

US Food & Drug Administration **Bioterrorism Act of 2002**

OVERVIEW

Counter-terrorism is changing the way business is done within the US. In response to the Bioterrorism Act, the FDA has issued final interim rules on the Registration of Food Facilities and Prior Notice of Imported Food Shipments.

SUMMARY OF WHAT YOU NEED TO DO

REQUIREMENT	RESPONSIBILITY	ACTION REQUIRED
Registration of facility	Owner, operator, or agent in charge of a domestic or foreign facility that manufactures/processes, packs, or holds food for human or animal consumption in the U.S., or an individual authorized by one of them	Complete Form 3537 before December 12, 2003. FDA is encouraging online registration via the Internet at www.cfsan.fda.gov/~furls/ovffreg.html , which operates 24 hours a day, 7 days a week. If registrants do not have access to the internet, requests for paper copies of Form 3537 can be made via telephone to the US on: +1 301 575 0156 or by mail to: U.S. Food and Drug Administration HFS-681 5600 Fishers Lane Rockville MD 20857 USA
Prior notification of shipment	US customs broker, importer or agent	Read the requirements below so you have an understanding of the Prior Notice rule. Discuss with your US importer or customs broker and clearly allocate the responsibility for who will be issuing FDA with Prior Notification of Shipment.

AUSTRADE ADVICE

Registration of Facilities

A foreign facility must designate a U.S. agent, who must live or maintain a place of business in the U.S. and be physically present in the U.S., for the purposes of registration. The main purpose of a U.S. based agent is as a communication link between the foreign-registered facility and FDA.

Obvious examples of an agent include your importer or broker. If you would prefer not to designate either of these parties, then there are numerous private U.S.-based organisations offering these services. While Austrade does not endorse or recommend the use of a private consultant, a non-exhaustive list of consultants can be provided upon request. You are also advised to 'shop around' to ensure you will be receiving competitive rates and reliable service.

Prior Notification of Shipments

Commencing 12 December 2003, FDA now requires advance notification of incoming food shipments no more than 5 days before arrival. Currently, entry notification is usually provided by importers and brokers to the Bureau of Customs and Border Protection (CBP). FDA and CBP are working together to implement the prior notification rule and will use the same systems that are currently in place.

US Food & Drug Administration
Bioterrorism Act of 2002

Logically, this will continue to be the function of the importer or customs broker. Therefore, Austrade advises that you discuss with your importer or customs broker the procedure for Prior Notification.

US Food & Drug Administration

Bioterrorism Act of 2002

FURTHER DETAILS AND BACKGROUND INFORMATION

1. Registration of facilities

What is required?

Any site that manufactures, processes, packs or holds food, which will be imported into the US for human or animal consumption must first be registered with the US FDA¹. Existing exporters must be registered by 12 December 2003. A facility is exempted from registration if food or wine from that facility undergoes further processing or packaging outside the United States. A facility is not exempted from registration if the processing or packaging activities of the subsequent facility are limited to the affixing of a label to a package.

Any food or wine arriving for import to the US that is not from a registered site will be held at the port of entry. Samples for trade shows will also have to be registered and comply with the prior notice requirement.

How is it done?

Registration should be done on the FDA website at www.cfsan.fda.gov/~furls/ovffreg.html. This process takes approximately 45 minutes. Registration can also be done by mail or fax although this is not encouraged by FDA.

Who does it?

The exporter should undertake the registration. Please note that Exporting companies will be required to name a point of contact in the US – this may be your importer, broker or even an acquaintance. Many organizations are offering to act as this 'point of contact' for a fee and you may have already been approached. While this is acceptable to the FDA, we would suggest careful screening of the costing and services being offered prior to contracting such an organization.

Next steps:

Register your facility no later than 12 December 2003. For those companies starting business after December 12, 2003 they must register prior to beginning activities (taking in grapes and/or wine).

For further detailed information see <http://www.cfsan.fda.gov/~dms/fsbtac12.html>

2. Prior Notice of Shipment of Imported Food or Wine

What is required?

FDA must be notified of the details of any food entering the United States. Prior Notice must be received and confirmed electronically by FDA no more than 5 days before arrival and, as specified by the mode of transportation below, no fewer than:

1. 2 hours before arrival by land by road
2. 4 hours before arrival by air or by land by rail
3. 8 hours before arrival by water
4. The time consistent with the timeframe established for the mode of transportation for an article of food carried by or otherwise accompanying an individual if it is subject to prior notice (The food must also be accompanied by the FDA confirmation)

In addition, prior notice must be received and confirmed electronically by FDA before food is mailed by international mail. The parcel must be accompanied by confirmation of FDA receipt of prior notice.

US Food & Drug Administration **Bioterrorism Act of 2002**

Prior notice applies to each separate article in a container (eg, if there are different products—for example, Chardonnay and Shiraz—in one container, a separate notification form must be submitted for each).

How is it done?

Notification can be made through the existing electronic Customs system (ABI/ACS interface), through the FDA website, or by email/fax.

Who does this?

Logically, your US importer or the customs broker they employ should undertake the Prior Notification, as they work with the existing Customs system on a daily basis. Another option is your shipping company or freight forwarder.

If submitted through the ABI/ACS interface, a Prior Notice confirmation number together with a "PN received" message will be provided. Ensure that you receive a copy of this from whoever does the notification.

Next steps?

It is important that you confirm responsibility for Prior Notice with your US consignee or representative.

Prior notice requirement will commence on 12 December 2003. For further detailed information on Prior Notice of Imported Food Shipments see <http://www.cfsan.fda.gov/~dms/fsbtac13.html>

FURTHER INFORMATION

FDA website

<http://www.fda.gov/oc/bioterrorism/bioact.html>

AWBC website

www.awbc.com.au

Austrade contacts

Food:

Kylie Macnamara, Austrade Los Angeles

kylie.macnamara@austrade.gov.au

Wine:

Helen Jenkin, Austrade San Francisco

helen.jenkin@austrade.gov.au

US Food & Drug Administration

Bioterrorism Act of 2002

Fact Sheet on Registration of Food Facilities: Frequently Asked Questions

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) directs the Secretary of Health and Human Services to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply. To carry out the provisions of the Bioterrorism Act, FDA published, on October 10, 2003, an interim final regulation, *Registration Of Food Facilities*, which requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with the FDA. Under this interim final regulation, all affected facilities must register by **December 12, 2003**. In the event of a potential or actual bioterrorism incident or an outbreak of food-borne illness, facility registration information will help FDA to determine the location and source of the event and permit the agency to notify quickly facilities that may be affected.

Facilities can register online via the Internet, by completing a paper form, or submitting to FDA a CD-ROM with relevant registration information. The online registration system will be available for use on October 16, 2003. For assistance with online registration: in the U.S call 1-800-216-7331 or 301-575-0156; from elsewhere call 301-575-0156; or send a fax to 301-210-0247. Requests for assistance also may be emailed to furls@fda.gov. Beginning October 16, 2003, the Online Registration Help Desk will be staffed on business days from 7 AM until 11 PM U.S. Eastern Time.

This new regulation pertains *only* to facilities that manufacture/process, pack, or hold food, as defined in the regulation, for consumption in the U.S. Examples of "food" include:

- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and shell eggs
- Raw agricultural commodities for use as food or components of food
- Canned and frozen foods
- Bakery goods, snack food, and candy (including chewing gum)
- Live food animals
- Animal feeds and pet food

Food contact substances and pesticides are not "food" for purposes of the interim final rule. Thus, a facility that manufactures/processes, packs, or holds a food contact substance or a pesticide is not required to register with FDA.

Who must register? The owner, operator, or agent in charge of a domestic or foreign facility that manufactures/processes, packs, or holds food for human or animal consumption in the U.S., or an individual authorized by one of them, must register that facility with FDA by **December 12, 2003**. A domestic facility must register whether or not food from the facility enters interstate commerce. A foreign facility must designate a **U.S. agent** (for example a facility's importer or broker), who must live or maintain a place of business in the U.S. and be physically present in the U.S., for purposes of registration.

US Food & Drug Administration **Bioterrorism Act of 2002**

What types of facilities do not have to register?

- ***Private residences of individuals***, even though food may be manufactured/processed, packed, or held there.
- ***Non-bottled water drinking water collection and distribution establishments and structures***, such as municipal water systems.
- ***Transport vehicles that hold food only in the usual course of their business as carriers.***
- ***Farms***, i.e., facilities in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves, and cooling of produce are considered part of harvesting. The term "farm" also includes facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership, and facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. A farm-operated roadside stand that sells food directly to consumers as its primary function would be exempt from registration as a retail food establishment.
- ***Restaurants***, i.e., facilities that prepare and sell food directly to consumers for immediate consumption, including pet shelters, kennels, and veterinary facilities that provide food directly to animals. Facilities that provide food to interstate conveyances, such as commercial aircraft, or central kitchens that do not prepare and serve food directly to consumers are not restaurants for purposes of the rule.
- ***Retail food establishments***, such as groceries, delis, and roadside stands, that sell food directly to consumers as their *primary function*, meaning that annual sales directly to consumers are of greater dollar value than annual sales to other buyers. An establishment that manufactures/processes, packs, or holds food and whose primary function is to sell food directly to consumers, including food that the establishment manufactures/processes, from that establishment is a retail food establishment and is not required to register.
- ***Nonprofit food establishments***, which are charitable entities that meet the terms of § 501(c)(3) of the Internal Revenue Code and that prepare or serve food directly to the consumer or otherwise provide food or meals for consumption by humans or animals in the U.S. Central food banks, soup kitchens, and nonprofit food delivery services are examples of nonprofit food establishments.
- ***Fishing vessels*** that harvest and transport fish. Such vessels may engage in practices such as heading, eviscerating, or freezing fish solely to prepare the fish for holding on board the vessel and remain exempt.
- ***Facilities regulated exclusively and throughout the entire facility by the U.S. Department of Agriculture***, that is, facilities handling only meat, poultry or egg products.

Do all foreign facilities that manufacture/process, pack, or hold food for consumption in the U.S have to register?

No. If a foreign facility that manufactures/processes, packs, or holds food sends it to another *foreign* facility for further manufacturing/processing or packaging before the food is exported to the U.S., only the *second* foreign facility is required to register. **However**, if the second foreign facility performs only a *de minimis* activity, such as putting on a label, *both* facilities would be required to register. Also, any foreign facility that *packs or holds* food after the last foreign manufacturer/processor of the food must register.

US Food & Drug Administration **Bioterrorism Act of 2002**

How often must you register? Registration is required only once for each food facility. However, required registration information must be updated if it changes.

What does the registration number mean? It means that the owner of the facility has complied with this rule by registering with FDA. Assignment of the number does not convey FDA approval or endorsement of the facility or its products.

Is there a fee for registration? There is no fee for registration or for updates of any registration.

How can a facility register? Registrants must use Form 3537 to register or update a registration. Facilities may register online via the Internet at www.fda.gov/furls, which will operate 24 hours a day, seven days a week, beginning October 16, 2003. This web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. In addition to the online help registrants can access at www.fda.gov/furls, there is also an Online Registration Help Desk:

- In the U.S call 1-800-216-7331 or 301-575-0156
- From elsewhere call 301-575-0156
- Fax questions to 301-210-0247
- Email questions to furls@fda.gov

Beginning October 16, 2003, these phone numbers will be staffed on business days from 7 AM until 11 PM U.S. Eastern Time.

If a facility does not have reasonable access to the Internet, a paper copy of the form may be obtained from FDA by calling 800-216-7331 or 301-575-0156 or by mailing a request to:

U.S. Food and Drug Administration
HFS-681
5600 Fishers Lane
Rockville MD 20857
USA

When the form has been filled out completely and legibly, it should be mailed to the above address or faxed to (301) 210-0247. Also, as noted immediately below, registrations for multiple facilities may be submitted to FDA on a CD-ROM.

Is there a mechanism for registering multiple food facilities at one time? FDA will accept multiple registrations submitted in CD-ROM format ISO 9660 (CD-R or CD-RW) data format. These files must be submitted on a Portable Document Format (PDF) of Form 3537 and be accompanied by one signed copy of the certification statement that appears on the registration form. Each submission on the CD-ROM must use the same preferred mailing address in the appropriate block on Form 3537. There is no maximum number of registrations that may be submitted in this manner. However, each registration on a CD-ROM 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 the information does not conform to these specifications, FDA will not process the registration(s) and will return the CD-ROM for correction. FDA will process CD-ROM submissions along with mailed and faxed submissions in the order received.

Why does FDA encourage electronic registration? FDA encourages this mode of registration as the least costly and most efficient means for the facility as well as FDA. With electronic registration, all required information must be entered before the system will accept the submission. At that point, registrants will receive immediate confirmation of registration and a registration number. Paper registration will be a more costly and less efficient process to supply both FDA with the necessary facility information and facilities with their registration numbers. Further, paper registration may have a higher number of errors or omissions on the form, requiring additional time to complete the registration process.

US Food & Drug Administration **Bioterrorism Act of 2002**

What information is required? Each registration must include the name, address, and phone number for the facility and its parent company (if applicable); the name, address, and phone number of the owner, operator, or agent in charge; all trade names the facility uses; applicable food product categories as identified in FDA's regulation, 21 CFR 170.3; a statement certifying that the information submitted is true and accurate and that the person submitting the registration, if not the owner, operator, or agent in charge, is authorized to submit the registration. A foreign facility must also provide the name, address, and phone number of its U.S. agent. The foreign facility must also provide the emergency contact phone number for its U.S. agent unless the facility designates another person to serve as the emergency contact. A domestic facility must also provide an emergency contact phone number.

Is additional information requested? FDA is asking for, but not requiring, certain *optional* information on the registration form. The optional information will help us communicate more effectively with facilities that may be the target of an actual or potential terrorist threat or other food-related emergency. For example, some food products are not identified in the list of food categories at 21 CFR 170.3, such as certain dietary supplements, infant formula, and animal feed, but foods in these categories may be the focus of a food-related emergency. Therefore, FDA encourages, but does not require, submission of the information identified as optional on Form 3537.

Is registration information available to the public? No. Neither the list of registered facilities, any registration documents submitted under this regulation, nor any information derived from the list or the documents that would reveal the identity or location of a specific registered person is subject to disclosure under the Freedom of Information Act (FOIA).

What if the submitted registration information changes? When a required element of a facility's registration information changes, e.g., change of operator, agent in charge, or U.S. agent, the owner, operator, or agent in charge, or an individual authorized by one of them, must submit an update to the facility's registration within 60 days of the change through the Internet at www.fda.gov/furls or through the paper update process.

What if a facility goes out of business? When a facility goes out of business, its registration must be canceled using Form 3537a, either through the Internet, at www.fda.gov/furls, or through the paper process.

What if a new owner acquires an already-registered facility? The former owner must cancel the facility's registration within 60 days of the change (using Form 3537a), and the new owner must re-register the facility using Form 3537. Both cancellation and re-registration may be completed through the Internet or through the paper process.

What happens if a facility does not register? Failure of a domestic or foreign facility to register, update required elements, or cancel its registration in accordance with this regulation is a prohibited act under the Federal Food, Drug, and Cosmetic Act. The Federal government can bring a civil action to ask a Federal court to enjoin persons who commit a prohibited act, or it can bring a criminal action in Federal court to prosecute persons who are responsible for the commission of a prohibited act. If a foreign facility is required to register but fails to do so, food from that foreign facility that is offered for import into the U.S. is subject to being held within the port of entry for the article unless otherwise directed by FDA or the Bureau of Customs and Border Protection (CBP). FDA plans to issue enforcement guidance regarding the agency's policies regarding refusals of imported food under section 801(m)(1) or holds of imported food under section 801(l). This guidance document will be available to the public, and FDA will publish a notice of its availability in the Federal Register.

Will additional comments be accepted on this interim final regulation? FDA is providing a 75-day comment period on specific issues related to this interim final rule. In addition, to ensure that those commenting on this interim final rule have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data

US Food & Drug Administration
Bioterrorism Act of 2002

elements of this interim final rule, the agency intends to reopen the comment period for an additional 30 days beginning in March 2004. Regularly updated information on this interim final rule and how to comment on it can be accessed electronically at <http://www.fda.gov/oc/bioterrorism/bioact.html>.

How will FDA enforce this interim final rule during the comment period? FDA will actively consider the exercise of its discretion in the enforcement of the Registration interim final rule while at the same time ensuring public health protection, both during initial implementation of the rule and thereafter. The Registration interim final rule takes effect on December 12, 2003 and covered entities are responsible for complying with the requirements in the rule at that time. FDA recognizes that a number of affected parties still may need assistance in understanding the rule's requirements and how to comply even after the extensive outreach and educational activities that FDA will be conducting before December 12th. Accordingly, for this and other reasons, FDA intends to put into place, during the initial months following the effective date, a policy that emphasizes assisting covered entities in understanding the requirements and how to comply. FDA will shortly publish a notice of availability for a Compliance Policy Guide that will outline how FDA generally intends to exercise its enforcement discretion. This guidance, however, will not affect FDA's ability to take actions that may be necessary, including conducting inspections for food safety and security concerns or taking any other action under the Federal Food, Drug, and Cosmetic Act. This policy will also not affect the ability of the Bureau of Customs and Border Protection to assess penalties under 19 U.S.C. 1595a(b) or to take enforcement action under any other authority.

For further information: For more details and information on the specific requirements of this interim final rule, please refer to the interim final rule itself. The interim final rule is available at <http://www.cfsan.fda.gov/~furls/ffregfr.html>.

US Food & Drug Administration

Bioterrorism Act of 2002

Fact Sheet on Prior Notice of Imported Food Shipments: Frequently Asked Questions

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) requires that FDA receive prior notice of food imported into the United States, **beginning on December 12, 2003**. Most of the prior notice information required by the interim final rule is data usually provided by importers or brokers to the Bureau of Customs and Border Protection (CBP) when foods arrive in the United States. Now, the Bioterrorism Act requires that this information also be provided to FDA in advance of an imported food's arrival to the United States. FDA will use this information in advance of the arrival to review, evaluate, and assess the information, and determine whether to inspect the imported food. FDA and CBP have collaborated on the implementation of the prior notice interim final rule. Nearly all of the current imported food shipments can comply by using CBP's Automated Broker Interface of the Automated Commercial System (ABI/ACS). **Prior notice can be submitted either through ABI/ACS or FDA's Prior Notice (PN) System Interface beginning December 12, 2003.**

When must prior notice be submitted? Prior notice must be received and confirmed electronically by FDA no more than 5 days before arrival and, as specified by the mode of transportation below, no fewer than:

1. 2 hours before arrival by land by road
2. 4 hours before arrival by air or by land by rail
3. 8 hours before arrival by water
4. The time consistent with the timeframe established for the mode of transportation for an article of food carried by or otherwise accompanying an individual if it is subject to prior notice (The food must also be accompanied by the FDA confirmation.)

In addition, prior notice must be received and confirmed electronically by FDA before food is mailed by international mail. (The parcel must be accompanied by confirmation of FDA receipt of prior notice.)

How must the prior notice be submitted? Prior notice must be submitted electronically. FDA estimates more than 80 percent of prior notice of imported food shipments submissions can be transmitted through ABI/ACS. Prior notice for international mail food shipments, other transaction types that cannot be made through ABI/ACS, or articles of food that have been refused admission under section 801(m)(1) of the Federal Food, Drug, and Cosmetic Act must be submitted to the FDA PN System Interface at www.access.fda.gov. **Beginning on December 12, 2003, for technical assistance in submitting prior notice:**

- **For the United States, call 1-800-216-7331 or 301-575-0156**
- **From all other countries and locations, call 301-575-0156**
- **Send a fax to 301-210-0247**

This technical assistance will be available on business days from 7 AM until 11 PM U.S. Eastern Time. Requests for assistance also may be emailed to furls@fda.gov. For assistance with ABI/ACS transmission, contact your CBP client representative.

Both the CBP and FDA systems for prior notice will be available 24 hours a day, 7 days a week for information submission beginning December 12, 2003.

If the ABI/ACS is not working, then prior notice must be submitted using the FDA PN System Interface. If the FDA PN System Interface does not appear to be working properly, the online Help Desk should be contacted first. If the system is not working, then the required prior notice information, which appears in the interim final rule and will be listed on FDA's website, must be submitted by fax or email. The fax number(s) and email address(es) where they can be sent will be posted on the FDA website (www.fda.gov).

US Food & Drug Administration

Bioterrorism Act of 2002

Who must submit prior notice? Any individual with knowledge of the required information may submit the prior notice, including, but not limited to, brokers, importers, and U.S. agents.

What food is subject to the requirement for submitting prior notice? Prior notice applies to food for humans and other animals that is imported or offered for import into the United States. For purposes of the interim final rule, "food" is defined by reference to section 201(f) of the Federal Food, Drug, and Cosmetic Act. Section 201(f) defines "food" as articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such articles. Examples of "food" include:

- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and shell eggs
- Raw agricultural commodities for use as food or components of food
- Canned and frozen foods
- Bakery goods, snack food, and candy (including chewing gum)
- Live food animals
- Animal feeds and pet food

What foods are excluded from the prior notice requirement? Foods that are excluded from the prior notice requirement are: (1) food carried by or otherwise accompanying an individual arriving in the United States for that individual's personal use (i.e., for consumption by themselves, family, or friends, and not for sale or other distribution); (2) food that is exported without leaving the port of arrival until export; (3) meat food products, poultry products and egg products that are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act; and (4) food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for non-business reasons) to an individual in the United States.

Will FDA provide confirmation of receipt of prior notice? Yes. FDA will issue a confirmation of prior notice to the transmitter upon successful receipt of the prior notice information.

What information must be included in the prior notice? The prior notice must be submitted electronically and contain the following information:

- Identification of the submitter, including name, telephone and fax numbers, email address, and firm name and address
- Identification of the transmitter (if different from the submitter), including name, telephone and fax numbers, email address, and firm name and address
- Entry type and CBP identifier
- The identification of the article of food, including complete FDA product code, the common or usual name or market name, the *estimated* quantity described from the smallest package size to the largest container, and the lot or code numbers or other identifier (if applicable)
- The identification of the manufacturer

US Food & Drug Administration **Bioterrorism Act of 2002**

- The identification of the grower, if known
- The FDA Country of Production
- The identification of the shipper, except for food imported by international mail
- The country from which the article of food is shipped or, if the food is imported by international mail, the anticipated date of mailing and country from which the food is mailed
- The anticipated arrival information (location, date, and time) or, if the food is imported by international mail, the U.S. recipient (name and address)
- The identification of the importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States
- The identification of the carrier and mode of transportation, except for food imported by international mail
- Planned shipment information, except for food imported by international mail

Does the carrier need the prior notice confirmation upon arrival? It is prudent to have the confirmation. For a prior notice that is submitted through the ABI/ACS interface, the prior notice confirmation number together with a "PN received" message will be made available to the filer through the ACS/ABI interface. If prior notice is submitted through the FDA PN System Interface, then the transmitter will receive a confirmation online as soon as the submission is confirmed. To make it easier for the carrier or individual at the port, the carrier should have a copy of the confirmation, which includes a prior notice confirmation number in his/her possession. For international mail packages, the Prior Notice Confirmation Number must accompany the package. For food carried by or otherwise accompanying an individual arriving in the United States, the Prior Notice Confirmation Number must accompany the food.

Can an incomplete prior notice be corrected? Yes. If the transmission fails the validation, it will be rejected and the transmitter will have an opportunity to make corrections. The FDA PN System Interface has Help features and interactive feedback to assist the submitter and minimize spelling mistakes and omissions. In addition, the online Help Desk will be available to assist users, beginning December 12, 2003. The Help Desk will be staffed on business days from 7 AM until 11 PM U.S. Eastern Time. Confirmation means the information has been received and is facially complete. Subsequent system and manual review by FDA staff may result in inspection of the imported food upon arrival.

What must be done if information changes after prior notice confirmation has been received? If any of the following required information changes after confirmation, then a new prior notice must be submitted:

- Identification of the submitter, including name, telephone and fax numbers, email address, and firm name and address
- Identification of the transmitter (if different from the submitter), including name, telephone and fax numbers, email address, and firm name and address
- Entry type and CBP identifier
- The identification of the article of food, except the estimated quantity
- The identification of the manufacturer
- The identification of the grower, if known

US Food & Drug Administration **Bioterrorism Act of 2002**

- The FDA Country of Production
- The identification of the shipper
- The country from which the article of food is shipped or, for food imported by international mail, the anticipated date of mailing
- The U.S. recipient (name and address) if the food is imported by international mail
- The identification of the importer, owner, and consignee
- The identification of the carrier and mode of transportation
- Planned shipment information unless the food will not be imported

Does food that has been refused for inadequate prior notice require any additional information in prior notice? Yes. The prior notice for food that has been refused for inadequate prior notice also must include the port of arrival, the location where the refused food is being held, the date it arrived or will arrive at that location, and the identification of the contact person at that location.

What are the consequences of failing to submit adequate prior notice information of an imported food shipment? Food that is imported or offered for import with inadequate prior notice is subject to refusal and holding at the port or in secure storage. FDA will provide its staff with enforcement guidance containing the Agency's policies on injunctions, prosecution, and debarment related to failure to provide timely and accurate prior notice, as well as the Agency's policies regarding refusals under § 801(m)(1) and holds under § 801(l). FDA intends to include a transition period in this guidance, during which it will emphasize education to achieve compliance. While FDA will nonetheless be authorized to take various types of enforcement action for violations of the prior notice requirements, this planned transition period will allow FDA to focus its resources on the most appropriate circumstances. FDA also intends to provide guidance to its staff on enforcing the prior notice requirements after a transition period. FDA's guidance documents will be available to the public, and FDA will publish a notice of availability in the *Federal Register*.

Will additional comments be accepted on this interim final regulation? FDA is providing a 75-day comment period on this interim final rule. In addition, to ensure that those commenting on this interim final rule have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of this interim final rule, the Agency intends to reopen the comment period in March 2004 for an additional 30 days. This date will coincide with the issuance of the plan by FDA and CBP relating to timeframes. Regularly updated information on this interim final rule and how to comment on it can be accessed electronically at <http://www.fda.gov/oc/bioterrorism/bioact.html>.

How will FDA enforce this interim final rule during the comment period? FDA will actively consider the exercise of its discretion in the enforcement of the prior notice interim final rule while at the same time ensuring public health protection, both during initial implementation of the interim final rule and thereafter. The prior notice interim final rule takes effect on December 12, 2003, and covered entities are responsible for complying with the requirements in the interim final rule at that time. FDA recognizes that a number of affected parties still may need assistance understanding the interim final rule's requirements and how to comply even after the extensive outreach and educational activities that FDA will be conducting before December 12th. Accordingly, for this and other reasons, FDA intends to put into place, during the initial months following the effective date, a policy that emphasizes assisting covered entities in understanding the requirements and how to comply. FDA will shortly publish a notice of availability for a Compliance Policy Guide that will outline how FDA generally intends to exercise its enforcement discretion. This guidance, however, will not affect FDA's ability to take actions that may be necessary, including conducting inspections

US Food & Drug Administration
Bioterrorism Act of 2002

for food safety and security concerns or taking any other action under the Federal Food, Drug, and Cosmetic Act. This policy will also not affect the ability of the Bureau of Customs and Border Protection to assess penalties under 19 U.S.C. 1595a(b) or to take enforcement action under any other authority.

For more details and information on the specific requirements of this interim final rule, please refer to the interim final rule itself. The interim final rule is available at <http://www.cfsan.fda.gov>.