

however, each submission must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company. If FDA receives a CD-ROM that does not comply with these specifications, it will send the CD-ROM back to the registrant unprocessed.

FDA notes that CD-ROM submissions are similar to submissions by mail or fax in terms of how they are processed. FDA will process these CD-ROM submissions along with the mailed and faxed submissions, in the order received. Therefore, registrants wanting to ensure that they receive their registration numbers quickly may wish to register electronically, as described previously. The principal advantage CD-ROMs offer over paper submissions is for firms that own many facilities and do not have reasonable access to the Internet. Using a CD-ROM to submit PDF typed registrations should increase legibility and save on mailing expenses. FDA reiterates, however, that submission by CD-ROM will be slower than submitting registrations electronically.

(Comment 104) Several commenters request that FDA's electronic system provide a way in which a single registrant entering data for many facilities can stop entering data on one day and resume from where they left off on another day.

(Response) FDA's electronic system will save registration data automatically with the completion of the entry of all data for a facility. Thus, it will be possible to stop entering data upon completion of the entry for one facility, and resume entering data for a subsequent facility on another day without loss of any previously entered data that would be applicable to both facilities, such as the name and address of the owner. The information needed for a registration is identified on the electronic registration form. A registrant will know what information is required for the registration before beginning to enter registration data into the system. Once a registrant has all of the required information, the time to register each subsequent facility should decrease, depending on how much of the information can be autofilled from the account information from previous registrations. However, the FDA electronic system does not allow a registrant to save data in the middle of registering a facility. Therefore, FDA suggests that registrants completely finish registering a particular facility before ending an online session.

(Comment 105) Some commenters ask whether the electronic system will allow multiple individuals from the

same company to enter registration information simultaneously.

(Response) The FDA electronic registration system is set up to allow a company to establish an enterprise (master) account and multiple subaccounts to allow several persons within a company to enter registrations simultaneously. The enterprise account can be used to enter facility registrations and it also can be used to establish and manage subaccounts. The subaccounts can only enter facility registrations, and unlike the enterprise account, they do not have access to other subaccounts. Generally, the enterprise account has access to all information entered via the subaccounts, unless, when created, the subaccount stipulates that the enterprise account is not to have access to that subaccount.

(Comment 106) Some commenters ask whether the electronic registration system will minimize the reporting burden. These commenters are concerned that the lack of detail FDA has provided regarding the Internet-based electronic registration system has made it difficult for them to evaluate the reporting burden.

(Response) FDA is working expeditiously to ensure that there will be a minimal reporting burden associated with registration in general, and electronic registration in particular. Registering electronically will be a relatively fast process once the registrant has all of the pertinent information available. Once the facility is registered electronically, its registration number should be provided automatically and instantaneously. FDA has received very positive comments at the several public demonstrations of the prototype of FDA's electronic registration system. Throughout the next couple of months, FDA will continue to conduct outreach activities to both foreign and domestic registrants to explain how the electronic registration system works to expedite registration.

(Comment 107) Some commenters express concern about the security of the electronic system. They state that the registration number alone should not be sufficient to access a facility's registration form in an electronic environment, because registration numbers will be required for prior notice of imports, and thus, are likely to be part of the commercial documentation between parties. These commenters emphasize that FDA must have procedures in place to ensure that only authorized persons can access and change a facility's registration information.

(Response) FDA has taken comprehensive steps to ensure that our

electronic registration system is secure. A risk assessment has been done and a formal security plan has been incorporated into the system that addresses both physical and electronic security. The system has undergone an independent security review and assessment as well as complete industry standard certification and accreditation. The system securely communicates with registrants using industry standard, secure socket layer with 128-bit encryption.

A facility's registration number alone is not sufficient to access a registration. To increase security, FDA has provided several layers of controls in the electronic access to registrations, thus preventing unauthorized access. First, an account ID and password must be established. Second, each registration has a unique registration number and PIN (Personal Identification Number), both of which are required to gain access to the registration and are only provided to the registrant. Only the registration number is disclosed as part of the prior notice of an imported food shipment. Thus, to prevent unauthorized access to a facility's registration, it is the responsibility of persons registering to secure their account IDs, passwords, and PINs.

(Comment 108) Some commenters request that the electronic system be available in every world language. Others ask whether shipments will be delayed if issues arise from translation discrepancies between a facility's registration in the English translation of its name and its prior notification with elements in the foreign language.

(Response) In response to the first part of the comment, FDA has determined that registration instructions will be provided in three languages: French, Spanish, and English. As noted, these are the three official languages of the WTO.

In response to the second part of the comment, FDA has determined that all registration information submitted must be in English. However, a person's name, the name of a company, the name of a street, or a trade name may be submitted in a language other than English. All information, including these items, must be submitted using the Latin (Roman) alphabet. These exceptions will ensure that inconsistencies will not arise between a facility's registration and prior notice.

Submissions must be in English (with the exceptions noted) so that FDA can understand the content of the registration, ensure that the registration information is correct, and have a database of facilities that its staff can readily access in the event of a