

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 1**

[Docket No. FDA-2002-N-0323]

RIN 0910-AG69

**Amendments to Registration of Food Facilities**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA or we) is amending its regulations for registration of food facilities that require 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 rule amends and updates 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. These 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:** This rule is effective September 12, 2016.

**FOR FURTHER INFORMATION CONTACT:** Courtney Buchanan, Center for Food Safety and Applied Nutrition (HFS-615), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2487.

**SUPPLEMENTARY INFORMATION:**

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**Executive Summary**

*Purpose and Coverage of the Final Rule*

This rule is part of FDA's implementation of FSMA (Pub. L. 111-353), which intends to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. This rule implements 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 FSMA, that relate to registration of food facilities. Furthermore, this rule amends and updates FDA's registration regulations and improves the utility of the food facility registration database 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 Major Provisions of the Final Rule*

Section 102 of FSMA amends section 415 of the FD&C Act by requiring that certain additional information be included in facility 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 included in this final rule to codify these provisions in 21 CFR part 1, subpart H, the food facility registration regulation.

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 implementing this provision in the final rule. However, we are delaying the date for mandatory electronic registration until January 4, 2020. Furthermore, we are including a waiver request provision in the rule to allow a registrant to submit a written request to FDA that explains why it is not reasonable to submit the registration, registration renewal, update, or cancellation to FDA electronically or to explain why it is not reasonable to provide the email address

of the owner, operator, or agent in charge of the facility.

Section 102(c) of FSMA also directs FDA to amend the definition of the term “retail food establishment” in § 1.227 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 revising the definition of retail food establishment at § 1.227 in this final rule consistent with section 102(c) of FSMA.

In addition, we are making changes to improve the utility of the food facility registration database. We are making changes in 21 CFR part 1, subpart H to: (1) Require certain additional data elements in food facility registrations (e.g., a unique facility identifier (UFI) for food facility registrations); (2) employ 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.

Further, we proposed to amend the regulation to shorten the timeframe for submitting updates and cancellations from 60 calendar days to 30 calendar days. In response to numerous comments received on this issue, the final rule does not shorten the timeframes as proposed. The final rule provides that updates to registration information or cancellation of registration must be submitted within 60 days of any change to any of the required information or the reason for the cancellation.

*Costs and Benefits*

Costs of meeting the requirements of this final 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 final rule. These costs are similar to what we estimated the proposed rule would cost, but with the additional implementation of a U.S. Agent Voluntary Identification System (VIS) and reduced costs to facilities resulting from postponing the requirements to provide a UFI and to submit registrations electronically. Estimated one-time costs to domestic and foreign facilities are about \$27 million. These estimated costs include a small reduction from the estimated one-time costs of provisions in the proposed rule. As explained in the preliminary regulatory impact analysis (PRIA), one-time costs in the first year stem from the self-implementing FSMA provisions that are already effective, including learning costs (i.e., the administrative costs incurred by domestic and foreign facilities in order to learn how to comply with any new regulation), first-time biennial registration renewal costs from the 2012 registration renewal cycle, and costs that stem from requirements for certain data elements in the registration form such as the email address for a domestic facility’s contact person and the email address for a foreign facility’s U.S. agent. These costs are approximately \$20 million. Estimated one-time costs to domestic and foreign facilities for the biennial renewal cycle in 2016, by which time the final rule will be effective, include \$4.6 million in one-time costs for entering additional data elements in the registration form and costs for U.S. agent verification procedures incurred in 2016. One-time costs in 2020 include the costs for the requirement to obtain a UFI plus the reduced costs associated with the mandatory electronic submission requirement (because the preamble to the final rule clarifies that food facilities will not be required to resubmit waivers with each biennial registration renewal cycle once FDA has

granted the waiver). These costs are approximately \$3 million.

Recurring biennial costs beginning in 2016 include costs from the requirement for both domestic and foreign food facilities to renew their registrations every 2 years and from requiring additional data elements in the registration form. Recurring costs for 2018 include costs from implementing the U.S. agent VIS. As was the case under Option 4 in the PRIA, these costs are based on the supposition that the U.S. agents for all foreign facilities will choose to use the VIS. In the PRIA (see pages 51 to 53), we estimated that implementing the system by 2018 could reduce estimated costs for the U.S. agent information viewing and verification provisions in the proposed rule by one-half. We estimated that this would result in roughly \$2 million of savings each year or about \$4 million every 2 years. We no longer assess the costs of requiring updates within 30 calendar days because we are not finalizing our proposal to shorten the time period for updates. The final rule does not change the currently required time periods. Thus, estimated recurring costs of this final rule are now approximately \$8.8 million every 2 years. The \$8.8 million in costs continue to accrue in each subsequent biennial registration renewal cycle, and include costs associated with registration renewal activities and costs associated with other provisions of the final rule, such as certain verification procedures.

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 \$4.7 million and \$4.9 million per year (\$24 and \$25 per facility) using a discount rate of 7 percent and 3 percent, respectively, over a period of 20 years. Annualized recurring costs to FDA are approximately \$0.9 and \$1.2 million, also using a discount rate of 7 percent and 3 percent, respectively.

TABLE 1—ANNUALIZED COST AND BENEFIT SUMMARY  
[\$Millions]

	Total one-time costs	Total annualized costs 7%	Total annualized costs 3%	Benefits
Domestic Facilities .....	\$9	\$1.4	\$1.4	Not Quantified.
Foreign Facilities .....	18	3.3	3.5	
Subtotal Facilities .....	27	4.7	4.9	

TABLE 1—ANNUALIZED COST AND BENEFIT SUMMARY—Continued  
[\$Millions]

	Total one-time costs	Total annualized costs 7%	Total annualized costs 3%	Benefits
Costs to FDA .....	.....	0.9	1.2	
Total .....	27	5.6	6.1	

This analysis estimates costs and benefits of the provisions in this final rule only, which are assumed to accrue in addition to the estimated annual costs already incurred due to the implementation of the provisions in the 2003 interim final rule issued jointly by the Secretary and the Department of Homeland Security (DHS) jointly to implement section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107–188) (68 FR 58894, October 10, 2003).<sup>1</sup> Those estimated costs were calculated in an economic impact analysis that accompanied the interim final rule (68 FR 58894 at 58932) (hereinafter referred to as the “2003 economic impact analysis”). For the final rule, the economic impact analysis was modified slightly with respect to the costs associated with the U.S. agent requirement at the final rule stage, which published in the **Federal Register** on October 3, 2005 (70 FR 57505 at 57506).

We also expect that at least some foreign food facilities could increase prices as a result of the costs they would have to incur as a result of the rule. Any such potential price increases that could occur as a result of compliance costs would likely be very small relative to

the total costs to manufacture, process, pack, and hold foods for sale in the United States. We expect that the benefits of the final 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. (For a more complete qualitative discussion of the benefits, see the PRIA) (Ref. 1). In addition, we update in this analysis the monetized impact associated with different foodborne outbreak scenarios from the PRIA in order to determine the amount of savings from illness reduction that would be required in order for the final rule to reduce costs that result from foodborne illness by approximately the same amount that the compliance costs of the final rule would impose on food facilities. We expect the final rule would have additional benefits that we are similarly unable to quantify, including providing for the more efficient use of FDA’s inspectional resources.

**I. Background**

*A. FDA Food Safety Modernization Act*

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), signed

into law by President Obama on January 4, 2011, is intended to allow FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law contains important new tools to better ensure the safety of imported foods and encourages partnerships with State, local, tribal, and territorial authorities. A top priority for FDA are those FSMA-required regulations that provide the framework for industry’s implementation of preventive controls and enhance our ability to oversee their implementation for both domestic and imported food. To that end, we proposed the seven foundational rules listed in Table 2 and requested comments on all aspects of these proposed rules.

TABLE 2—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2013 proposed human preventive controls regulation.	78 FR 3646, January 16, 2013.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2013 proposed produce safety regulation.	78 FR 3504, January 16, 2013.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2013 proposed animal preventive controls regulation.	78 FR 64736, October 29, 2013.
Foreign Supplier Verification Programs (FSVP) or Importers of Food for Humans and Animals.	2013 proposed FSVP regulation ...	78 FR 45730, July 29, 2013.
Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.	2013 proposed third-party certification regulation.	78 FR 45782, July 29, 2013.
Focused Mitigation Strategies To Protect Food Against Intentional Adulteration.	2013 proposed intentional adulteration regulation.	78 FR 78014, December 24, 2013.
Sanitary Transportation of Human and Animal Food .....	2014 proposed sanitary transportation regulation.	79 FR 7006, February 5, 2014.

<sup>1</sup> 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 (21 U.S.C. 381) were

transferred to DHS when DHS was created by an act of Congress in 2002.

We also issued a supplemental notice of proposed rulemaking for the rules listed in Table 3 and requested comments on specific issues identified in each supplemental notice of proposed rulemaking.

TABLE 3—PUBLISHED SUPPLEMENTAL NOTICES OF PROPOSED RULEMAKING FOR THE FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2014 supplemental human preventive controls notice.	79 FR 58524, September 29, 2014.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2014 supplemental produce safety notice.	79 FR 58434, September 29, 2014.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2014 supplemental animal preventive controls notice.	79 FR 58476, September 29, 2014.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2014 supplemental FSVP notice; Supplemental Notice.	79 FR 58574, September 29, 2014.

We finalized two of the foundational rulemakings listed in Table 4 in September 2015 and three additional rules in November 2015. In April 2016, we finalized the sanitary transportation regulation. In May 2016, we finalized the intentional adulteration regulation.

TABLE 4—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food.	Final human preventive controls regulation.	80 FR 55908, September 17, 2015.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	Final animal preventive controls regulation.	80 FR 56170, September 17, 2015.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	Final produce safety regulation .....	80 FR 74354, November 27, 2015.
Foreign Supplier Verification Programs (FSVP) or Importers of Food for Humans and Animals.	Final FSVP regulation .....	80 FR 74226, November 27, 2015.
Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.	Final third-party certification regulation.	80 FR 74570, November 27, 2015.
Focused Mitigation Strategies To Protect Food Against Intentional Adulteration.	Final intentional adulteration regulation.	81 FR 34165, May 27, 2016.
Sanitary Transportation of Human and Animal Food .....	Final sanitary transportation regulation.	81 FR 20092, April 6, 2016.

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, a number of provisions in FSMA apply to only facilities that are required to register under section 415 of the FD&C Act, including hazard analysis and risk-based preventive controls and mandatory recall authority.

With the finalization of the seven foundational rulemakings, we are putting in place a modern, risk-based framework for food safety that is based on the most recent science, that focuses effort where the hazards are reasonably likely to occur, and that is flexible and practical given our current knowledge of food safety practices. To achieve this, FDA has engaged in a great deal of outreach to the stakeholder community to find the right balance in these regulations of flexibility and accountability.

After FSMA was enacted in 2011, we have been involved in approximately

600 engagements on FSMA and the proposed rules, including public meetings, Webinars, listening sessions, farm tours, and extensive presentations and meetings with various stakeholder groups (Refs. 2 to 4). As a result of this stakeholder dialogue, FDA decided to issue the four supplemental notices of proposed rulemaking to share our current thinking on key issues and get additional stakeholder input on those issues. As we move forward into the next phase of FSMA implementation, we intend to continue this dialogue and collaboration with our stakeholders, through guidance, education, training, and assistance, to ensure that everyone understands and engages in their role in food safety. FDA believes these seven foundational final rules, when implemented, will fulfill the paradigm shift toward prevention that was envisioned in FSMA and be a major step forward for food safety that will help protect consumers into the future.

*B. Purpose of This Rulemaking*

We published the proposed rule regarding amendments to registration of

food facilities in the **Federal Register** on April 9, 2015 (80 FR 19160). We received numerous comments submitted on the proposed rule.

This rule is part of FDA's implementation of FSMA, which intends to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. This regulation would implement certain provisions in section 415 of the FD&C Act, as amended by section 102 of FSMA, that relate to registration of food facilities. In addition, this regulation amends and updates FDA's registration regulations and improves the utility of the food facility registration database to further enhance FDA's capabilities with respect to responding to food-related emergencies, and in addition, provides FDA with information that we can use to focus and better utilize our limited inspection resources.

*C. Summary of the Major Provisions of the Proposed Rule*

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 were included in the proposed rule to codify the provisions in 21 CFR part 1, subpart H, the registration of food facilities regulation.

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 Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107-188), 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” (Ref. 5). 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 (21 U.S.C. 331(d)), 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). We proposed to add a waiver request provision to allow a registrant to submit a written request to FDA that explains why it is not reasonable to submit the registration or registration renewal to FDA electronically.

Lastly, section 102(c) of FSMA directs FDA to amend the definition of the term “retail food establishment” in § 1.227 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.

#### 2. Discussion of 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. 350i), 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(f) of the FD&C Act (21 U.S.C. 321(f)). 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.

### 3. 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. We finalized the rulemaking on September 17, 2015. See “Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food,” 80 FR 55908. That rule is a separate rulemaking and not the subject of this rulemaking.

#### D. Public Comments

We received over 1,000 submissions on the proposed amendments to food facility registration rule by the close of the comment period, each containing one or more comments on various aspects of the proposal. We received submissions from a wide array of members of the public, including individual farmers; cooperatives; coalitions; trade organizations;

consulting firms; law firms; academia; public health organizations; public advocacy groups; consumers; consumer groups; government agencies; and other organizations. Some submissions included signatures and statements from multiple individuals. Comments addressed numerous provisions of the proposed food facility registration rule, including our requests for comments on various topics. Some comments addressed issues that are outside of the scope of this rule. We do not discuss such comments in this document.

In sections III through XIII of this document, we describe the comments we received on the rule, respond to them, and explain any changes we made to the proposed food facility registration rule. We discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. Our responses to the comments include our reasons for determining whether to modify any of the proposed requirements.

## II. Legal Authority

We are issuing this final rule under the FD&C Act, FSMA, and the Bioterrorism Act. 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 31 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.

As discussed in this final rule, we are revising our regulations to require additional 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, 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 rule under section 305 of the Bioterrorism Act, sections 102 and 107 of FSMA, and sections 301(dd), 415, 701(a), 704, and 801 of the FD&C Act.

We are including in this final rule 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 (21 CFR part 1, subpart H). In addition, we are including in this final rule other requirements of section 102 of FSMA, such as mandatory electronic registration submissions and amendments to the definition of "retail food establishment" in § 1.227. Lastly, we are including in this final rule other changes to improve the utility of the food facility registration database and adding a waiver request provision to allow a facility to submit a written request to FDA that explains why it is not reasonable to submit the registration, registration renewal, updates, and cancellations to FDA electronically or to explain why it is not reasonable to provide the email address of the owner, operator, or agent in charge of the facility.

## III. General Comments on the Proposed Rule

(Comment 1) Comments urge FDA to exempt all facilities that make less than \$500,000 a year in sales who also sell most of their food locally.

(Response 1) To the extent that the comment is asking that all facilities with annual sales of less than \$500,000 be exempt from the registration requirement, we do not agree. Neither the Bioterrorism Act nor the FSMA amendments regarding food facility registration exempt facilities from the requirement to register based on their size. Furthermore, facilities under this size may be linked to food-related emergencies, and having registration information for these facilities can facilitate FDA's response to such emergencies.

(Comment 2) Several comments state that small food producers or hobbyists who make food out of their home and also sell the food at farmers' markets and to other consumers should not be required to register.

(Response 2) Under 21 CFR 1.227, a private residence is not a "facility" and thus, is not required to be registered. A private residence must meet customary expectations for a private home and does not otherwise include commercial

facilities in which a person also happens to reside. Thus, a private residence that meets customary expectations for a private residence that is also used to manufacture, process, pack, or hold food need not be registered. Accordingly, if the activities of small food producers or hobbyists meet customary expectations for a private residence, the producers or hobbyists would not be required to register.

(Comment 3) One comment requests that FDA exclude seed conditioning facilities that direct some seeds to animal food use from the requirement to register. The comment describes seed conditioning facilities as facilities that clean, grade, size, disinfect, dry, sort, screen, fumigate, and/or blend seeds to prepare seed intended for cultivation for commercial sales. The comment states that these establishments do not intend to manufacture, process, pack, or hold food for consumption and are therefore “not in the animal food business.” The comment states that such establishments instead intend to prepare seed for planting purposes. The comment states that when some seeds become cracked, damaged during the process, or they may not be suitable for cultivation, they cannot be used for planting. In those situations, the establishment may direct the seeds for use in animal food (or, alternatively, may direct the seeds for incineration and landfilling). The comment further states that establishments may direct the seeds for animal food use if there is an oversupply of seeds that would otherwise be cultivated. In addition, the comment asks that FDA revise the Agency’s “Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Fifth Edition)” to state that seed conditioning facilities are not required to register. In that guidance, FDA stated that an establishment that manufactures/processes and sells seed to farmers is a facility that must be registered if the owner, operator, or agent in charge of the establishment reasonably believes that the seed is reasonably expected to be directed to a food use, including animal food use or as an ingredient in animal food. However, if the seed is reasonably expected only to be cultivated, the guidance states that the establishment is not required to be registered. The comment states that because FSMA added certain preventive control requirements under section 418 of the FD&C Act for food facilities that are required to register under section 415, FDA should rethink the aspect of the registration guidance regarding seed

conditioning. The comment states that establishments that are required to register are now subject to more considerable regulatory requirements.

(Response 3) FDA requires registration of any facility that manufactures/processes, packs, or holds food for consumption in the United States. “Food” is defined in section 201(f) of the FD&C Act to include articles used for food or drink for man or other animals. The comment states that seed conditioning establishments should not be required to register because they do not intend to manufacture, process, pack, or hold food for animal consumption. We decline to provide any specific exclusions for seed conditioning establishments from the requirements for registration. As we stated in the Agency’s “Guidance for Industry: Questions and Answers Regarding Food Facility Registration,” an establishment that conditions seed for planting purposes is a facility that must be registered if the owner, operator, or agent in charge of the establishment reasonably believes that the seed is reasonably expected to be directed to food use, including animal food use or as an ingredient in animal food (Ref. 6). Whether a particular establishment is required to register will depend on the specific nature of the establishment. The comment describes establishments that may direct cracked, damaged, culled, or excess seeds for use in animal food. If an establishment that manufactures/process, packs, or holds the seed reasonably believes that the seed is reasonably expected to be directed to such food use, the establishment must be registered. The comment also states that some establishments may direct such cracked, damaged, culled, or excess seeds for incineration and landfilling. If a seed conditioning establishment directs the seeds only to uses such as cultivation or to destruction (such as incineration or landfill), the establishment would not be required to register.

Discussion on the application of the “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals” rule (80 FR 56170, September 17, 2015) is outside the scope of this rule making.

(Comment 4) A comment suggests that FDA should reconsider whether foreign facilities should be required to register. The comment states that most countries have an authorization or registration system and businesses in those countries will already be registered with the relevant authority in their country. The comment states that where FDA has

a relationship with a foreign authority, the foreign registration could be accepted as assurance that foreign businesses are in good standing with the national competent authority. The comment also states that the requirement to register is particularly onerous for foreign businesses and that many foreign businesses are not familiar with the norms of U.S. government agencies.

(Response 4) We disagree that a foreign facility should not be required to register. Section 415(a)(1) of the FD&C Act requires that each domestic and foreign facility be registered. “Facility” is defined as “any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food” (21 U.S.C. 350d(c)(1)). In addition, “foreign facility” is defined as a facility that “manufactures, processes, packs, or holds food, but only if food from such a facility is exported to the United States for consumption in this country without further processing or packaging outside the United States” (21 U.S.C. 350d(c)(3)(A)). Therefore, food facilities that are foreign facilities and do not qualify for an exemption under § 1.226 must register. Further, obtaining registration information from other foreign government agencies would not guarantee that FDA has all of the required information for food facility registration purposes for all foreign facilities. Foreign governments might not require the same registration information as required in this final rule, in part because the registration systems in foreign countries might serve different purposes from FDA’s. The registration information required in this final rule is designed to assist FDA in responding to bioterrorist or other food-related emergencies and to assist FDA in better utilizing its limited inspection resources, among other purposes.

(Comment 5) Several comments recommend amending the definition of retail food establishment to exclude vending machines that manufacture food within the vending unit itself before selling it directly to the consumer. Comments state that vending machines should have to register and that self-serve ice vending machines are packaging ice and reselling packaged food to retail clients. The comments state that an outbreak in foodborne illness linked to retail vending machines would have a devastating impact on the packaged ice industry as a whole.

(Response 5) Under § 1.227, a “retail food establishment” includes grocery stores, convenience stores, and vending

machines. We disagree that we should amend the definition of retail food establishments to remove vending machines. Vending machines that sell food products directly to consumers as their primary function are properly exempt from registration as retail food establishments. This is consistent with section 415(c)(1) of the FD&C Act, which provides that the term “facility” does not include retail food establishments. We acknowledge that outbreaks in any segment of industry have a significant impact. We note, however, that while vending machines and other retail food establishments are not required to register, they still have responsibility for ensuring the safety of their products.

(Comment 6) One comment encourages FDA to require farms to register to prevent what the comment describes as a gap in oversight.

(Response 6) FDA declines to require farms to register as food facilities under section 415 of the FD&C Act. The requirement in section 415 that a facility must register does not apply to farms. See section 415(c) of the FD&C Act (providing that the term “facility” does not include farms). The comment does not explain how requiring farms to register would be consistent with section 415.

(Comment 7) One comment requests modifications to Form FDA 3537. In particular, the comment requests that the registration system should clear all information from section 13 of the current Form FDA 3537 whenever a registration is updated or renewed. The comment also states that many owners, operators, or agents in charge of a facility may be corporations, not individuals, and therefore suggests that FDA add a field linked to the requirement that facilities provide the email address for the owner, operator, or agent in charge. Specifically, the comment requests that facilities be able to provide the name of the individual associated with that email address. The comment also recommends making technical edits to the electronic version of the form, such as changes to the pull-down selections in the Facility Name Suffix category (allowing facilities to indicate, for instance, whether they are cooperatives or limited liability corporations) and the automatically populated telephone country codes.

(Response 7) Section 13 of the current Form FDA 3537 includes a certification statement providing that the owner, operator, or agent in charge of the facility, or an individual authorized by the owner, operator or agent in charge of the facility, must submit the form. The certification states that by

submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the owner, operator, or agent in charge of the facility certifies that the registration information is true and accurate. An individual (other than the owner, operator, or agent in charge of the facility) who submits the form to FDA also certifies that the registration information is true and accurate and that he/she is authorized to submit the registration on the facility’s behalf. Section 13 also provides for the individual authorized by the owner, operator, or agent in charge to identify the individual who authorized submission of the registration and to provide specified contact information for that individual. With regard to the electronic version of Form FDA 3537, section 13 of the form prepopulates with information (as do the other fields). This is done to keep the process for registration renewal or updates as streamlined as possible. We understand that some applicants will need to edit this section to indicate changes to who submits the form, while others may not. Therefore, we decline the recommendation to not pre-populate this section for electronic registration renewals or updates. In addition, we decline the recommendation to require the name of the individual associated with the email address provided for the owner, operator, or agent in charge. We currently believe that the final rule already requires sufficient facility contact information. However, we will consider adding an optional field for an individual’s name associated with the required email address in a future version of Form FDA 3537. If we add such a field, we will issue a guidance document in accordance with our good guidance practice (GGP) regulations in 21 CFR 10.115 describing this change.

With regard to the requested additional technical changes to the electronic version of the form, we will consider the recommendations and make changes if appropriate.

(Comment 8) A comment suggests that FDA should share the list of registered businesses with the authorities in the relevant third country.

(Response 8) FDA’s list of registered facilities and registration documents are not subject to disclosure under the Freedom of Information Act (FOIA). In addition, any information derived from the list of facilities or registration documents that would disclose the identity or location of a specific registered person also is not subject to disclosure under FOIA (21 U.S.C. 350d(a)(5)).

However, FDA believes that in certain circumstances it may be appropriate to

share information derived from our registration database with foreign government officials consistent with FDA’s laws and procedures. Any sharing of information with another foreign government would typically be done under 21 CFR 20.89, which includes confidentiality provisions.

#### IV. Comments on Proposed Amendments to § 1.227—Definitions

We proposed to replace the phrase “the owner, operator, or agent in charge of a facility” with “you” throughout the regulatory text in 21 CFR part 1, subpart H, because “you” is defined in current § 1.227 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. We are finalizing this change as proposed.

Furthermore, we note that we have redesignated all definitions in § 1.227 in 21 CFR part 1, subpart H, to eliminate paragraph designations (such as (a) and (b)). FDA made this change in the final rule for “Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food” (80 FR 55908).

##### A. Retail Food Establishment

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 to mean an establishment that sells food products directly to consumers as its primary function.

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. In addition, section 102(c) provides that the term “consumer” does not include a business.

We proposed to amend § 1.227 to address off-farm sales by an establishment located on a farm. Specifically, we proposed to clarify 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. We proposed that, in determining the primary function of an establishment located on a farm, the sale of food directly to consumers from such an establishment would include sales at a roadside stand or farmer’s market, and that the roadside stand or farmers’ market would not need to be on the farm where the establishment is located. In determining the primary function of an establishment located on a farm, we also proposed that the sale of food directly to consumers would also include the sale and distribution of such food through a community supported agriculture program (CSA). In addition, we proposed that the sale of food directly to consumers would include the sale and distribution of such food at other direct-to-consumer platforms, including door-to-door sales; mail, catalog and Internet orders; online farmers’ markets and online grocery deliveries; religious or other organization bazaars; and state and local fairs.

We proposed to define “roadside stand”, “farmers’ market”, and “community supported agriculture program” in § 1.227, based on definitions found in 7 CFR 249.2. Specifically, we proposed to specify that a farmers’ market would mean a location where one or more local farmers assemble to sell from their farms directly to consumers and that a roadside stand would mean 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.

Finally, we proposed that a CSA program would mean 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. Under our proposal, this would include CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers.

We requested comment on what, if any, limitations should be included in the proposed definitions for roadside stands and farmers’ markets, such as distance of the roadside stand or farmers’ market from the farm (80 FR 19160 at 19166). In addition, we requested comment on whether it is appropriate to limit the amendment to the retail food establishment definition to on-farm establishments, as we proposed (Id.). We also requested comment on whether we should provide that off-farm sales to businesses also be considered in determining an establishment’s primary function (Id.).

#### 1. Applicability to On-Farm Establishments

(Comment 9) Numerous comments state that the amendment to the retail food establishment definition should not be limited to on-farm establishments. These comments maintain that it should not matter if an establishment is on a farm. Some comments state that there is no statutory language directing or justifying the proposal to limit the amendment of the retail food establishment definition to on-farm establishments. Comments suggest that Congress intended the law to apply equally to all direct-to-consumer sales from farms, whether the sales occur on, or off, the farm. One comment indicates that this definition should reflect the reality of modern farming operations. One comment also states that local and regional food entrepreneurs make use of shared commercial kitchens and have no storefronts from which to make sales, and that the limitation of the amendment to on-farm establishments would mean that these entities would have to register even if all of their sales are directly to consumers.

(Response 9) We are convinced by the comments to expand the amendment to the retail food establishment definition to include some non-farm establishments. In particular, we agree with the comments that we should revise the retail food establishment definition to reflect modern farming-related practices. We agree that limiting the amendment to on-farm establishments is overly simplistic, given the diverse ways farmers today engage in value-added processing of their raw agricultural commodities (RACs).

The comments raise the question of what type of businesses section 102(c) of FSMA is intended to address. In construing the scope of section 102(c) of FSMA, FDA is confronted with two questions. First, has Congress directly spoken to the precise question

presented (*Chevron* step one)? (*Chevron U.S.A., Inc., v. NRDC, Inc.*, 467 U.S. 837, 842 (1984)). If the “intent of Congress is clear,” an Agency “must give effect to the unambiguously expressed intent of Congress.” Id. at 843. However, if “Congress has not directly addressed the precise question at issue,” and the statute is “silent or ambiguous with respect to the specific issue,” then our interpretation of the term “establishment” will be upheld as long as it is based on a “permissible construction of the statute” (*Chevron* step two). *Chevron*, 467 U.S. at 842–43; *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000). To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue. See *e.g., Young v. Community Nutrition Institute*, 476 U.S. 974, 980 (1986). We have determined that, in enacting section 102(c) of FSMA, Congress did not speak directly and precisely to the provision’s scope. For instance, in section 102(c)(1) of FSMA, Congress provided that FDA amend the definition of retail food establishment to clarify that, “in determining the primary function of an establishment or a retail food establishment under such section,” the sale of certain direct-to-consumer foods should be counted (emphasis added). An “establishment” could be any number of types of businesses. An “establishment” could be any business that manufactures/processes, packs, or holds food for consumption in the United States. Alternatively, an “establishment” could be the type of business that commonly sells foods at the direct-to-consumer platforms enumerated in section 102(c) of FSMA (*i.e.*, at roadside stands, farmers’ markets, and CSAs).

The language in section 102(c) of FSMA provides an express delegation of authority to the Secretary to amend the definition of the term “retail food establishment” in § 1.227 to provide for the inclusion of certain specified sales (*i.e.*, farmers’ market, roadside stand, and CSA sales) in determining an establishment’s primary function (FSMA section 102(c)(1)(A)-(B)), as well as other sales that the Agency may determine (FSMA section 102(c)(1)(C)). The decision to direct the Secretary to amend § 1.227, and the decision to provide that certain sales may be included as determined by the Secretary, contemplates the Secretary having certain discretion in effectuating the amendment. While Congress intended for certain specific sales (*i.e.*, farmers’ market, roadside stand, and CSA sales) to be counted in conducting

a primary function analysis, Congress did not specify to what kind of businesses the new analysis would apply. Instead, Congress left a gap for the Secretary to fill by regulation.

Because Congress left a gap for the Secretary to fill, under *Chevron* step two FDA may interpret the scope of FSMA section 102(c)(1), provided that FDA's interpretation is not arbitrary, capricious, or manifestly contrary to the statute. *Chevron*, 467 U.S. at 843 (noting that if a statute is silent with respect to an issue the Agency's answer to the issue should be based on a permissible interpretation of the statute).

The language in section 102(c) of FSMA does not specifically prescribe the provision's scope, but it does provide examples of the kind of circumstances in which Congress intended the retail food establishment amendment applying. In directing the Secretary to include certain sales in determining the primary function, section 102(c) directs the Secretary to include sales at roadside stands and farmers' markets located other than where the food was manufactured or processed, as well as CSAs (FSMA section 102(c)(1)(A)–(B)). Sales platforms such as these are closely associated with food produced by farmers. Even in section 102(c)(1)(C) of FSMA, Congress directed the Secretary to include the sale and distribution of “such food at any other such direct sales platform” as determined by the Secretary (emphasis added). This suggests that the other platforms Congress contemplated were platforms that were akin to those listed in section 102(c)(1)(A)–(B) and involved food akin to that contemplated by section 102(c)(1)(A)–(B). Given that farmers represent the overwhelming majority of businesses that commonly sell foods at the direct-to-consumer platforms enumerated in section 102(c) of FSMA (i.e., at roadside stands, farmers' markets, and CSAs), it is reasonable to interpret section 102(c) of FSMA as applying to farmers and businesses closely tied to farms. Under this interpretation, section 102(c) allows farmers to manufacture/process food for sale without triggering registration, provided that the primary function of the farmer's manufacturing/processing operation is the sale of food directly to consumers.

Our proposal to clarify the retail food establishment definition recognized that some farmers conduct manufacturing/processing. However, our proposed clarification would have only applied to establishments located on farms. We recognize that while some farmers have the space and equipment on their farms

to manufacture/process foods for sale at direct-to-consumer platforms, other farmers conduct value-added processing off of the farm, such as by renting space at a shared kitchen. The clarification to the retail food establishment definition that we included in the proposed rule would have captured the on-farm operations, but not the off-farm operations.

Because farmers conduct manufacturing/processing in establishments located on farms and off of farms, we conclude that it is reasonable to interpret section 102(c) of FSMA to apply to on-farm establishments and certain off-farm operations tied to farms. Accordingly, we have finalized our proposal to address off-farm sales by establishments located on farms. In addition, in the final rule, we have revised the retail food establishment definition to also state that the sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers: At a roadside stand or farmers market; through a CSA; and at other such direct-to-consumer sales platforms. By “farm-operated business,” we mean a business that is managed by one or more farms and that conducts manufacturing/processing not on the farm(s). Thus, under the final rule, an establishment located on a farm that sells apples it grows and apple pies it manufactures directly to consumers at a farmer's market would consider those sales in determining its primary function. At the same time, if a farmer manufactures or manages the manufacturing of jellies from the apples that he grows at an off-farm location, such as an incubator kitchen, and sells those jellies at a farmer's market, the jelly-making operation would be a farm-operated business and may consider those sales in determining its primary function.

We recognize that some farmers rent space at off-farm manufacturing/processing facilities, like shared kitchens, to conduct value-added processing. The “business” we are referring to in “farm-operated business” is the business entity conducting the manufacturing/processing operations. The ownership of the physical building, e.g., the ownership of the shared kitchen, where the manufacturing/processing occurs is not relevant. Thus, if an apple grower leases space at an off-farm incubator kitchen to manufacture apple jellies, ownership of the incubator kitchen building would not be relevant. Because the apple farmer manages the off-farm apple jelly manufacturing operation, the apply jelly manufacturing

operation is a farm-operated business and eligible for the retail food establishment exemption from registration.

In addition, we recognize that some farms are members of cooperatives that pool RACs grown, harvested, or raised by member farms for value-added processing. The phrase “one or more farms” in the explanation of the meaning of “farm-operated business” allows cooperatives comprised of multiple farms performing certain manufacturing/processing activities to be eligible for the retail food establishment exemption from registration.

Regarding the example of shared commercial kitchens in the comment, if an establishment is a retail food establishment under § 1.227, a commercial kitchen that is co-located with, and thus, part of, the retail food establishment, is not required to be registered.

## 2. Sale of Food Directly to Consumers at a Roadside Stand or Farmers' Market

(Comment 10) One comment states that farmers' markets and roadside stands should be considered retail food establishments, including those markets and stands that handle products or produce grown on a particular farmer's property.

(Response 10) We agree that farmers' markets and roadside stands may be considered retail food establishments even when they sell products not manufactured or grown on the property of the farmers selling those foods. The test for whether such farmers' markets and roadside stands are retail food establishments is whether they sell food directly to consumers as their primary function. The food sold directly to consumers can be produced by the farmers selling the food, but need not be.

(Comment 11) One comment states that because farms may aggregate food produced by other farms, the definition for farmers' markets should not specify that the food sold by local farmers is “from their farms.” Comments also argue that the definition of roadside stands and farmers' markets should encompass stands at which any vendors sell food directly to consumers, and that it should not be limited to stands at which farmers sell food from their farms directly to consumers as FDA proposed.

(Response 11) The definitions of farmers' markets and roadside stands are based on definitions found in 7 CFR 249.2, and we are wary of adopting definitions of these terms that are significantly different from the definitions of the same terms held by

USDA. Moreover, we do not believe that changing the definitions as suggested by the comments would have any practical effect. That's because the presence of non-farmers at a farmers' market or roadside stand would not mean that a location that would otherwise meet the definition of a farmers' market or roadside stand would not be considered a farmers' market or roadside stand.

Further, whether food is sold at farmers' markets or roadside stands is less important for the purposes of this rule than whether the food is sold directly to consumers. An establishment is exempt from registration as a retail food establishment if the establishment's primary function is to sell food directly to consumers, regardless of whether the food is sold through farmers' markets, roadside stands, or other direct-to-consumer platforms. Farmers' markets and roadside stands are examples of direct-to-consumer sales platforms that are specifically mentioned in the amendment to the definition of retail food establishment, but the catchall provisions in paragraphs (1)(iii) and (2)(iii) provide that the sale of food directly to consumers includes the sale and distribution of food at other direct-to-consumer platforms. As a result, changing the definitions of farmers' market and roadside stand as the comments suggest would have little, if any, impact on the scope of this rule. Therefore, we decline the comments' suggestions and are finalizing definitions consistent with our proposal.

(Comment 12) One comment recommends that we specify that the "local farmers" at a farmers' market be from within the same state as the point of sale or within 275 miles of the point of sale. However, most of the comments that addressed our request for comments on distance limitations for farmers' markets and roadside stands expressed concern about any such limitations. Some comments state there should be no distance limitation because the distance from a farm to a roadside stand or farmers' market does not change the fact that the food is being provided directly to consumers. Some comments state that there is no established public health risk related to the distance between a farm and sales locations such as farmers' markets and roadside stands. One comment states that there is no risk-based justification for including distance limitations in the definitions for farmers' markets and roadside stands. Comments also note it is not uncommon for farms to locate stands or take part in farmers' markets in metropolitan areas where they are likely

to interact with and have more ready access to a larger customer base, and that these metropolitan areas are removed from the rural areas where growing takes place. Comments also state that grocery stores and other entities that identify as retail food establishments have no mileage limitations connected to their headquarters, so there should be no reason to apply such a distinction to similarly situated businesses.

(Response 12) FDA agrees with the comments recommending against distance limitations in the definitions for farmers' markets and roadside stands. In enacting section 102(c) of FSMA, Congress directed FDA to clarify that in determining the primary function of an establishment, the sale of food directly to consumers by such establishments includes the sale of food at a roadside stand or farmers' market, where such stand or market is located other than where the food was manufactured or processed. Section 102(c) of FSMA does not provide a limitation on distance, and we decline to add such a limitation on our own accord.

### 3. Sale and Distribution of Food Through a Community Supported Agriculture Program

(Comment 13) One comment urges FDA to define CSAs as involving the sale of "food" rather than "crops," as we proposed. The comment states that CSAs may involve the distribution of food other than crops.

(Response 13) FDA agrees that CSA activities are not limited to only selling "crops." For example, a farm mixed-type facility may sell strawberries it grows and strawberry jam that it manufactures directly to consumers through a CSA. Whether the on-farm manufacturing establishment is a retail food establishment, and thus exempt from registration, would depend on whether its primary function is to sell food directly to consumers.

As to whether we should change the proposed definition of CSAs to refer to "food" instead of "crop(s)," we do not believe such a change is warranted. 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 . . . in section 249.2 of title 7, Code of Federal Regulations (or any successor regulation)." Because 7 CFR 249.2 refers to "crop(s)," not "food," we do not believe that the change suggested by the comments would be consistent with section 102(c) of FSMA. However, the sale of food directly to consumers

through a platform that resembles a CSA but does not sell crops could still be used in determining the establishment's primary function in the final rule. Paragraphs (1)(iii) and (2)(iii) of the retail food establishment amendment are catchalls that include the sale of food at other direct-to-consumer platforms. Provided that the requirements of those paragraphs are satisfied, an establishment could consider sales through that platform in determining its primary function if either the establishment is: (1) Located on a farm; or (2) is a farm-operated business and the requirements applicable to farm-operated businesses are met.

### 4. Sale and Distribution of Food at Any Other Direct-to-Consumer Sales Platforms

(Comment 14) Most comments agree with the list of direct-to-consumer platforms that we proposed. One comment, however, states that FDA should not consider as direct-to-consumer sales those sales by mail, catalog or Internet order, or through online farmers' markets or online grocery delivery. The comment states that allowing these types of sales creates an opportunity for an on-farm manufacturing operation that sells large volumes of food in interstate commerce to fall within the retail food establishment definition. The comment further states that a common feature of sales at roadside stands, farmers' markets, and CSAs listed in section 102(c)(1) of FSMA is that they are conducted face-to-face and it is likely that Congress meant to provide FDA with flexibility to consider as direct-to-consumer sales other local face-to-face transactions that are similar to the specified exempt activities, but not platforms such as direct-to-consumer mail, catalog, or Internet sales that would allow for national sales.

(Response 14) We agree that section 102(c) of FSMA directs FDA to address certain direct-to-consumer sales in clarifying the retail food establishment definition. However, we disagree with the objection to including the sale of food through mail, catalog and Internet orders, including online farmers' markets and online grocery delivery, in determining the primary function of an establishment that is either located on a farm or that is a farm-operated business. As discussed in the proposed rule (80 FR 19160 at 19166), these direct sales platforms are common platforms for direct-to-consumer sales of foods from farms. Although such sales might not be face-to-face, direct-to-consumer sales of food from local farms and

establishments closely associated with farms are similar to farmers' markets and CSAs because they are direct-to-consumer. We think that including these direct-to-consumer sales is consistent with section 102(c) of FSMA because section 102(c) provides that the sales of food directly to consumers for the purposes of determining an establishment's primary function may be at "any other such direct sales platform as determined by the Secretary." Section 102(c) of FSMA does not specify that direct-to-consumer sales be face-to-face in determining the primary function of an establishment. Even if some establishments that use mail, catalog, and Internet orders in determining their primary function are larger establishments and can reach consumers on a national level, we do not believe that is inconsistent with section 102(c) of FSMA, which does not specify that FDA's amendment to the retail food establishment definition only pertain to establishments of a specific size. We believe that if an establishment's annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products directly to all other buyers, the establishment's primary function is to sell food directly to consumers and that the establishment should qualify as a retail food establishment. Further, we note that, in determining whether an establishment is a retail food establishment, our regulation has always allowed for establishments selling food directly to consumers via the Internet or mail order to be covered under the definition of "retail food establishment," provided that they meet the other criteria of the retail food establishment definition (see 68 FR 58894 at 58914 to 58915).

(Comment 15) Some comments urge FDA to include "produce auctions" in the list of platforms where direct-to-consumer sales take place.

(Response 15) Because the list of direct-to-consumer sales platforms is not exhaustive, we do not agree that it is necessary to include produce auctions in the list of direct-to-consumer platforms that may be used in determining an establishment's primary function. Provided that a sales platform is direct-to-consumers, sales made through such platforms may help establish that an establishment's primary function is to sell food directly to consumers (with an establishment qualifying as a retail food establishment only 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). Furthermore, we

understand that sales at produce auctions can be to different types of entities. In some cases, sales may be to consumers. However, we understand that many sales at produce auctions are sales to restaurants, wholesalers and other businesses. An establishment's direct sales to individual consumers at an auction can be counted as sales to consumers. A direct sale to a business at an auction, however, cannot be counted as sales to consumers. Further, a direct sale to a separate business that runs a produce auction, rather than to specific buyers, would not be counted as sales to consumers because businesses (including businesses that run produce auctions) are not consumers. Section 102(c)(2) of FSMA explicitly states that the term "consumer" does not include a business.

(Comment 16) Comments request that FDA specifically exempt produce auctions from the requirements of food facility registration. These comments state that produce auctions are frequently misunderstood to be "food facilities," but that they are in fact very similar to farmers' markets in that the auction does not take individual ownership of any products or manufacture/process, hold, pack or package food. The comments note that buyers represent a mix of direct consumers and commercial business entities.

(Response 16) We decline the request to exempt produce auctions from the requirement to register. The registration requirement applies to all facilities that manufacture/process, pack, or hold food for consumption in the United States, and does not hinge on whether the establishment in question actually owns the food (see section 415(a)(1) of the FD&C Act). We note, however, that not all produce auctions will necessarily be required to register. Whether registration is required would depend on the facts of a particular case. It is possible that some produce auctions would qualify as retail food establishments and therefore be exempt from registration. Produce auctions would qualify as retail food establishments if their primary function is to sell food directly to consumers. Produce auctions with direct-to-consumer sales that exceed sales to businesses would be considered retail food establishments. Further, as stated in the final rule for "Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food" (80 FR 55908 at 55992), to the extent that these operations are simply a location for buyers and sellers to meet and to sell

and transfer produce and the food is not stored, we do not consider such facilities to be holding food and would not expect them to register.

(Comment 17) Some comments request that we expand the list of direct-to-consumer platforms that we proposed to specify to also include food hubs, buying clubs, and non-farm community supported food distribution models.

(Response 17) We decline to revise the retail food establishment definition in § 1.227 to specifically discuss food hubs, buying clubs, and non-farm community supported distribution models. With respect to food hubs, the comments do not explain why food hubs necessarily involve direct-to-consumer sales that should be used in determining an establishment's primary function. FDA discussed food hubs in the final preventive controls for human food regulation (see 80 FR 55908 at 55992). As FDA noted in that rulemaking, USDA defines a regional food hub as "a business or organization that actively manages the aggregation, distribution, and marketing of source-identified food products primarily from local and regional producers to strengthen their ability to satisfy wholesale, retail, and institutional demand" (Ref. 7). Some food hubs have a farm-to-business model (e.g., selling to food cooperatives, grocery stores, institutional foodservice companies, and restaurants), while others have a farm-to-consumer model (i.e., selling directly to the consumer, e.g., through a CSA), and some are hybrids that do both (Ref. 7). Because all sales at food hubs are not necessarily direct-to-consumer, we do not agree that it is appropriate to include food hubs in the list of direct-to-consumer platforms that may be used in determining an establishment's primary function. However, if an establishment located on a farm or an establishment described in paragraph (2) of the retail food establishment definition has food hub sales that are directly to consumers, we agree that, in those circumstances, it would be appropriate for those sales to be used in determining the establishment's primary function. The catchall provisions in paragraphs (1)(iii) and (2)(iii) of the definition provide that the sale of food directly to consumers includes the sale and distribution at other direct-to-consumer platforms. For similar reasons, we do not agree that it is appropriate to amend the retail food establishment definition to include buying clubs and non-farm community supported food distribution models. The comments have not provided information to allow FDA to assess whether such platforms necessarily

involve direct-to-consumer sales. However, if on-farm establishments or establishments described in paragraph (2) have sales at such platforms that are directly to consumers, the sales may also be used in determining those establishments' primary function in accordance with paragraphs (1)(iii) and (2)(iii).

#### 5. Other Issues Related to the Definition of Retail Food Establishment

(Comment 18) One comment states that there should not be any income or value limitation included in the retail food establishment definition.

(Response 18) We agree that there is no income limitation for establishments to qualify as retail food establishments, and we have not included one in the final rule. As long as an establishment's primary function is to sell food directly to consumers, it is a retail food establishment. 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.

(Comment 19) One comment urges FDA to recognize that even low-risk activities can cause problems and recommends limiting the application of section 102(c) of FSMA to the types of on-farm manufacturing activities that the Agency tentatively identified as low-risk activities in proposed 21 CFR 117.5(g) and (h) in the proposed regulation for hazard analysis and risk-based preventive controls for human food. This is based on the argument that section 102(c) of FSMA, which directed FDA to clarify the retail food establishment definition, should be read in connection with section 103(c)(1) of FSMA, which formed the basis for proposed § 117.5(g) and (h). Specifically, section 103(c)(1) of FSMA directed FDA to conduct a science-based risk analysis of specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as well as of specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership. Section 103(c)(1) of FSMA further directed FDA to consider the results of the science-based risk analysis and exempt certain facilities from the requirements in sections 418 of the FD&C Act (related to risk-based preventive controls) and section 421 of the FD&C Act (related to targeting of inspection resources) for small and very small businesses, or modify those

requirements for small and very small businesses. In addition, the comment recommends that the amendment to the retail food establishment definition should only apply to small and very small farms, as defined in the proposed regulation for produce safety. The comment states that Congress intended for the retail food establishment amendment to only apply to small and very small farms, as evidenced by certain statements made on the Senate floor regarding small farmers.

(Response 19) Consistent with the statutory direction in section 103(c) of FSMA, including the direction to conduct a qualitative risk assessment, FDA established exemptions for on-farm activity/food combinations conducted by farm-mixed-type facilities that are small or very small businesses in the final rule for preventive controls for human food (§ 117.5(g) and (h)). We do not agree that section 102(c) of FSMA, which directed FDA to clarify the retail food establishment definition, should be read to only apply to entities that qualify for the exemptions we established in accordance with section 103(c) of FSMA. Congress's direction in section 102(c) of FSMA to amend the definition of retail food establishment was separate and distinct from Congress's direction in section 103(c) of FSMA to establish exemptions and modifications for certain on-farm activities, and we are not aware of any evidence that Congress intended for the amendment to the retail food establishment definition to be limited by the entities that qualify for exemptions in accordance with section 103(c) of FSMA. As to the comment that the amendment to the retail food establishment definition should only apply to small and very small farms, we similarly do not agree. Section 102(c) of FSMA does not provide that the determination of the primary function be different for establishments of particular sizes. Although there is some legislative history indicating that some legislators anticipated that the amendment would affect small enterprises, we are not aware of evidence that Congress intended for the amendment to only apply to smaller enterprises, and there is no such limitation in the statutory provision. Moreover, we believe it is appropriate to apply the same primary function analysis to all establishments regardless of size, with an establishment's primary function being 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.

(Comment 20) One comment states that our amendment to the retail food establishment definition should incorporate a method to evaluate potential risks to allow the Agency to determine if the establishment has food safety issues or is subject to proper oversight.

(Response 20) We decline this request. The comment does not explain how FDA would evaluate potential risks or what kind of food safety and/or oversight criteria the Agency would apply. Further, the comment does not explain how the request would be consistent with section 102(c) of FSMA. That provision, which directs FDA to clarify the retail food establishment definition, does not state that the clarification to the definition should involve FDA performing any kind of risk evaluation of individual establishments.

(Comment 21) One comment states that our amendment to the retail food establishment definition should consider off-farm sales to businesses in the primary function calculation, and not just consumers. The comment states that similar to the determination for whether an entity is a qualified farm under the produce safety regulation or a qualified facility under the preventive controls regulations, the determination for whether an establishment is a retail food establishment should consider sales to "qualified end users." Another comment states that the amendment to the definition should only consider sales at "the retail distribution level directly to consumers[.]"

(Response 21) We disagree with the comment requesting that sales to businesses be included in the primary function calculation, and agree with the comment that the amendment should only consider sales "at the retail distribution level directly to consumers" to the extent that comment requests that the primary function calculation only include direct-to-consumer sales. Section 102(c)(2)(B) of FSMA provides that the term "consumer" does not include a business, and we think it is consistent with that provision to establish that sales to consumers do not include sales to businesses for the purpose of determining an establishment's primary function. It is true that the preventive controls and produce safety regulations provide for certain specified businesses to be qualified end-users. Under the preventive controls regulations, qualified end-users include restaurants or retail food establishments located in the same State as the qualified facility

that sold the food to such restaurant or establishment or are not more than 275 miles from such facility or farm and are purchasing the food for sale directly to consumers at such restaurant or retail food establishment. Under the produce safety regulation, a qualified end-user includes a restaurant or retail food establishment that is located in the same State or the same Indian reservation as the farm that produced the food or not more than 275 miles from such farm. Whether a facility or farm sells food directly to a qualified end-user is significant under the preventive controls and produce regulations because sales to qualified end-users may be used in determining whether facilities or farms are eligible for qualified exemptions under those regulations. Although sales to qualified end-users are significant under those regulations, we do not agree that sales to such qualified end-users that are not consumers should be used in determining an establishment's primary function as a retail food establishment for the purposes of registration. Congress specified that qualified end-users include certain restaurants and retail food establishments for purposes of the preventive controls and produce safety regulations (see sections 418(l)(4)(B) and 419(f)(4)(A) (21 U.S.C. 350h(f)(4)(A)) of the FD&C Act), but specified that for purposes of amending the retail food establishment definition the term "consumer" does not include businesses (see section 102(c)(2)(B) of FSMA).

#### B. U.S. Agent

We proposed to amend the definition of U.S. agent in § 1.227 to add that the U.S. agent of a foreign facility may view the information submitted in the foreign facility's registration.

In addition, we proposed to replace the word "cannot" in the current definition for U.S. agent in § 1.227 with "may not." Accordingly, the pertinent sentence in that provision will 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).

(Comment 22) Comments state that it is confusing to distinguish the U.S. agent for food facility registration and the U.S. agent for purposes of the foreign supplier verification program ("FSVP") requirements under 21 CFR part 1, subpart L, and urge FDA to include language in the registration final rule that clarifies that the U.S. agent for purposes of food facility registration and the U.S. agent for purposes of FSVP are

not the same and must be designated through separate procedures.

(Response 22) We do not agree that any amendments to the regulatory text of the final rule are necessary. Section 805(a)(2)(B) of the FD&C Act (21 U.S.C. 384a(a)(2)(B)), which pertains to FSVP, provides that when there is no U.S. owner or consignee with respect to an article of food at the time of entry of the article into the United States, the term "importer" for purposes of FSVP requirements means "the *United States agent* or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States" (emphasis added). Under the FSVP final rule, the "importer" is responsible for verifying the safety of food imported into the United States. In addition, section 415(a)(1)(B) of the FD&C Act provides that foreign food facilities must submit the name of the "United States agent" for the facility as part of the facility's registration under section 415. FDA's regulations implementing the food facility registration requirements in section 415 of the FD&C Act require that the registration for foreign facilities must include the name of the U.S. agent for the facility (21 CFR 1.232(c)(1)). The facility registration regulations also define the term U.S. agent to mean 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 (§ 1.227). The regulations further specify that the U.S. agent "acts as a communications link between FDA and the foreign facility for both emergency and routine communications" (§ 1.227).

Although Congress used the term "United States agent" in both section 805(a)(2)(B) and section 415(a)(1)(B) of the FD&C Act, we do not interpret the use of the term "United States agent" in section 805(a)(2)(B) to mean the U.S. agent for a foreign facility under section 415(a)(1)(B). U.S. agents that foreign food facilities must designate for purposes of food facility registration perform a very different role than the "United States agent" that a foreign owner or consignee may designate under section 805(a)(2)(B) of the FD&C Act to serve as the "importer" for purposes of the FSVP regulations. For food facility registration, the "U.S. agent" acts as a communications link. For FSVP, however, an importer (whether a "United States agent" or otherwise) is responsible for the full breadth of supplier verification activities required under the FSVP regulation. These activities involve

ensuring the safety of imported food, which is qualitatively different from serving as a communications link (80 FR 74226 at 74241; November 27, 2015). Thus, we do not interpret the use of the term "United States agent" under section 805(a)(2)(B) to have the same meaning as the U.S. agent that food facilities are required to designate under section 415(a)(1)(B) and FDA's food facility registration regulations. As we state in the FSVP final rule, however, this interpretation does not prohibit a foreign owner or consignee from designating a person who serves as a U.S. agent under the food facility regulations as the "importer" for purposes of FSVP (Id.).

Because we do not interpret the use of the terms to have the same meaning, we do not think it is necessary to add regulatory text in this final rule stating that the U.S. agent for purposes of food facility registration is not the same as the U.S. agent for purposes of the FSVP final rule. Additionally, we think such language could be confusing because there is no prohibition on the same person serving as both the U.S. agent for purposes of food facility registration and the U.S. agent for purposes of satisfying the FSVP "importer" requirements (provided that such person meets the relevant requirements of each regulation).

(Comment 23) Comments request FDA clarify that the communications link between the U.S. agent and FDA goes both ways and that FDA also clarify that communications to and from the U.S. agent have the same legal effect as if sent to or by the facility directly for both routine and emergency communications.

(Response 23) As established in current § 1.227, the U.S. agent acts as a communications link between FDA and a foreign facility for both routine and emergency communications. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies another emergency contact. In functioning as the communications link with FDA, a U.S. agent may choose to initiate communications with FDA, and FDA may likewise choose to initiate communications with the U.S. agent. Further, as stated in § 1.227, 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. In that sense, information or documents provided to the U.S. agent has the same effect as if FDA provided the information or documents to the foreign

facility, in that FDA will consider providing information or documents to the U.S. agent the equivalent of providing the information or documents to the foreign facility.

(Comment 24) One comment requests FDA outline and clarify the roles and responsibilities of the U.S. agent.

(Response 24) The roles and responsibilities of a U.S. agent are outlined in current § 1.227. As stated previously, the U.S. agent acts as a communications link between FDA and the foreign facility for both emergency and routine communications.

(Comment 25) Comments request that FDA clarify that the U.S. agent for a foreign food facility may access the facility's FDA Unified Registration and Listing Systems (FURLS) and help desk on behalf of the foreign facility, and that the U.S. agent should have access to Form FDA 483s and Establishment Inspection Reports (EIR) pertaining to the foreign facility.

(Response 25) The final rule provides that the U.S. agent of a foreign facility may view the information submitted in the foreign facility's registration. The U.S. agent will be able to view the information electronically via FURLS Food Facility Registration Module, in the interim, U.S. agents may contact FDA's help desk with questions about foreign facilities that they represent. In addition, a U.S. agent may contact FDA's help desk on behalf of the foreign facility. As to whether U.S. agents may have access to any Form FDA 483s and EIRs related to the foreign facility, certain information (such as confidential commercial information and trade secret information) in such records is protected from disclosure. FDA also generally does not proactively make available information related to FDA inspections of facilities, including FDA Form 483s and EIRs, although it is possible that a U.S. agent could obtain such information from the foreign facility or from FDA through a FOIA (5 U.S.C. 552) request. Any confidential commercial information, trade secret information, or other protected information in FDA Form 483s and EIRs that we provide through a FOIA request would be redacted (*i.e.*, deleted) in accordance with the disclosure exemptions set forth in the FOIA and 21 CFR part 20.

## V. Comments on Proposed Amendments to § 1.230—When Must You Register or Renew Your Registration?

### A. Proposed § 1.230(a)—When Must You Register?

We proposed to delete the reference to the December 12, 2003, deadline in

current § 1.230(a) and instead require 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 did not receive any comments on this change and are finalizing as proposed.

### B. Proposed § 1.230(b)—Registration Renewal

We proposed amending § 1.230 to require biennial registration renewal and provide for an abbreviated registration renewal process. Proposed § 1.230(b) would require that during the period beginning on October 1 and ending on December 31 of each even-numbered year, the owner, operator, or agent in charge of a facility would be required to submit a registration renewal to FDA containing the information required under § 1.232. Under proposed § 1.230(b), the owner, operator, or agent in charge of a facility would be able to authorize an individual to renew the facility's registration on its behalf. We proposed that 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. We proposed that each registration renewal must include the name of the individual submitting the registration renewal, and the individual's signature (for the paper option).

We are finalizing these requirements, with two modifications. First, we have modified the proposed requirement to provide the email address for the individual who authorized submission of the registration renewal if the individual submitting the registration renewal is not the owner, operator, or agent in charge of the facility. For registration renewals not submitted by the owner, operator, or agent in charge, final § 1.230(b) provides that the registration renewal must identify the individual who authorized submission of the registration renewal by email address, unless FDA has granted a waiver under § 1.245. Registration renewals not submitted by the owner, operator, or agent in charge must also identify by name, address, and telephone number the individual who authorized the submission, as proposed. Second, we have added a requirement that each electronic registration renewal

must include the name of the individual submitting the renewal. We have made this change because we believe that this information will aid our ability to verify that the individual submitting the registration information is authorized to do so.

(Comment 26) A comment states a concern with the potential for a bottleneck or system overload during the October 1 to December 31 registration renewal period. The comment asks if FDA would consider a biennial renewal expired if it was properly submitted on or prior to the December 31 deadline but was not timely administered or accepted by FDA on or prior to the December 31 deadline. The comment also requests that FDA consider extending the biennial registration deadline so that properly and timely submitted biennial renewals are not considered expired if FDA has not administered or accepted the facility's submission.

(Response 26) Beginning with the first biennial registration renewal period in 2012, information technology (IT) capabilities were added to support the system to help prevent any system failure or overload. FDA will continue this protocol during all biennial registration renewal periods to ensure that our IT systems can operate during high-traffic times. Given these IT investments, FDA does not anticipate that IT failures will cause problems with our registration system administering or accepting submissions during the registration renewal period. However, if any technical problems do arise during the biennial registration renewal period, FDA may consider extending the time period for biennial registration renewals, for instance by providing registrants at least the same number of calendar days for biennial registration renewal as allowed for under the FSMA amendments to section 415 of the FD&C Act. During the first biennial renewal period in 2012, FDA took such an approach. At that time, there was a delay with the registration renewal period becoming operational and FDA extended the deadline for facilities to complete renewals. As to the concerns regarding expired registrations, as discussed in section XI of this document, we are adding § 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). If a food facility registration or renewal registration is submitted (or postmarked for paper submissions) on or before the renewal deadline and includes all required information, we will not consider such a registration to be

expired. As described in section XI of this document, § 1.241(c) provides that 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). For registrations that we do not consider to be expired, we will not cancel the registrations under § 1.241(c). In addition, in the event that any IT problems complicate the submission and receipt of registration renewals, we would take that into account in determining whether to consider any registrations to have expired.

Prior to the beginning of the biennial registration renewal period on October 1, FDA intends to send an email to all registrants and U.S. agents notifying them of the upcoming registration renewal period. In these emails, we plan to provide information about the deadline for registration renewal. Once the renewal period begins, if a registrant has not submitted a renewal, we plan to continue to send emails reminding registrants of the upcoming deadline through the end of the registration renewal period on December 31.

#### *C. Proposed § 1.230(c)—Abbreviated Registration Renewal Process*

Under proposed § 1.230(c), we proposed to provide for an abbreviated registration renewal process for registrations that do not have any changes to the information required under § 1.232 since the submission of the preceding registration or registration renewal. The abbreviated registration renewal process that we proposed 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 also proposed that registrants must use Form FDA 3537 to submit abbreviated registration renewals to FDA. In response to some comments, we have made some changes to these requirements.

In addition, on our own initiative, we have changed § 1.230(c) to require that each abbreviated renewal include the name of the individual making the submission and the individual's signature (for the paper option). We have made this change because we believe that this information will aid our ability to verify that the individual submitting the registration information is authorized. We have also changed § 1.230(c) to require that for abbreviated

renewals not submitted by the owner, operator, or agent in charge of the facility, the abbreviated renewal must provide the email address of the individual who authorized submission of the abbreviated renewal, unless FDA has granted a waiver under § 1.245. We made this change in order to enable us to more efficiently perform the verification process established in § 1.231(a)(4) and (b)(6) for abbreviated renewals not submitted by the owner, operator, or agent in charge of the facility. Under those provisions, after submission of the abbreviated renewal (whether submitted electronically or by mail or fax), FDA will verify that the individual identified as having authorized submission of the registration renewal in fact authorized the submission on behalf of the facility. FDA will not provide a confirmation of the abbreviated renewal until that individual confirms that he or she authorized the submission. Having the email address for the individual who authorized submission of the registration renewal will enable us to more quickly and efficiently conduct the verification so that we can more quickly provide confirmation of the renewal. Finally, we have changed § 1.230(c) to allow food facilities to submit abbreviated registration renewals if the information required in the registration has not changed since the facility submitted an update or since the facility submitted the preceding registration or registration renewal. Under the proposed rule, the abbreviated option would only have been available if no information changed since the facility submitted the preceding registration or registration renewal. We made this change so that food facilities will not be required to complete the standard renewal process if the required information is unchanged since the facility's most recent registration update. We believe that this change will make the renewal requirement less burdensome for food facilities.

Furthermore, we note that we consider abbreviated renewals to be included as part of the registration renewal process explained in § 1.231 of the final rule.

(Comment 27) Comments recommend FDA simplify its proposal for "abbreviated" renewals by requiring only that a box be checked to confirm that there have not been any changes to the registration information previously submitted, including to the previously submitted certification regarding the truthfulness and accuracy of the registration information.

(Response 27) We agree that registrants submitting abbreviated registration renewals need not confirm that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. We believe that the requirement in the final rule in § 1.230(c) that registrants confirm that no changes have been made to the information required under § 1.232 since the preceding registration or registration renewal encompasses a confirmation regarding FDA being permitted to inspect. Accordingly, we have revised § 1.230(c) in the final rule to no longer require that abbreviated registration renewals provide confirmation regarding FDA being permitted to inspect. However, we continue to believe that it is appropriate for abbreviated registration renewals to certify that the information submitted is truthful and accurate. We believe such certifications will help deter individuals from submitting false information, including falsely certifying that no changes have been made to the required information. For the reasons discussed in the previous paragraphs, we also believe it is appropriate for abbreviated renewals to include the name of the individual submitting the renewal and, for abbreviated renewals not submitted by the owner, operator, or agent in charge of the facility, the email address of the individual who authorized the submission.

#### **VI. Comments on Proposed Amendments to § 1.231—How and Where Do You Register or Renew Your Registration?**

##### *A. Proposed § 1.231(a)—Electronic Registration and Registration Renewal*

In proposed § 1.231(a), we proposed to require mandatory electronic registration and registration renewals beginning January 4, 2016, unless a waiver has been granted under § 1.245. In the proposed rule, we proposed in § 1.245 to provide that to request a waiver from the electronic registration or renewal requirement, a registrant must submit a written request to FDA that explains why it is not reasonable for the registrant to submit a registration or registration renewal electronically to FDA. In the proposed rule, FDA tentatively concluded 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 (80 FR 19160 at 19177 to 19178).

We requested comment on the proposed requirements for mandatory electronic registration and registration renewals to begin in the year 2016 and the proposal to allow for a waiver from these requirements. We also requested comment 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.

(Comment 28) One comment states that small foreign facilities may not be able to submit registrations electronically by 2016 because there is no reliable access to the Internet. The comment requests that paper submissions remain an option.

(Response 28) We recognize that there may be a need for additional flexibility regarding the deadline for requiring electronic registrations and registration renewals. In response to this comment, we are revising § 1.231(a)(2) to replace the proposed January 4, 2016, deadline for electronic registrations and registration renewals with a January 4, 2020, deadline. In addition, we are also revising § 1.231(a)(2) to state that registrations or registration renewals must be submitted electronically “unless FDA has granted” a waiver. The proposed provision would have stated that the electronic registration requirement applies “unless you have been granted a waiver.” We believe that this change is consistent with § 1.245, which makes clear that the waivers are granted by FDA. Accordingly, final § 1.231(a)(2) provides that owners, operators, or agents in charge must submit their registration or registration renewal to FDA electronically beginning on January 4, 2020, unless FDA has granted a waiver under § 1.245. If FDA has granted a waiver, registrations and registration renewals may be submitted through mail or fax.

#### *B. Proposed § 1.231(b)—Registration or Registration Renewal by Mail or Fax*

In proposed § 1.231(b), we proposed that, beginning January 4, 2016, we would allow registrants to submit registration or registration renewals by mail or fax if a waiver has been granted under proposed § 1.245. As we explained in Response 30, we are replacing the January 4, 2016, deadline with a January 4, 2020, deadline.

As revised, final § 1.231(b) states that beginning January 4, 2020, registrants must submit their registrations or registration renewals to FDA electronically, unless FDA has granted a waiver under § 1.245. If FDA has granted a waiver under § 1.245, the registrant may register or renew a registration by mail or by fax. The

revisions reflect our decision to delay the requirement to submit registrations electronically until January 4, 2020, and also to be consistent with § 1.245 in making clear that waivers under § 1.245 are granted by FDA.

#### *C. Proposed §§ 1.231(a)(3) and (b)(5) and 1.234(c)(2) and (d)(5)—Unique Facility Identifier and Verification Procedures for FDA*

In proposed § 1.232(a)(2), we proposed to require the D–U–N–S number of a domestic and foreign facility be included in the facility’s registration. We proposed for this requirement to function in connection with proposed § 1.231(a)(3) and (b)(5), which would provide that after a facility completes its registration or updates its D–U–N–S number as part of registration renewal, FDA would verify the accuracy of the facility’s D–U–N–S number and would 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. We also proposed for the requirement to submit D–U–N–S numbers to function in connection with proposed § 1.234(c)(2) and (d)(5), which proposed to provide that FDA would 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. As discussed more fully in section VII.B of this document, § 1.232(a) of the final rule requires domestic and foreign facilities to submit a UFI recognized as acceptable to FDA in the facility’s registration. We are not finalizing the proposal to include a D–U–N–S number.

(Comment 29) Comments recommend FDA verify registration information with the U.S. agent for foreign facilities rather than using D–U–N–S numbers. The comments state that such a verification process would be less burdensome and complex.

(Response 29) We decline this suggestion. We believe that a verification process that will function in connection with a UFI will be more efficient and effective than relying on the U.S. agent. In addition, only foreign facilities have U.S. agents. Domestic facilities do not have U.S. agents.

(Comment 30) Comments state that users should be given additional attempts to input registration information if the verification step is unsuccessful. Comments also ask how FDA will inform a facility of an unsuccessful UFI verification step and how facilities will be able to correct information.

(Response 30) For electronic registration submissions, the registration screen would immediately notify the food facility if we are unable to verify the UFI or if the facility-specific address associated with the UFI is the same address associated with the registration. For registration submissions by mail or fax, FDA will use the contact information available for the facility to notify the facility of any such occurrence. If FDA is unable to verify the UFI or to verify that the facility-specific address associated with the UFI is the same address associated with the registration, the facility would have the opportunity to fix the information in the registration. However, if it turns out that FDA is unable to verify this information because the UFI provider has incorrect information about the facility, the facility may contact the UFI provider to resolve the discrepancy. If verification problems persist, the facility may contact FDA.

(Comment 31) One comment asks that FDA allow U.S. agents to “search for D–U–N–S numbers of facilities” before a facility registers. The comment states that this will help ensure the accuracy of the registration information submitted to FDA.

(Response 31) To the extent that the comment is asking that U.S. agents be able to search the Dun and Bradstreet

database, we will consider this comment when we implement the UFI requirement. Whether U.S. agents may search the database of the UFI system that FDA recognizes as acceptable may depend on a number of factors, including what database information, if any, the UFI provider makes public. If U.S. agents wish to ensure the accuracy of foreign facilities' registration information, they may wish to work with the foreign facilities directly.

(Comment 32) Many comments state that requiring the submission of D-U-N-S numbers will not enhance the accuracy of FDA's registration database. A comment states that a D-U-N-S number cross-check is an additional time-consuming step and is not effective at preventing inaccurate information from being submitted to FDA. One comment states that discrepancies in the FDA database and the Dun and Bradstreet database may cause disruptions and delays in registration.

(Response 32) We disagree with the comments asserting that the UFI verification step will not enhance the accuracy of FDA's registration database. A UFI system such as D-U-N-S will allow the Agency to leverage the information in the UFI system, providing assurance that the address associated with the food facility is accurate. For instance, FDA uses D-U-N-S numbers for drug establishment registration (Ref. 8). FDA has found that the use of D-U-N-S numbers for drug establishment registration has been a useful resource for identifying and verifying certain business information. Regarding concerns about disruptions and delays, we do not anticipate significant problems. We are postponing the requirement for providing a UFI in registrations until the registration renewal period beginning October 1, 2020, which should provide food facilities sufficient time to obtain a UFI. If any facilities encounter delays associated with the UFI requirement or verification step, they may contact FDA.

(Comment 33) Comments recommend using inspection information obtained by FDA investigators during inspections to confirm and verify registration information instead of requiring information about D-U-N-S numbers.

(Response 33) To the extent possible, FDA investigators do confirm the accuracy of food facility registration information when conducting inspections. However, FDA investigators are not able to ensure the accuracy of FDA's registration information in an efficient or comprehensive manner. Due to limited resources, FDA is not able to inspect every registered facility with the

frequency needed to ensure that the registration information for any particular facility is accurate at any particular time. Information might change in-between inspections, and inaccurate registration information could hinder FDA's ability to locate facilities for inspection. We believe that requiring a UFI recognized as acceptable to FDA is a more efficient and effective way to help ensure the accuracy and reliability of the registration information and to help ensure that the registration database is up-to-date.

(Comment 34) Comments question the capacity of the registration database to save registrations for completion at a later date so that the registrant can obtain a D-U-N-S number.

(Response 34) FDA's registration system has the needed capacity to save registration information for completion at a later date. While FDA will not save an incomplete registration on the server indefinitely, the information will be stored for a period of time greater than the maximum amount of time needed to acquire a UFI.

(Comment 35) One comment addresses "pharmaceutical wholesale distributors" that hold only a small amount of food. For these facilities, the comment suggests that FDA verify the facility-specific address using means other than a D-U-N-S number. The comment states that the Agency can instead refer to facility-specific information collected by CDER and/or information collected by State licensing authorities.

(Response 35) We do not think it is appropriate to establish different registration requirements for facilities of different sizes or for facilities that manufacture, process, pack, or hold different amounts of food. Food facilities of any size that handle any amount of food may be linked to terrorism attacks or other food-related emergencies. In the event that any attacks or other emergencies occur, it will be important for FDA to have accurate and up-to-date information about all facilities. Even if FDA has certain information about facilities through other regulatory processes, we expect that obtaining a UFI through food facility registration will be a more efficient way for FDA to verify the facility's address. However, we may refer to information collected by other FDA regulatory processes as appropriate.

*D. Proposed §§ 1.231(a)(4) and (b)(6), 1.234(c)(3) and (d)(6), and 1.235(c)(3) and (d)(6)—Verification Procedures for Submissions Not Made by the Owner, Operator, or Agent in Charge of the Facility*

We proposed in proposed § 1.231(a)(4) and (b)(6) that FDA would 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 if the registration or registration renewal was not submitted by the owner, operator, or agent in charge of the facility. We further proposed that FDA would 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, under proposed § 1.231(a)(4) and (b)(6), 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. In addition, 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 cancellation confirms that he or she in fact authorized the cancellation on behalf of the facility. We proposed this verification step to address the problem with unauthorized third party registration submissions discussed in the preamble to the proposed rule (80 FR 19160 at 19171). The unauthorized registrations have resulted both in duplicate registrations for food facilities and registrations for facilities that do not in fact manufacture/process, pack, or hold food for consumption in the United States.

(Comment 36) Comments state that it is not evident that use of email verification will sufficiently prevent unauthorized facility registrations, as an email address can be falsified.

(Response 36) We have revised the regulatory text regarding the verification step in the final rule to no longer specify that FDA will email the owner, operator, or agent in charge to conduct the verification. Instead, the final regulatory text provides that FDA will verify that the individual identified as having authorized the submission in fact

authorized the applicable submission on behalf of the facility. We have made this change in final §§ 1.231(a)(4) and (b)(6) (for registrations and registration renewals), 1.234(c)(3) and (d)(6) (for updates), and 1.235(c)(3) and (d)(6) (for cancellations). We plan to issue guidance providing more detailed information about how FDA will conduct this verification step. It is possible that the guidance will provide for using email, phone, U.S. mail, or other methods, as appropriate. In determining what methods are appropriate for conducting the verification, FDA will consider the effectiveness of the method for preventing unauthorized registrations. The final rule continues to provide in §§ 1.231(a)(4) and (b)(6) that FDA will not confirm a registration or registration renewal or provide a registration number until the individual confirms that he or she authorized the submission. For updates and cancellations, the final rule continues to provide in §§ 1.234(c)(3) and (d)(6) (for updates), and 1.235(c)(3) and (d)(6) (for cancellations) that FDA will not provide a confirmation of the registration update or cancellation until the individual confirms that he or she authorized the submission.

(Comment 37) Comments suggest that instead of the proposed verifications step, FDA run cross-checks in the food facility registration database to determine if a facility is registered multiple times. These comments argue that contacting the owner, operator, or agent in charge of a facility to verify a registration can be burdensome, especially for owners, operators, or agents in charge of multiple facilities. Comments further suggest FDA run cross-checks in the database to identify submissions for companies with information that does not appear consistent (e.g., different email suffix used, different phone numbers) to identify fraudulent third-party registrations. Other comments encourage FDA to conduct the verification process only after the registration has been submitted. The comments state that this will prevent delays in the registration process.

(Response 37) Due to a large number of registrations and limited resources, it is not possible for FDA to individually monitor every registration and contact every facility outside of the processes provided in the final rule. Under the final rule, if the registration submission is not made by the owner, operator, or agent in charge, we will confirm that the individual identified as having authorized a registration submission in fact authorized the submission. We will

provide guidance about how we will conduct this verification step, which may provide for emailing the individual identified as having authorized the submission. Any such process that we outline in guidance will be aimed at ensuring the accuracy of the verification process, while also being efficient and not unduly resource-intensive. Conducting across-the-board surveillance of each registration, by contrast, would demand extensive resources. However, FDA will continue its current practice of individually contacting facilities if specific questions arise regarding the facility's registration. Regarding the request to conduct the verification later in the registration process, we decline that request. We believe that delaying confirmation of the registration submission until after we complete the verification will help deter individuals from submitting unauthorized registrations.

(Comment 38) Several comments suggest that FDA provide the owner, operator, or agent in charge an identification number that they can give to authorized personnel submitting registration, renewals, updates, and cancellations, similar to the VIS for U.S. agents.

(Response 38) We will consider in the future whether to create an identification number to provide to the owner, operator, or agent in charge as suggested in the comments.

#### *E. Proposed §§ 1.231(a)(5) and (b)(7) and 1.234(c)(2) and (d)(5)—Verification Procedures for U.S. Agents*

We proposed in § 1.231(a)(5) and (b)(7) that 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, to verify that the person agreed to serve as the U.S. agent. We further proposed that FDA would not confirm the registration or provide a registration number until that person confirms that the person agreed to serve as the U.S. agent for the facility. In addition, we proposed a similar process for emailing the U.S. agent when foreign facilities update U.S. agent information in proposed § 1.234(c)(2) and (d)(5). Specifically, we proposed that when foreign facilities update the U.S. agent information as part of registration renewal, FDA would not confirm the registration renewal until the person confirms having agreed to serve as the U.S. agent. We also proposed that for registration updates, we would not provide an update confirmation until that person confirms having agreed to serve as the U.S. agent.

In the final rule, we are continuing to require a verification step for U.S. agent information. However, we have revised the regulatory text regarding the verification step to no longer specify that FDA will email the person listed as the U.S. agent to conduct the verification. Instead, the final regulatory text provides that FDA will verify that the person identified as the U.S. agent for the foreign facility agreed to serve as the U.S. agent. We have made this change in final §§ 1.231(a)(5) and (b)(6) (for registrations and registration renewals) and 1.234(c)(2) and (d)(5) (for updates). We plan to issue guidance providing more detailed information about how FDA will conduct this verification step. It is possible that the guidance will provide for using email. The final rule continues to provide in § 1.231(a)(5) and (b)(7) that FDA will not confirm a registration or registration renewal or provide a registration number until the person identified as the U.S. agent for the foreign facility confirms that the person agreed to serve as the U.S. agent. For updates, the final rule continues to provide in § 1.234(c)(2) and (d)(5) that FDA will not provide a confirmation of the registration update until the person identified as the U.S. agent for the foreign facility confirms that the person agreed to serve as the U.S. agent.

(Comment 39) One comment suggests that the verification email sent to the U.S. agent should include a statement where the U.S. agent affirmatively acknowledges that the U.S. agent may be liable for fees for reinspection costs.

(Response 39) The U.S. agent acts as a communications link between FDA and the foreign facility for both emergency and routine communications. See 21 CFR 1.227. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies another emergency contact. See *id.* Under the final rule, FDA will verify that the person identified as the U.S. agent for foreign facilities has agreed to serve in that role. FDA will not confirm the registration or provide the facility with a registration number until that person confirms that the person agreed to serve as the U.S. agent. See 21 CFR 1.231(a)(5); 21 CFR 1.231(b)(7). In addition, for registration updates, FDA will not provide an update confirmation until the person identified as the U.S. agent confirms that the person agreed to serve as the U.S. agent for the foreign facility. See 21 CFR 1.234(c)(2); 21 CFR 1.234(d)(5). We have revised the regulatory text for the final rule to no longer specify that FDA will email the person listed as the U.S. agent to

conduct the verification. Instead, we plan to issue guidance with information about how FDA will verify that the person identified as the U.S. agent agreed to serve in that role. We have not decided on what language we will use in any communications to the person identified as the U.S. agent, whether those communications are conducted using email or through other means. We will consider this comment as we work to implement the U.S. agent verification step.

*F. Proposed § 1.231(a)(6) and (b)(9)—Requirement to Update Incorrect Registration Information*

We proposed in § 1.231(a)(6) and (b)(9) that if any information previously submitted was incorrect at the time of submission, the registrant must immediately update the facility's registration as specified in § 1.234. We did not receive any comments on these provisions and are finalizing the provisions as proposed.

**VII. Comments on Proposed Amendments to § 1.232—What Information Is Required in the Registration?**

We proposed in § 1.232(b)(1) to 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. This requirement went into effect upon enactment of FSMA. In proposed § 1.232(c)(1), we also proposed to codify 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 U.S. agent for the foreign facility. This requirement also went into effect upon enactment of FSMA.

In addition, we also proposed to require that a food facility registration include the email address of the owner, operator, or agent in charge, and that registrations include the D-U-N-S number of a domestic and foreign facility be included in the facility's registration. We further proposed to require the type of activity conducted at the facility for each food product category defined. We proposed that facilities 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; (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. Although we proposed to specify the specific activity types that food facilities must select, we did not propose to define those activity types. Instead, we requested comments on whether we should do so, and also requested comments on possible definitions. We further sought comment on whether processing of thermally processed low-acid foods packaged in hermetically sealed containers ("LACF") and acidified foods 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.

We further proposed to update the registration regulation regarding food product categories.

The rule also proposed to codify in FDA's registration regulation the requirement for food facility registrations 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. This requirement went into effect upon enactment of FSMA.

The rule further proposed certain changes related to registrations not submitted by the owner, operator, or agent in charge of the facility. 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 proposed to recodify this provision in proposed § 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.

In addition, we proposed to require domestic facilities (proposed § 1.232(b)(2)) provide an emergency

contact phone number and an email address if the email address is different from the facility contact person email address required in proposed § 1.232(b)(1). For foreign facilities, we proposed to require (in § 1.232(c)(2)) that the foreign facility provide an emergency contact number and email address. Further, we proposed to retain the requirement in current § 1.232(g) (proposed § 1.232(a)(7)) that food facilities provide information regarding food product categories, but to change that requirement to be consistent with the changes FDA has made to food product categories in response to the FSMA amendments.

*A. Requirement for Certain Email Address Information*

(Comment 40) Comments state that requiring email addresses for the emergency contact of a domestic facility and a foreign facility will not be effective if the email address is for a third party other than the facility. Some comments recommend that the rule should be amended so that food facilities can indicate their preferred means of contact in an emergency on the registration form, whether by email, phone, fax or other.

(Response 40) We believe that having the required email addresses will assist FDA in responding to food-related emergencies even when the email address is for a third party, and therefore disagree with the comments suggesting otherwise. Email is a fast and efficient method to communicate, and we anticipate that having the email address for the emergency contact for a domestic facility and foreign facility will assist us in reaching those contacts. Regarding the request to allow facilities to indicate their preferred means of contact during an emergency (e.g., email, phone, fax, or other), we will consider whether to add an optional field on Form FDA 3537 that would allow facilities to indicate this. If we add any such optional field, we will issue guidance in accordance with our GGP regulations in 21 CFR 10.115.

(Comment 41) A comment opposes having to provide an email address for the U.S. agent in addition to the name, full address, and phone number of the U.S. agent. The comment states that a U.S. agent's email address will be of little assistance to FDA during an emergency because once submitted, the contact information could change and may never be updated.

(Response 41) 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. Section 1.232(c)(1) of the final rule will codify the requirement in FDA's registration regulation. Further, FDA disagrees that the email address for the U.S. agent will not be useful for the Agency. We plan to use the email address information to assist us in routine and emergency communications with the U.S. agent. In addition, we plan to use the email address information to help us verify that the person identified as a U.S. agent in a facility's registration has agreed to serve in that role. As described elsewhere in this **Federal Register** document, after a foreign facility completes its registration or updates its U.S. agent information (including as part of registration renewal), FDA will verify that the person identified as the U.S. agent for the foreign facility has agreed to serve as the facility's U.S. agent (see §§ 1.231(a)(5) and (b)(7) and 1.234(c)(2) and (d)(5)). In addition, as described in section IX of this document, facilities must submit updates within 60 calendar days of any change to any of the registration information previously submitted, including information about the U.S. agent.

(Comment 42) Comments recommend that FDA create an exemption from the requirement that facilities provide an email address for the owner, operator, or agent in charge of a facility for facilities that do not have email addresses or Internet access. One comment requests that providing the email address of the owner, operator, or agent in charge be optional.

(Response 42) Although section 102(a)(1)(A) of FSMA requires submission of email address information for the contact person of domestic facilities and the U.S. agent of foreign facilities, often these persons are not the same as the owner, operator, or agent in charge of the facility. We are requiring email addresses for the owner, operator, or agent in charge of food facilities in § 1.232(a)(6) 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. However, we understand that there may be circumstances in which an owner, operator or agent in charge of a facility is not able to obtain an email address. We expect that these circumstances will be the same or similar to the circumstances that may cause a facility to receive a waiver from the electronic registration requirement in accordance with § 1.245.

To account for these circumstances, we are providing in final § 1.232(a)(6) that the email address be added to the information required regarding the owner, operator, or agent in charge of the facility, except when FDA has granted a waiver under § 1.245. Consequently, under final § 1.232(a)(6), a food facility registration must include the name, address, and phone number of the owner, operator or agent in charge. In addition, the email address of the owner, operator, or agent in charge is required, unless FDA has granted a waiver under § 1.245.

#### *B. Requirement for a Unique Facility Identifier*

(Comment 43) Comments state that FDA does not have express legal authority to require a D-U-N-S number. The comments state that Congress amended the registration requirements in section 415 of the FD&C Act as part of FSMA, and that Congress could have, but did not, require the submission of D-U-N-S numbers.

(Response 43) We have replaced the proposed requirement that registrations include a D-U-N-S number with a requirement that they include a UFI recognized as acceptable to FDA. We believe that we have adequate legal authority for this requirement in the final rule. As to the comments' statement that Congress could have, but chose not to, include a UFI requirement in FSMA, we do not believe that the lack of such a requirement in FSMA indicates that Congress did not authorize FDA to require such identifiers. As we stated in the proposed rule, the UFI requirement is grounded in the statutory objective of efficiently enforcing the food safety and other requirements of the FD&C Act. By requiring UFIs, FDA will be able to verify the facility-specific address information associated with those identifiers. Such verification should increase the accuracy of FDA's food facility registration database. As a consequence, FDA investigators will have access to more accurate food facility information, and will therefore be able to more efficiently identify and locate food facilities for inspection. As a result, FDA will 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 decision to require UFIs 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 UFIs provide will 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 will aid FDA in efficiently responding to a terrorist threat or other food-related emergency. Finally, FDA's decision to require unique facility identifiers is consistent with the direction contained in section 305(d) of the Bioterrorism Act (Pub. L. 107-188, 116 Stat. 594, 668-69) to ensure adequate authentication protocols to enable identification of the registrant and validation of the registration data for registrations submitted to FDA electronically. Verifying information in connection with a UFI for a food facility will provide FDA with a protocol to enable FDA to identify food facilities and verify certain registration information for those facilities.

(Comment 44) Comments suggest obtaining a D-U-N-S number is a duplicative effort for facilities and would not provide assurance of the most up-to-date and accurate information for a facility considering that information in both databases is voluntarily entered by the facility. One comment states that use of an identification number such as a D-U-N-S number would not lead to increased accuracy because with both a D-U-N-S number and food facility registration, facilities self-report information. Comments urge FDA to allow multiple identifiers for facilities as opposed to solely relying on D-U-N-S. Some comments recommend FDA utilize the U.S. Customs and Border Protection's (CBP) identification number system and/or the Prior Notice (PN) system for foreign registration verification as opposed to a D-U-N-S number. Comments encourage FDA to allow facilities other options for a specific facility identifier that include using certifications and identifiers from State agencies. Comments state that programs for use of identifying traders are best dealt with at an international level by the World Customs Organization. This comment states that no one identification system is better than another and that FDA should not impose this particular system worldwide. One comment encourages FDA to work with State, local, and tribal

agencies to develop a UFI without relying on a third-party system.

(Response 44) As stated previously in this **Federal Register** document, the final rule requires that registrations include UFIs, not D-U-N-S numbers. We believe that this change provides additional flexibility. We anticipate that we will issue guidance specifying which UFIs or identifiers FDA recognizes as acceptable, and we expect to recognize D-U-N-S numbers as acceptable identifiers.

We disagree with the comments stating that UFIs will be duplicative and will not assist FDA in obtaining up-to-date information about food facilities. We anticipate that UFIs will help ensure that the identified facility is, in fact, the food facility in the food facility registration submission. The D-U-N-S number system, for instance, is an internationally recognized unique number system that is updated on a regular basis. D-U-N-S numbers also provide for site-specific identification of business entities. Although business establishments may provide information about themselves to Dun and Bradstreet, Dun and Bradstreet does not rely on self-reported information alone. The company independently verifies certain information associated with establishments. The ability to verify the accuracy of this information will increase the accuracy of the registration database and, as a consequence, help provide FDA investigators with more accurate food facility information that they can use to more efficiently identify and locate food facilities for inspection. In addition, we expect that the UFI verification process will make it more difficult for unauthorized individuals to submit registrations on behalf of facilities because unauthorized individuals may not know a particular facility's UFI, or may be unable to provide an accurate facility-specific address.

To the extent that the comments are concerned about the burden of the requirement, we note that Dun and Bradstreet makes D-U-N-S numbers available at no cost. Further, as of mid-2013, approximately 70 percent of domestic facilities required to register with FDA and 64 percent of foreign facilities required to register with FDA, have D-U-N-S numbers (Ref. 9).

As to the comments suggesting we use CBP or PN systems, we do not agree that such identification systems would be appropriate. Not all food facilities import food, and therefore not all food facilities will necessarily have access to any CBP or PN system. Furthermore, we do not believe that any certifications and identifiers from State agencies

would be adequate UFIs because any such certifications and identifiers would likely differ State by State, and States might not develop UFIs for foreign facilities. For these reasons, we do not agree that using the alternative identifiers suggested by the comments would allow FDA to accurately identify food facilities. Consequently, they would not allow FDA to efficiently enforce section 415 of the FD&C Act.

With respect to the comment stating that programs for use of identifying traders are best dealt with at an international level by the World Customs Organization and that FDA should not impose this particular system worldwide, FDA is responsible for administering the requirements of section 415 of the FD&C Act. Those requirements include the responsibility to maintain an accurate and up-to-date registration database. Our database needs are specific to the laws and regulations we implement, and we believe that we are in the best position to determine what UFIs should be acceptable. In addition, by requiring the submission of an acceptable UFI, we are not requiring worldwide adoption of any particular identification system. The requirement would only apply to food facilities that are required to register with FDA (*i.e.*, food facilities that manufacture/process, pack, or hold food for consumption in the United States).

Regarding the comment encouraging FDA to work with State, local, and tribal agencies to develop a UFI without relying on a third-party system, we may consider whether such an approach would be appropriate. However, we expect that undertaking the development of a new UFI system could entail significant resources.

(Comment 45) One comment states that a U.S. Government Accountability Office report stated that the U.S. General Services Administration has concerns regarding reliance on D-U-N-S numbers and has been looking into alternatives that would encourage competition (Ref. 10). The comment urges FDA not to require a D-U-N-S number for food facility registration.

(Response 45) As stated previously, the final rule does not require the submissions of D-U-N-S numbers; instead it requires the submission of UFIs recognized as acceptable to FDA. We will consider recognizing as acceptable UFIs other than D-U-N-S numbers.

(Comment 46) Comments state that the proposed requirement to obtain a D-U-N-S number would be burdensome and unfamiliar to many. Comments recommend FDA make the proposed D-

U-N-S requirement optional for foreign facilities. They state that this would help alleviate the burden for foreign facilities because they state that it can take up to 2 weeks for foreign facilities to obtain D-U-N-S numbers. One comment states that facilities need time to implement the D-U-N-S number requirement, especially foreign facilities that may be unfamiliar with the process of obtaining a D-U-N-S number. The comment is also concerned that Dun and Bradstreet will be inundated with requests during the next biennial renewal period. In addition, comments state that it would be burdensome for facilities to maintain both food facility registration numbers and D-U-N-S numbers. One comment suggests that FDA should work with Dun and Bradstreet to make the iUpdate system available to facilities and make it clear to food facilities that they have access to the iUpdate system when obtaining a D-U-N-S number. One comment states that the Dun and Bradstreet Web site for obtaining D-U-N-S numbers is not reliable, and facilities may be prompted to request D-U-N-S number by telephone (at a large cost).

(Response 46) As stated in the previous paragraphs, we conclude that it is appropriate to require that food facilities, including foreign facilities, submit UFIs in their registrations. Use of a UFI, such as a D-U-N-S number, provides additional information than that provided by food facility registration numbers, because UFIs such as D-U-N-S numbers allow FDA to verify certain information submitted in registrations. Such verification is important for both domestic and foreign food facilities. As to the concern about the burden of this requirement, we do not agree that the process of applying for a UFI is unreasonably burdensome, including for foreign facilities. Nevertheless, in response to the comments, we are delaying the requirement to submit a UFI until the registration renewal period beginning October 1, 2020. We believe that this will provide adequate time for domestic and foreign facilities to obtain D-U-N-S numbers without cost and for facilities (both domestic and foreign) to become familiar with the process for obtaining D-U-N-S numbers. In addition, a D-U-N-S number can be acquired at any time, not only within the biennial registration renewal period. We do not anticipate that facilities will have difficulty obtaining UFIs as a result of the UFI provider being overburdened or its Web site being unreliable. But if such difficulties do arise, facilities should contact us so that we can look

into the matter. Regarding the request in the comment that FDA work with Dun and Bradstreet to make the iUpdate system available to food facilities, we will look into the possibility and determine whether the system is appropriate for food facility registration.

(Comment 47) Comments state that the food facility registration number will serve as an adequate facility identifier. Comments state that there does not appear to be a problem with inaccurate data in the food facility registration database and state that requiring an additional identifier is therefore not necessary.

(Response 47) FDA will not discontinue the use of registration numbers. However, since FDA implemented the registration requirement in 2003, we have identified a number of accuracy-related problems in the registration database. One such problem involves incorrect facility address information. Accurate address information is critical to scheduling inspections efficiently, and without it FDA often faces the problem of “inspectional washouts,” where an FDA investigator arrives for an unannounced inspection at a listed address only to find that the facility has gone out of business or is otherwise not located at the listed address. In fiscal year 2015, FDA experienced 629 inspectional washouts for foreign and domestic food facilities. We believe that requiring UFIs in registrations and verifying the facility-specific address associated with those numbers will help increase the accuracy of the address information contained in FDA’s food facility registration database.

(Comment 48) Numerous comments state that it does not make sense for small businesses or hobbyists who operate out of their homes to obtain D–U–N–S numbers for the sole reason of registering with FDA.

(Response 48) Under § 1.227, a private residence is not a “facility.” Thus, a private residence that meets customary expectations for a private residence that is also used to manufacture, process, pack, or hold food need not be registered. Accordingly, if the activities of small businesses or hobbyists who operate out of their homes meet customary expectations for a private residence, they would not have to register and therefore would not be required to obtain a UFI under this final rule. If, however, their activities do not meet customary expectations for a private residence, the small businesses or hobbyists would be required to register as food facilities and obtain a UFI. For the reasons outlined in the previous paragraphs, we believe that the

process of applying for a UFI is reasonable and that it will not be unduly burdensome.

(Comment 49) Comments express concern over the confidentiality of D–U–N–S numbers. Comments state that FDA should confirm and clarify that D–U–N–S numbers as well as facility names, addresses, and other information submitted in registrations are not subject to public disclosures. One comment states that disclosure of D–U–N–S numbers could allow third parties to obtain the address of “pharmaceutical distribution warehouses” that also hold food, and that disclosure would allow criminals to identify large quantities of drugs. The comment also expresses concern about inadvertent disclosure of D–U–N–S numbers by FDA FOIA staff. Comments ask that FDA consult with the State Department and Foreign Governments “since mandating the collection of private data might run afoul of European privacy laws.”

(Response 49) With respect to concerns about use of UFIs, including D–U–N–S numbers, leading to the disclosure of confidential information, we take appropriate measures to secure all data and records provided to the Agency, including data contained in food facility registrations. Furthermore, we note that under section 415(a)(5) of the FD&C Act, FDA’s list of registered facilities and registration documents are not subject to disclosure under FOIA. In addition, any information derived from such list or registration documents that would disclose the identity or location of a specific registered person also is not subject to disclosure under FOIA. With respect to public disclosure, FDA intends to treat information about facilities’ UFIs the same as it treats other information derived from registration submissions. It should also be noted that no registration information will be disclosed to a UFI provider, such as Dun and Bradstreet, as part of the verification process. Dun and Bradstreet could disclose the identity or location associated with a D–U–N–S number in some circumstances (such as for persons that pay for Dun and Bradstreet services), but any information that Dun and Bradstreet could disclose would not indicate whether a facility is registered or include any information provided to FDA as part of the registration process.

Regarding the concern expressed in one comment about the security of facilities that store both foods and drugs, it is unclear how the submission of a UFI for purposes of food facility registration places the facility at any additional risk. The food facility registration regulations do not require

facilities to provide information about any products other than the food manufactured/processed, packed, or held by the food facilities, and, as previously stated, information derived from the registration list or registration documents are not subject to disclosure under FOIA if they would disclose the identity or location of a specific registered person.

With regard to concerns raised about foreign country privacy standards, we requested comment on the proposed requirements, and a wide range of entities had the chance to provide us feedback. We are not aware of information, nor did we receive information from comments, that a UFI requirement would violate a European Union privacy law. If an entity finds that a UFI requirement conflicts with specific local laws, they should contact FDA.

We also believe that finalizing a UFI requirement, as opposed to a D–U–N–S number requirement, will help foster potential competition with other UFI providers and encourage better customer service from providers recognized as acceptable to FDA.

(Comment 50) Comments request clarity regarding facilities that require a D–U–N–S number (*i.e.* headquarters and/or sub sites). Other comments encourage FDA to allow the use of the parent company’s D–U–N–S number for separate facilities that a company may own so that companies that own multiple facilities need only use one D–U–N–S number. Comments also state that many companies’ D–U–N–S numbers are typically handled by headquarters personnel who may be located at a different address than the facility itself.

(Response 50) Under the final rule, each facility must provide a UFI recognized as acceptable by FDA. Requiring identifiers that are unique to individual facilities is necessary to enable FDA to verify the facility-specific address information associated with those identifiers. Such verification will allow FDA to more efficiently identify and locate food facilities for inspection and to maintain an accurate and up-to-date registration database. Accordingly, FDA declines the suggestions to allow identifiers that are specific to parent companies instead of individual facilities.

(Comment 51) Comments ask if the requirement to supply a D–U–N–S number will apply to all facilities immediately, or if it will only apply to facilities not currently registered.

(Response 51) The requirement to provide a UFI will apply to all registrants, new and existing. For all

registrants, as we stated previously in this document, we are delaying the compliance date for the requirement to submit a UFI recognized as acceptable to FDA until the registration renewal period beginning October 1, 2020. After a food facility provides a UFI, it will be required to update its registration with any changes to the identifier in accordance with § 1.234 of the final rule.

(Comment 52) Comments ask if facilities will have to provide a new D-U-N-S numbers if they change ownership.

(Response 52) If a facility comes under new ownership, the former owner must cancel the old registration in accordance with § 1.235 of the final rule, and the new owner must submit a new registration for the facility as specified in § 1.231 (see 21 CFR 1.234(b)). If a facility cancels its registration due to a change in ownership, the new owner, operator, or agent in charge must provide the appropriate UFI when registering the facility under new ownership.

(Comment 53) A comment states that FDA should prominently display on the registration Web site that a D-U-N-S number can be obtained at no cost and within a reasonable timeframe. In addition, the comment suggests that FDA provide a link on the FURLS Web page that facilities can use to contact FDA if they are asked to pay for a D-U-N-S number or to purchase additional D-U-N-S services, or if they cannot obtain a number within a reasonable time.

(Response 53) We will consider making changes to the registration Web site and the FURLS Web page to clarify which UFIs are recognized as acceptable to FDA and how to obtain a UFI. If facilities have difficulty obtaining a UFI, they are welcome to contact FDA at any time. We will consider providing further instructions regarding how to contact FDA on the FURLS Web page as well.

(Comment 54) One comment states that foreign facilities should be able to submit registrations without a D-U-N-S number, and then have 30 days to update the registration with the D-U-N-S number. The comment suggests that FDA conduct the verification step at that time. Furthermore, the comment recommends that FDA can maintain a log of instances involving registrations that were cancelled because a foreign facility did not have a D-U-N-S number and that FDA place those facilities on Import Alert. Furthermore, the comment suggests that in the 12 months prior to the next biennial registration period,

FDA should add an optional D-U-N-S number field to Form FDA 3537.

(Response 54) We disagree that foreign facilities should have 30 days to update their registrations with a UFI. For all registrants, we are delaying the requirement to submit a UFI recognized as acceptable by FDA until the registration renewal period beginning October 1, 2020, and we believe that this delay will provide all facilities, including foreign facilities, with sufficient time to obtain a UFI recognized as acceptable by FDA. We also believe that it would be administratively difficult to implement the comment's suggestion that different registration information be submitted at different times. The Agency will consider adding an optional UFI field to allow facilities to voluntarily submit UFI information in advance of the October 1, 2020, date.

(Comment 55) Comments express concern over the availability of the D-U-N-S system to small facilities that do not have reliable access to the Internet.

(Response 55) Our understanding is that access to the Internet is not required for D-U-N-S numbers, and that a D-U-N-S number can be obtained by phone. If any food facilities have difficulty obtaining a UFI recognized as acceptable by FDA due to lack of access to the Internet or phone, they may contact FDA.

(Comment 56) Comments state that Dun and Bradstreet does not appear to account for additions or deletions to the Specially Designated Nationals (SDN) List. These comments suggest FDA establish an ongoing monitoring process that routinely verifies the food facility registration database against the current SDN list.

(Response 56) The U.S. Treasury Department's Office of Foreign Assets Control publishes a list of individuals and companies owned or controlled by, or acting for or on behalf of, targeted countries. It also lists individuals, groups, and entities, such as terrorists and narcotics traffickers designated under programs that are not country-specific. Collectively, such individuals and companies are called "Specially Designated Nationals" or "SDNs" (Ref. 11). The comment has not identified a compelling reason why we should establish an ongoing monitoring process that routinely verifies the facility registration database against the SDN list, and we decline to do so.

(Comment 57) Comments recommend FDA require that each facility's registration include its geographical coordinates instead of D-U-N-S numbers. Comments state that geographical coordinates are more easily

accessible for each facility and are directly linked to a facility's physical location.

(Response 57) FDA declines to implement this recommendation. While geographical coordinates can provide longitude and latitude information about a facility, geographical coordinates may not always provide the same relevant and detailed information as a UFI. For instance, multiple, separate facilities may operate from a location with the same geographical coordinates, and geographical coordinate information may not reveal the complete address of a facility.

(Comment 58) Comments state that some individuals will have religious objections to the D-U-N-S number requirement because D-U-N-S numbers involve a mandatory universal numbering system.

(Response 58) If a registrant has religious beliefs that conflict with obtaining a UFI, they should contact FDA and explain why they are not able to comply with the requirement in the final rule.

### *C. Requirement To Include Food Product Categories*

We proposed to amend § 1.232 to be consistent with FDA's October 2012 guidance document entitled "Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories" (Food Product Categories Guidance) (Ref. 5) 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. We stated that we intend to address any further amendments of the food product categories contained on Form FDA 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."

(Comment 59) Comments state that it is confusing to update required food product categories by guidance since the guidance document is binding and, the comments say, looks indistinguishable from other guidance documents that are not binding. Comments recommend that the Food Product Category guidance document be called something other than "Guidance," such as "Binding Guidance," to set it apart. Comments encourage FDA to consider amending

the food product categories through a mechanism other than guidance.

(Response 59) We disagree with these comments. 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. We therefore believe it is appropriate to establish food product categories using guidance, and also to use the term “guidance” in describing the document. Because of Congress’s explicit statutory authorization to effectuate a binding requirement based on findings in guidance, the Food Product Categories guidance document is not subject to the usual restrictions in FDA’s 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 (see 21 CFR 10.115(d) and (i)). Although we appreciate the comments’ concern that this causes the Food Product Categories Guidance to differ from other guidance documents, we think that the guidance document itself makes this difference clear. In particular, we stated in the Food Product Categories guidance that we did not include the standard language regarding the “nonbinding effect of guidance” in the guidance because it is not an accurate description of the effect of the guidance (Ref. 5).

(Comment 60) Comments suggest that FDA should not require warehouses and storage facilities to identify food product categories that they handle because this information constantly changes. The comments state that it would therefore be burdensome for these facilities to be required to “constantly update” their food product category information.

(Response 60) Information about the categories of food a facility handles helps FDA conduct investigations and surveillance operations in response to food-related emergencies and to quickly alert facilities affected by such an incident if FDA receives information indicating the type of food affected. This is true for warehouse and storage facilities, as well as other facilities that manufacture/process, pack, or hold food. We therefore disagree with the suggestion to exempt warehouses and storage facilities from the requirement to

include food product category information in their registrations. That said, it may not be necessary for warehouse facilities to “constantly update” their registrations. For warehouse facilities engaged in ongoing operations that frequently change food product categories, these facilities may select all of the food product categories that are normally part of their operations. If the warehouse has any updates to the food product categories that it handles, it is required to update its registration in accordance with § 1.234. The Agency will consider possible IT solutions to reduce the burden associated with selection of food product category information.

(Comment 61) Comments question whether FDA is proposing to remove animal feed product categories from Form FDA 3537 and, if not, request clarity on the definitions of each of the animal food product category listed on the form.

(Response 61) This final rule does not remove animal food product categories from Form FDA 3537, and registrants will continue to be required to provide information about food product categories for animal food. As to the comment’s request for guidance on the meaning of the different food product categories for animal food, we do not agree that such guidance is necessary. We believe that many of the food product categories on Form FDA 3537 do not require elaboration. For instance, we believe that registrants understand the meaning of the term “pet food,” which is one of the food product categories for animal food. To the extent that the comment seeks clarification on the categories that pertain to animal food ingredients, we believe that these categories are well understood in the animal food industry. For instance, every year the Association of American Feed Control Officials (AAFCO) issues the *Official Publication* (OP) that includes categories for various animal food ingredients, many of which overlap with the food product categories listed on Form FDA 3537 for animal food. In order to provide even greater consistency with the categories used by the animal food industry, FDA plans to update the Food Product Categories guidance to add several additional food product categories for animal food. Those categories are: Botanicals and herbs; direct fed microbials; forage products; and technical additives. In addition, we plan to revise the Food Product Categories Guidance to replace certain food product categories. Specifically, we plan to replace the “animal derived products” category with an “animal protein products”

category, replace the “food processing byproducts” category with a “human food by-products not otherwise listed” category, and replace the “recycled animal waste products” category with a “processed animal waste products” category. We will update Form FDA 3537 to reflect changes that we make to the Food Product Categories guidance.

If facilities have specific questions about the food product categories for animal food, they may contact FDA.

(Comment 62) Comments propose utilizing FDA Product Codes instead of the food product categories currently on Form FDA 3537. Comments state FDA Product Codes “more specifically identify foods and thus allow FDA to more accurately assess risk,” and note that FDA’s draft guidance for industry on the voluntary qualified importer program (VQIP) recommends use of the product codes.

(Response 62) FDA’s product code is a unique alpha-numeric code used by FDA and customs brokers and self-filers to describe food products, as well as other products regulated by FDA. FDA requires submission of this data element for prior notice (21 CFR 1.281(a)(5)(i)), in part because the specificity provided by the FDA product code helps facilitate risk-based screening of imported products. The use of FDA product codes is also part of the application process for VQIP, as explained in the VQIP draft guidance (Ref. 12). At the same time, FDA requires the submission of food product category information for registration. Food product categories are for the most part more general and are tailored to food facility registration. FDA may use the food product categories in connection with product codes at the time of import. Specifically, FDA is able to use the information about food product categories to screen food imports because the Agency is able to match a registrant’s food product category with the product code and common or usual market name submitted as part of prior notice. However, food product categories provide certain information that the product codes do not provide. For example, the fruit and vegetable categories include separate sub-categories for fresh-cut fruits and vegetables, raw agricultural commodities, and other fruit and vegetable products. Because fresh-cut fruit and vegetables present different risks from other fruits and vegetables, this information helps FDA target communications with facilities. The product codes do not distinguish fresh-cut from other fruit or vegetable products. For all of these reasons, we believe it is appropriate to continue to

require food product categories for registration, and not FDA product codes. Further, we note that food facility registration and VQIP serve different purposes.

(Comment 63) One comment suggests that we modify Form FDA 3537 to allow facilities to write in the type of food that is being held at the facility in order to minimize the content of sections 10a and 10b on the form.

(Response 63) We decline the suggestion to modify sections 10a (general product categories for human consumption) and 10b (general product categories for animal consumption) to a blank column for the facility to write in a food category. We believe that it makes the registration process easier for facilities if there are designated food product categories from which they can choose. We also believe that the specific food product categories currently on Form FDA 3537 are necessary and appropriate for food facility registration, as indicated in the Food Product Categories Guidance.

(Comment 64) One comment agrees with the designation of “Bakery products, dough mixes, or icings [21 CFR 170.3(n)(1),(9)]” as a food product category, provided that the food product category is intended to encompass all of the foods covered by § 170.3(n)(1) and (9). The comment would alternatively support separate food product categories for the products covered by § 170.3(n)(1) and (9) if the different products covered by the two different provisions have unique risk profiles.

(Response 64) The food product category “Bakery products, dough mixes, or icings [21 CFR 170.3(n)(1),(9)]” is intended to encompass all of the foods covered by § 170.3(n)(1) and (9). If we make changes to the food product categories, we will update the Food Product Categories Guidance.

#### *D. Requirement To Identify Activity Type*

(Comment 65) Some comments state that requiring activity type information would be burdensome for facilities that hold many products (*i.e.*, warehouses) and perform various activities. Comments also state that this information is irrelevant to FDA’s mission and operations, including inspection planning, determining inspection frequency, and responding to food-related emergencies. These comments suggest that activity type information should remain optional, as it is under the current food facility registration regulation. Other comments, however, state that they support the requirement that facilities provide

activity type information. One comment states that the requirement will reduce the need for FDA to reach out to facilities to gather this same information. One comment suggests that FDA obtain activity type information in a written text field on the registration form instead of using a matrix similar to that currently used on Form FDA 3537, which matches activity type information with food product category information. The comment is concerned that warehouses that hold a number of different foods would be required to make frequent updates.

(Response 65) We disagree with the comments suggesting that we not require activity type information. As stated in the proposed rule (80 FR 19160 at 19173), information about activity type will provide FDA with important information regarding a facility’s role in the U.S. food supply system, allowing us to better assess the facility’s potential impact in cases of bioterrorist incidents or other food-related emergencies.

Improved information about activity types will also allow us to better prepare investigators for inspections and assign appropriate investigators, and 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 will aid FDA in implementing section 421 of the FD&C Act, which requires FDA to identify high-risk facilities and mandates more frequent inspections for domestic high-risk facilities than for domestic non-high-risk facilities.

Section 421(a)(1) of the FD&C Act 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” (see section 421(a)(1)(F) of the FD&C Act). Among the criteria we have deemed necessary and appropriate for this purpose are type of activity conducted at the facility (manufacturer/processor, packer/repacker, etc.). Because the risk-based inspection mandate in section 421 of the FD&C Act applies to facilities registered under section 415, and because we have 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 of the FD&C Act, the activity type information will allow us to more efficiently enforce section 421.

Therefore, we decline the recommendation to keep the activity types as optional data elements. We will consider IT and formatting solutions

that will make it less burdensome to provide this information, such as drop down menus or “Select all” options. Regarding the request that FDA obtain activity type information through a written text field, we decline that request. We do not believe that using written text fields would easily enable facilities to match the activity type information with the food product category information. Also, the comment does not explain why written text fields would be less burdensome than the matrix used on current Form FDA 3537, which allows facilities to check boxes indicating applicable activity types. (Currently, the activity type information on Form FDA 3537 is optional.)

(Comment 66) One comment asks whether foreign facilities must provide activity type information about all foods associated with the facility, or only about foods exported for consumption in the United States.

(Response 66) Facilities are only required to provide activity type information about food that the facility manufactures/processes, packs, or holds for consumption in the United States. FDA is requiring information about activity types to help FDA better assess the facility’s potential impact in cases of bioterrorist incidents or other food-related emergencies, and to help the Agency identify facilities with which to communicate on various issues, among the other reasons discussed in the previous paragraphs. We anticipate that we will only need to assess facilities and communicate with facilities with respect to foods that are consumed in the United States.

(Comment 67) A comment suggests that FDA provide definitions for the following activity types: Ambient human food storage warehouse/holding facility; refrigerated human food warehouse/holding facility; and frozen human food warehouse/holding facility.

(Response 67) In the proposed rule, we provided tentative definitions for the activity types required in § 1.232 (80 FR 19160 at 19173 to 19174) and we requested comment on whether to define the specified activity types. We conclude that it is not necessary to provide definitions in the regulatory text, considering that we provided tentative definitions in the proposed rule and that we understand the activity type terms to be generally well-understood by industry. If additional clarification is needed, we will consider providing guidance on the activity type definitions, as appropriate. We believe that any such clarification will be better provided in a guidance document that follows our GGP regulations in 21 CFR

10.115 because we will be better able to provide clarification quickly as the need may arise.

(Comment 68) One comment recommends that FDA divide the “ambient human food warehouse/holding facility,” “refrigerated human food warehouse/holding facility”, and “frozen human food warehouse/holding facility” activity types into two sub-categories: “Ambient human food warehouse/holding facility”, and “refrigerated/frozen human food warehouse/holding facility.” The comment states that three sub-categories are not useful and may lead to confusion.

(Response 68) We disagree with this comment. Information distinguishing whether a facility is engaged in refrigerated or frozen warehousing/holding is important to the Agency when responding to food-related emergencies. Generally speaking, the closer a refrigerated or frozen food gets to ambient temperature, the more potential there is for spoilage and foodborne illness to occur. Refrigerated foods have a more narrow window before they reach a temperature where spoilage occurs. Facilities that warehouse such foods would therefore be of most concern to FDA in an emergency involving power outages. For example, during a response to a natural disaster in which power outages occur, the Agency might choose to first focus on refrigerated warehouses to ensure proper handling of foods that are at risk of spoilage and foodborne illness.

(Comment 69) A comment requests that FDA provide clarification regarding the “farm mixed-type facility” activity type. Specifically, the comment asks FDA to confirm whether it is acceptable for a farm that packs fresh produce from other farms to register as a “farm mixed-type facility.” The comment also asks FDA to confirm that a farm that packs its own produce should not register.

(Response 69) In § 1.227 of our regulations, we define a mixed-type facility as an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the “farm” definition that require the establishment to be registered. FDA added the definition in § 1.227 for mixed-type facilities in the final rule for “Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food.” Also in that rulemaking, we revised the “farm”

definition in § 1.227 so that it no longer limits establishments that fall within the “farm” definition to those that pack or hold food grown, raised, or consumed on that farm or another farm under the same ownership. Under the revised “farm” definition in § 1.227, an establishment devoted to the growing of crops, the raising of animals, or both, would remain within the “farm” definition if it packs and holds RACs grown on that farm or another farm under the same ownership, and also if it packs and holds RACs grown on another farm. Any such establishment that meets the “farm” definition is not subject to the requirement to register under section 415 and therefore is not required to provide FDA with activity type information in accordance with this final rule. However, if the farm engages in other activities that require the establishment to be registered, it is required to provide FDA with activity type information in accordance with § 1.232(a)(8) and select farm mixed-type facility.

(Comment 70) One comment asks FDA to clarify what it means by farm mixed-type facility as a facility type and to develop a plan for on-farm inspections and to train investigators on conducting such inspections. Furthermore, the comment requests that FDA develop outreach and education plans to help farms understand the registration process, in particular farms that have to register because they are mixed-type facilities.

(Response 70) In § 1.227 of our regulations, we explain that a mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered. We will consider appropriate ways to train and prepare investigators for inspections of mixed-type facilities. As to the request that FDA provide education and outreach to help farms understand the registration process, we agree with comments that stress the importance of education and outreach. Within the Agency, we are establishing a Food Safety Technical Assistance Network and we plan to provide updated guidance concerning the registration requirements.

(Comment 71) Comments encourage FDA to allow the activity type for facilities that warehouse/hold food to indicate that their storage facilities are solely engaged in the storage of

packaged food not exposed to the environment. The comment states that this information will assist FDA in setting inspection priorities and conducting inspections at storage facilities. The comment states that such facilities pose a very limited, if any, food-safety risk. The comment also mentions that a citizen petition submitted for FDA review requests an exemption from certain FSMA requirements for storage facilities that are solely engaged in the storage of packaged food not exposed to the environment.

(Response 71) FDA declines this suggestion. We agree that different food safety requirements should apply to facilities solely engaged in the storage of unexposed packaged food, and in the final rule for preventive controls for human food we have exempted such facilities from 21 CFR part 117, subparts C (hazard analysis and risk-based preventive controls) and G (supply-chain program), and provided for modified requirements if the food requires time/temperature control for safety. However, for purposes of food facility registration, we do not agree that it is necessary for facilities to separately identify whether they are solely engaged in the storage of packaged food not exposed to the environment. In the final rule, we are dividing the (previously optional) activity type of “warehouse/holding facility” for facilities that hold food for human consumption into three sub-categories. Those three sub-categories are “ambient human food temperature warehouse/holding facility,” “refrigerated human food warehouse/holding facility,” and “frozen human food warehouse/holding facility.” We anticipate that the information that we will gather from these sub-categories will be sufficient to allow us to more efficiently respond to food-related emergencies. 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. We do not anticipate that information about whether a facility is solely engaged in the storage of unexposed packaged food will be of much additional utility in responding to an emergency food incident.

Regarding the citizen petition submitted to FDA (Docket No. FDA 2011-P-0561-CP), the Agency will respond to the citizen petition in accordance with 21 CFR part 10.

(Comment 72) A comment encourages FDA to leave sections 8 and 9 on form FDA 3537. The comment states that

these sections contain important information about food facilities.

(Response 72) We do not plan to remove sections 8 (“Seasonal facility date”) from Form FDA 3537. In that section, we provide an optional field for facilities to give the approximate dates that they are open for business, if their operations are on a seasonal basis. We plan to retain seasonal facility dates as an optional field. Section 1.233 of the final rule provides that FDA encourages, but does not require, registrants to submit items that are indicated as optional on Form FDA 3537.

Regarding section 9 (“Types of storage”) on Form FDA 3537, we are removing this section from the form. In that section, which is for facilities that are primarily holders, we make it optional for facilities to identify whether the facility’s type of storage is ambient storage, refrigerated storage, or frozen storage. Because facilities are now required to provide this information as part of the activity type requirement in § 1.232(a)(8) of the final rule, it would be duplicative to provide facilities with the option of completing this information in a separate section of the registration form.

(Comment 73) Comments recommend that LACF and acidified food processing be treated as an activity type, not a food product category. Comments state that there are many foods that are LACF or acidified foods that also fall within other food product categories (such as baby food, cheese, and salad dressings). Comments state that FDA investigators would be able to better prepare for inspections if facilities select the activity type “low-acid and acidified food processing” in conjunction with the applicable food product category (e.g., cheese) for the food produced at the facility.

(Response 73) We agree with these comments. The final rule includes acidified food and low-acid food processing in the list of activity type options. In addition, we will update the Food Product Categories Guidance to remove acidified foods and LACF as food product categories. We also plan to update the Food Product Categories Guidance to list molluscan shellfish as a food product category. Previously, Form FDA 3537 included “molluscan shellfish establishment” as an optional activity type. However, the list of activity types in this final rule does not include molluscan shellfish establishments. We are revising Form FDA 3537 to reflect these changes.

#### *E. Requirement To Provide Assurance That FDA Will Be Permitted To Inspect*

(Comment 74) One comment disagrees with the requirement that facilities provide assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. The comment states that this requirement violates a country’s sovereignty and that facilities are subject to the national laws of the country in which they are located, and should therefore not be required to agree to inspection by FDA without the permission of their country’s government.

(Response 74) Section 415(a)(2) of the FD&C Act, as amended by section 102(b) of FSMA, requires that food facility registrations 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. We do not agree that requiring this assurance violates the sovereignty of countries in which foreign facilities are located. The assurance is required for food facilities in order to complete their food facility registration. The assurance does not require foreign facilities to disregard the laws of the countries in which they are located, nor does it require the foreign countries to relinquish any sovereignty. When FDA selects foreign food facilities for inspection that have registered with FDA because they manufacture/process, pack, or hold food for consumption in the United States, FDA involves the foreign governments by generally sending an advance notification to the Competent Authority responsible for food safety in the country where FDA will be conducting an inspection. Under the FSMA amendments to the FD&C Act, FDA has the authority to take action if the Agency encounters inspection refusals. Specifically, FDA may refuse admission of food into the United States when that food is from a foreign factory, warehouse, or other establishment of which the owner, operator, or agent in charge, or the government of the foreign country, that refuses to allow inspection (see section 807(b) of the FD&C Act).

#### **VIII. Comments on Proposed § 1.233—Are There Optional Items Included in the Registration Form?**

We proposed to amend § 1.233 to provide that FDA encourages, but does not require, registrants to submit items that are indicated as optional on the Form FDA 3537. We proposed for this amendment to remove the optional items currently listed § 1.233. We are finalizing this amendment as proposed, for two reasons. First, the final rule

converts several of the optional items in current § 1.233 into required items in revised § 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.

#### **IX. Comments on Proposed Amendments to § 1.234—How and When Do You Update Your Facility’s Registration Information?**

We proposed to amend § 1.234(a) to shorten the time period for a food facility to update its registration from 60 to 30 calendar days. We also proposed to amend § 1.234(b) to provide that when the reason for the update is a change in owner, the former owner must cancel the registration in 30 calendar days instead of the 60 calendar days allotted in current § 1.234(b). As discussed in the paragraphs that follow, we are not finalizing these proposals.

In addition, we proposed to amend § 1.234(a) to require that 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. We are finalizing this requirement in the final rule, with modifications. Final § 1.234(a) provides that for updates not submitted by the owner, operator, or agent in charge, the update must include the email address of the individual who authorized the update, unless FDA has granted a waiver under § 1.245. We are allowing for a waiver for the same reasons as those discussed in Response 44.

Further, we proposed to amend § 1.234(d) to provide that beginning January 4, 2016, electronic updates will be mandatory unless a waiver under § 1.245 has been granted. For the reasons discussed in section VI.A of this document, final § 1.234(d) delays the requirement for electronic submission of cancellations. Specifically, final § 1.234(d) provides that updates must be submitted electronically beginning January 4, 2020. Final § 1.234(d) also provides that if FDA has granted a waiver under § 1.245, cancellations may be made by mail or fax.

(Comment 75) Comments oppose shortening the time period for registration updates. Comments state that FDA did not provide any examples of when a shortened time period for updates would have better enabled FDA to schedule inspections or more effectively respond to food safety issues. Comments state that a shortened time period would increase the regulatory burden on food facilities. One comment

encourages FDA to consider the difference in public holidays as well as time and language differences between the United States and foreign countries. The comment states that facilities in foreign countries may need a longer amount of time to update the information and suggests keeping 60 calendar days for submitting updates. Some comments state that, given the potential for criminal penalties for committing prohibited acts under the FD&C Act, the shortened time period does not provide a reasonable amount of time for compliance, particularly for businesses that are in the midst of reorganizations.

(Response 75) In response to these comments, we are not shortening the time period for the submission of updates in § 1.234(a). Consequently, we will continue to allow owners, operators, or agents in charge of a facility 60 calendar days to submit updates to any changes of the required registration elements previously submitted. We believe that this strikes an appropriate balance between the concerns expressed in the comments and FDA's need to maintain an accurate and up-to-date registration database. In addition, we are not shortening the time period in § 1.234(b). Consequently, when the reason for the update is a change in owner, the former owner will continue to have 60 calendar days to cancel the registration, as is currently provided in current § 1.234(b).

#### **X. Comments on Proposed Amendments To § 1.235—How and When Do You Cancel Your Facility's Registration Information?**

We proposed to amend § 1.235 to shorten the time period for cancelling registrations from 60 calendar days to 30 calendar days. Specifically, proposed § 1.235(a) would 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). As discussed in the following paragraphs, we are not finalizing this proposal.

In addition, we proposed to amend § 1.235 to require in § 1.235(d) that beginning January 4, 2016, owners, operators, or agents in charge must cancel their registrations electronically, unless a waiver under § 1.245 has been granted. For the reasons discussed in section VI.A of this document, final § 1.235(d) delays the requirement for electronic submission of cancellations.

Specifically, final § 1.235(d) provides that cancellations must be submitted electronically beginning January 4, 2020. Final § 1.235(d) also provides that if FDA has granted a waiver under § 1.245, cancellations may be made by mail or fax. Also in the proposed rule, we proposed to amend § 1.235(b)(5) to require that for cancellations not submitted by the owner, operator, or agent in charge of the facility, the cancellation must include the email address of the owner, operator, or agent in charge who authorized the cancellation. We are finalizing this requirement in the final rule, with modifications. Final § 1.235(b)(5) provides that cancellations not submitted by the owner, operator, or agent in charge must include the email address for the individual who authorized the cancellation, unless FDA has granted a waiver under § 1.245 of the final rule. We are allowing for waivers for the same reasons discussed in Response 44.

In addition, we are deleting proposed § 1.235(d)(7) of the final rule, because it is not applicable for cancellations. Furthermore, we have redesignated proposed § 1.235(d)(8) to § 1.235(d)(7) in the final rule and are making edits to clarify the process FDA will use to confirm cancellations submitted through mail or fax. We state in § 1.235(d)(7) of the final rule that the registration will be considered cancelled once FDA enters the facility's cancellation data into the registration system. FDA will send the registrant a cancellation confirmation.

(Comment 76) Comments disagree with FDA's proposal to shorten the time period for cancellations from 60 calendar days to 30 calendar days. Comments state that reducing the time period for cancellations would be burdensome without providing any commensurate benefit to public health. Additionally, some comments suggest that the time period should be increased, not decreased, to 90 days.

(Response 76) In response to these comments, we are not shortening the time period for the submission of cancellations in § 1.235(a) of the final rule. Consequently, owners, operators, and agents in charge will continue to be required to cancel registrations within 60 calendar days of the reason for cancellation. Just as with our decision to not shorten the time period for the submission of updates in § 1.234(a) of the final rule, we believe that this strikes an appropriate balance between the concerns expressed in the comments and FDA's need to maintain an accurate and up-to-date registration database. We do not believe that lengthening the time

period for submitting cancellations would strike an appropriate balance. Current § 1.235 provides 60 calendar days to cancel, and we are not aware of any specific instances in which facilities have found this time period to cause difficulties.

#### **XI. Comments on Proposed Amendments to § 1.241—What Are the Consequences of Failing To Register, Update, Renew, or Cancel Your Registration?**

Proposed § 1.241(c) proposed to amend the registration regulation to provide that FDA may cancel registrations in certain additional circumstances in addition to those currently specified in current § 1.241. Specifically, we proposed to amend § 1.241(c) to provide that FDA will cancel a registration if FDA 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 FDA by a person not authorized to submit the registration under § 1.225. In addition, proposed § 1.241(c) proposed to further amend the registration 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). Similarly, we proposed to add § 1.241(b) to the registration regulation 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.

FDA proposed 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 accuracy and utility of the food facility registration database such that FDA would be able to maintain a more up-to-date list of registered facilities in accordance with section 415(a)(5) of the FD&C Act. A more accurate and up-to-date list will enable investigators to more efficiently locate food facilities for inspection and will better enable FDA to act quickly in responding to a threatened or actual terrorist attack on the U.S. food supply or other food-related emergency. In addition, our proposal to cancel registrations when a facility has failed to renew its registration in accordance with § 1.230(b) was designed to respond

to the FSMA amendments. 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 will allow FDA to efficiently enforce the renewal requirement. It will 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. The proposal is also 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 are finalizing the amendments to § 1.241 as proposed, with one modification. We are revising § 1.241(c) of the final rule to state that if we cancel a facility's registration, we will send a confirmation of the cancellation using contact information submitted by the facility in the registration database. We are making these edits to clarify the process FDA will use to confirm cancellations in these additional circumstances.

(Comment 77) Comments request that the final rule include safeguards for when inadvertent technical mistake are the basis for cancellation, such as a period of time during which facilities may make corrections or a response process initiated by FDA. Comments also state the final regulations should specifically state that FDA will send notice to facilities facing potential cancellations indicating the Agency's intent to cancel the registration and the basis for the cancellation. Comments state that wrongful cancellations could cause significant hardship. Some comments also state that facilities should have 60 days to take corrective action before FDA cancels a registration. Some comments state that registrants should have due process prior to FDA cancelling a registration.

(Response 77) Our amendments to § 1.241(c) will maintain the requirement in current § 1.241(b) that FDA will cancel registrations if the Agency "independently verifies" that the specified circumstances are satisfied. In the proposed rule, we stated that we anticipate that in many cases it would be appropriate for FDA to send notices to facilities facing potential cancellation indicating our intent to cancel their registrations and the basis for such cancellations. We also stated that we anticipated 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 further

stated that we 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 FDA. We also stated in the proposed rule that we anticipated 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 those circumstances, a facility would have already received notice of its obligation to renew (80 FR 19160 at 19177). FDA understands the serious nature of cancelling a registration, and we plan to provide appropriate notice to facilities facing cancellation consistent with our statements in the proposed rule. However, we decline the request to amend the regulatory text to specify the specific notice we will provide. The facts in each scenario involving a potential cancellation are likely to be unique, and we do not think it would be appropriate to follow a single procedure for each cancellation. In addition, we decline to commit to providing registrants 60 days after notice is provided before cancelling registrations. We believe that 30 days will generally provide registrants with sufficient time to respond to any questions or concerns raised by FDA and take corrective action if appropriate. 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 believe that this approach will provide adequate due process to facilities.

(Comment 78) Other comments urge FDA to provide a 30-day notice before a registration is considered expired, to ensure due process, and to allow facilities to respond. The comments state that facilities should have the opportunity to allow potential gaps in communication or misunderstandings to be resolved.

(Response 78) We do not agree that it is necessary to provide a 30-day notice before a registration is considered expired. Leading up to and throughout the registration renewal period, we plan to notify registrants of their obligation to renew their registrations and the deadline for doing so. We also plan to notify registrants that failure to renew their registrations in accordance with § 1.230(b) will cause FDA to consider the registrations expired. Additionally,

we plan to notify registrants that we will consider a food facility with an expired registration to have failed to register in accordance with section 415 of the FD&C Act. Because facilities will already receive notice of their obligation to renew throughout this process, we do not agree that it is necessary to provide an additional 30-day notice before cancelling registrations that expired because the facility has failed to renew its registration in accordance with § 1.230(b).

(Comment 79) Comments recommend that FDA provide similar procedures when cancelling a registration to those that the Agency provides when suspending a facility's registration, such as providing an opportunity for a hearing and an opportunity to reinstate the registration.

(Response 79) We disagree. As specified in section 415(b)(2) regarding registration suspensions, FDA will provide a registrant subject to a suspension order with an opportunity for an informal hearing on the actions required for reinstatement of registration and why the registration that is subject to suspension should be reinstated. Suspensions involve a factual determination by FDA that there is a reasonable probability of serious adverse health consequences or death. See section 415(b)(1) of the FD&C Act (providing that the Secretary may suspend a facility's registration if the Secretary 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). We do not believe that the same procedures used for registration suspensions are necessary for registration cancellations because registration cancellations are unlikely to present the kind of factual issues involved in registration suspensions.

Registration cancellations under § 1.241 do not involve determinations made by FDA regarding the probability of food safety hazards. They are instead based on a facility's failure to itself comply with certain requirements for food facility registration. Those requirements are administrative in nature. Further, we believe that the procedures in § 1.241 are adequate to ensure fairness. 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) of the final rule or the registration was submitted by a person not authorized to submit the registration under § 1.225. FDA will not cancel registrations in these circumstances if it does not independently verify the relevant facts. In addition, for registrations that FDA cancels as a result of the facility's failure to renew the registration, the facility will have received multiple notices from FDA reminding it of the registration renewal requirement. If we nevertheless cancel a registration in error, facilities should contact FDA so that we can look into the matter.

(Comment 80) Comments recommend that FDA annually review imports to determine whether registered foreign facilities have imported food into the United States during the preceding year and cancelling registrations for facilities that have not done so.

(Response 80) We decline to conduct such a review of registrations. The comment does not explain why such a use of FDA resources would be warranted, especially in light of the effect that the biennial registration renewal requirement has helped to routinely remove inactive registrations.

(Comment 81) One comment states that criminal and civil liability for lack of compliance with the registration requirements would be a disproportionate response from FDA. The comment states that the possibility of such liability may "result in a lack of willingness by U.S.-based agents to take responsibility" for foreign entities.

(Response 81) Under section 415 of the FD&C Act, owners, operators, and agents in charge of facilities are required to register with FDA. In addition, under section 301(dd) of the FD&C Act, the failure to register in accordance with section 415 is a prohibited act. Further, the causing of a prohibited act and being responsible for the commission of a prohibited act are subject to civil and criminal sanction under the FD&C Act (see sections 301, 302 (21 U.S.C. 332), and 303 (21 U.S.C. 333) of the FD&C Act). We believe that it is consistent with the FD&C Act for the registration regulation to specify in § 1.241 that the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act and a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act. Indeed, the registration regulation has specified this since 2003. To the extent that the comment is concerned about liability for a foreign facility's violations of requirements under section 415 of the

FD&C Act, FDA's practice is to take enforcement action based on the facts of the case and the seriousness of the violations.

(Comment 82) Comments state that some establishments, such as farms, have registered with FDA even though they are not required to. The comments state that FDA should not cancel the registrations for such establishments. In addition, some comments urge FDA to allow entities to register that are not required to register, stating that FDA may find it useful to have information about such entities.

(Response 82) We disagree. Not all food-related establishments are required to register under section 415 of the FD&C Act. Only food facilities not exempt under § 1.266 are required to register, and farms are not food facilities. See section 415(c)(1) (providing that the term "facility" does not include farms); 21 CFR 1.226 (establishing that the registration requirements in 21 CFR part 1, subpart H, do not apply to farms); 21 CFR 1.227 (establishing separate definitions for "facility" and "farm"). FDA uses registration information to identify facilities for inspection and for communications on both routine and emergency matters. A registration database that includes establishments registered as food facilities but that are not, in fact, food facilities hinders these efforts, compromising FDA's ability to strategically target inspections and communications. We therefore believe it is appropriate for FDA to cancel the registrations for such establishments. In addition, we do not believe that the comment has identified reasons why it would be useful to have entities participate in food facility registration under section 415 of the FD&C Act that are not required to register under section 415.

(Comment 83) A comment recommends that FDA conduct broad education and outreach regarding registration requirements, before seeking civil or criminal penalties on entities that are newly subject to registration requirements, and that therefore may be unfamiliar with the requirements.

(Response 83) We recognize that there will be questions about registration requirements. We agree that education and outreach are important, and we plan to develop additional education and outreach strategies as appropriate. In addition, we are establishing a Food Safety Technical Assistance Network to allow us to respond in a timely and consistent way to industry questions.

(Comment 84) Some comments urge FDA not to dispose of registration information from cancelled

registrations, stating that keeping this additional information on file could prove useful to FDA.

(Response 84) FDA will archive information from inactive food facility registrations as appropriate.

## **XII. Comments on Proposed Addition of § 1.245—Waiver Request**

In the proposed rule, we proposed for § 1.245 to provide that to request a waiver from the requirement to submit registrations and registration renewals electronically, a registrant must submit a written request to FDA that explains why it is not reasonable for the registrant to submit a registration or registration renewal electronically to FDA. In the proposed rule, FDA tentatively concluded 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 (80 FR 19160 at 19177 to 19178).

In the final rule, we are finalizing the option of a waiver. However, we are revising § 1.245 of the final rule to clarify that FDA must have already granted the waiver in order for the electronic submission requirement to not apply. We believe that this requirement was implicit in proposed § 1.245, but we have revised the regulatory text to avoid any possible confusion. We are also revising § 1.245 of the final rule to provide that a waiver is available not only from the requirement to submit registrations and registration renewals (which also includes abbreviated renewals) electronically, but also from the requirement to submit updates and cancellations electronically. In addition, we are also expanding the waiver option so that waivers are also available from the requirement in § 1.232(a)(6) to provide the email address of the owner, operator, or agent in charge of the facility, and also from the requirement in §§ 1.230(b) and (c), 1.232(a)(10), 1.234(a), and 1.235(b)(5) to provide the email address for the individual who authorized submission of a registration renewal, registration, update, or cancellation, respectively, when such submissions are not made by the owner, operator, or agent in charge of the facility. Finally, we are revising proposed § 1.245 to no longer refer to January 4, 2016, as the date on which electronic registration submissions will begin to be required. Instead of January 4, 2016, we now refer to January 4, 2020. Accordingly, final § 1.245 provides that under §§ 1.231(a)(2) and

(b), 1.234(d), and 1.235(d), beginning January 4, 2020, the owner, operator, or agent in charge must submit registrations, registration renewals, updates, and cancellations to FDA electronically unless FDA has granted a waiver from such requirement. Section 1.245 of the final rule also provides that under § 1.232(a)(6), the registration must include the email address of the owner, operator, or agent in charge of the facility, unless FDA has granted a waiver from such requirement. In addition, § 1.245 provides that under §§ 1.230(b) and (c), 1.232(a)(10), 1.234(a), and 1.235(b)(5), registration renewals, registrations, updates, and cancellations not submitted by the owner, operator, or agent in charge must include the email address for the individual who authorized the submission, unless FDA has granted a waiver. Section 1.245 of the final rule further provides that to request a waiver from these requirements, the registrant must submit a written request to FDA that explains why it is not reasonable to submit the registration, registration renewal, update, or cancellation to FDA electronically or to provide the email address of the owner, operator, or agent in charge of the facility.

(Comment 85) Comments support the proposed waiver provision, but some comments request that we clarify the grounds for granting waivers from the electronic registration requirement. Some comments request that FDA consider reasons for why a registrant would request a waiver from electronic submission of food facility registration in addition to those discussed in the proposed rule. Comments state that conflicting religious beliefs are not necessarily the only beliefs that lead an individual or entity to decide not to use technology. Comments state that there may be other reasons, such as philosophical or political reasons. Other comments state that the regulatory text should specifically recognize religious objections and lack of reasonable access to the Internet as reasons to grant a waiver from the electronic registration requirement.

(Response 85) We do not believe it is necessary to provide examples in the regulatory text for when FDA would grant a waiver because we believe that each waiver request should provide an explanation as to why it is not reasonable for the particular facility to submit a registration or registration renewal electronically to FDA, and we intend to consider each waiver request on a case-by-case basis. FDA stated in the proposed rule 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. However, we do not intend to limit waivers only to those facilities that identify a religious reason for seeking a waiver or that point to lack of access to the Internet.

We will consider whether it would be helpful to provide additional guidance on the process for requesting waivers under § 1.245 of the final rule.

(Comment 86) Comments request that registrants not be required to submit additional waiver requests after a request has already been granted.

(Response 86) We agree that if a waiver has been requested and granted, the facility should not be required to submit future waiver requests each time the facility submits a renewal or updates the facility's registration information. Accordingly, once FDA grants a waiver, we will consider the waiver to be in effect for as long as the reasons for the waiver remain unchanged and the registration has not been cancelled.

### **XIII. U.S. Agent Voluntary Identification System**

We requested comment on whether to issue a future guidance document to provide for the establishment of a U.S. Agent Voluntary Identification System (VIS or the system), or to otherwise create such a system. As 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.

We sought comments on the creation of this voluntary system and whether it 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.

(Comment 87) Numerous comments state the creation of a VIS would be beneficial.

(Response 87) We agree, and we plan to implement a voluntary U.S. agent identification system as described in the proposed rule. As we stated in the proposed rule, we will follow our GGP regulations in 21 CFR 10.115 when we implement this system (80 FR 19160 at 19179).

(Comment 88) Comments request that the system provide a mechanism for electronic resignation by the U.S. agent, as well as notice of changes to the foreign facility's registration, including when the registration is cancelled.

(Response 88) Under § 1.234(a) of the final rule, the owner, operator, or agent in charge of a facility may authorize an individual to update a facility's registration. The authorized individual may be, but is not required to be, the U.S. agent for the facility. If the authorized individual is the U.S. agent for the facility, the U.S. agent may update the information in the registration about who serves in that role. In addition, FDA plans to allow U.S. agents to electronically notify FDA that they no longer serve as the U.S. agent for a foreign facility. We also anticipate that the system will notify the U.S. agent if the registration for the foreign facility is cancelled. We plan to provide further information and details about the system in a future guidance document.

### **XIV. Editorial Changes and Other Changes**

#### *A. Editorial Changes*

Proposed § 1.231 would provide that beginning January 4, 2016, electronic registration will be mandatory, including registration renewals, unless a waiver has been granted for the registrant. Proposed § 1.231 would also provide that beginning on 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. Proposed § 1.234 would require updates to be submitted electronically after January 4, 2016, unless a waiver has been granted in § 1.245. Proposed § 1.235 would require cancellations to be submitted electronically after January 4, 2016, unless a waiver has been granted in § 1.245. Proposed § 1.245 also mentions January 4, 2016. Because the final rule

is being published after January 4, 2016, we are finalizing §§ 1.231, 1.234, 1.235, and 1.245 without a reference to “January 4, 2016.” Furthermore, we note that for reasons stated elsewhere in this **Federal Register** document, we are replacing “January 4, 2016” with “January 4, 2020” in §§ 1.231, 1.234, 1.235, and 1.245 of the final rule.

We are making other changes in §§ 1.231, 1.232, 1.234, and 1.235 of the final rule to improve clarity. The changes are as follows:

- Using “submit” or “submission” instead of “complete” or “completion” in §§ 1.231, 1.234, and 1.235 of the final rule;
- Using “sends” instead of “transmits” in §§ 1.231 and 1.234 of the final rule;
- Adding “you” in §§ 1.231, 1.232, and 1.234 of the final rule to clarify that we are referring to the registrant;
- Deleting language that mentions the registrant not having “reasonable access to the Internet” in §§ 1.231, 1.234, and 1.235 of the final rule;
- Deleting “electronic” and “automatically” in §§ 1.231 and 1.235, respectively, in the final rule.

Furthermore, we stated in proposed §§ 1.231, 1.234, 1.235, and 1.245 that the zip code for our College Park, Maryland address is “20993.” In §§ 1.231, 1.234, 1.235, and 1.245 of the final rule, we are correcting the zip code to “20740.” In addition, the street has been renamed from “Paint Branch Parkway” to “Campus Drive” and the street number has been changed from “5100” to “5001.” Therefore, in the final rule, we are changing the street name and number to “5001 Campus Drive.”

#### *B. CD-ROM Submissions*

We proposed to delete the option to submit and update multiple registrations by CD-ROM. Specifically, we proposed to remove the option to use CD-ROM for multiple registration submissions in § 1.231(c) as well as the option to use CD-ROM for updates of multiple submissions in § 1.234(e). FDA stated that it proposed to make this change because we tentatively concluded that this method of submitting, updating, and canceling registrations is outdated and obsolete. We did not receive comments on this issue and we are finalizing these changes as proposed.

In addition, in the preamble to the proposed rule, we stated that we were proposing to remove the option to use CD-ROM in § 1.235(e) (*i.e.*, the option for cancellations of multiple registrations). In our proposed regulatory text, however, we

inadvertently retained the option to submit multiple cancellations using CD-ROM in § 1.235(e). That was an error, and this final rule removes § 1.235(e) from § 1.235.

#### **XV. Economic Analysis of Impacts**

FDA has examined the impacts of this final 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). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the additional costs per entity of this rule are small, the Agency also believes that this final rule will not have a significant economic impact on a substantial number of small entities.

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 issuing “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 \$146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The final analyses conducted in accordance with these Executive Orders and statutes will be made available in the docket for this rulemaking (Ref. 13).

#### **XVI. Paperwork Reduction Act of 1995**

This final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with

an estimate of the annual reporting burden. Included in the 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.

*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:* In the **Federal Register** of April 9, 2015 (80 FR 19159), we published a notice of proposed rulemaking including a Paperwork Reduction Act (PRA) analysis of the information collection provisions found in the proposed regulation. In the analysis we invited comments 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.

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 final rule will require food facilities to submit certain additional registration information to FDA with initial registrations, updates, and biennial renewals. The final rule will also require mandatory electronic registration submissions beginning in 2020, which we estimate would cause some food facilities to submit a request for a waiver from that requirement. Finally, the final rule will establish certain verification procedures. These requirements are discussed in depth in the preamble to the final rule.

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 final rule is 278,382 hours, a decrease of 189,735 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 appear to have had the effect of removing many out-of-date registrations from the registration system. As discussed in the PRA for the proposed rule, we are making 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.

We received many comments regarding requirements of this rule, but none of the comments specifically addressed the four topics about which we invited comments in the PRA

analysis that accompanied the proposed rule.

Although FDA is making some generally minor revisions to the proposed rule, we are finalizing most of the key aspects of the proposed rule. The following three changes are substantial enough to require us to revise the estimates in the PRA for the proposed rule: (1) We are clarifying that if a waiver under § 1.245 has been granted from the electronic submission requirement, the facility is not required to submit future waiver requests each time the facility submits a renewal or update; (2) we will continue to allow 60 calendar days to submit updates to registrations in § 1.234, instead of shortening the time period to 30 calendar days as we proposed; and finally (3) we plan to implement a VIS for U.S. agents.

These revisions are necessary to address changes to the proposed regulation included in this final rule, as discussed in the following paragraphs. For more information on our original calculations of the information collection burden associated with this rulemaking, you may refer to the PRA analyses found under Docket No. FDA–2002–N–0323 at <http://www.regulations.gov>.

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

TABLE 5—ESTIMATED ONE TIME REPORTING BURDEN <sup>1</sup>

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 minutes) .....	31,009
Waiver requests (1.245) .....	2,121	1	2,121	0.17 (10 minutes) .....	361
<b>Total One Time Reporting Burden .....</b>	.....	.....	.....	.....	<b>31,370</b>

<sup>1</sup> There are no operations and maintenance costs associated with one-time recordkeeping burden.

To determine the number of facilities in table 5, 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 Small Business Administration’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 already 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 this final rule. We estimate an increase in the average burden per response due to the new data elements required by this final 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 will 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. As explained in the preamble to the final rule, we revised the final rule and no longer require facilities to use D-U-N-S numbers. Instead, the final rule requires the use of a UFI recognized as acceptable by FDA. We are also postponing the requirement to submit a UFI until the registration renewal period beginning October 1, 2020. We estimate that entering a unique facility identifier requires, on average, an additional minute per response. Thus, we estimate that entering these five new data

elements will require a total of 5 additional minutes. We estimate that the submission of the FSMA data elements and new data elements will 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 172,274 facilities × 0.18 hours = 31,009 hours. According to 2014 registration data, 2,121 registrations were from facilities that submitted paper registrations. We believe these same facilities are more likely to request a waiver from the requirement to

electronically submit their registration. We estimate that it will take a respondent 10 minutes to prepare the waiver request submission and attach it to their paper Form FDA 3537 registration submission. Thus, the one-time burden of submitting waiver requests is estimated to be 361 hours (2,121 × 0.17 hours), as reported in table 5. The estimated total one-time burden for currently registered facilities is therefore 31,370 hours.

We estimate the annual burden for this information collection as follows:

TABLE 6—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

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) .....	53,836	1	53,836	1.2	64,603
Cancellations (1.230(b)) .....	6,390	1	6,390	1	6,390
Biennial renewals (1.235) .....	97,883	1	97,883	0.38	37,196
Third party registration verification procedure .....	41,256	1	41,256	0.25	10,314
U.S. Agent verification procedure with VIS .....	57,070	1	57,070	0.25	14,268
<b>Total Hours</b> .....					<b>278,382</b>

<sup>1</sup> 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 this final rule is 278,382 hours, a decrease of 189,735 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 making 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 on an annualized basis 97,833 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.) We expect that this final rule will add an additional 11 minutes to that burden as a result of the required 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 6, rows 1 and 2.

This final rule does not shorten the time period for updates from 60 calendar days to 30 calendar days as originally proposed. We are not finalizing our proposal to change the current requirement that updates take places within 30 calendar days; instead, we are continuing to allow 60 calendar days for updates, as provided in current § 1.234. In the PRA analysis for the proposed rule, in which we estimated

the burden for the proposed 30-day update requirement, we estimated that 68,518 respondents (70 percent of facilities) would submit updates each year. For a 60-day update requirement, we estimated that the number of respondents was 53,836 per year (55 percent of facilities). The average burden per response for updates remains unchanged as 1.2 hours, as reported in table 6 row 3. In the proposed rule, we also proposed to shorten the time period to submit cancellations from 60 calendar days to 30 calendar days. Although we are not finalizing that proposal, we have not changed our estimate of the average burden per response for cancellations because this final rule does not add new data elements for cancellations.

This final rule also establishes an abbreviated renewal process, which modifies our previous estimate that on average it will 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 6, row 5. This estimate takes into account that some registered firms will be able to

take advantage of the abbreviated renewal process, while other firms will take more time to prepare and submit the renewal, as discussed in the preliminary economic impact analysis.

Furthermore, this final rule also establishes 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. In connection with requiring this verification process, this final rule adds 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 takes 15 minutes (0.25 hour) to participate in FDA's verification procedure. We have not changed this estimate. We further estimate that 82,513 registrations will be affected once every other year, or 41,256 annually. Thus, the total annual burden of these verifications is estimated to be 10,314 hours ( $41,256 \times 0.25 \text{ hour} = 10,314 \text{ hours}$ ), as reported in table 6, row 6.

For the U.S. agent verification process, in the PRIA we estimated a resulting burden from the verification procedure to be about 30 minutes (0.5 hours) by 114,139 affected registrations once every 2 years, or 57,070 facility registrations annually. However, this final rule also provides for the creation of a U.S. agent VIS, which we estimate will cut the time for verification procedures for U.S. agents in half (from 30 minutes to 15 minutes). As currently envisioned, the system is 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 will allow a U.S. agent to directly provide their 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 created and updated by the facility, rather than the U.S. agent for the facility. We expect that the system will allow agents to provide their name, full mailing address, phone number, email address, and an 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 provides this information, FDA will provide the agent with an

identification number that the agent could provide to foreign facilities it has agreed to represent as a U.S. agent. If a foreign facility uses a U.S. agent identified in the system, the facility will have the option of providing the name and 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 will 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, it will 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.

We expect that 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, that we will consider the use of that identification a verification of U.S. agent information for purposes of the U.S. agent verification step. Thus, we estimate the total annual burden of the foreign facility U.S. agent verifications to be 14,268 hours ( $57,070 \times 0.25 \text{ hour} = 14,268$ ), as reported in table 6, row 7.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

#### **XVII. Analysis of Environmental Impact**

We have determined under 21 CFR 25.30(j) 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.

#### **XVIII. Federalism**

We have analyzed the final rule in accordance with the principles set forth in Executive Order 13132. We have

determined that the rule does not contain policies that 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 conclude that the 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.

#### **XIX. References**

The following references are on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA, Amendments to Registration of Food Facilities—Preliminary Regulatory Impact Analysis FDA-2002-N-0323, (<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM444325.pdf>), April 2015.
2. FDA Memorandum to Dockets on Records of Outreach," 2013. See Reference 7 to the 2014 supplemental human preventive controls notice.
3. FDA Memorandum, "Memoranda of Outreach," 2015.
4. FDA, "Food CGMP Modernization—A Focus on Food Safety," (<http://www.fda.gov/Food/GuidanceRegulation/CGMP/ucm207458.htm>), November 2, 2005. Accessed and printed on March 20, 2015. See Reference 1 to the 2013 proposed human preventive controls rule.
5. 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/ucm324778.htm>), October 2012. Accessed and printed on April 5, 2016.
6. FDA, "Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Sixth Edition)," (<http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM332460.pdf>), November 2014. Accessed on May 2, 2016.
7. USDA Agricultural Marketing Service, "Regional Food Hub Resource Guide," (<https://www.ams.usda.gov/sites/default/files/media/Regional%20Food%20Hub%20Resource%20Guide.pdf>), April

2012. Accessed and printed on April 6, 2016.
8. FDA, "Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration," Guidance for Industry, (<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm421827.pdf>), November 2014. Accessed and printed on April 6, 2016.
  9. FDA Memorandum, "D-U-N-S and Registered Facilities," July 9, 2014, from John Gardner, MD, MPH Senior Technical Advisor, Medical Informatics, Office of Informatics and Technology Innovation, Office of Information Management and Technology, Office of Operations.
  10. U.S. Government Accountability Office, "Government Is Analyzing Alternatives for Contractor Identification Numbers," (<http://www.gao.gov/assets/600/591551.pdf>), June 2012. Accessed and printed on April 5, 2016.
  11. Specially Designated Nationals List (SDN) (<https://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx>). Accessed on April 5, 2016.
  12. FDA, "FDA's Voluntary Qualified Importer Program," Draft Guidance for Industry, (<http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM448558.pdf>), June 2015. Accessed and printed on April 6, 2016.
  13. FDA, "Amendments to Registration of Food Facilities: Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, and Final Unfunded Mandates Reform Act Analysis," 2016.

**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, 21 CFR part 1 is amended to read as follows:

**PART 1—GENERAL ENFORCEMENT REGULATIONS**

■ 1. The authority citation for 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, 360ccc, 360ccc-1, 360ccc-2, 362, 371, 374, 379j-31, 381, 382, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271; Pub. L. 107-188, 116 Stat. 594, 668-69; Pub. L. 111-353, 124 Stat. 3885, 3889.

■ 2. In § 1.227, revise the definitions for "Retail food establishment" and "U.S. agent" to read as follows:

**§ 1.227 What definitions apply to this subpart?**

\* \* \* \* \*

*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. A "retail food establishment" also includes certain farm-operated businesses selling food directly to consumers as their primary function.

(1) 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.

(2) Sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business 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.

(3) For the purposes of this definition, "farm-operated business" means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).

\* \* \* \* \*

*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.

(1) 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.

(2) 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.

(3) 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, and telephone number, the individual who authorized submission of the registration renewal. In addition, the registration renewal must also identify the individual who authorized submission of the registration renewal by email address, unless FDA has granted a waiver under § 1.245. Each registration renewal must include the name of the individual submitting the registration renewal, and the individual's signature (for the paper option). Each electronic registration renewal must include the name of the individual submitting the renewal.

(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, registration renewal, or update 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, registration renewal or update, and you must certify that the information submitted is truthful and accurate. Each abbreviated registration renewal must include the name of the individual submitting the abbreviated renewal, and the individual's signature (for the paper option). Each electronic abbreviated registration renewal must include the name of the individual submitting the abbreviated renewal. For abbreviated registration renewals not submitted by the owner, operator, or agent in charge of the facility, the

abbreviated renewal must provide the email address of the individual who authorized submission of the abbreviated renewal, unless FDA has granted a waiver under § 1.245. 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, 2020, you must submit your registration or registration renewal to FDA electronically, unless FDA has granted you a waiver under § 1.245.

(3) After you submit your electronic registration, FDA will verify the accuracy of your unique facility identifier (UFI) recognized as acceptable by FDA and will also verify that the facility-specific address associated with the UFI 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 UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. With respect to electronic registration renewals, after you submit your electronic registration renewal, FDA will provide you with an electronic confirmation of your registration renewal. When you update your facility's UFI as part of your electronic registration renewal, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI 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 UFI and verifies that the facility-specific address associated with the UFI 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 submission of the registration, FDA will verify that the individual identified as having authorized submission of the

registration in fact authorized the submission 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 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 verify that the individual identified as having authorized submission of the registration renewal in fact authorized the submission 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 submission.

(5) For a foreign facility, after you submit your electronic registration, FDA will verify that the person identified as the U.S. agent for your foreign facility 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 verify that the person identified as the U.S. agent for your foreign facility 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 sends you your confirmation and registration number.

(b) *Registration or registration renewal by mail or fax.* Beginning January 4, 2020, you must submit your registration or registration renewal to FDA electronically, unless FDA has granted you a waiver under § 1.245. If FDA has granted you a waiver under § 1.245, you may register or renew a registration by mail or by fax.

(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, 5001 Campus Dr. (HFS-681), College Park, MD 20740 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 submit your registration, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI 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 UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. With respect to registration renewals, after you submit your registration renewal by mail or fax, FDA will provide you with a confirmation of your registration renewal. When you update your facility's UFI as part of your registration renewal, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI 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 UFI and verifies that the facility-specific address associated with the UFI 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 submission of the registration by mail or fax, FDA will verify that the individual identified as having authorized submission of the registration in fact authorized the submission 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 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 verify that the individual identified as having authorized submission of the registration renewal in fact authorized the submission 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 submission.

(7) For a foreign facility, after you submit your registration by mail or fax, FDA will verify that the person identified as the U.S. agent for your foreign facility 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 verify that the person identified as the U.S. agent for your foreign facility 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 you 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) Beginning October 1, 2020, the facility's UFI recognized as acceptable by FDA;

(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, and phone number of the owner, operator, or agent in charge of the facility. In addition, the email address of the owner, operator, or agent in charge is required, unless FDA has granted you a waiver under § 1.245;

(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) Acidified food processor;

(ix) Low-acid food processor;

(x) Farm mixed-type facility;

(xi) Packer/repacker;

(xii) Salvage operator (reconditioner);

(xiii) Animal food warehouse/holding facility;

(xiv) 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, and

telephone number, the individual who authorized submission of the registration. In addition, the registration must identify the individual who authorized submission of the registration by email address, unless FDA has granted a waiver under § 1.245. Each registration must include the name of the individual 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 60 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 individual who authorized submission of the update, unless FDA has granted a waiver under § 1.245.

(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 60 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 submit your electronic update, FDA will provide you with an electronic confirmation of your update. When updating UFI information, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI 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 UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. For foreign facilities, when updating information about your U.S. agent, FDA will verify that the person identified as the U.S. agent for your foreign facility 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 submission of the electronic update, FDA will verify that the individual identified as having authorized submission of the update in fact authorized the submission on behalf of the facility. FDA will not confirm the update to the registration until that individual confirms that he or she authorized the submission.

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

(d) *Update by mail or fax.* Beginning January 4, 2020, you must submit your update electronically, unless FDA has granted you a waiver under § 1.245. If FDA has granted you a waiver under § 1.245, you may update your facility's registration by mail or by fax.

(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, 5001 Campus Dr. (HFS-681), College Park, MD 20740 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 submit your update by mail or fax, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI 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 UFI and verifies that the facility-specific address associated with the UFI is the same address associated with your registration. For foreign facilities, when updating information about your U.S. agent, FDA will verify that the person identified as the U.S. agent for your foreign facility 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 submission of the registration update by mail or fax, FDA will verify that the individual identified as having authorized submission of the update in fact authorized the submission 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 60 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 individual who authorized submission of the registration cancellation, unless FDA has granted a waiver under § 1.245; 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 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 submission of the registration cancellation, FDA will verify that the individual identified as having authorized submission of the cancellation in fact authorized the submission 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 sends you your cancellation confirmation.

(d) *Cancellation by mail or fax.* Beginning January 4, 2020, you must cancel your registration electronically, unless FDA has granted you a waiver under § 1.245. If FDA has granted a waiver under § 1.245, you may cancel your facility's registration by mail or fax.

(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, 5001 Campus Dr. (HFS-681), College Park, MD 20740 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 submission of the registration cancellation by mail or fax, FDA will verify that the individual identified as having authorized submission of the cancellation in fact authorized the submission 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) Your registration will be considered cancelled once FDA enters your facility's cancellation data into the registration system. FDA will send you your cancellation confirmation.

■ 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 send a confirmation of the cancellation using contact information submitted by the facility in the registration database.

(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), 1.234(d), and 1.235(d), beginning January 4, 2020, you must submit your registration, registration renewal, updates, and cancellations to FDA electronically unless FDA has granted a waiver from such requirement. Under § 1.232(a)(6), you must provide the email address of the owner, operator, or agent in charge

of the facility unless FDA has granted a waiver from such requirement. In addition, under §§ 1.230(b) and (c), 1.232(a)(10), 1.234(a), and 1.235(b)(5), registration renewals, abbreviated registration renewals, registrations, updates, and cancellations not submitted by the owner, operator, or agent in charge must include the email address for the individual who

authorized the submission, unless FDA has granted a waiver. To request a waiver from these requirements, you must submit a written request to FDA that explains why it is not reasonable for you to submit your registration, registration renewal, update, or cancellation to FDA electronically or to provide the email address of the owner, operator, or agent in charge of the

facility. You must submit your request to: U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS-681), College Park, MD 20740.

Dated: July 7, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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