

and assign a unique registration number to each registered facility;

- FDA may encourage electronic registration;
- Registered facilities must notify FDA in a timely manner of changes to their registration information;
- FDA is required to compile and maintain an up-to-date list of registered facilities; and
- FDA's list of facilities and registration documents are not subject to public disclosure under 5 U.S.C. 552 (the Freedom of Information Act). Information derived from this list or these documents is also not subject to such disclosure to the extent that it discloses the identity or location of a specific registered facility.

In addition to section 305 of the Bioterrorism Act, FDA is relying on section 701(a) and (b) of the FD&C Act (21 U.S.C. 371(a) and (b)) in issuing this interim final rule. Section 701(a) authorizes the agency to issue regulations for the efficient enforcement of the act, while section 701(b) of the FD&C Act authorizes FDA and the Department of Treasury jointly to prescribe regulations for the efficient enforcement of section 801 of the FD&C Act (21 U.S.C. 381).

This interim final rule implements the food facility registration requirements in section 305 of the Bioterrorism Act. Elsewhere in this issue of the **Federal Register**, FDA is issuing an interim final rule implementing section 307 (prior notice of imported food). The two interim final rules published in this issue of the **Federal Register**, as well as the regulations FDA will issue to implement section 306 (recordkeeping/records access) and section 303 (administrative detention) of the Bioterrorism Act, will help FDA act quickly in responding to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies. Registration will provide FDA with information about facilities that manufacture/process, pack, or hold food for consumption in the United States. In the event of an outbreak of foodborne illness, such information will help FDA and other authorities determine the source and cause of the event. In addition, the registration information will enable FDA to notify more quickly the facilities that might be affected by the outbreak. In developing this interim final rule, FDA has complied with its international trade obligations, including the applicable World Trade Organization (WTO) agreements and the North American Free Trade Agreement (NAFTA).

II. Highlights of the Interim Final Rule and Summary of the Significant Changes Made to the Proposed Rule

A. The Highlights of This Interim Final Rule Are Described Briefly Below and Are Discussed in More Detail Later in the Preamble

The highlights of this interim final rule are as follows:

- The owner, operator, or agent in charge of a facility engaged in manufacturing/processing, packing, or holding food for consumption in the United States by humans or animals is responsible for registering the facility with FDA;
- The owner, operator, or agent in charge of a facility that is required to register may authorize an individual to submit the facility's registration to FDA;
- Facilities covered under this rule must be registered by December 12, 2003;
- A foreign facility is exempt from registering if food from the facility undergoes further processing or packaging by another facility outside the United States. The facility is not exempt from registration if the processing or packaging activities of the subsequent facility are limited to affixing a label to a package or other de minimis activity. The facility that conducts the de minimis activity also must register;
- The following domestic and foreign facilities are also exempt from registration: Farms; restaurants and other retail food establishments; nonprofit food facilities that prepare or serve food directly to the consumer or otherwise provide food or meals for consumption by humans or animals in the United States; fishing vessels not engaged in processing as defined in § 123.3(k); and facilities regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*);
- Registrants must use Form 3537 to register. This form is available either on the Internet (see address below) or via mail or phone request. FDA will begin processing paper registrations on October 16, 2003. Registrants must use Form 3537a to cancel their registration;
- FDA strongly encourages electronic registration, which will be quicker and more convenient for both facilities and FDA than registration by mail or CD-ROM;
- To register electronically, beginning on October 16, 2003, a registrant may visit <http://www.fda.gov/furls>, which is

available for registration 24 hours a day, 7 days a week. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes, as well as through a foreign facility's U.S. agent or other authorized individual if the facility makes such arrangements;

- Regardless of the mode of submission (electronic, paper, or CD-ROM), each registration must include the name and contact information for the facility and its parent company (if applicable); all trade names the facility uses; applicable food product categories as identified in § 170.3 of this chapter; a statement certifying that the information submitted is true and accurate and that the person submitting the registration is authorized by the facility to register on its behalf; and if a foreign facility, the name of and contact information for the facility's U.S. agent. A domestic facility must provide emergency contact information;
- No registration fee is required;
- Updates to registration information or cancellation of registration must be submitted within 60 calendar days of any change to any of the required information previously submitted;
- Failure of a domestic or foreign facility to register, update, or cancel its registration in accordance with this regulation is a prohibited act under section 301(dd) of the FD&C Act;
- The disposition of food imported or offered for import from an unregistered foreign facility will be governed by the procedures set out in subpart I of this part 1 (21 CFR part 1) (Prior Notice of Imported Food); and
- Assignment of a registration number to a facility means that the facility is registered with FDA. Assignment of a registration number does not in any way convey FDA's approval or endorsement of a facility or its products.

B. Significant Changes Made to the Proposed Rule

The significant changes FDA made to the proposed rule are as follows:

- The interim final rule provides that private residences of individuals and nonbottled water drinking water collection and distribution establishments and structures are not facilities and, therefore, are not required to register;
- The interim final rule clarifies that transport vehicles are not facilities if they hold food only in the usual course of business as carriers;
- The definition of farm now states that washing, trimming of outer leaves, and cooling produce are part of harvesting;