or self-filer, but not every import has a broker. Other comments state that the entry number is not assigned until the customs broker or self-filer transmits entry information through the ABI to ACS. Thus, the entry number is not available by noon of the day before arrival. Other comments state that entry and line numbers are not available earlier than 4 hours before arrival at land ports. Some comments suggest that FDA make this information voluntary.

(Response) FDA agrees in part and has removed the requirement for submission of line numbers. The interim final rule only requires submission of a CBP entry identifier. FDA believes that the entry identifier is necessary for proper identification of the information in a prior notice with the appropriate articles for inspection. FDA also believes that submission of the entry identifier is critical for matching the prior notice to the corresponding CBP entry, which is necessary to assess the adequacy of the prior notice when shipments arrive and are presented for review. For in-bond entries and FTZ