DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2002–N–0323]

Amendments to Registration of Food Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to amend its regulation for registration of food facilities that requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with FDA. This proposed rule would amend and update FDA's registration regulations and is part of our implementation of the FDA Food Safety Modernization Act (FSMA), which added new provisions for the registration of food facilities. Moreover, a number of provisions in FSMA apply only to facilities required to register, including hazard analysis and risk-based preventive controls and mandatory recall authority. The proposed amendments will further enhance FDA's capabilities with respect to responding to food safety issues, and in addition, provide FDA with information that we can use to focus and better utilize our limited inspection resources.

DATES: Submit either electronic or written comments on the proposed rule by June 8, 2015. Submit comments on the information collection issues under the Paperwork Reduction Act of 1995 by May 11, 2015, (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments by any of the following methods, except that comments on the information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA–2002–N–0323 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *With regard to the proposed rule:* Monica Storozyszyn, Center for Food Safety and Applied Nutrition (HFS–615), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1367. *With regard to the information collection:* FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Proposed Rule

This proposed regulation would implement certain provisions in section 415 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350d), as amended by section 102 of the FDA Food Safety Modernization Act (FSMA), that relate to registration of food facilities. In addition, this proposed regulation would amend and update FDA's registration regulations to further enhance FDA's capabilities with respect to responding to food-related emergencies, and in addition, provide FDA with information that we can use to focus and better utilize our limited inspection resources.

Summary of the Major Provisions of the Proposed Rule

Section 102 of FSMA amends section 415 of the FD&C Act by requiring that certain additional information be included in registrations. More specifically, section 102(a)(1)(A) of FSMA amends section 415 to provide that registrations for domestic food facilities are required to contain the email address for the contact person of the facility, and registrations for foreign food facilities are required to contain the email address of the U.S. agent for the facility. Further, section 102(a)(3) of FSMA amends section 415 to provide that food facilities required to register with FDA must renew their registrations with FDA every 2 years, between October 1 and December 31 of each even-numbered year, by submitting registration renewals to FDA. Also, section 102(b)(1)(A) of FSMA provides that all food facility registrations are required to contain an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. These FSMA amendments were self-implementing and became effective upon enactment of FSMA. These FSMA amendments are being included in this proposed rule to codify the provisions in the food facility registration regulations in 21 CFR part 1, subpart H.

In addition, section 102(b) of FSMA authorizes FDA to require that all food facility registrations be submitted to FDA in an electronic format; however, such requirement cannot take effect before the date that is 5 years after the date of enactment of FSMA (*i.e.,* January 4, 2016). We are proposing to implement this provision in this proposed rule.

Section 102(c) of FSMA also directs FDA to amend the definition of the term ''retail food establishment'' in § 1.227(b)(11) of title 21, Code of Federal Regulations to clarify that, in determining the primary function of an establishment or a retail food establishment under such section, the sale of food products directly to consumers by such establishment and the sale of food directly to consumers by such retail food establishment include: (1) The sale of food products or food directly to consumers by such establishment at a roadside stand or farmers' market where such stand or market is located other than where the food was manufactured or processed; (2) the sale and distribution of such food through a community supported agriculture program; and (3) the sale and distribution of such food at any other such direct sales platform as determined by the Secretary. We are proposing to implement these provisions in this proposed rule.

Lastly, we are proposing changes to improve the utility of the food facility registration database. We are proposing, among other things, to: (1) Require

certain additional data elements in food facility registrations; (2) employ additional measures to verify certain information submitted in registrations; and (3) take additional steps to ensure that our registration database is up-to-date by identifying additional circumstances under which FDA will cancel registrations.

Costs and Benefits

Costs of meeting the proposed requirements of this rule will be incurred by both FDA and food facilities that are required to register. Table 1 presents estimated costs associated with the provisions in this proposed rule. Estimated one-time costs to domestic and foreign facilities are about $22 million. Annualized costs are calculated using a discount rate of 7 percent and 3 percent over 20 years. Total annualized costs to food facilities, which include annualized one-time costs and annualized recurring costs, are approximately $5 million and $6 million. Annualized recurring costs to FDA are approximately $1 million, using both discount rates. We expect that the benefits of the proposed rule would include aiding FDA's ability to deter and limit the effects of foodborne outbreaks and other food-related emergencies. Although we are unable to quantify these and other benefits, we discuss the expected benefits qualitatively in the preliminary regulatory impact analysis (PRIA).

TABLE 1—ANNUALIZED COST AND BENEFIT SUMMARY

[$Millions]

	Total one time costs	Total annualized costs 7%	Total annualized costs 3%	Benefits
Domestic Facilities	$9	$1	$1	Not Quantified.
Foreign Facilities	13	4	5	
Subtotal Facilities	22	5	6	
Costs to FDA		1	1	
Total	22	6	7	

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I. Background

A. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and FDA's Current Regulations for Registration of Food Facilities

After the events of September 11, 2001, highlighted the need to enhance the security of the infrastructure of the United States, including the food supply, Congress responded by enacting the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107–188), which was signed into law on June 12, 2002. The Bioterrorism Act included a provision in Title III (Protecting Safety and Security of Food and Drug Supply), Subtitle A—Protection of Food Supply, section 305, which required the Secretary of Health and Human Services (the Secretary) to develop a regulation to require domestic and foreign facilities that manufacture, process, pack, or hold food for consumption in the United States to register with FDA by December 12, 2003. The provision created section 415 and amended sections 301 and 801 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 331 and 381). Section 415 of the FD&C Act, as added by the Bioterrorism Act, generally requires food facilities to register with FDA by submitting certain information to the Agency and updating such information as necessary. Section 301(dd) of the FD&C Act provides that failure to register in accordance with section 415 of the FD&C Act is a prohibited act. Section 801(l) of the FD&C Act, as added by the Bioterrorism Act, generally provides that an article of food imported or offered for import into the United States from a foreign facility for which a registration has not been submitted to FDA under section 415 shall be held at the port of entry for the article.

The Secretary and the Department of Treasury (Treasury) jointly issued a proposed rule for food facility registration (2003 proposed rule) in the **Federal Register** on October 10, 2003 (68 FR 58894). On October 10, 2003, the Secretary and the Department of Homeland Security (DHS) jointly issued an interim final rule for registration of food facilities under the Bioterrorism Act.[1] The interim final rule implemented section 305 of the Bioterrorism Act, and required domestic and foreign facilities to be registered with FDA by December 12, 2003 (68 FR 58894). On October 3, 2005, FDA issued a final rule in the **Federal Register** (70 FR 57505) that confirmed the interim final rule entitled ''Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' FDA's implementing regulation for section 415 of the FD&C Act is codified in part 1 (21 CFR part 1), subpart H. Highlights of FDA's current registration of food facilities regulation are as follows:

- The owner, operator, or agent in charge of a domestic or foreign facility engaged in manufacturing/processing, packing, or holding food for consumption by humans or animals in

[1] The authorities of Treasury under section 701(b) of the FD&C Act (21 U.S.C. 371(b)) to jointly prescribe regulations with the Department of Health and Human Services for the efficient enforcement of section 801 of the FD&C Act were transferred to DHS when DHS was created by an act of Congress in 2002.

the United States is required to register the facility with FDA.

- The owner, operator, or agent in charge of a facility that is required to register may authorize an individual to register the facility on its behalf.
- Facilities covered under the interim final rule had to be registered by December 12, 2003.
- A foreign facility is exempt from registering if food from the facility undergoes further manufacturing/processing (including packaging) by another facility outside the United States. The foreign facility is not exempt from registration if the further manufacturing/processing (including packaging) activities of the subsequent facility are limited to affixing a label to a package or other de minimis activity.
- The following domestic and foreign facilities are also excluded from the registration requirement: Farms; retail food establishments; restaurants; nonprofit food establishments in which food is prepared for, or served directly to, the consumer; certain fishing vessels not engaged in processing; 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 FDA 3537 to register. This form is available either on the Internet or via mail or phone request. Registrants must use Form FDA 3537(a) to cancel their registrations.
- FDA strongly encourages electronic registration, which is quicker and more convenient for both facilities and FDA than registration by mail.
- To register electronically, 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 method of submission (paper or electronic), each registration must include the names, full addresses, and phone numbers for the facility, its parent company (if applicable), and the owner, operator and agent in charge; for a foreign facility, the name, address, and phone number, and, if no emergency contact is designated, the emergency contact phone number of the foreign facility's U.S. agent; for a domestic facility, an emergency contact phone number; all trade names the facility uses; applicable food product categories as identified in § 170.3 (21 CFR 170.3); and a statement certifying that the information submitted is true and accurate and, if the individual submitting the registration is not the owner, operator, or agent in charge of the facility, a statement in which the individual certifies that he/she is authorized to submit the registration.
- 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, except a change of the owner.
- If a facility has a new owner, the former owner must cancel the facility's registration within 60 calendar days of the change and the new owner must re-register the facility.
- Failure of a domestic or foreign facility to register, update, or cancel its registration in accordance with the regulation is a prohibited act under section 301(dd) of the FD&C Act.
- FDA will cancel a registration if the Agency independently verifies that the facility is no longer in business or has changed owners, and the owner, operator, or agent in charge of the facility fails to cancel the registration, or if FDA determines that the registration is for a facility that does not exist.
- The disposition of food imported or offered for import from an unregistered foreign facility is governed by the procedures set out in subpart I of part 1 (21 CFR part 1) (Prior Notice of Imported Food).
- 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.
- The list of registered facilities and registration documents submitted 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.

B. The FDA Food Safety Modernization Act and Food Facility Registration

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), signed into law on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the food supply. Section 102 of FSMA, entitled Registration of Food Facilities, amends section 415 of the FD&C Act regarding requirements for food facility registration along with other sections of the FD&C Act involving food facility registration. Further, other sections of FSMA include amendments that apply to facilities that are required to register under section 415 of the FD&C Act.

1. Section 102 of FSMA: Registration of Food Facilities

Section 102 of FSMA includes a number of amendments to food facility registration requirements or sections of the FD&C Act involving food facility registration. First, section 102 of FSMA amends section 415 by requiring that certain additional information be included in registrations. More specifically, section 102(a)(1)(A) of FSMA amends section 415 to provide that registrations for domestic food facilities are required to contain the email address for the contact person of the facility, and registrations for foreign food facilities are required to contain the email address of the U.S. agent for the facility. Also, section 102(b)(1)(A) of FSMA provides that all food facility registrations are required to contain an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. These FSMA amendments were self-implementing and became effective upon enactment of FSMA. These FSMA amendments are being included in this proposed rule to codify the provisions in the registration of food facilities regulations in 21 CFR part 1, subpart H.

Second, section 102 of FSMA amends section 415 with respect to updating food product category information required in food facility registrations. Before FSMA was enacted, section 415(a)(2) of the FD&C Act, as added by section 305 of the Bioterrorism Act, provided in relevant part that, when determined necessary by FDA ''through guidance,'' a registrant must submit a registration to FDA containing information necessary to notify FDA of the general food category (as identified in § 170.3) of food manufactured, processed, packed, or held at such facility. On July 17, 2003, FDA issued a guidance document stating that FDA had determined that the inclusion of food product categories in food facility registrations was necessary for a quick, accurate, and focused response to an actual or potential bioterrorist incident or other food-related emergency (see 68 FR 42415). Section 102(a)(1)(B) of FSMA amends section 415(a)(2) of the FD&C Act with respect to food product category information by authorizing FDA to determine other food product categories, including those not

specifically identified in § 170.3. Specifically, section 415(a)(2) of the FD&C Act, as amended by section 102(a)(1)(B) of FSMA, provides in relevant part that, when determined necessary by FDA ''through guidance,'' a registrant is required to submit a registration to FDA containing information necessary to notify FDA of the general food category (as identified in § 170.3 or any other food categories, as determined appropriate by FDA, including by guidance) of any food manufactured, processed, packed, or held at such facility. In October 2012, FDA issued a guidance entitled ''Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories.'' This guidance represents FDA's conclusion on the necessity of food product categories in food facility registrations and identifies other food product categories that are necessary and appropriate for food facility registration, as provided by section 415(a)(2) of the FD&C Act.

Third, section 102(a)(3) of FSMA amends section 415 to provide that food facilities required to register with FDA must renew their registrations with FDA every 2 years, between October 1 and December 31 of each even-numbered year, by submitting registration renewals to FDA. Further, section 102(a)(3) of FSMA directs FDA to provide for an abbreviated registration renewal process for any registrant that has not had any changes to such information since the registrant submitted the preceding registration or registration renewal for the facility.

Fourth, section 102(b) of FSMA amends section 415(b) of the FD&C Act by adding new provisions authorizing FDA to suspend the registration of a food facility in certain circumstances. Specifically, if FDA determines that food manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that created, caused, or was otherwise responsible for such reasonable probability; or knew of, or had reason to know of, such reasonable probability and packed, received, or held such food. Under section 415(b)(4) of the FD&C Act, as amended by section 102(b) of FSMA, if the registration of a food facility is suspended, no person can import or export, or offer to import or export, food from the facility into the United States, or otherwise introduce food from the facility into interstate or intrastate commerce in the United States. Under section 301(d) of the FD&C Act, as amended by section 102(b) of FSMA, the introduction or delivery for introduction into interstate commerce of an article of food in violation of section 415 is a prohibited act. Further, section 801(l) of the FD&C Act, as amended by section 102(b) of FSMA, provides, in relevant part, that an article of food being imported or offered for import into the United States that is from a foreign facility for which a registration has been suspended under section 415 must be held at the port of entry for the article of food, and may not be delivered to the importer, owner, or consignee of the article. FDA intends to address the suspension of registration provisions in section 102(b) of FSMA in a separate rulemaking.

Section 102(b) of FSMA also authorizes FDA to require that all food facility registrations be submitted to FDA in an electronic format; however, such requirement cannot take effect before the date that is 5 years after the date of enactment of FSMA (*i.e.,* January 4, 2016).

Lastly, section 102(c) of FSMA directs FDA to amend the definition of the term ''retail food establishment'' in § 1.227(b)(11) of title 21, Code of Federal Regulations to clarify that, in determining the primary function of an establishment or a retail food establishment under such section, the sale of food products directly to consumers by such establishment and the sale of food directly to consumers by such retail food establishment include: (1) The sale of food products or food directly to consumers by such establishment at a roadside stand or farmers' market where such stand or market is located other than where the food was manufactured or processed; (2) the sale and distribution of such food through a community supported agriculture program; and (3) the sale and distribution of such food at any other such direct sales platform as determined by the Secretary. As discussed more fully in the paragraphs that follow, we are proposing to implement these provisions in this proposed rule.

2. Other FSMA Amendments Involving Food Facilities Required To Register Under Section 415 of the FD&C Act

In addition to amending section 415 of the FD&C Act and the other related sections of the FD&C Act as discussed in the preceding section, FSMA also amended the FD&C Act such that section 415 functions in connection with other food safety provisions. For instance, FSMA added section 418 of the FD&C Act (21 U.S.C. 350g), which establishes certain preventive control requirements for food facilities that are required to register under section 415. In general, section 418(a) requires the owner, operator, or agent in charge of a ''facility'' to evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. The term ''facility'' is defined in section 418(*o*)(2) as ''a domestic facility or a foreign facility that is required to register under section 415.''

In addition, section 201(a) of FSMA created section 421 of the FD&C Act (21 U.S.C. 350j), which also ties to section 415. In particular, section 421 requires the Agency to identify high-risk ''facilities'' and mandates more frequent inspections for domestic high-risk ''facilities'' than for domestic non-high-risk facilities. Section 421 also includes an inspection mandate for foreign facilities. For the purposes of section 421, the term ''facility'' refers to facilities that are required to register under section 415. (See section 421(e)). In addition, section 306 of FSMA added section 807(a)(1) of the FD&C Act (21 U.S.C. 384c(a)(1)), which provides that FDA may enter into arrangements and agreements with foreign governments to facilitate the inspection of foreign facilities registered under section 415.

FSMA also created section 423 of the FD&C Act (21 U.S.C. 350*l*), which provides a ''responsible party'' an opportunity to voluntarily cease distribution and recall a food under specified circumstances and also provides FDA with authority to mandate a recall under specified circumstances. The term ''responsible party'' is defined by reference to the definition in section 417 of the FD&C Act (21 U.S.C. 350f), which in turn defines that term as a person that submits the registration under section 415(a) of the FD&C Act for a food facility that is required to register under section 415(a) of the FD&C Act, at which such article of food is manufactured, processed, packed, or held. (See section 417(a)(1) of the FD&C Act.) In addition, FSMA created section 808 of the FD&C Act (21 U.S.C. 384d), which provides for the recognition of accreditation bodies that accredit third-party auditors to conduct food safety audits of foreign food entities, including foreign food facilities registered under section 415.

Further, section 107 of FSMA amended the FD&C Act to provide FDA with the authority to collect fees related to reinspections of facilities required to register under section 415 of the FD&C Act. Specifically, section 107 of FSMA

added section 743(a)(1)(A) of the FD&C Act (21 U.S.C. 379j–31(a)(1)(A)), which provides FDA with the authority to assess and collect fees from domestic facilities (as defined in section 415(b) of the FD&C Act) and U.S. agents for foreign facilities (also as defined in section 415(b) of the FD&C Act) subject to reinspection to cover reinspection-related costs.

FSMA is not the only act in which Congress has linked food facility registration to specific food safety requirements. The Food and Drug Administration Amendments Act of 2007 (FDAAA) also tied food safety requirements to food facility registration. FDAAA amended the FD&C Act by creating section 417, which generally requires a ''responsible party'' to submit a report to FDA through the Reportable Food Registry after determining that an article of food is a reportable food as defined in section 417(a)(2) and further defined in section 201(ff) of the FD&C Act (21 U.S.C. 321(ff))). As stated previously, section 417 of the FD&C Act defines the term ''responsible party'' as a person that submits the registration under section 415(a) of the FD&C Act for a food facility that is required to register under section 415(a) of the FD&C Act, at which such article of food is manufactured, processed, packed, or held. (See section 417(a)(1) of the FD&C Act.)

As a result of these links between food facility registration and additional requirements in the FD&C Act, food facility registration now serves additional functions to those originally identified in the food facility registration regulations issued in 2003 and finalized in 2005 (68 FR 58894; 70 FR 57505). More specifically, the interim final rule noted that food facility registration would 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 (68 FR 58894 at 58895). It also noted that registration would provide FDA with information about food facilities that would help FDA and other authorities determine the source and cause of an outbreak of foodborne illness, while also enabling FDA to notify more quickly the facilities that might be affected by the outbreak (68 FR 58894 at 58895). While food facility registration continues to serve all of those functions, with the passage of FSMA and FDAAA, food facility registration now also serves to determine the applicability of provisions in other sections of the FD&C Act, including sections 417, 418, 421, 423, 743, 807, and 808 of the FD&C Act. Thus, food facility registration now relates to many more food safety requirements than when the system was first implemented in 2003.

C. Rulemaking Required by Section 103(c) of FSMA: On-Farm Activities

Section 103(c)(1)(A) of FSMA, regarding Hazard Analysis and Risk-Based Preventive Controls, requires that the Secretary publish a notice of proposed rulemaking in the **Federal Register** to issue regulations with respect to ''activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership'' and ''activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership'' within the context of section 415 of the FD&C Act. Section 103(c)(1)(B) of FSMA provides that such rulemaking will ''enhance the implementation of . . . section 415 and clarify the activities that are included as part of the definition of the term 'facility' under such section 415.'' In the **Federal Register** of January 16, 2013 (78 FR 3646), we published a proposed rule entitled ''Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food'' to implement section 103 of FSMA and we discuss our proposal to revise the registration of food facilities regulations (part 1, subpart H) as specified by section 103(c)(1) of FSMA. In the **Federal Register** of September 29, 2014 (79 FR 58524), we published a supplemental notice of proposed rulemaking to amend the 2013 preventive controls proposed rule. That proposed rule is a separate rulemaking and not the subject of this rulemaking.

II. Legal Authority

We are issuing this proposed rule under the FD&C Act, FSMA, and the Bioterrorism Act. We are proposing to codify the requirements of section 102 of FSMA that were self-implementing and effective upon enactment of FSMA, as discussed previously, in the Registration of Food Facilities Regulation (part 1, subpart H). In addition, we are proposing to implement other requirements of section 102 of FSMA, as discussed previously, including mandatory electronic registration submissions beginning in 2016 and amendments to the retail food establishment definition. Lastly, we are proposing other changes to improve the utility of the food facility registration database.

FDA's legal authority to implement requirements of section 102 of FSMA derives from section 102 of FSMA and sections 415, 301(dd), 801(l), and 701(a) of the FD&C Act. As discussed previously, section 415 of the FD&C Act requires food facilities that manufacture/process, pack, or hold food for consumption in the United States to register with FDA by submitting certain information to the Agency and updating such information as necessary. Section 415(a)(2) of the FD&C Act, as amended by section 102 of FSMA, requires, in relevant part, food facility registrations to include additional information, including the email addresses of contact persons for domestic facilities and U.S. agents for foreign facilities; an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act; and updated food product category information, if determined necessary and appropriate by FDA. Further, section 415(a)(3) of the FD&C Act, as amended by section 102 of FSMA, requires, in relevant part, food facilities required to register to renew their registrations with FDA between October 1 and December 1 of each even-numbered year, and directs FDA to provide for an abbreviated registration renewal process for registrants that have not had any changes to registration information since the registrant submitted the preceding registration or registration renewal for the facility involved. Section 301(dd) of the FD&C Act provides that failure to register in accordance with section 415 of the FD&C is a prohibited act. Section 801(l) of the FD&C Act provides that an article of food being imported or offered for import into the United States that is from a foreign facility for which a registration has not been submitted to FDA under section 415 (or for which a registration has been suspended under such section) must be held at the port of entry for the article of food, and may not be delivered to the importer, owner, or consignee of the article until the foreign facility is so registered. Section 701(a) of the FD&C Act authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act. As discussed previously, section 102(c) of FSMA also directs FDA to amend the definition of the term ''retail food establishment'' in FDA's Registration of Food Facilities Regulation at § 1.227(b)(11).

As discussed in detail in the paragraphs that follow, FDA is proposing additional required data elements in food facility registrations to provide for more efficient and effective communications during a public health emergency and to provide FDA information that we can use to focus

and better deploy the Agency's limited inspectional resources. FDA's legal authority to implement these and other changes to improve the utility of the food facility registration database also derives from section 102 of FSMA and the sections of the FD&C Act described in the previous paragraph. Section 415(a)(2) of the FD&C Act requires foreign facilities to submit registrations to FDA that include the name of the U.S. agent for the facility. Further, FDA is relying on section 107 of FSMA and sections 421 and 704 (21 U.S.C. 374) of the FD&C Act in issuing these proposed changes. Section 107 of FSMA amended the FD&C Act to provide FDA with the authority to assess and collect certain fees from, *inter alia,* U.S. agents for foreign facilities (as defined in section 415(b) of the FD&C Act) subject to reinspection to cover reinspection-related costs. Section 704 gives FDA the authority to inspect factories, warehouses, and other establishments in which foods are manufactured, processed, packed, or held. Section 421 of the FD&C Act requires the Agency to identify high-risk facilities and mandates more frequent inspections for domestic high-risk facilities than for domestic non-high-risk facilities. FDA is also relying on section 305(d) of the Bioterrorism Act (Pub. L. 107–188), which directs FDA, in relevant part, to ensure adequate authentication protocols are used to enable identification of the registrant and validation of the registration data, as appropriate, for registrations submitted to FDA electronically. Thus, FDA has the authority to issue this proposed rule under section 305 of the Bioterrorism Act, sections 102 and 107 of FSMA, and sections 301(dd), 415,701(a), and 704 of the FD&C Act.

III. The Proposed Rule

This proposed rule would revise FDA's current regulations in part 1, subpart H, regarding registration of food facilities in two fundamental ways. First, it would add new provisions to the current regulations to implement certain provisions of section 102 of FSMA or otherwise codify amendments of section 102 of FSMA that were self-implementing and effective upon enactment of FSMA, as discussed previously. Second, we are proposing changes to improve the utility of the food facility registration database. We are proposing to do this by proposing, among other things, to: (1) Require certain additional data elements in food facility registrations; (2) employ additional measures to verify certain information submitted in registrations; and (3) take additional steps to ensure that our registration database is up to date by identifying additional circumstances under which FDA will cancel registrations. The following description of the proposed rule describes both new provisions and changes to the existing regulations in part 1, subpart H.

A. Proposed Amendments to Registration of Food Facilities Under FSMA

1. Retail Food Establishment Definition

Under section 415 of the FD&C Act and FDA's registration regulation (21 CFR 1.226(c)), a retail food establishment is not required to register with FDA. A ''retail food establishment'' is defined in current § 1.227(b)(11) to mean an establishment that sells food products directly to consumers as its primary function. Under current § 1.227(b)(11), a retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufacturers/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The definition of retail food establishment also provides that the term ''consumers'' does not include businesses, and a ''retail food establishment'' includes grocery stores, convenience stores, and vending machine locations.

Section 102(c) of FSMA directs FDA to amend the definition of ''retail food establishment'' to clarify that, in determining the primary function of an establishment, the sale of food directly to consumers by such establishment includes: (1) The sale of food directly to consumers by such establishment at a roadside stand or farmers' market where such stand or market is located other than where the food was manufactured or processed; (2) the sale and distribution of such food through a community supported agriculture program; and (3) the sale and distribution of such food at any other such direct sales platform as determined by the Secretary.

The proposed amendment to the retail food establishment definition addresses off-farm sales by an establishment located on a farm. How these off-farm sales relate to an establishment's status as a retail food establishment is significant because if manufacturing/processing activities on a farm are part of a retail food establishment, they do not trigger the requirement to register. Otherwise, unless all food used in such activities is consumed on that farm or another farm under the same ownership, the manufacturing/processing operation is required to register (see § 1.227(b)(3)(ii)). If all sales from an on-farm manufacturing/processing operation must be made on-farm for that operation to qualify as a retail food establishment, then an on-farm establishment that sells processed food at a direct sales platform such as a farmer's market could not qualify as a retail food establishment and would be required to register. To prevent this, proposed § 1.227(b)(11) clarifies that all sales by an on-farm establishment do not have to be on the farm by specifically addressing how off-farm sales directly to consumers are to be counted in determining whether the on-farm establishment is a retail food establishment.

a. Sale of food directly to consumers at a roadside stand or farmers' market. Under proposed § 1.227(b)(11)(i), in determining the primary function of an establishment located on a farm, the sale of food directly to consumers from such establishment would include the sale of food directly to consumers by such establishment at a roadside stand or farmers' market. The roadside stand or farmer's market would not need to be on the farm where the establishment is located. For example, an establishment located on a farm that sells jams and jellies it manufacturers, along with produce it grows, directly to consumers at a farmers' market would consider those sales in determining its primary function and thus whether it would meet the requirements to be considered a retail food establishment. Note that whether the farmers' market would be a retail food establishment involves a separate primary function calculation involving only sales made at the farmers' market and would not include, for example, sales at the farm. This analysis is not affected by the proposed amendment and is similar to how primary function would be determined at a grocery or convenience store.

FDA is proposing that a farmers' market is a location where one or more local farmers assemble to sell from their farms directly to consumers. FDA is proposing that a roadside stand is a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers. These definitions are based on definitions found in 7 CFR 249.2, with modifications to more specifically describe foods sold by on-farm establishments at direct sales

platforms such as roadside stands and farmers' markets. We seek comments on this proposed amendment, and specifically, what, if any, limitations should be included such as distance of the roadside stand or farmers' market from the farm, for example, not more than 275 miles from the farm. In addition, we seek comments on the proposed definitions for farmers' market and roadside stand and if any of the terms within these proposed definitions should be further defined.

b. Sale and distribution of food through a community supported agriculture program. Under proposed § 1.227(b)(11)(ii), in determining the primary function of an establishment located on a farm, the sale of food directly to consumers from such establishment would also include the sale and distribution of such food through a community supported agriculture program. For example, an establishment located on a farm that sells apples it grows and apple pies it manufacturers directly to consumers through a CSA would consider those sales in determining its primary function and thus whether it would meet the requirements to be considered a retail food establishment.

Section 102(c) of FSMA provides that for the purposes of the retail food establishment definition, ''the term 'community supported agriculture program' has the same meaning given the term 'community supported agriculture (CSA) program' in section 249.2 of title 7, Code of Federal Regulations (or any successor regulation).'' Under 7 CFR 249.2, a ''community supported agriculture (CSA) program'' means ''a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. State agencies may purchase shares or subscribe to a community supported agriculture program on behalf of individual SFMNP [Senior Farmers' Market Nutrition Program] participants.'' Accordingly, we are proposing that the term ''community supported agriculture program'' in proposed § 1.227(b)(11) have the same meaning used for the term in 7 CFR 249.2. We note that, under proposed § 1.227(b)(11)(ii), a CSA program would include CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers.

c. Sale and distribution of food at any other direct-to-consumer sales platforms. Under proposed § 1.227(b)(11)(iii), in determining the primary function of an establishment located on a farm, the sale of food directly to consumers from such establishment would include the sale and distribution of such food at other direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet orders, including online farmers markets and online grocery delivery; religious or other organization bazaars, and State and local fairs. The specified direct sales platforms are common platforms for direct-to-consumer sales of foods from farms, and to the extent that such platforms typically provide direct-to-consumer sales of food from local farms, they are similar to farmers' markets and CSAs. We seek comments on the direct sales platforms we have specified and what, if any, other such direct sales platforms we should specify.

d. *Other issues.* As proposed, this amendment to the retail food establishment definition would be limited to on-farm establishments. We believe such a limitation is consistent with section 102(c) of FSMA, which addresses the sale of foods directly to consumers at specific locations (*i.e.,* roadside stands, farmers' markets, and community supported agriculture programs) where the food for sale directly to consumers is sourced directly from farms. We request comment on whether such a limitation is appropriate.

Further, proposed § 1.227(b)(11) provides for considering certain off-farm sales directly to consumers when determining an on-farm establishment's primary function, but does not provide for considering off-farm sales to businesses in the primary function calculation. In doing so, the proposal reflected section 102(c) of FSMA, which addresses only sales to consumers. We request comment on whether, in addition to implementing the specific clarification in section 102(c), we should provide that off-farm sales to businesses also be considered in determining the primary function of an on-farm establishment.

In addition, proposed § 1.227(b)(11) provides for, in determining the primary function of an on-farm establishment, considering the off-farm sales of ''food'' directly to consumers, which would include both food that has been manufactured/processed and food that has not (raw agricultural commodities). FDA requests comment on whether, in light of the reference to ''other than where the food was manufactured or processed'' in section 102(c)(1)(A) of FSMA or for other reasons, only the sale of processed foods off the farm should be considered in determining the primary function of an establishment located on a farm.

2. Biennial Registration Renewal and Abbreviated Registration Renewal Process

Section 415(a)(3) of the FD&C Act, as amended by section 102(a) of FSMA, requires that during the period beginning on October 1 and ending on December 31 of each even-numbered year, a registrant that has submitted a registration to FDA under section 415(a)(1) of the FD&C Act must submit to FDA a renewal registration containing the information described in section 415(a)(2) of the FD&C Act. This requirement went into effect upon enactment of FSMA. Food facilities were required to renew their registrations with FDA after the enactment of FSMA during the 2012 registration renewal period.

Proposed § 1.230(b) would require the owner, operator, or agent in charge of a facility to submit a registration renewal to FDA containing the information required under § 1.232 every other year, during the period beginning on October 1 and ending on December 31 of each even-numbered year. Under proposed § 1.230(b), the owner, operator, or agent in charge of a facility may authorize an individual to renew the facility's registration on its behalf. As discussed in section III.B.12.b, we are proposing to replace ''the owner, operator, or agent in charge of a facility'' with ''you'' throughout the regulation because ''you'' is defined in the regulation under current § 1.227(b)(14) to mean the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

Section 415(a)(3) of the FD&C Act, as amended by section 102(a)(3) of FSMA, directs FDA to provide for an abbreviated registration renewal process for any registrant that has not had any changes to its registration information since the registrant submitted the preceding registration or registration renewal for the facility. Proposed § 1.230(c) would provide for an abbreviated registration renewal process for registrations that do not have any changes to the information required under § 1.232 since the registrant submitted the preceding registration or registration renewal for the facility to FDA. The abbreviated registration renewal process would require a registrant to confirm that no changes have been made to the information required in the registration since the registrant submitted the preceding registration or registration renewal, confirm that FDA will be permitted to

inspect the facility at the times and in the manner permitted by the FD&C Act, and certify that the information submitted is truthful and accurate. FDA is proposing that registrants must use Form FDA 3537 to submit abbreviated registration renewals to FDA. This form will be available electronically at *www.fda.gov* or via mail or phone request until mandatory electronic registration and registration renewals begin in the 2016 registration renewal period, as described in proposed § 1.231(a)(2).

Proposed § 1.230(b) would codify in FDA's registration regulation the biennial registration renewal requirement of section 415(a)(3) of the FD&C Act (as added by section 102(a)(3) of FSMA), which is already in effect. Proposed § 1.230(c) would implement the provision of section 415(a)(3) of the FD&C Act providing for an abbreviated registration renewal process for registrants that have not had any changes to required registration information since such registrations submitted the preceding registration or registration renewal for the facility involved. The abbreviated registration renewal process was not available for the 2012 registration renewal period because section 102(a) of FSMA established new registration data elements, meaning all registrants would have had changes to their registration information since such registrations were previously submitted or updated.

3. Mandatory Electronic Submission of Food Facility Registration and Registration Renewals

Section 415(b)(5)(B) of the FD&C Act, as added by section 102(b) of FSMA, provides that FDA may require that registration under section 415 be submitted to FDA in an electronic format. However, section 415(b)(5)(B) specifies that such requirement may not take effect before the date that is 5 years after the date of enactment of FSMA, which is January 4, 2016. Proposed § 1.231(a)(2) would provide that beginning January 4, 2016, electronic registration will be mandatory, unless a waiver has been granted for the registrant. In addition, proposed § 1.231(a)(2) would require mandatory electronic registration renewals beginning in the 2016 registration renewal period. Proposed § 1.231(b) would also provide that beginning January 4, 2016, registration or registration renewals by mail or fax would no longer be permitted, unless a waiver has been granted for the registrant. Such waivers are further discussed in section III.B.11.

FDA tentatively concludes that mandatory electronic submission of registration and registration renewals would provide a number of advantages over submission of registration and registration renewals on the FDA paper form, including the following:

- The mandatory electronic system would improve the timeliness and accuracy of submissions.
- The electronic transmission of information would be easier and more efficient for both industry and FDA than the use of paper forms. For example, a registrant would receive onscreen feedback if the information submitted was not complete, reducing errors and time and cost of communicating with FDA. Similarly, electronic transmission of the information would reduce significantly the time and cost associated with processing paper forms and communicating with industry concerning errors on those forms.
- Information search and retrieval time would be reduced, allowing quicker access to the information in the database.
- FDA has strongly encouraged electronic registration for the benefit of both FDA and the registrant. FDA tentatively concludes that the majority of facilities, both in the United States and abroad, have access to the Internet, either within their facilities or parent companies or through public libraries, copy centers, schools, or Internet cafes, as well as through a foreign facility's U.S. agent if the facility makes such arrangements. If the U.S. agent does not have Internet access onsite, the agent may register the facility electronically from a local library or other public facility that offers Internet access.
- FDA is able to accept electronic registrations from anywhere in the world where the Internet is available 24 hours a day, 7 days a week.
- Electronic registration also enables a facility to be registered more quickly than if registering by mail. Registration by mail can take several weeks to several months, depending on the efficiency of the mail system, the number of paper registrations that FDA would need to enter manually into the system, whether the Agency would have to return an incomplete or illegible form to a registrant, and because FDA would have to subsequently mail the registration number and receipt of registration to the registrant.

We are seeking comments on the proposed requirements for mandatory electronic registration and registration renewals to begin in the year 2016. We are also requesting comments and data on the number of facilities, if any, that believe they would be unable to register or renew their registrations electronically, and the reasons for such belief, such as, no access to the Internet or for religious beliefs. In addition, as further discussed in section III.B.11, we are seeking comments on our proposal to allow for a waiver from the requirement for mandatory registration and registration renewals beginning in 2016.

4. Email Address for the Contact Person as Required Information

Section 415(a)(2) of the FD&C Act, as amended by section 102(a) of FSMA, requires, among other things, that a registration for a domestic facility contain the email address for the contact person of the facility. This requirement went into effect upon enactment of FSMA. Proposed § 1.232(b)(1) would require the email address for the contact person of a domestic facility be included in the registration. Proposed § 1.232(b)(1) would codify in FDA's registration regulation the requirement of section 415(a)(2) of the FD&C Act that a registration for a domestic facility contain the email address for the contact person of the facility.

FDA has received questions from some registrants related to the requirement that a registration for a domestic facility include the email address for the contact person of the facility. Specifically, some registrants have indicated that they are unable to obtain email addresses or otherwise use computers or similar electronic devices because of their religious beliefs. While section 415(a)(2) of the FD&C Act requires a registration for a domestic food facility to include the email address for the contact person of the facility, such contact person is not required to be the owner, operator, or agent in charge. Accordingly, a registrant can provide the email address of a third-party contact person in a registration (to be used for email communications between FDA and the facility), meaning that the registrant would not be required to obtain an email address or otherwise use a computer or similar electronic device within this context.

As further discussed throughout this document, it is critical that FDA be able to contact facilities in a quick manner in the event of a threatened or actual terrorist attack, an outbreak of foodborne illness, or other food-related emergency. Moreover, section 415(a)(2) of the FD&C Act, as amended by FSMA, specifically requires domestic facilities to submit the email addresses of contact persons in food facility registrations. For these reasons, FDA tentatively concludes that all registrations for

domestic facilities are required to include the email addresses of a contact person of the facility. However, FDA recognizes that because of religious beliefs some registrants may disfavor the use of email communications between FDA and the facility in non-emergency situations, such as for routine communications, where the Agency can communicate with the facility by postal mail. We request comment on whether proposed § 1.232 should be modified to allow for registrants to request that the Agency only use email communications in emergency situations, such as during a terrorist attack, an outbreak of foodborne illness, or other food-related emergency.

5. Email Address for the U.S. Agent as Required Information

Section 415(a)(2) of the FD&C Act, as amended by section 102(a) of FSMA, requires, among other things, that a registration for a foreign facility contain the email address of the U.S. agent for the foreign facility. This requirement went into effect upon enactment of FSMA. Proposed § 1.232(c)(1) would require that a registration for a foreign facility include the email address of the foreign facility's U.S. agent in addition to the U.S. agent's name, full address, and phone number. Proposed § 1.232(c)(1) would therefore codify in FDA's registration regulation the requirement of section 415(a)(2) of the FD&C Act that a registration for a foreign facility contain the email address of the foreign facility's U.S. agent.

6. Assurance Statement That FDA Will Be Permitted To Inspect

Section 415(a)(2) of the FD&C Act, as amended by section 102(b) of FSMA, also requires, among other things, that food facility registrations contain an assurance that the Secretary (and by delegation, FDA) will be permitted to inspect such facility at the times and in the manner permitted by the FD&C Act. This requirement went into effect upon enactment of FSMA. Proposed § 1.232(a)(9) would codify such requirement in FDA's registration regulations. Specifically, proposed § 1.232(a)(9) would require a food facility registration to include a statement in which the owner, operator, or agent in charge provides an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act.

7. Consequences of Failing To Renew Registration

Currently, § 1.241 specifies the consequences of failing to register, update, or cancel a food facility registration. As described in current § 1.241(a), the failure of an owner, operator, or agent in charge of a food facility to register its facility, to update required elements of its facility's registration, or to cancel its registration in accordance with part 1, subpart H is a prohibited action under section 301(dd) of the FD&C Act. Accordingly, as further described in current § 1.241(a), the consequences of failing to register, update, or cancel a food facility registration include civil injunction proceedings under section 302 of the FD&C Act (21 U.S.C. 332), criminal penalties under section 303 of the FD&C Act (21 U.S.C. 333), and debarment of a person who has been convicted of a felony relating to importation of food into the United States under section 306 of the FD&C Act (21 U.S.C. 335a).

Proposed § 1.241(a) would amend current § 1.241(a) by adding the failure to renew a food facility registration among the list of actions related to food facility registration that could subject a person to the consequences specified in § 1.241(a). As discussed in section II, section 415(a)(3) of the FD&C Act, as amended by section 102(a) of FSMA, requires registrants to renew their facility registrations with FDA every other year. This requirement went into effect upon enactment of FSMA. Further, section 301(dd) of the FD&C Act provides that the failure to register in accordance with section 415 is a prohibited act. On June 2, 2014, FDA issued a guidance entitled ''Compliance Policy Guide Sec. 100.250 Food Facility Registration—Human and Animal Food'' stating that FDA will consider a registration to be expired if the registration is not renewed, as required by section 415(a)(3) of the FD&C Act, and the failure of a food facility to renew its registration with FDA, as required by section 415(a)(3) of the FD&C Act, means that the facility has failed to register in accordance with section 415 of the FD&C Act and thereby has committed a prohibited act under section 301(dd) of the FD&C Act (Ref. 1).

Accordingly, in addition to proposing to amend § 1.241(a), we are proposing to add proposed § 1.241(b) to specify that FDA will consider a registration for a food facility to be expired if the registration is not renewed, as required by § 1.230(b), and FDA will consider a food facility with an expired registration to have failed to register in accordance with section 415 of the FD&C Act. In addition, as discussed more fully in section III.B.10, under proposed § 1.241(c), FDA would cancel a registration that is expired for failure to renew if the facility has failed to renew its registration in accordance with proposed § 1.230(b).

B. Other Proposed Amendments to Registration of Food Facilities

1. U.S. Agent Information Sharing and Responsibilities

Section 415(a)(1)(B) of the FD&C Act provides in relevant part that the registration of a foreign food facility must include the name of the U.S. agent for the facility. Currently, § 1.227(b)(13) defines a U.S. agent, in relevant part, as a person (as defined in section 201(e) of the FD&C Act) residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of food facility registration. In addition, § 1.227(b)(13)(i) currently provides that the U.S. agent acts as a communications link between FDA and the foreign facility for both routine and emergency situations and that FDA will contact the U.S. agent when an emergency occurs, unless the registration specifies another emergency contact (see also 68 FR 58894 at 58915). Further, § 1.227(b)(13)(ii) currently provides that FDA will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent the equivalent of providing the information or documents to the foreign facility.

Section 107 of FSMA amended the FD&C Act to provide U.S. agents with an additional role. Specifically, section 107 of FSMA added section 743(a)(1)(A) of the FD&C Act, which provides FDA with the authority to assess and collect fees from the U.S. agent for each foreign facility subject to reinspection to cover reinspection-related costs.

In order to further enable U.S. agents to serve their intended role, we are proposing to amend § 1.227(b)(13)(ii). Specifically, we are proposing to add that the U.S. agent of a foreign facility may view the information submitted in the foreign facility's registration. Making registration information available to U.S. agents would allow agents to obtain the most current information contained in FDA's registration database. U.S. agents could use such information to be in contact with foreign facilities, thereby enabling U.S. agents to more efficiently and effectively function as communications links between foreign food facilities and FDA. (See § 1.227(b)(13)(i) (establishing that a U.S. agent ''acts as a communications link between FDA and the foreign facility for both emergency and routine communications'').) Further, U.S. agents could use such information to better represent foreign facilities when

communicating with FDA. (See § 1.227(b)(13)(ii) (specifying that FDA will treat representations by the U.S. agent as those of the foreign facility).) The proposal is also consistent with the status of information and documents provided to U.S. agents. Indeed, FDA's current regulations establish that ''information or documents provided to the U.S. agent [are] the equivalent of providing the information or documents to the foreign facility.'' (§ 1.227(b)(13)(ii).)

In proposing to make information submitted in a foreign facility's registration available to the U.S. agent for that facility, we have considered FDA's regulations governing public information (21 CFR part 20) among other factors. Section 20.21 (21 CFR 20.21) provides that any record of FDA that is disclosed in an authorized manner to any member of the public is available for disclosure to all members of the public (subject to certain exceptions). If U.S. agents had the same status as any member of the public, making registration information available to U.S. agents for review likely would constitute disclosure to the public and obligate FDA to make the same records available to any person who requests them under the Freedom of Information Act (FOIA). FDA tentatively concludes, however, that U.S. agents for foreign facilities do not have the same status as any member of the public within the context of registration for such facilities. Indeed, FDA's current registration regulations establish that U.S. agents function as stand-ins for foreign facilities with respect to communications and information sharing. Specifically, FDA's regulations establish that a U.S. agent ''acts as a communications link between FDA and the foreign facility for both emergency and routine communications.'' (§ 1.227(b)(13)(i).) Further, FDA's regulations establish that ''information or documents provided to the U.S. agent [are] the equivalent of providing the information or documents to the foreign facility.'' (§ 1.227(b)(13)(ii).) Put another way, making information or documents available to a U.S. agent has the same status as making information or documents available to a foreign facility. Thus, making registration information available for review to U.S. agents is the equivalent to making that information available for review to the U.S. agent's foreign facility. FDA tentatively concludes, therefore, that the requirement for uniform access in § 20.21 would not be triggered by FDA's proposed amendment to § 1.227(b)(13)(ii). FDA invites comments on this tentative conclusion.

For this same reason, FDA also tentatively concludes that making foreign facilities' registration information available to U.S. agents is consistent with the disclosure provision in section 415(a)(5) of the FD&C Act. That provision of the FD&C Act provides, in relevant part, that FDA's list of registered food facilities and registration documents submitted to FDA under section 415 shall not be subject to disclosure under FOIA. That provision also provides that information derived from such list shall not be subject to disclosure under FOIA to the extent that it discloses the identity or location of a specific registered person. Because § 1.227(b)(13)(ii) establishes that ''information or documents provided to the U.S. agent [are] the equivalent of providing the information or documents to the foreign facility,'' FDA's proposal to allow U.S. agents to view a foreign facility's registration information would not result in any disclosures. That is, allowing U.S. agents to view foreign facilities' registration information is the equivalent to allowing foreign facilities to view that information. Accordingly, FDA tentatively concludes that its proposal to amend § 1.227(b)(13)(ii) is consistent with the disclosure provision in section 415(a)(5) of the FD&C Act.

2. Verification Procedures for U.S. Agent

Proposed § 1.231(a)(5) and (b)(7) would provide that after a foreign facility completes its registration or updates its U.S. agent information as part of registration renewal, FDA will email the person identified as the U.S. agent for the foreign facility, using the email address for the person identified as the U.S. agent in the facility's registration, to verify that the person has agreed to serve as the facility's U.S. agent. FDA would not confirm the foreign facility's registration or registration renewal until that person confirms that the person agreed to serve as the U.S. agent for the foreign facility. In addition, with respect to initial registrations, FDA will not provide the facility with a registration number until that person confirms that the person agreed to serve as the U.S. agent for the foreign facility. Proposed § 1.231(a)(5) would apply this verification requirement to electronic registrations, and proposed § 1.231(b)(7) would apply this requirement to registrations submitted by mail or fax. Under proposed § 1.234(c)(2) and (d)(5), this verification step would also take place when foreign facilities update U.S. agent information. Those proposed provisions provide that when updating U.S. agent information, FDA will email the person identified as the U.S. agent for the foreign facility, using the email address for the person identified as the U.S. agent in the facility's registration, to verify that the person has agreed to serve as the U.S. agent. Under proposed § 1.234(c)(2) and (d)(5), FDA would not provide an update confirmation until that person confirms that the person agreed to serve as the U.S. agent for the foreign facility. Proposed § 1.234(c)(2) would apply this verification requirement to electronic updates, and proposed § 1.234(d)(5) would apply this requirement to updates submitted by mail or fax.

We are proposing this verification step for three reasons. First, we have learned that in some cases persons identified as U.S. agents in foreign food facility registrations were unaware that they had been so identified, and had not in fact agreed to serve as U.S. agents. Adding a verification step would help ensure that FDA's registration database is accurate and up to date. Second, the verification step would allow FDA to more efficiently enforce section 743 of the FD&C Act. As stated elsewhere in this proposed rule, section 743(a)(1)(A) of the FD&C Act authorizes FDA to assess and collect fees from the U.S. agent for each foreign facility subject to reinspection to cover reinspection-related costs. Verifying that individuals identified as U.S. agents in foreign facilities' registrations have actually agreed to serve as U.S. agents for those facilities would help ensure that FDA is assessing and collecting foreign facility reinspection fees from the appropriate individuals and allow for efficient enforcement of section 743 of the FD&C Act. Third, section 305(d) of the Bioterrorism Act (Pub. L. 107–188) directs FDA, in relevant part, to ensure adequate authentication protocols are used to enable identification of the registrant and validation of the registration data, as appropriate, for registrations submitted to FDA electronically. FDA tentatively concludes that a verification step for U.S. agent information would serve as an authentication protocol and help validate registration data concerning U.S. agents, including in those registrations submitted electronically.

We seek comments on these proposed provisions, including on whether the proposed email verification step will be effective in preventing the unauthorized listing of persons as U.S. agents. Further, we seek comment on the effectiveness of this proposed email verification step in connection with two

other ideas about which we request comment elsewhere in this document: The idea for a U.S. Agent Voluntary Identification System discussed in section III.C., and the idea to require Data Universal Numbering System (D–U–N–S®) numbers for U.S. agents discussed in section III.B.3. We also seek comments on what alternative approaches, if any, FDA should take to prevent unauthorized U.S. agent listings.

3. Proposed Requirement for D–U–N–S® Number and Verification Procedures

Proposed § 1.232(a)(2) would require the D–U–N–S® number of a domestic and foreign facility be included in the facility's registration. This requirement would function in connection with proposed § 1.231(a)(3) and (b)(5), which provide that after a facility completes its registration or updates its D–U–N–S® number as part of registration renewal, FDA will verify the accuracy of the food facility's D–U–N–S® number and will also verify that the facility-specific address associated with the D–U–N–S® number is the same address associated with the facility's registration. Under proposed § 1.231(a)(3) and (b)(5), FDA would not confirm a food facility's registration or registration renewal until FDA verifies the accuracy of its D–U–N–S® number and verifies that the facility-specific address associated with the D–U–N–S® number is the same address associated with the facility's registration. With respect to initial registrations, proposed § 1.231(a)(3) and (b)(5) would also provide that FDA would not provide a facility with a registration number until FDA verifies the accuracy of its D–U–N–S® number and verifies that the facility-specific address associated with the D–U–N–S® number is the same address associated with the facility's registration. Proposed § 1.231(a)(3) would apply this verification requirement to electronic registrations, and proposed § 1.231(b)(5) would apply this requirement to registrations submitted by mail or fax. The requirement to submit D–U–N–S® numbers would also function in connection with proposed § 1.234(c)(2) and (d)(5), which provide that FDA will perform the same verification step after facilities complete their registration updates. Under proposed § 1.234(c)(2) and (d)(5), FDA would not provide an update confirmation until FDA verifies the accuracy of the food facility's D–U–N–S® number and also verifies that the facility-specific address associated with the D–U–N–S® number is the same address associated with the facility's registration. Proposed § 1.234(c)(2) would apply this verification requirement to electronic updates, and proposed § 1.234(d)(5) would apply this requirement to updates submitted by mail or fax.

Dun & Bradstreet assigns and maintains a database of the D–U–N–S® numbers, which serve as unique identifiers (codes) of business entities. A D–U–N–S® number is a unique nine-digit sequence provided by Dun & Bradstreet that can be specific for each site. The site-specific number is a widely recognized business identification tool and serves as a useful resource for FDA in identifying and verifying certain business information submitted by a user. Upon application, each physical location of a business entity may be assigned a distinct site-specific nine-digit D–U–N–S® number. D–U–N–S® Numbers are proprietary to and controlled by Dun & Bradstreet (D&B).

If a food facility has not obtained a D–U–N–S® number, it may obtain one for no cost directly from Dun & Bradstreet (*http://www.dnb.com*). If a registrant does not include a D–U–N–S® number for its facility in a registration, FDA intends to make arrangements for obtaining a D–U–N–S® number for the facility by providing a direct link to Dun and Bradstreet in the registration system. FDA intends to allow a registrant attempting to register a facility without a D–U–N–S® number to temporarily save its registration information in the registration system and return to the registration system to complete its registration once the required D–U–N–S® number is obtained. Having registration information saved in the registration system, however, would not be equivalent to completing a registration. As discussed previously, under proposed § 1.231(a)(3) and (b)(5), FDA would not confirm a food facility's registration or registration renewal until FDA verifies the accuracy of its D–U–N–S® number and verifies that the facility-specific address associated with the D–U–N–S® number is the same address associated with the facility's registration.

FDA's tentative decision to require and verify D–U–N–S® numbers is grounded in the statutory objective of efficiently enforcing the food safety and other requirements of the FD&C Act. By requiring D–U–N–S® numbers of facilities, FDA would be able to verify the facility-specific address information associated with those numbers. Such verification would increase the accuracy of FDA's food facility registration database. As a consequence, FDA investigators would have access to more accurate food facility information, and would therefore be able to more efficiently identify and locate food facilities for inspection. As a result, FDA would be able to more efficiently conduct inspections under section 704 to enforce the food safety and other requirements of the FD&C Act.

FDA's tentative decision to require D–U–N–S® numbers in food facility registration is also consistent with FDA's mandate under section 415(a)(5) of the FD&C Act to compile and maintain an up-to-date list of registered food facilities, as well as the requirement in section 415(a)(2) of the FD&C Act that registrants submit information necessary to notify FDA of the name and address of each facility at which the registrant conducts business. Indeed, the verification that D–U–N–S® numbers provides would help ensure that the food facility list is up to date and contains accurate information concerning the addresses of food facilities. Moreover, an up-to-date list that includes information necessary to notify FDA of the name and address of food facilities would aid FDA in efficiently responding to a terrorist threat or other food-related emergency. Finally, FDA's tentative decision to require D–U–N–S® numbers is consistent with the direction contained in section 305(d) of the Bioterrorism Act (Pub. L. 107–188) to ensure adequate authentication protocols to enable identification of the registrant and validation of the registration data for registrations submitted to FDA electronically. FDA tentatively concludes that verifying information in connection with a D–U–N–S® number for a food facility would provide FDA with a protocol to enable FDA to identify food facilities and verify certain registration information for those facilities. We are seeking comment on these proposed provisions.

In addition to requesting comment on the proposals related to requiring facility-specific D–U–N–S® numbers, we request comment on whether FDA should require use of a different facility identifier and, if so, what that identifier should be. If you recommend that FDA use a different identifier, we request comment on whether FDA should verify that identifier and whether FDA should verify facility-specific address information in connection with that identifier. We also request comment on whether FDA should also require that the registrations of foreign facilities also include a D–U–N–S® number or other identifier for the facility's U.S. agent. To the extent FDA does pursue a D–U–N–S® number requirement, we seek comment on whether, as with the D–U–N–S® number for food facilities, FDA

should verify the accuracy of the U.S. agent D–U–N–S® numbers and whether FDA should verify that the contact information associated with the D–U–N–S® numbers is the same contact information submitted as part of the foreign food facilities' registrations. In addition, we request comment on whether FDA should perform such verification after a facility completes or updates its registration, and whether FDA should verify this information prior to confirming a food facility's registration, prior to confirming a registration renewal, prior to providing an update confirmation, and prior to providing the facility with a registration number when the facility first registers. If you recommend that FDA require that registrations of foreign facilities include an identifier other than a D–U–N–S® number for their U.S. agents, we request comment on whether FDA should verify that identifier and whether FDA should verify contact information in connection with that identifier.

We are requesting comment related to requiring D–U–N–S® numbers and other identifiers for U.S. agents because FDA has encountered instances in which foreign food facilities have included invalid U.S. agent information in their registrations. We are considering whether to require D–U–N–S® numbers or other identifiers for U.S. agents and verify the information associated with such numbers in order to increase the accuracy and reliability of the U.S. agent information. We also believe that more accurate U.S. agent information would allow FDA to more efficiently enforce section 743 of the FD&C Act, which authorizes FDA to assess and collect fees from the U.S. agent for each foreign facility subject to reinspection to cover reinspection-related costs. In addition, and as noted elsewhere in this proposed rule, section 305(d) of the Bioterrorism Act (Pub. L. 107–188) directs FDA, in relevant part, to ensure adequate authentication protocols are used to enable identification of the registrant and validation of the registration data, as appropriate, for registrations submitted to FDA electronically. FDA believes that requiring D–U–N–S® numbers or other identifiers and verifying information associated with such numbers could serve as an authentication protocol and help validate registration data concerning U.S. agents, including in those registrations submitted electronically. We seek comment on whether the D–U–N–S® numbers or other identifiers for U.S. agents and verification of such numbers and related information would, in fact, increase the accuracy and reliability of the U.S. agent information. We also seek comment on any burdens that requiring D–U–N–S® numbers or other identifiers for U.S. agents would entail, both for foreign facilities and any persons registered as U.S. agents.

4. Proposed Requirement for Email Address of Owner, Operator or Agent in Charge Who Authorized a Third Party To Act on Behalf of the Facility and Verification Procedure

The only individuals permitted to register a facility are the owner, operator, or the agent in charge of the facility or an individual authorized to register the facility on behalf of the owner, operator, or agent in charge. (Section 415(a)(1) of the FD&C Act; §§ 1.225 and 1.232 (21 CFR 1.225 and 1.232).) Currently, § 1.232(i) provides that if the individual submitting the registration form is not the owner, operator, or agent in charge of the facility, the registration must include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit the registration, and identifies by name, address, and telephone number, the individual who authorized submission of the registration. We are proposing to recodify this provision at § 1.232(a)(10), and also to add the email address of the individual who authorized submission of the registration to the list of required information identifying the individual who authorized submission of such registrations. Proposed § 1.230(b) would apply this requirement to registration renewals. Thus, for registrations and registration renewals submitted by an individual who is not the owner, operator, or agent in charge, such submissions would be required to include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit the registration, and identifies by name, address, email address, and telephone number, the individual who authorized submission of the registration. In addition, proposed § 1.234(a) would provide that updates not submitted by the owner, operator, or agent in charge of the facility must include the email address of the owner, operator, or agent in charge who authorized submission of the update, and proposed § 1.235(b)(5) would provide this same email address requirement for cancellations not submitted by the owner, operator, or agent in charge of the facility.

These requirements would function in connection with proposed §§ 1.231(a)(4) and (b)(6), 1.234(c)(3) and (d)(6), and 1.235(c)(3) and (d)(6), which provide a verification step for electronic registrations and registration renewals, mail/fax registrations and registration renewals, electronic updates, mail/fax updates, electronic cancellations, and mail/fax cancellations not submitted by the owner, operator or agent in charge of the facility. Specifically, these proposals provide that after completion of such submissions, FDA will email the individual identified as the owner, operator, or agent in charge who authorized the submission to verify that the individual in fact authorized the submission on behalf of the facility. Under proposed § 1.231(a)(4) and (b)(6), FDA would not confirm the registration or provide a registration number until that individual confirms that he or she authorized the registration. With respect to registration renewals, proposed § 1.231(a)(4) and (b)(6) provide that FDA would not provide a confirmation of the registration renewal until the individual confirms that he or she authorized the registration renewal. Under proposed § 1.234(c)(3) and (d)(6), FDA would not confirm a registration update until the individual identified as the owner, operator, or agent in charge who authorized the update confirms that he or she in fact authorized the update on behalf of the facility. And under proposed § 1.235(c)(3) and (d)(6), FDA would not confirm a registration cancellation until the individual identified as the owner, operator, or agent in charge who authorized the update confirms that he or she in fact authorized the cancellation on behalf of the facility. Proposed § 1.231(a)(4) would apply this verification requirement to electronic registrations and registration renewals; proposed § 1.231(b)(6) would apply the verification requirement to registration and registration renewals submitted by mail or fax; proposed § 1.234(c)(3) would apply the verification requirement to electronic updates; proposed § 1.234(d)(6) would apply the verification requirement to updates submitted by mail or fax; proposed § 1.235(c)(3) would apply the verification requirement to electronic cancellations; and proposed § 1.235(d)(6) would apply the verification requirement to cancellations submitted by mail or fax.

We are proposing this email requirement and verification step to address a problem with unauthorized third party registration submissions that FDA has encountered in the course of implementing food facility registration. In some cases, this has resulted in duplicate registrations for foreign food facilities. In other cases, registrations

have been created for facilities that do not in fact manufacture/process, pack, or hold food for consumption in the United States. Unauthorized third party registrations threaten the accuracy of FDA's food facility registration database, resulting in false entries that make it more difficult for the Agency to use its database to respond to food-related emergencies, as well as to identify food facilities for inspection. Such registrations also create potential problems for the facilities that are the subject of the unauthorized registrations. We tentatively conclude that the proposed email address and verification requirements are necessary to ensure the accuracy and truthfulness of food facility registrations. By requiring the email address of the owner, operator, or agent who authorizes third party registration submissions and using that email address to conduct a verification step, we believe that we would incentivize authorized, truthful registration submissions. As such, we tentatively conclude that these proposals would assist FDA in efficiently meeting its statutory obligation under section 415(a)(5) of the FD&C Act to compile and maintain an up-to-date list of food facilities. We further tentatively conclude that these proposals would help in ensuring compliance with section 415(a)(1) of the FD&C Act. Under section 415(a)(1) of the FD&C Act and §§ 1.225 and 1.232, the only individuals permitted to register a facility are the owner, operator, or agent in charge of the facility or an individual authorized to register the facility on behalf of the owner, operator, or agent in charge. Registrations submitted by non-authorized individuals would not be in compliance with those provisions. In addition, we tentatively conclude that the proposed email address and verification step requirements would assist FDA in achieving the key objectives of food facility registration. Those objectives include using the registration database to prevent and respond to food-related emergencies, and meeting them requires an accurate and up-to-date list of registered facilities. Finally, we tentatively conclude that the proposals are consistent with section 305(d) of the Bioterrorism Act (Pub. L. 107–188), which directs FDA, in relevant part, to ensure adequate authentication protocols are used to enable identification of the registrant and validation of the registration data, as appropriate, for registrations submitted to FDA electronically. FDA tentatively concludes that the proposed verification step for registration submissions made by individuals other than the owner, operator, or agent in charge would serve as an authentication protocol and help validate registration data.

We seek comment on these proposed provisions, including on whether the proposed email verification step will be effective in preventing the unauthorized submission of registrations, registration renewals, updates, and cancellations. We also seek comment on whether we should require any alternative or additional checks to ensure that the individual registering a facility is authorized to do so by the owner, operator, and agent in charge. For instance, should FDA require that owners, operators, or agents in charge create some type of authorization documentation to provide documentation for the fact that the owner, operator or agent in charge has authorized the individual to make a registration submission? If so, should such documentation be required to be submitted to FDA or maintained at the facility? Should such documentation include a letter signed by the owner, operator, or agent in charge authorizing the individual to make a registration submission? Are there other types of documentation that would provide another check that is necessary to ensure that the owner, operator, or agent in charge in fact provided authorization?

5. Proposal To Require Certain Information in Food Facility Registration That Is Currently Optional

a. Preferred mailing address information. Proposed § 1.232(a)(3) would require that domestic and foreign food facilities provide a preferred mailing address if such mailing address is different from the mailing address of the facility. We are proposing to require this information because we need to be able to efficiently contact food facilities with information regarding potential food-related emergencies and, when applicable, information regarding a suspension of a food facility's registration. If food facilities provide preferred mailing addresses that are different from the mailing address of a food facility, FDA would be able to more efficiently contact food facilities and share such information. Proposed § 1.232(a)(3) would therefore assist FDA in efficiently enforcing section 415 of the FD&C Act. We are seeking comments on this proposed provision.

b. Email address for the owner, operator or agent in charge of the facility. Currently § 1.232(c) requires a food facility registration to include the name, address, and phone number of the owner, operator, or agent in charge of domestic and foreign facilities, but does not require that individual's email address. Proposed § 1.232(a)(6) would add email address to the contact information required for the owner, operator, or agent in charge of the facility (for both domestic and foreign facilities). Although the FSMA amendments provide that registrations for domestic food facilities are now required to contain the email address for the contact person of the facility, often the contact person for the facility is not the same as the owner, operator, or agent in charge of the facility. We are proposing to require email addresses for the owner, operator, or agent in charge of food facilities in order to facilitate quick communications with those individuals. Such communications may be necessary in the event of food-related emergencies and, where applicable, suspensions of a food facility's registration. Accordingly, we tentatively conclude that such information is necessary for FDA's efficient enforcement of section 415 of the FD&C Act.

We are proposing this requirement in addition to the requirements in §§ 1.232(a)(10), 1.230(b), 1.234(a), and 1.235(b)(5) discussed earlier in this document with respect to registrations, registration renewals, updates, and cancellations submitted by individuals other than the owner, operator, or agent in charge of the facility. For such submissions, we are proposing in §§ 1.232(a)(10), 1.230(b), 1.234(a), and 1.235(b)(5) to require the email address of the owner, operator, or agent in charge who authorized such submissions. We realize that in some cases the owner, operator, or agent in charge email address in proposed § 1.232(a)(6) may be the same email address as the email address for the owner, operator, or agent in charge who authorized third party registration submissions in proposed §§ 1.232(a)(10), 1.230(b), 1.234(a), and 1.235(b)(5). In some cases, however, the email addresses might differ.

We are seeking comments on this proposed provision. Further, we are seeking comments on whether a waiver for this proposed requirement should be available in limited circumstances such as when and if the religious beliefs of an owner, operator or agent in charge prevent that individual from obtaining an email address. We are also seeking comments on how a food facility should request such a waiver, including whether such waivers should be requested in writing.

c. Type of activity conducted at the facility. Proposed § 1.232(a)(8) would

require the type of activity conducted at the facility for each food product category identified. In addition, proposed § 1.232(a)(8) would require facilities to choose among the following activity types: (1) Ambient human food storage warehouse/holding facility; (2) Refrigerated human food warehouse/holding facility; (3) Frozen human food warehouse/holding facility; (4) Interstate conveyance caterer/catering point; (5) Contract Sterilizer; (6) Labeler/Relabeler; (7) Manufacturer/Processor; (8) Farm Mixed-Type Facility; (9) Packer/Repacker; (10) Salvage Operator (Reconditioner); (11) Animal food warehouse/holding facility; and (12) Other Activity. Facilities would be permitted to select more than one activity type for each food product category identified. The ''Other Activity'' option would only be available if the facility engages in an activity that is not covered by the other options. Facilities that select ''Other Activity'' would be required to enter text onto the food facility registration form describing the activity.

FDA believes that information regarding activity type is necessary to assist the Agency in using its limited resources efficiently, including with regard to inspectional oversight. Among other purposes, food facility registration was designed to provide FDA with a complete list of foreign and domestic facilities that manufacture/process, pack, or hold food for consumption into the United States. In the approximately 10 years since food facility registration was originally implemented, the list of facilities has helped FDA accomplish one of its most important regulatory activities: Scheduling and planning inspections of establishments in which foods are manufactured/processed, packed, or held under section 704 of the FD&C Act. Specifically, FDA has used the food facility registration list to identify food facilities for inspection.

Although the creation of food facility registration has led to improvements in FDA's ability to identify food facilities for inspection, the limited nature of the information provided through food facility registration has meant that the information has not functioned as the most efficient tool for planning inspections. For instance, registrants have not been required to provide the Agency with such basic information as whether a facility manufactures/processes or holds foods, or both. The difference between manufacturing/processing and holding is important. FDA might prepare for inspections of manufacturing/processing and holding facilities quite differently, and might assign different personnel for the different types of inspections. With information about activity type, however, the Agency would be better able to prepare investigators for inspections and assign appropriate investigators. This would provide for more efficient use of the Agency's limited inspectional resources, as sending appropriate, well-prepared investigators helps ensure that inspections are thorough and meaningful. Requiring information regarding activity type would therefore allow for the more efficient use of FDA's inspectional authority under section 704.

The activity type requirement would serve additional purposes as well. Information about a facility's activity type would provide FDA with important information regarding a facility's role in the U.S. food supply system. This would allow FDA to better assess the facility's potential impact in cases of bioterrorist incidents or other food-related emergencies. Better information about a facility's impact would assist FDA in using its limited resources efficiently during such incidents, for instance helping the Agency identify manufacturers/processors that may receive contaminated ingredients or frozen storage facilities impacted by power outages. The improved information would also allow FDA to communicate more quickly and efficiently on various non-emergency issues, such as new regulatory requirements or policies.

In addition, the activity type information would aid FDA in implementing FSMA's mandate to determine inspectional frequency based on safety risks. Specifically, section 201(a) of FSMA created section 421 of the FD&C Act, which requires the Agency to identify high-risk facilities and mandates more frequent inspections for domestic high-risk facilities than for domestic non-high-risk facilities. For the purposes of section 421, the term ''facility'' refers to facilities that are required to register under section 415. (See section 421(e).) Section 421(a)(1) sets forth the factors for FDA to use in identifying high-risk facilities, which include ''[a]ny . . . criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.'' (Section 421(a)(1)(F).) Among the criteria the Agency has deemed necessary and appropriate for this purpose are type of activity conducted at the facility (manufacturer/processor, packer/repacker, etc.). Because section 421's risk-based inspection mandate applies to facilities registered under section 415, and because the Agency has identified information about the type of activity conducted at a facility as an important factor to consider when identifying high-risk facilities under section 421, FDA tentatively concludes that the proposed activity type requirement for registration would allow the Agency to more efficiently enforce section 421.

For all of these reasons, FDA tentatively concludes that section 415 of the FD&C Act, along with sections 421, 701(a), and 704, authorize FDA to require the submission of the activity type information specified in this proposed rulemaking.

Although proposed § 1.232(a)(8) lists the specific activity types that food facilities must select, the proposed provision does not define those activity types. FDA is requesting comments on whether it should define the specified activity types in FDA's food facility registration regulations. To the extent that FDA does define the activity types, FDA anticipates that the Agency would model the activity type definitions from the definitions for establishment types contained in the Agency's Field Management Directive (Ref. 2), while also modifying the Field Management Directive definitions to reflect the nature of activities conducted by registered food facilities and the information required on other parts of the food facility registration form. FDA tentatively concludes that modeling the activity type definitions from the Field Management Directive definitions would allow for the efficient use of FDA inspectional resources. FDA investigators are already familiar with the Field Management Directive, and consistency between the food facility registration and Field Management Directive definitions would minimize confusion about the nature of activities performed at food facilities. FDA's tentative definitions for food facility activity types for food facilities that are required to register under section 415 of the FD&C Act are as follows:

- Ambient human food storage warehouse/holding facility: A facility that holds or stores food for human consumption at ambient air temperatures (approximately 21 °C/70 °F). Examples include storage tanks and grain elevators.
- Refrigerated human food warehouse/holding facility: A facility that holds or stores food products for human consumption at refrigerated temperatures (approximately 4 °C/40 °F–0 °C/32 °F).
- Frozen human food warehouse/holding facility: A facility that holds or stores food for human consumption at frozen temperatures (approximately 0 °C/32 °F or below).

• Interstate conveyance caterer/catering point: A facility that prepares complete or partial meals or drinks from raw or partially processed materials for service to passengers or crew aboard an interstate conveyance or for consumption by these groups at a location other than where prepared.

• Contract Sterilizer: A facility that performs sterilization or irradiation of foods or components of foods.

• Labeler/Relabeler: A facility that affixes the original labeling to a food product or changes in any way the labeling on a food product without affecting the product or its container.

• Manufacturer/Processor: A non-farm facility that makes food from one or more ingredients, or synthesizes, prepares, treats, modifies, or manipulates food, including food crops or ingredients. For purposes of this activity type option, examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, or packaging.

• Farm Mixed-Type Facility: An establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition in § 1.227, but also conducts activities that require the establishment to be registered.

• Packer/Repacker: A facility that packs a food product or products into different containers without making any change in the form of the product.

• Salvage Operator (Reconditioner): A facility that deals in the resale and reconditioning of damaged foods.

• Animal food warehouse/holding facility (*e.g.,* storage facilities, including storage tanks, grain elevators): A facility that holds or stores food for animal consumption at any temperature.

FDA requests comment on whether the above definitions provide sufficient information for food facilities to select from the activity type options. To the extent that the definitions do not provide sufficient information, FDA requests comment on how the activity type definitions should be amended. In addition to seeking comment on whether and how to define the above activity types, FDA seeks comment on whether the activity types listed in proposed § 1.232(a)(8) encompass the full range of activities conducted by registered food facilities and whether they are otherwise appropriate. FDA selected the list of activity types in proposed § 1.232(a)(8) because that list largely reflects the optional activity types on current Form FDA 3537. At the same time, we are proposing several modifications to the current optional list of activity types. The modifications are designed to help FDA communicate more quickly with food facilities in the case of food-related emergencies, as well as to more accurately reflect the types of activities conducted at human and animal food facilities. Such modifications include dividing the optional activity type of ''warehouse/holding facility'' for facilities that hold food for human consumption into three subcategories. Those three subcategories would be ''ambient human food temperature warehouse/holding facility,'' ''refrigerated human food warehouse/holding facility,'' and ''frozen human food warehouse/holding facility.'' These additional subcategories would enable FDA to more quickly alert facilities potentially affected by an emergency food incident if FDA receives information indicating the type of facility affected. For example, if FDA receives information indicating that refrigerated or frozen warehouses/holding facilities could be affected by power outages, FDA would be able to communicate with such facilities about the incident. For animal food warehouse/holding facilities, however, FDA is not proposing to modify the activity types (that are currently optional) on current Form FDA 3537. FDA has tentatively concluded that the nature of animal food warehouse/holding facilities differs from human food warehouse/holding facilities, and that the current list of activity types—which has only one option for warehouse/holding—sufficiently enables FDA to respond quickly in the case of emergencies related to animal food. Indeed, animal food warehouse/holding facilities typically hold or store animal food at ambient temperature, negating the need for FDA to have information about the temperature storage conditions at animal food facilities.

In addition, FDA is proposing to add a ''farm mixed-type facility'' activity type option. FDA is proposing to add this activity type option in order to help the Agency efficiently inspect farm mixed-type facilities. The expertise required to inspect such facilities may differ from the expertise required to inspect non-farm manufacturing/processing facilities. Information about whether a facility is a farm mixed-type facility would therefore allow FDA to identify appropriate investigators to conduct such inspections.

Another change FDA is proposing to make from the optional activity types on current Form FDA 3537 is to eliminate the ''commissary'' activity type option. FDA is proposing this change because the Agency has tentatively concluded that the other activity type options listed in proposed § 1.232(a)(8)(i) through (a)(8)(xi) sufficiently address the types of activities conducted by facilities that identify as commissaries and that are required to register under section 415 of the FD&C Act.

Finally, FDA seeks comment on whether low-acid and acidified food processing should be treated as activity types, or whether there should be food product category options related to low-acid canned foods and acidified foods, or both. Currently, low-acid food and acidified food processing are optional activity types on current Form FDA 3537. In addition, FDA identified low-acid canned food products and acidified foods as food product categories in the October 2012 guidance the Agency issued concerning food product categories. (See ''Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories.'') As a result of the October 2012 guidance, low-acid foods and acidified foods have been listed on Form FDA 3537 as food product categories, while also being included as optional activity types. FDA recognizes that it may be confusing and redundant for there to be both food product categories and activity type categories related to low-acid canned foods and acidified foods. FDA also recognizes that the food product categories for low-acid canned foods and acidified foods may be broad in certain circumstances and may encompass a number of foods for which there may also be other applicable food categories. For example, a low-acid food might also be a baby food, which is another food product category option. And an acidified food might also be a fruit or fruit product, which is also another food product category option. A facility that manufactures/processes, packs, or holds low-acid food that is a baby food or an acidified food that is fruit or fruit product might therefore be confused about which food product categories to select. Accordingly, FDA seeks comment on whether low-acid and acidified foods should be included in only one portion of Form FDA 3537. We further seek comment on whether to include these products in the activity type section or the food product category section of Form FDA 3537. We also seek comment on all aspects of our proposal related to requiring food facilities to identify the type of activity conducted at the facility for each food product category identified.

d. Email address of the emergency contact of a domestic facility. Proposed

§ 1.232(b)(2) would add an email address to the emergency contact information registrants are required to provide for a domestic facility. Thus, in addition to the emergency contact phone number required under current § 1.232(e), registrants would also be required to provide an emergency contact email address. This proposed change would not affect the role of the emergency contact information. The emergency contact information would continue to be used in the event that we need to correspond with the facility during a terrorist threat or other food-related emergency. The purpose of requiring an email address is that such information would provide an efficient method of reaching the emergency contact in addition to the already required emergency contact phone number. We realize that in some cases the emergency contact email address may be the same email address as the email address for the facility contact person required in proposed § 1.232(b)(1) for domestic facilities. Consequently, proposed § 1.232(b)(2) would require an emergency contact email address to be provided only if that email address is different from the facility contact person email address required in proposed § 1.232(b)(1). Accordingly, the email address for the facility contact person required in proposed § 1.232(b)(1) would serve as the default emergency contact email address unless a facility provides a different emergency contact email address. We are seeking comments on this proposed provision.

6. Proposal To Identify and Update Food Product Categories

Proposed § 1.232(a)(7) would retain the requirement in current § 1.232(g) that food facilities provide information regarding food product categories, but would change that requirement to be consistent with the changes FDA has made to food product categories in response to the FSMA amendments.

Section 415(a)(2) of the FD&C Act, as added by section 305 of the Bioterrorism Act, provided in relevant part that, when determined necessary by FDA ''through guidance,'' a registrant must submit a registration to FDA containing information necessary to notify FDA of the general food category (as identified in § 170.3) of food manufactured, processed, packed, or held at such facility. On July 17, 2003, FDA issued a guidance document stating that FDA had determined that the inclusion of food product categories in food facility registrations was necessary for a quick, accurate, and focused response to an actual or potential bioterrorist incident or other food-related emergency (see 68 FR 42415). On October 10, 2003, FDA issued an interim final rule that also required facilities to submit registrations to FDA containing information regarding applicable food product categories as identified in § 170.3. Specifically, current § 1.232(g) provides that food facility registrations include applicable food product categories as defined in § 170.3, unless facilities check either ''most/all human food product categories,'' according to § 1.233(j), or ''none of the above mandatory categories'' because a facility manufactures/processes, packs, or holds a food that is not identified in § 170.3. On October 3, 2005, FDA issued a final rule for food facility registration, which generally confirmed the interim final rule (70 FR 57505).

As discussed previously, section 102 of FSMA amends section 415(a)(2) of the FD&C Act, to now provide, in relevant part, that, when determined necessary by FDA ''through guidance,'' a registrant is required to submit a registration to FDA containing information necessary to notify FDA of the general food category (as identified in § 170.3 or any other food categories, as determined appropriate by FDA, including by guidance) of any food manufactured, processed, packed, or held at such facility. In October 2012, FDA issued a guidance document entitled ''Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories'' (Ref. 3). This guidance document represents FDA's conclusion on the necessity of food product categories in food facility registrations and identifies additional food product categories, as provided by section 415(a)(2) of the FD&C Act. In the guidance document, FDA explained that because of Congress's explicit statutory authorization to effectuate a binding requirement based on findings in a guidance, the document is not subject to the usual restrictions in FDA's good guidance practice (GGP) regulations, such as the requirements that guidances not establish legally enforceable responsibilities and that they prominently display a statement of the document's nonbinding effect (21 CFR 10.115(d) and (i)).

Proposed § 1.232(a)(7) would be consistent with FDA's October 2012 guidance and the FSMA amendments. Specifically, the proposed provision would require that a food facility registration include applicable food product categories of any food manufactured/processed, packed, or held at the facility, as identified on Form FDA 3537. FDA intends to address any further amendments of the food product categories contained on FDA Form 3537, if necessary and appropriate, through updates to the guidance document ''Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories.'' We are seeking comments on this proposed provision.

7. Proposal To Remove List of Optional Items Included in the Registration

Proposed § 1.233 would provide that FDA encourages, but does not require, registrants to submit items that are indicated as optional on the Form FDA 3537. This proposed amendment would remove the list of optional items currently codified in § 1.233. We are proposing this change for two reasons. First, we are proposing elsewhere in this document to convert several of the optional items in current § 1.233 into required items in proposed § 1.232. Second, we believe FDA recommendations for optional items to include in food facility registrations are better addressed in guidance documents that follow our GGP regulations in 21 CFR 10.115. We are seeking comments on this proposed amendment.

8. Proposal To Require Immediate Updates to Incorrect Registration Information

Proposed § 1.231(a)(6) would require a food facility to immediately update any previously submitted registration information that was incorrect at the time of submission of an electronic registration or registration renewal. This proposal is consistent with the current requirement in § 1.231(b)(6) for registrations submitted by mail or fax, as well as with the current requirement in § 1.231(c)(10) for registrations submitted by CD–ROM. Under current § 1.231(b)(6) and (c)(10), any information that was incorrect at the time of submission of a registration submitted by mail or fax or CD–ROM must be immediately updated. Under the proposed rule, § 1.231(b)(6) would be recodified as § 1.231(b)(9). (Current § 1.231(c)(10) would not be recodified, as FDA is proposing to no longer allow registration submissions to be submitted by CD–ROM.) That requirement would also apply to registration renewals submitted by mail or fax, as we are proposing for all of the requirements in § 1.231(b) to apply to both registrations and registration renewals submitted by mail or fax.

We are proposing to require the immediate update of incorrect information submitted in electronic

registrations and registration renewals so that the requirement to immediately update incorrect information applies equally to registration submissions that are made electronically and by mail or fax. When FDA first implemented food facility registration in 2003, the Agency was concerned that a requirement for immediate updates of electronically submitted incorrect information would burden the food facility registration data system. Now, however, we have no such concerns. Due to advances in technology, we are confident in the ability of our data systems to maintain functionality while frequent updates are made in the system. Additionally, the majority of registrants now submit their registrations electronically, and FDA is proposing to require electronic registration beginning in 2016. With so many electronic registrations, the accuracy of the registration database depends on food facilities providing correct information. We tentatively conclude that the requirement for immediate updates of incorrect information submitted in electronic registrations and registration renewals would help ensure that FDA's registration database is accurate and up to date. Such an outcome would be consistent with FDA's mandate under section 415(a)(5) of the FD&C Act to compile and maintain an up-to-date list of food facilities. It would also be consistent with the requirement in section 415(a)(2) of the FD&C Act that registrants notify FDA ''in a timely manner'' of changes to the registration information they submit under that provision. Importantly, a more accurate and up-to-date registration database would help FDA more efficiently and effectively prevent and respond to food-related emergencies. To the extent that any incorrect information is relevant to FDA in planning for inspections, the proposed requirement would also aid the Agency in more efficiently and effectively locating and identifying food facilities for inspection. We request comments on this proposed provision.

9. Proposal To Change Requirement To Update and Cancel Registration Within 60 Calendar Days

Proposed § 1.234(a) and § 1.235(a) would shorten the time period for a food facility to update or cancel its registration from 60 calendar days to 30 calendar days. Specifically, proposed § 1.234(a) would require facilities to update their registration information, previously submitted under § 1.232, within 30 calendar days, replacing the 60-calendar-day requirement in current § 1.234(a). Proposed § 1.234(a) would not amend the other requirements in current § 1.234(a). For instance, it would not amend the requirement that such updates occur when there is any change to any of the information previously submitted under § 1.232 (*e.g.,* change of operator, agent in charge, or U.S. agent), except a change of the owner. It would similarly not amend the provision that owners, operators, or agents in charge may authorize an individual to update a facility's registration. Proposed § 1.235(a) would also replace a 60-calendar-day requirement with a 30-calendar-day requirement, providing that facilities cancel their registrations within 30 calendar days of the reason for cancellation (*e.g.,* facility ceases operations, ceases providing food for consumption in the United States, or is sold to a new owner) instead of the 60 calendar days in current § 1.235(a).

We are proposing to shorten the time period for updates and cancellations because we have learned over the past 10 years of food facility registration that: (1) We need registration information to be accurate and (2) for such information to be accurate, it needs to be more timely. For instance, we need to know as soon as possible when vital contact information has changed and when a facility has changed the food products it manufactures/processes, packs, or holds. We also need to know as soon as possible when a facility ceases operations or has been sold to a new owner. This information is important in both scheduling inspections and in responding to actual or threatened terrorist attacks and other food-related emergencies. Furthermore, the proposed timeframe is consistent with FDA's requirement under section 415(a)(5) of the FD&C Act to maintain an up-to-date list of facilities that are registered, as well as with registrants' obligation under section 415(a)(2) of the FD&C Act to notify FDA ''in a timely manner'' of changes to registration information. For these reasons, we tentatively conclude that the expedited receipt of updates to registration information and cancellations would help promote the efficient enforcement of section 415 of the FD&C Act.

10. Proposal To Cancel Registrations in Additional Circumstances

Currently, § 1.241(b) provides that FDA will cancel a registration if FDA independently verifies that the facility is no longer in business or has changed owners, and the owner, operator, or agent in charge of the facility fails to cancel the registration, or if FDA determines that the registration is for a facility that does not exist. Proposed § 1.241(c) would amend the regulation by also providing that FDA will cancel a registration if the Agency independently verifies that the facility is not required to register, if information about the facility's address was not updated in a timely manner in accordance with § 1.234(a), or if the registration was submitted to the Agency by a person not authorized to submit the registration under § 1.225. Proposed § 1.241(c) would further amend the regulation by also providing that FDA will cancel a registration if the facility's registration has expired because the facility has failed to renew the registration in accordance with § 1.230(b).

FDA is proposing to cancel registrations in these additional circumstances based on our experiences with invalid registrations during the approximately 10 years we have spent administering food facility registration, as well as to improve the utility of the food facility registration database and to make registration cancellations more consistent with the FSMA amendments. Examples of such invalid registrations have included instances in which an importer has registered a foreign food facility and listed himself as the U.S. agent as well as the owner, operator, or agent in charge for the facility without the facility's authorization. There have also been instances in which other third parties have created duplicate registrations for foreign food facilities, without authorization from the foreign facilities. Such registrations do not comply with food facility registration requirements and undermine the main objectives of food facility registration. The only individuals permitted to register a facility are the owner, operator, or the agent in charge of the facility or an individual authorized to register the facility on behalf of the owner, operator, or agent in charge. (Section 415 (a)(2) of the FD&C Act; §§ 1.225 and 1.232.) Registration information submitted to FDA must be true and accurate. (§ 1.232(i).) Where a registration is submitted to the Agency by an unauthorized person, the registration is not submitted in accordance with section 415 of the FD&C Act and FDA's registration regulations. Further, such registrations are less likely to be accurate or complete because unauthorized persons generally do not have access to a facility's information. Registrations containing false, inaccurate, or incomplete information hinder the Agency's ability to act quickly in responding to a threatened or actual terrorist attack on the U.S. food supply or other food-related emergency. Moreover, such registrations could hinder the Agency's

ability to enforce or implement other provisions of the FD&C Act, including conducting facility inspections. Finally, such registrations could adversely impact food facilities as such facilities may not be aware that a person is falsely submitting information to the Agency on the facility's behalf.

As to our proposal to cancel registrations when a facility has failed to renew its registration in accordance with § 1.230(b), this proposal is designed to respond to the FSMA amendments. As discussed elsewhere in this document, FSMA amended section 415 of the FD&C Act to require food facilities that are required to register with FDA to renew their registrations with FDA every other year. Cancelling the registrations of facilities that have failed to do so would allow FDA to efficiently enforce the renewal requirement. It would also allow FDA to efficiently implement its obligation under section 415(a)(5) of the FD&C Act to maintain an up-to-date list of facilities that are registered—as would the proposals to cancel registrations for facilities that are not required to register and registrations submitted to the Agency by unauthorized officials. A registration database that includes unnecessary, un-updated, or unauthorized entries would not be an up-to-date list of food facilities required to register with FDA under section 415 of the FD&C Act.

As to our proposal to cancel registrations when information about the facility's address was not updated in a timely manner in accordance with proposed § 1.234(a), this proposal is designed to assist FDA in using its limited inspectional resources efficiently. Inaccurate address information makes it difficult for FDA investigators to efficiently inspect food facilities, as investigators may invest time traveling to a particular address location only to find that the facility is not located there. FDA tentatively concludes that canceling registrations where a food facility has failed to update its address information in a timely manner in accordance with proposed § 1.234(a) would increase the accuracy of the address information contained in FDA's food facility registration database, and would therefore enable FDA investigators to more efficiently locate food facilities for inspection. FDA also tentatively concludes that such cancellations would allow FDA to efficiently implement its obligation under section 415(a)(5) to maintain an up-to-date list of facilities that are registered and would be consistent with the requirement in section 415(a)(2) of the FD&C Act that facilities notify FDA in a ''timely manner'' as to changes in their registration information, including their address information. We have also tentatively concluded that canceling registrations where a facility has failed to update its address information would supplement the requirement in FSMA that food facilities participate in biennial registration. Biennial registration renewal serves as a general mechanism to ensure all registrations are accurate and up to date, while cancellations based on failure to update allow FDA to respond to specific facilities that have failed to update address information. In addition, in enacting biennial registration renewal, Congress did not eliminate the requirement in section 415(a)(2) of the FD&C Act that registrants provide updates to their registration information in a ''timely manner.'' Instead, Congress added biennial renewal as a supplemental requirement. Thus, biennial renewal and the proposal to cancel registrations based on un-updated address information would both operate to improve the accuracy of FDA's food facility registration database, but would provide different mechanisms for doing so.

Proposed § 1.241(c) would maintain the requirement in current § 1.241(b) that FDA will cancel registrations in the specified circumstances if the Agency ''independently verifies'' those circumstances. Specifically, proposed § 1.241(c) would provide that FDA will cancel registrations if it ''independently verifies'' that the facility is no longer in business or has changed owners, and the owner, operator, or agent in charge of the facility fails to cancel the registration, or if FDA determines that the registration is for a facility that does not exist, is not required to register, or where the information about the facility's address was not updated in a timely manner in accordance with § 1.234(a) or the registration was submitted by a person not authorized to submit the registration under § 1.225. In maintaining the ''independently verif[y]'' requirement, we realize that each potential cancellation is likely to present unique facts, and thus may require the Agency to take an individualized approach in independently verifying the circumstances that merit registration cancellation. Nevertheless, we believe that in many cases it would be appropriate for us to send notices to facilities facing potential cancellation indicating our intent to cancel their registrations and the basis for such cancellations. We anticipate that we would send such notices prior to canceling registrations. We also anticipate that, when appropriate, if the circumstances meriting possible cancellation are corrected within 30 days after notice is provided, we would not cancel the registration. We anticipate that it would not be appropriate to provide the 30-day window for corrective action if the basis for cancellation is an expired registration due to failure to renew a registration in accordance with § 1.230(b). In such circumstances, we anticipate that a facility would have already received notice of its obligation to renew its registration, and therefore would have already have had the amount of time specified in section 415(a)(3) of the FD&C Act—the period beginning on October 1 and ending on December 31 of each even-numbered year—to renew its registration. Accordingly, when a facility's registration has expired due to failure to renew, we do not anticipate that FDA would need to provide the facility with additional time to take corrective action prior to canceling that facility's registration. We further anticipate that if facilities do not respond within 30 days, or if corrective action is otherwise not taken within that time period, we would determine that we conducted an independent verification and would then cancel the registration. If a facility believes its registration was cancelled in error, the facility would be able to contact the FDA Industry Systems Help Desk via telephone at 1–800–216–7331 or 301–575–0156.

Finally, proposed § 1.241(c) would maintain the requirement in current § 1.241(b) that if FDA cancels a facility's registration, FDA will mail a confirmation of the cancellation to the facility at the address provided in the facility's registration.

We are seeking comments on proposed § 1.241(c), as well as the Agency's approach to independently verifying the circumstances that may merit registration cancellation.

11. Proposal To Provide for a Waiver Request From Submitting Your Registration Electronically

As discussed previously, section 415(b)(5)(B) of the FD&C Act, as added by section 102(b) of FSMA, provides that FDA may require that registrations under section 415 be submitted to FDA in an electronic format. Section 415(b)(5)(B) specifies that such requirement may not take effect before the date that is 5 years after the date of enactment of FSMA, which is January 4, 2016. Proposed § 1.231(a)(2) would provide that beginning January 4, 2016,

electronic registration will be mandatory, unless a waiver has been granted for the registrant. Proposed § 1.245 would allow a registrant to request a waiver from the electronic registration requirement. Specifically, proposed § 1.245 would provide that a registrant may request such a waiver by submitting a written request to FDA explaining why it is not reasonable for the registrant to submit a registration or registration renewal electronically to FDA. FDA tentatively concludes that reasons for why it may not be reasonable for a registrant to submit a registration or registration renewal to FDA electronically may include conflicting religious beliefs or where a registrant does not have reasonable access to the Internet. We are seeking comments on this proposed provision and what, if any, other such reason should be considered for granting a waiver from the mandatory electronic registration and email requirements. We are also seeking comments on what information should be provided in a written request for a waiver from the electronic registration requirement.

12. Other Proposed Modifications to Registration of Food Facilities Regulations

a. Proposal to delete date from § 1.230(a)—When must you register? Current § 1.230(a) provides that the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States must register the facility no later than December 12, 2003. It also provides that the owner, operator, or agent in charge of a facility that begins to manufacture/process, pack, or hold food for consumption in the United States on or after December 12, 2003, must register before the facility begins such activities. The regulation contains the December 12, 2003, deadline because the Bioterrorism Act required facilities subject to food facility registration requirements to register with FDA no later than December 12, 2003. Because the December 12, 2003, deadline has now passed and is no longer relevant, we are proposing to delete the reference to that deadline in proposed § 1.230(a). Thus, proposed § 1.230(a) would contain no deadline, and would instead provide that owners, operators, or agents in charge must register before the facility begins to manufacture, process, pack, or hold food for consumption in the United States. We are seeking comments on this proposed modification.

In addition, proposed § 1.230(a) would retain the provision in current § 1.230(a) that owners, operators and agents in charge may authorize an individual to register the facility on their behalf. Currently, registrations submitted by such authorized individuals must include a statement from such individuals certifying that the information submitted is truthful and accurate and the individual is authorized to submit the registrations on the facility's behalf, and the individual must identify by name, address, and telephone number the individual who authorized submission of the registration. (21 CFR 1.232(i).) The certification statement also states that anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties under 18 U.S.C. 1001. (Under the proposed rule, this certification provision would be recodified at § 1.232(a)(10)). Further, as discussed in section III.B.4., for registrations submitted by individuals other than the owner, operator, or agent in charge, we are proposing to add the email address to the information required for identifying the individual who authorized submission of the registration on behalf of the facility. In addition, we are proposing that FDA will email the individual identified as the owner, operator, or agent in charge who authorized submission of the registration to verify that the individual in fact authorized submission of the registration on behalf of the facility. Further, we are proposing that FDA will not confirm the registration or provide a registration number until that individual confirms that he or she authorized the registration submission.

b. Proposal to replace ''owner, operator, or agent in charge of a facility'' with ''you'' and make other minor changes. We are proposing to replace the phrase ''owner, operator, or agent in charge of a facility'' throughout the codified at part 1, subpart H, with the term ''you'' as defined in current § 1.227(b)(14) as ''you or registrant means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.'' We are seeking comments on this proposed modification. In addition, we are proposing to replace the word ''cannot'' in current § 1.227(b)(13) with the term ''may not.'' Accordingly, the pertinent sentence in that provision would provide that, ''A U.S. agent *may not* be in the form of a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present'' (emphasis added). We are proposing this change to make clear that we are not concerned about a U.S. agent's ability to be in the form of a mailbox, answering machine, or service, or other place where a U.S. agent is not physically present, but rather that we do not authorize a U.S. agent to be in such forms or locations. We are also seeking comments on this proposed modification.

c. Proposal to delete option for CD–ROM submissions. We are proposing to delete the option to submit, update, and cancel multiple registrations by CD–ROM. Specifically, we are proposing to remove the option to use CD–ROM for multiple registration submissions in current § 1.231(c), as well as the option to use CD–ROM for updates of multiple submissions in current § 1.234(e) and for cancellations of multiple registrations in current § 1.235(e). FDA is proposing to make these changes because the Agency has tentatively concluded that this method of submitting, updating, and canceling registrations is outdated and obsolete. The Agency has only received 11 CD–ROM submissions since the registration requirements took effect. We are seeking comments on this proposal.

C. Request for Comment on Establishment of a U.S. Agent Voluntary Identification System

We are requesting comments on whether we should issue a future guidance document to provide for the creation of a U.S. Agent Voluntary Identification System (VIS or the system), or otherwise create such a system. As currently envisioned, the system would be designed to ensure the accuracy of U.S. agent information and enable U.S. agents to independently identify the facility or facilities for which the agent has agreed to serve. Specifically, the system would allow a U.S. agent to directly provide FDA with the agent's contact information (that is, the same contact information required for foreign food facility registration) and the name of the facility or facilities for which the agent has agreed to serve. Currently, FDA only receives U.S. agent contact information through foreign food facility registrations, many of which are submitted and updated by the facility, rather than the U.S. agent for the facility. The new system would allow agents to provide information about themselves, including their name, mailing address, phone number, email address, and emergency contact phone number, as well as the name of the facility or facilities for which the agent agrees to serve. After a U.S. agent has provided such information to FDA through the system, the Agency would provide the U.S. agent with an

identification number. The U.S. agent could then provide the identification number to foreign facilities that the U.S. agent agrees to represent as a U.S. agent. The foreign facilities, in turn, would have the option of providing the identification number for the U.S. agent in its registration rather than the specific U.S. agent's contact information required for food facility registrations (*e.g.,* address, email address, phone number). After using the identification number, and if the foreign facility name matches a facility name the U.S. agent identified in the system, the U.S. agent contact information in the system would then be linked and automatically populated in the foreign facility registration. When the confirmation copy of a foreign facility registration is sent to the U.S. agent, the confirmation copy would be sent to the contact information provided by the U.S. agent to ensure that the U.S. agent is aware of the connection with each foreign facility registration.

As we envision the voluntary system, U.S. agents would have discretion as to whom they provide their U.S. agent identification numbers. Because U.S. agents would be notified any time a foreign facility registers with FDA using their U.S. agent identification numbers, U.S. agents would have the opportunity to contact FDA in the event the U.S. agent is falsely identified in a food facility registration. U.S. agents would also have the ability to directly update or correct their contact information themselves. If we implement the voluntary U.S. agent verification system, we anticipate that we would also create update requirements that would mirror the update requirements for food facility registration (*i.e.,* 30 calendar days from any of the information previously submitted, as proposed elsewhere in this document). When a foreign facility uses an identification number for a registered U.S. agent and the name of the facility matches the facility name the agent has identified, we would consider the use of that identification a verification for purposes of proposed § 1.231(b)(6), and would therefore provide the facility with a registration number without FDA taking any additional steps to verify the U.S. agent as provided in proposed § 1.231(b)(6). Because the use of an identification number would constitute verification for purposes of proposed § 1.231(b)(6), foreign facilities would have an incentive to use U.S. agents registered in the system. Additionally, because U.S. agents would have direct access to a list of facilities listing them as U.S. agent, they would have an incentive to use the identification system, which we anticipate will limit the number of unauthorized and/or fraudulent U.S. agent listings. We would consider the use by a foreign facility of a U.S. agent identification number to be confirmation that the U.S. agent agrees to serve in that capacity for that foreign facility. If, however, the person designated as the U.S. agent then contacts FDA to state that the person did not agree to serve as the U.S. agent or declines the assignment, FDA would provide the facility with 30 calendar days to correct the U.S. agent information. If the facility does not take correction action, FDA would then take appropriate action.

We are seeking comment on creating this voluntary system because we find merit in the notion that a system that allows U.S. agents to provide their own contact information is likely to increase the accuracy of U.S. agent contact information and reduce the number of unauthorized and/or fraudulent U.S. agent listings.

If we pursue this system, we would follow our Good Guidance Practice regulations in 21 CFR 10.115. We are seeking comments on the proposed U.S. Agent Voluntary Identification System.

IV. Preliminary Regulatory Impact Analysis

A. Overview

FDA has examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA has developed a PRIA that presents the benefits and costs of this proposed rule (Ref. 4). FDA believes that the proposed rule will not be a significant regulatory action as defined by Executive Order 12866.

For interested persons, the detailed PRIA (Ref. 4) is available at *http://www.regulations.gov* (enter Docket No. FDA–2002–N–0323), and is also available on FDA's Web site at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm440616.htm.*

B. Regulatory Flexibility Act

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. We expect compliance costs generated by this proposed rule to be small. Nevertheless, we are unsure whether this proposed rule would have a significant economic impact on a substantial number of small entities and have analyzed various regulatory options to examine the impact on small entities.

C. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

D. Public Access to the Analyses

The analyses that FDA has performed in order to examine the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), are available to the public in the docket for this proposed rule (Ref. 4).

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given in the *Description* section of this document with an estimate of the annual reporting burden. Included in the burden estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comment on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions,

including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Registration of Food Facilities (OMB Control Number 0910–0502)—Revision.

Description of Respondents: Respondents to this collection of information are owners, operators, or agents-in-charge of domestic or foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States.

Description: FDA is proposing to amend its regulations governing food facility registration. We are proposing to codify the requirements of section 102 of FSMA that were self-implementing and effective upon enactment of FSMA. In addition, we are proposing to implement other requirements of section 102 of FSMA, as discussed previously, including mandatory electronic registration submissions beginning in 2016 and amendments to the retail food establishment definition. Lastly, we are proposing other changes to improve the utility of the food facility registration database. As discussed in the preamble to the proposed rule, FDA has the authority to issue this proposed rule under section 305(d) of the Bioterrorism Act, sections 102 and 107 of FSMA, and sections 301(dd), 415, 421, 701(a) 704 and 801(l) of the FD&C Act.

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), enacted on January 4, 2011, amended section 415 of the FD&C Act to require, among other things, that registrants for food facilities renew registrations biennially (section 415(a)(3) of the FD&C Act). FSMA also amended section 415 of the FD&C Act to require that food facility registrations include the email address for the contact person of a domestic facility and the email address of the United States agent for a foreign facility, as well as an assurance that FDA will be permitted to inspect the facility (section 415(a)(2) of the FD&C Act). These requirements went into effect upon enactment of FSMA. In addition, section 415(a)(2) of the FD&C Act, as amended by FSMA, also provides that, when determined necessary by FDA ''through guidance,'' a food facility is required to submit to FDA information about the general food category of a food manufactured, processed, packed, or held at such facility, as determined appropriate by FDA, including by guidance. FDA issued a guidance document entitled ''Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories'' in October 2012.

To comply with the statutory deadline under the provisions of FSMA, FDA initially obtained a 6-month OMB approval of these self-implementing FSMA reporting burdens under the emergency processing provisions of the PRA, and subsequently obtained a 3-year approval of these requirements under the same assigned OMB control number 0910–0502. OMB extended the approval for an additional 3 years in 2013. The current expiration date of the information collection is August 31, 2016.

The proposed rule would require food facilities to submit additional registration information to FDA with initial registrations, updates, and biennial renewals. The proposed rule would make the submission of the following currently optional information mandatory: (1) Preferred mailing address; (2) email address for the owner, operator, or agent in charge; (3) type of activity conducted at the facility; and (4) email address of the emergency contact of a domestic facility. In addition, the proposed rule would require food facilities to submit a D–U–N–S Number and, for registrations submitted by individuals other than the owner, operator, or agent in charge, the email address for the owner, operator, or agent in charge who authorized the registration submission on behalf of the facility. The proposed rule would also require mandatory electronic registration submissions beginning in 2016, which we estimate would cause some food facilities to submit a request for a waiver from that requirement. Finally, the proposed rule would establish a verification procedure for registration submissions made by individuals other than the owner, operator, or agent in charge, as well as a verification procedure for U.S. Agents.

Registration is one of several tools implemented under the Bioterrorism Act that enables FDA to act quickly in responding to a threatened or actual terrorist attack on the U.S. food supply or other food-related emergency by giving FDA information about facilities that manufacture/process, pack, or hold food for consumption in the United States. Further, in the event of an outbreak of foodborne illness, such information helps FDA determine the source and cause of the event. In addition, registration information enables FDA to quickly notify food facilities that might be affected by an outbreak, terrorist attack, threat, or other emergency. The proposed amendments will further enhance FDA's capabilities with respect to responding to food safety issues, and in addition, provide FDA with information that we can use to focus and better utilize our limited inspection resources.

The currently approved reporting burden for food facility registration under OMB control number 0910–0502 is 468,117 hours. The estimated reporting burden for food facility registration under the proposed rule is 413,153 hours, a decrease of 54,964 hours. This decrease is due in large part to a reduction in the number of registered food facilities, which we believe is reflective of the fact that the 2012 biennial registration renewal cycle appears to have had the effect of removing many out-of-date registrations from the registration system. We are proposing to make additional changes to the currently approved reporting burden as well. Since obtaining the FSMA-related emergency OMB approval and subsequent 3-year approval, we have refined our estimates for the time required to comply with the self-implementing FSMA provisions. As we explain in detail in the preliminary economic impact analysis, this is in part because we no longer assume that it will take domestic and foreign facilities different amounts of time to comply with the provisions of the proposed rule. It is also in part because the option to submit abbreviated registration renewals did not previously exist and in part because we have revised additional assumptions.

FDA revises its estimate of the one-time burden of the FSMA-related provisions of the proposed rule on registered facilities as follows:

TABLE 2—ESTIMATED ONE-TIME REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
All facility registrations (1.230–1.233)	172,274	1	172,274	0.18 (11 mins)	31,584

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

To determine the number of facilities in table 2, we assume that some of the participants in the 2012 biennial registration renewal cycle were new registrants. We do not consider those new registrations in estimating the total burden associated with the FSMA requirements. FDA used the the Small Business Administraiton's (SBA's) estimate that 12 percent of all businesses are new. Although SBA's estimate does not necessarily mean that 12 percent of all food facilities are new, we nevertheless find the SBA's estimate sufficiently relevant to apply to food facilities. We therefore estimate that 12 percent of currently registered food facilities were not registered at the time of the 2012 registration renewal cycle. As such, we estimate that 88 percent of currently registered food facilities, or 172,274 facilities, were registered in 2012.

Using our updated estimates for the time required to comply with the self-implementing FSMA provisions, we now estimate that the requirement for an email address for a domestic facility's contact person and a foreign facility's U.S. Agent will take 1 minute. We also now estimate that the assurance statement required by FSMA will take 5 minutes to provide and that the post-FSMA changes to food product categories will not result in any additional burden for facilities.

We also estimate the one-time burden from the new data elements in the proposed rule. We estimate that the average burden per response would be increased by the new data elements in the proposed rule. FDA believes that the new information will be readily available to the firms. We estimate that entering the four additional pieces of information that are currently optional would require, on average, an additional minute for each new data element per response. The four additional pieces of information that are currently optional are: (1) Preferred mailing address; (2) email address for the owner, operator, or agent in charge; (3) type of activity or type of storage conducted at the facility; and (4) email address of the emergency contact of a domestic facility. In addition, we estimate that entering a D–U–N–S® Number would require, on average, an additional minute per response. Thus, we estimate that these five proposed new data elements will require a total of 5 additional minutes. We estimate that the submission of the FSMA data elements and proposed new data elements would jointly increase the one-time burden from those activities by a total of 11 minutes (0.18 hour). The estimated one-time burden for currently registered facilities is therefore 172,274 facilities × 0.18 hours = 31,584 hours.

FDA estimates the annual burden of the proposed rule's revision of this information collection as follows:

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total
New domestic facility registrations (1.230–1.233)	9,795	1	9,795	2.7	26,447
New foreign facility registrations (1.230–1.233)	13,697	1	13,697	8.7	119,164
Updates (1.234)	68,518	1	68,518	1.5	102,777
Cancellations (1.235)	6,390	1	6,390	1	6,390
Biennial renewals (1.235)	97,883	1	97,883	0.38 (23 minutes)	37,196
Waiver requests (1.245)	1,061	1	1,061	0.17 (10 minutes)	180
Third party registration verification procedure	41,256	1	41,256	0.25 (15 minutes)	10,314
U.S. Agent verification procedure	57,070	1	57,070	0.5 (30 minutes)	28,535
Total Hours					331,002

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The currently approved annual reporting burden for food facility registration under OMB control number 0910–0502 is 468,117 hours. The estimated reporting burden for food facility registration under the proposed rule is 332,971 hours, a decrease of 135,146 hours. This decrease is due to the recently reduced number of active registrations in the food facility registration database.

Our estimates of the number of facilities that will submit new facility registrations are based on estimates by SBA that 12 percent of all businesses each year are new. As such, we estimate that 12 percent of registrations (or 23,500 registrations) are from new facilities entering the market. We are proposing to make additional changes to the currently approved reporting burden as well. As discussed previously, FDA obtained a 6-month emergency OMB approval of the self-implementing FSMA reporting burdens, and subsequently obtained a 3-year approval of these requirements. As described in the preliminary economic impact analysis, we estimate that 68,518 respondents will file updates, a decrease from the estimated number of 118,530 respondents reported in the 2013 request for extension, and we estimate that 97,883 respondents will file biennial renewals, a decrease from the

estimated number of 224,930 respondents reported in the 2013 request for extension. These decreases are due to recent reductions in the number of active registrations in the food facility registration database.

Prior to FSMA, FDA estimated that the average burden associated with new domestic and foreign facility registrations was a respective 2.5 and 8.5 hours. (See 75 FR 30033, May 28, 2010.) We expect that the proposed rule would add an additional 11 minutes to that burden as a result of the proposed new data elements. Based on estimates by SBA that 12 percent of all businesses are new, we estimate that all new facilities each year will be equal to 12 percent of the total number of registered facilities. Thus, we estimate that each year there will be 9,795 new domestic and 13,697 new foreign facility registrations, and that the average burden for those new registrations will be of 2.7 hours (2.5 hours plus 11 minutes) for new domestic facility registrations and 8.7 hours (8.5 hours plus 11 minutes) for new foreign facility registrations, as reported in table 28, rows 1 and 2) (p. 64 of Ref. 4).

The proposed rule would also shorten the time period for updates from 60 calendar days to 30 calendar days. The average burden per response for updates would increase from 1.2 hours to 1.54 hours (difference of 0.34 hours, or about 20 minutes), as reported in table 28, row 3 (p. 64 of Ref. 4).

This proposed rule would also establish an abbreviated renewal process, which modifies our previous estimate that on average it would take 0.5 hours per renewal. With the option for an abbreviated renewal process, we estimate that half the facilities will take 15 minutes per renewal using the abbreviated renewal process and that half of facilities will take 30 minutes. This alters our previous estimate of 0.5 hours to submit a renewal to an average of 0.38 hours (23 minutes) to submit a renewal, as reported in table 28, row 5 (p. 64 of Ref. 4). This estimate takes into account that some registered firms would be able to take advantage of the abbreviated renewal process, while other firms would take more time to prepare and submit the renewal, as discussed in the preliminary economic impact analysis. We have not changed our estimate of the average burden per response for cancellations because the proposed rule does not add new data elements for cancellations.

If the rule is finalized as proposed, it would mandate the electronic submission of food facility registrations, while also allowing respondents to submit a request for waiver of the requirement to electronically submit their registration. As described in the preliminary economic impact analysis, we estimate that, on average, 1,061 facilities will seek a waiver each year. We also estimate that it would take a respondent 10 minutes to prepare the proposed waiver request submission and attach it to their paper Form FDA 3537 registration submission. Thus, the total annual burden of submitting waiver requests is estimated to be 180 hours ($1{,}061 \times 0.17$ hours), as reported in table 28, row 6 (p. 64 of Ref. 4).

If the rule is finalized as proposed, it would establish a verification procedure for registrations submitted by individuals other than the owner, operator, or agent-in-charge (third party registrations), as well as a verification procedure for U.S. Agents. To verify third-party registrations, FDA would send an email to the owner, operator, or agent in charge with a link allowing the owner, operator, or agent in charge to either confirm or deny that he or she authorized the registration submission on behalf of the facility. In connection with requiring his verification process, the proposed rule would add email address to the list of required information identifying the individual who authorized submission of registrations submitted by individuals other than the owner, operator, or agent in charge. As described in the preliminary economic impact analysis, we estimate that it would take an owner, operator, or agent in charge 15 minutes (0.25 hour) to participate in FDA's verification procedure. This estimate includes the time required to enter the email address of the owner, operator, or agent in charge who authorized the submission. We further estimate that 82,513 registrations would be affected once every other year, or 41,257 annually. Thus, the total annual burden of these verifications is estimated to be 10,314 hours ($41{,}257 \times 0.25$ hour = 10,314 hours), as reported in table 28, row 7 (p. 64 of Ref. 4).

To verify the U.S. Agent, FDA would send an email to the U.S. Agent at the email address provided by the registrant. The email address would include a link that would connect the U.S. Agent to FDA's food facility registration module, allowing the U.S. Agent to either accept or decline assignment with the facility. If the U.S. Agent accepts the assignment, FDA would also email the facility of the U.S. Agent's acceptance. If, however, a U.S. Agent declines the assignment, the issuance of the registration number could be delayed. We estimate that the burden that will result from the verification procedure would be about 30 minutes (0.5 hours). We also estimate that 114,139 registrations would be affected once every 2 years, or 57,070 facility registrations annually. Thus, the total annual burden of these verifications is estimated to be 28,535 hours ($57{,}070 \times 0.5$ hour = 28,535 hours), as reported in table 28, row 8 (p. 64 of Ref. 4).

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection to the Office of Information and Regulatory Affairs, OMB.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title ''Registration of Food Facilities.'' These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

VI. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we tentatively conclude that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Request for Comments

We invite public comment on the matters specified in this document as well as any other matters concerning this proposed rule that are of interest.

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (We have verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA, ''Compliance Policy Guide Sec. 100.250 Food Facility Registration—Human and Animal Food'' (*http://www.fda.gov/downloads/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/UCM399369.pdf*), accessed on March 27, 2015.
2. FDA, ''Field Management Directives,'' (*http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm096034.htm*), accessed on March 27, 2015.
3. FDA, ''Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories,'' (*http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm324778.htm*), accessed on March 27, 2015.
4. FDA, ''Preliminary Regulatory Impact Analysis,'' 2014.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 is revised to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 350j, 352, 355, 360b, 362, 371, 374, 379j–31, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264; Pub. L. 107–188, 116 Stat. 594, 668–69.

■ 2. Revise § 1.227 (b)(11) and (13) to read as follows:

§ 1.227 What definitions apply to this subpart?

* * * * *

(b) * * *

(11) *Retail food establishment* means an establishment that sells food products directly to consumers as its primary function. The term ''retail food establishment'' includes facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term ''consumers'' does not include businesses. A ''retail food establishment'' includes grocery stores, convenience stores, and vending machine locations. Sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

* * * * *

(13) *U.S. agent* means a person (as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(e))) residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of this subpart. A U.S. agent may not be in the form of a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present.

(i) The U.S. agent acts as a communications link between FDA and the foreign facility for both emergency and routine communications. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies another emergency contact.

(ii) FDA will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent the equivalent of providing the information or documents to the foreign facility. FDA will consider the U.S. agent the equivalent of the registrant for purposes of sharing information and communications. The U.S. agent of a foreign facility may view the information submitted in the foreign facility's registration.

(iii) Having a single U.S. agent for the purposes of this subpart does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes. A firm's commercial business in the United States need not be conducted through the U.S. agent designated for purposes of this subpart.

* * * * *

■ 3. Revise § 1.230 to read as follows:

§ 1.230 When must you register or renew your registration?

(a) *Registration.* You must register before your facility begins to manufacture, process, pack, or hold food for consumption in the United States. You may authorize an individual to register the facility on your behalf.

(b) *Registration renewal.* You must submit a registration renewal containing the information required under § 1.232 every other year, during the period beginning on October 1 and ending on December 31 of each even-numbered year. You may authorize an individual to renew a facility's registration on your behalf. If the individual submitting the registration renewal is not the owner, operator, or agent in charge of the facility, the registration renewal must also include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit the registration renewal, and identifies by name, address, email address, and

telephone number, the individual who authorized submission of the registration renewal. Each registration renewal must include the name of the individual submitting the registration renewal, and the individual's signature (for the paper option).

(c) *Abbreviated registration renewal process.* If you do not have any changes to the information required under § 1.232 since you submitted the preceding registration or registration renewal for your facility, you may use the abbreviated registration renewal process. If you use the abbreviated registration renewal process, you must confirm that no changes have been made to the information required under § 1.232 since you submitted the preceding registration or registration renewal, confirm that FDA will be permitted to inspect the facility at the times and in the manner permitted by the Federal Food, Drug, and Cosmetic Act, and certify that the information submitted is truthful and accurate. You must use Form FDA 3537 to submit abbreviated registration renewals to FDA.

■ 4. Revise § 1.231 to read as follows:

§ 1.231 How and where do you register or renew your registration?

(a) *Electronic registration and registration renewal.* (1) To register or renew a registration electronically, you must go to *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. An individual authorized by the owner, operator, or agent in charge of a facility may also register a facility electronically.

(2) Beginning on January 4, 2016, you must submit your registration or registration renewal to FDA electronically, unless you have been granted a waiver under § 1.245.

(3) After you complete your electronic registration, FDA will verify the accuracy of your facility's Data Universal Numbering System (D–U–N–S® number) and will also verify that the facility-specific address associated with the D–U–N–S® number is the same address associated with your registration. FDA will not confirm your registration or provide you with a registration number until FDA verifies the accuracy of your facility's D–U–N–S® number and verifies that the facility-specific address associated with the D–U–N–S® number is the same address associated with your registration. With respect to electronic registration renewals, after you complete your electronic registration renewal, FDA will provide you with an electronic confirmation of your registration renewal. When you update your facility's D–U–N–S® number as part of your electronic registration renewal, FDA will verify the accuracy of your facility's D–U–N–S® number and will also verify that the facility-specific address associated with the D–U–N–S® number is the same address associated with your registration. FDA will not provide you with an electronic confirmation of your registration renewal until FDA verifies the accuracy of your D–U–N–S® number and verifies that the facility-specific address associated with the D–U–N–S® number is the same address associated with your registration.

(4) For electronic registrations not submitted by the owner, operator, or agent in charge of the facility, after completion of the electronic registration, FDA will email the individual identified as the owner, operator, or agent in charge who authorized submission of the registration to verify that the individual in fact authorized submission of the registration on behalf of the facility. FDA will not confirm the registration or provide a registration number until that individual confirms that he or she authorized the registration submission. With respect to electronic registration renewals, after completion of the electronic registration renewal, FDA will provide an electronic confirmation of the registration renewal. For electronic registration renewals not submitted by the owner, operator, or agent in charge of the facility, FDA will email the individual identified as the owner, operator, or agent in charge who authorized submission of the registration renewal to verify that the individual in fact authorized submission of the registration renewal on behalf of the facility. FDA will not provide an electronic confirmation of the registration renewal until that individual confirms that he or she authorized the registration renewal.

(5) For a foreign facility, after you complete your electronic registration, FDA will email the person identified as the U.S. agent for your foreign facility, using the email address for the person identified as your U.S. agent, to verify that the person has agreed to serve as your U.S. agent. FDA will not confirm your registration or provide you with a registration number until that person confirms that the person agreed to serve as your U.S. agent. With respect to electronic registration renewals, after you complete your electronic registration renewal, FDA will provide you with an electronic confirmation of your registration renewal. When you update information about your U.S. agent as part of your electronic registration renewal, FDA will email the person identified as the U.S. agent for your foreign facility, using the email address for the person identified as your U.S. agent, to verify that the person has agreed to serve as your U.S. agent. FDA will not provide you with an electronic confirmation of your registration renewal until that person confirms that the person agreed to serve as your U.S. agent.

(6) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration as specified in § 1.234.

(7) You will be considered registered once FDA electronically transmits your confirmation and registration number.

(b) *Registration or registration renewal by mail or fax.* Before January 4, 2016, if you do not have reasonable access to the Internet through any of the methods described in paragraph (a) of this section, you may register or renew a registration by mail or by fax. Beginning January 4, 2016, you must submit your registration or registration renewal to FDA electronically, unless you have been granted a waiver under § 1.245.

(1) You must register or renew a registration (including abbreviated registration renewals) using Form FDA 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy. (HFS–681), College Park, MD 20993, or by requesting the form by phone at 1–800–216–7331 or 301–575–0156.

(2) When you receive the form, you must fill it out completely and legibly and either mail it to the address in paragraph (b)(1) of this section or fax it to 301–436–2804.

(3) If any required information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the form was received by the Agency (*i.e.,* by mail or fax).

(4) FDA will enter complete and legible mailed and faxed registration submissions into its registration system, as soon as practicable, in the order FDA receives them.

(5) After you complete your registration, FDA will verify the accuracy of your facility's D–U–N–S® number and will also verify that the

facility-specific address associated with the D–U–N–S® number is the same address associated with your registration. FDA will not confirm your registration or provide you with a registration number until FDA verifies the accuracy of your facility's D–U–N–S® number and verifies that the facility-specific address associated with the D–U–N–S® number is the same address associated with your registration. With respect to registration renewals, after you complete your registration renewal by mail or fax, FDA will provide you with a confirmation of your registration renewal. When you update your facility's D–U–N–S® number as part of your registration renewal, FDA will verify the accuracy of your facility's D–U–N–S® number and will also verify that the facility-specific address associated with the D–U–N–S® number is the same address associated with your registration. FDA will not provide you with a confirmation of your registration renewal until FDA verifies the accuracy of your D–U–N–S® number and verifies that the facility-specific address associated with the D–U–N–S® number is the same address associated with your registration.

(6) For registrations not submitted by the owner, operator, or agent in charge of the facility, after completion of the registration by mail or fax, FDA will email the individual identified as the owner, operator, or agent in charge who authorized submission of the registration to verify that the individual in fact authorized submission of the registration on behalf of the facility. FDA will not confirm the registration or provide a registration number until that individual confirms that he or she authorized the registration submission. With respect to registration renewals, after completion of the registration renewal by mail or fax, FDA will provide a confirmation of the registration renewal. For registration renewals not submitted by the owner, operator, or agent in charge of the facility, FDA will email the individual identified as the owner, operator or agent in charge who authorized submission of the registration renewal to verify that the individual in fact authorized the submission of the registration renewal on behalf of the facility. FDA will not provide a confirmation of the registration renewal until that individual confirms that he or she authorized the registration renewal.

(7) For a foreign facility, after you complete your registration by mail or fax, FDA will email the person identified as the U.S. agent for your foreign facility, using the email address for the person identified as the U.S. agent in your registration, to verify that the person has agreed to serve as your U.S. agent. FDA will not confirm your registration or provide you with a registration number until that person confirms that the person agreed to serve as your U.S. agent. With respect to registration renewals, after you complete your registration renewal by mail or fax, FDA will provide you with a confirmation of your registration renewal. When you update information about your U.S. agent as part of your registration renewal, FDA will email the person identified as the U.S. agent for your foreign facility, using the email address for the person identified as your U.S. agent, to verify that the person has agreed to serve as your U.S. agent. FDA will not provide you with a confirmation of your registration renewal until that person confirms that the person agreed to serve as your U.S. agent.

(8) FDA will mail or fax a copy of the registration as entered, confirmation of registration, and your registration number. When responding to a registration submission, FDA will use the means by which the registration was received by the Agency (*i.e.,* by mail or fax).

(9) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration as specified in § 1.234.

(10) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(c) *Fees.* No registration fee is required.

(d) *Language.* You must submit all registration information in the English language except an individual's name, the name of a company, the name of a street, and a trade name may be submitted in a foreign language. All information, including these items, must be submitted using the Latin (Roman) alphabet.

■ 5. Revise § 1.232 to read as follows:

§ 1.232 What information is required in the registration?

(a) For a domestic and foreign facility, the following information is required:

(1) The name, full address, and phone number of the facility;

(2) The D–U–N–S® number of the facility;

(3) The preferred mailing address, if different from that of the facility;

(4) The name, full address, and phone number of the parent company, if the facility is a subsidiary of the parent company;

(5) All trade names the facility uses;

(6) The name, full address, phone number, and email address of the owner, operator, or agent in charge of the facility;

(7) The applicable food product categories of any food manufactured/processed, packed, or held at the facility as identified on Form FDA 3537;

(8) The type of activity conducted at the facility for each food product category identified. You may select more than one activity type for each food product category identified. The activity type options are as follows:

(i) Ambient human food storage warehouse/holding facility;

(ii) Refrigerated human food warehouse/holding facility;

(iii) Frozen human food warehouse/holding facility;

(iv) Interstate conveyance caterer/catering point;

(v) Contract Sterilizer;

(vi) Labeler/Relabeler;

(vii) Manufacturer/Processor;

(viii) Farm Mixed-Type Facility;

(ix) Packer/Repacker;

(x) Salvage Operator (Reconditioner);

(xi) Animal food warehouse/holding facility;

(xii) Other Activity.

(9) A statement in which the owner, operator, or agent in charge provides an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the Federal Food, Drug, and Cosmetic Act;

(10) A statement in which the owner, operator, or agent in charge certifies that the information submitted is true and accurate. If the individual submitting the form is not the owner, operator, or agent in charge of the facility, the registration must also include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit the registration, and identifies by name, address, email address and telephone number, the individual who authorized submission of the registration. Each registration must include the name of the individual registering the facility submitting the registration, and the individual's signature (for the paper option).

(b) For a domestic facility, the following additional information is required:

(1) The email address for the contact person of the facility;

(2) An emergency contact phone number and email address if different from the email address for the contact person in paragraph (b)(1) of this section.

(c) For a foreign facility, the following additional information is required:

(1) The name, full address, phone number, and email address of the foreign facility's U.S. agent;

(2) An emergency contact phone number and email address.

■ 6. Revise § 1.233 to read as follows:

§ 1.233 Are there optional items included in the registration form?

Yes. FDA encourages, but does not require, you to submit items that are indicated as optional on the Form FDA 3537 that you submit.

■ 7. Revise § 1.234 to read as follows:

§ 1.234 How and when do you update your facility's registration information?

(a) *Update requirements.* You must update a facility's registration within 30 calendar days of any change to any of the information previously submitted under § 1.232 (*e.g.,* change of operator, agent in charge, or U.S. agent), except a change of the owner. You may authorize an individual to update a facility's registration on your behalf. For updates not submitted by the owner, operator, or agent in charge of the facility, the update must provide the email address of the owner, operator, or agent in charge who authorized submission of the update.

(b) *Cancellation due to ownership changes.* If the reason for the update is that the facility has a new owner, the former owner must cancel the facility's registration as specified in § 1.235 within 30 calendar days of the change and the new owner must submit a new registration for the facility as specified in § 1.231. The former owner may authorize an individual to cancel a facility's registration.

(c) *Electronic update.* (1) To update your registration electronically, you must update at *http://www.fda.gov/furls.*

(2) After you complete your electronic update, FDA will provide you with an electronic confirmation of your update. When updating D–U–N–S® number information, FDA will verify the accuracy of your facility's D–U–N–S® number and will also verify that the facility-specific address associated with the D–U–N–S® number is the same address associated with your registration. FDA will not provide you with an electronic confirmation of your registration update until FDA verifies the accuracy of your facility's D–U–N–S® number and verifies that the facility-specific address associated with the D–U–N–S® number is the same address associated with your registration. For foreign facilities, when updating information about your U.S. agent, FDA will email the person identified as the U.S. agent for your foreign facility, using the email address for the person identified as your U.S. agent, to verify that the person has agreed to serve as your U.S. agent. FDA will not provide you with an electronic confirmation of your registration update until that person confirms that the person agreed to serve as your U.S. agent.

(3) For electronic updates not submitted by the owner, operator, or agent in charge of the facility, after completion of the electronic update, FDA will email the individual identified as the owner, operator, or agent in charge who authorized submission of the update to verify that the individual in fact authorized submission of the update on behalf of the facility. FDA will not confirm the update to the registration until that individual confirms that he or she authorized the update.

(4) Your registration will be considered updated once FDA transmits your update confirmation, unless notified otherwise.

(d) *Update by mail or fax.* Before January 4, 2016, if you do not have reasonable access to the Internet through any of the methods described in § 1.231(a), you may update your facility's registration by mail or by fax. Beginning January 4, 2016, electronic updates will be mandatory, unless a waiver under § 1.245 has been granted.

(1) You must update your registration using Form FDA 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy. (HFS–681), College Park, MD 20993 or by requesting the form by phone at 1–800–216–7331 or 301–575–0156.

(2) When you receive the form, you must legibly fill out the sections of the form reflecting your updated information and either mail it to the address in paragraph (d)(1) of this section or fax it to 301–436–2804.

(3) If the information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the registration was received by the Agency (*i.e.,* by mail or fax).

(4) FDA will enter complete and legible updates into its registration system as soon as practicable, in the order FDA receives them.

(5) FDA will then mail to the address or fax to the fax number on the registration form a copy of the update as entered and confirmation of the update. When responding to an update submission, FDA will use the means by which the form was received by the Agency (*i.e.,* by mail or fax). After you complete your update by mail or fax, FDA will verify the accuracy of your facility's D–U–N–S® number and will also verify that the facility-specific address associated with the D–U–N–S® number is the same address associated with your registration. FDA will not provide a confirmation of your registration update until FDA verifies the accuracy of your facility's D–U–N–S® number and verifies that the facility-specific address associated with the D–U–N–S® number is the same address associated with your registration. For foreign facilities, when updating information about your U.S. agent, FDA will email the person identified as the U.S. agent for your foreign facility, using the email address for the person identified as your U.S. agent, to verify that the person has agreed to serve as your U.S. agent. FDA will not provide you with a confirmation of your registration update until that person confirms that the person agreed to serve as your U.S. agent.

(6) For registration updates not submitted by the owner, operator, or agent in charge of the facility, after completion of the registration update by mail or fax, FDA will email the individual identified as the owner, operator, or agent in charge who authorized submission of the registration update to verify that the individual in fact authorized submission of the update on behalf of the facility. FDA will not confirm the registration update until that individual confirms that he or she authorized the update.

(7) If any update information you previously submitted was incorrect at the time of submission, you must immediately resubmit your update.

(8) Your registration will be considered updated once FDA enters your facility's update data into the registration system and the system generates an update confirmation.

■ 8. Revise § 1.235 to read as follows:

§ 1.235 How and when do you cancel your facility's registration information?

(a) *Notification of registration cancellation.* You must cancel a registration within 30 calendar days of the reason for cancellation (*e.g.,* your facility ceases operations, ceases providing food for consumption in the United States, or is sold to a new owner).

(b) *Cancellation requirements.* The cancellation of a facility's registration must include the following information:

(1) The facility's registration number;

(2) Whether the facility is domestic or foreign;

(3) The facility name and address;

(4) The name, address, and email address (if available) of the individual submitting the cancellation;

(5) For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, the email address of the owner, operator, or agent in charge who authorized submission of the registration cancellation; and

(6) A statement certifying that the information submitted is true and accurate, and that the person submitting the cancellation is authorized by the facility to cancel its registration.

(c) *Electronic cancellation.* (1) To cancel your registration electronically, you must cancel at *http://www.fda.gov/furls.*

(2) Once you complete your electronic cancellation, FDA will automatically provide you with an electronic confirmation of your cancellation.

(3) For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, after completion of the registration cancellation, FDA will email the individual identified as the owner, operator, or agent in charge who authorized submission of the registration cancellation to verify that the individual in fact authorized submission of the registration cancellation on behalf of the facility. FDA will not confirm the registration cancellation until that individual confirms that he or she authorized the registration cancellation.

(4) Your registration will be considered cancelled once FDA transmits your cancellation confirmation.

(d) *Cancellation by mail or fax.* Before January 4, 2016, if you do not have reasonable access to the Internet through any of the methods described in § 1.231(a), you may cancel your facility's registration by mail or fax. Beginning January 4, 2016, you must cancel your registration electronically unless a waiver under § 1.245 has been granted.

(1) You must cancel your registration using Form FDA 3537a. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy. (HFS–681), College Park, MD 20993 or by requesting the form by phone at 1–800–216–7331 or 301–575–0156.

(2) When you receive the form, you must completely and legibly fill out the form and either mail it to the address in paragraph (d)(1) of this section or fax it to 301–436–2804.

(3) If the information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a cancellation form for revision, FDA will use the means by which the cancellation was received by the Agency (*i.e.,* by mail or fax).

(4) FDA will enter complete and legible mailed and faxed cancellations into its registration system as soon as practicable, in the order FDA receives them.

(5) FDA will mail to the address or fax to the fax number on the cancellation form a copy of the cancellation as entered and confirmation of the cancellation. When responding to a cancellation, FDA will use the means by which the form was received by the Agency (*i.e.,* by mail or fax).

(6) For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, after completion of the registration cancellation by mail or fax, FDA will email the individual identified as the owner, operator, or agent in charge who authorized submission of the registration cancellation to verify that the individual in fact authorized submission of the registration cancellation on behalf of the facility. FDA will not confirm the registration cancellation until that individual confirms that he or she authorized the registration cancellation.

(7) If any information you previously submitted was incorrect at the time of submission, you must immediately resubmit your cancellation.

(8) Your registration will be considered cancelled once FDA enters your facility's cancellation data into the registration system and the system generates a confirmation.

(e) *Cancellation by CD–ROM for multiple submissions.* If, for example, you do not have reasonable access to the Internet through any of the methods described in § 1.231(a), you may cancel your facilities' registrations using a CD–ROM.

■ 9. Revise § 1.241 to read as follows:

§ 1.241 What are the consequences of failing to register, update, renew, or cancel your registration?

(a) Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done. Under section 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. Under section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act. Under section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States. Failure of an owner, operator, or agent in charge of a domestic or foreign facility to register its facility, renew the registration of its facility, update required elements of its facility's registration, or cancel its registration in accordance with the requirements of this subpart is a prohibited act under section 301(dd) of the Federal Food, Drug, and Cosmetic Act.

(b) FDA will consider a registration for a food facility to be expired if the registration is not renewed, as required by § 1.230(b). Thus, if you previously submitted a registration to FDA, but do not submit a registration renewal to FDA during the period beginning on October 1 and ending on December 31 of each even-numbered year, FDA will consider the registration for the facility to be expired. FDA will consider a food facility with an expired registration to have failed to register in accordance with section 415 of the Federal Food, Drug, and Cosmetic Act.

(c) FDA will cancel a registration if FDA independently verifies that the facility is no longer in business or has changed owners, and the owner, operator, or agent in charge of the facility fails to cancel the registration, or if FDA determines that the registration is for a facility that does not exist, is not required to register, or where the information about the facility's address was not updated in a timely manner in accordance with § 1.234(a) or the registration was submitted by a person not authorized to submit the registration under § 1.225. Also, FDA will cancel a registration if the facility's registration has expired because the facility has failed to renew its registration in accordance with § 1.230(b). If FDA cancels a facility's registration, FDA will mail a confirmation of the cancellation to the facility at the address provided in the facility's registration.

(d) If an article of food is imported or offered for import into the United States and a foreign facility that manufactured/processed, packed, or held that article of food has not registered in accordance with this subpart, the disposition of the article of food shall be governed by the procedures set out in subpart I of this part.

■ 10. Add § 1.245 to subpart H to read as follows:

§ 1.245 Waiver request.

Under § 1.231(a)(2) and (b), beginning January 4, 2016, you must submit your registration or registration renewal to FDA electronically unless FDA grants a waiver from such requirement. To request a waiver from such requirement, you must submit a written request to FDA that explains why it is not reasonable for you to submit your registration or registration renewal to FDA electronically. You must submit your request to: U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy. (HFS–681), College Park, MD 20993.

Dated: April 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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