the rule would submit detailed comments weighing the burdens against benefits of continuing to include such non-material terms.

I look forward to thoughtful comments on all aspects of the proposal.

[FR Doc. 2015–24021 Filed 9–21–15; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 11, 16, 106, 110, 114, 117, 120, 123, 129, 179, 211, 225, 500, 507, and 579

[Docket No. FDA–2015–N–001]

RIN 0910–AG10 and 0910–AG36

The Food and Drug Administration Food Safety Modernization Act: Final Rules To Establish Requirements for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human and Animal Food; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meeting.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing a public meeting entitled ''FDA Food Safety Modernization Act: Final Rules to Establish Requirements for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human and Animal Food.'' The public meeting will provide interested persons an opportunity to discuss the final rules for current good manufacturing practice, hazard analysis, and risk-based preventive controls for human and animal food (the preventive controls final rules) and FDA's comprehensive planning effort for the next phase of the FDA Food Safety Modernization Act (FSMA) implementation, which involves putting in place the new public health prevention measures and the risk-based industry oversight framework that is at the core of FSMA. The purpose of the public meeting is to brief stakeholders and interested persons on the key components of the preventive controls final rules, respond to questions, and discuss the next phase of FSMA implementation with respect to human and animal food preventive controls requirements.

DATES: See section III, ''How to Participate in the Public Meeting'' in the **SUPPLEMENTARY INFORMATION** section of this document for dates and times of the public meeting, closing dates for advance registration, and requesting special accommodations due to disability.

ADDRESSES: See section III, ''How to Participate in the Public Meeting'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: *For questions about registering for the meeting or to register by phone:* Courtney Treece, Planning Professionals Ltd., 1210 West McDermott St., Suite 111, Allen, TX 75013, 704–258–4983, FAX: 469–854–6992, email: *ctreece@planningprofessionals.com*.

For general questions about the meeting or for special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition (HFS–009), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1731, email: *Juanita.yates@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Food Safety Modernization Act (FSMA) (Pub. L.111–353), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish the foundation of a modernized, prevention-based food safety system. Among other things, FSMA requires FDA to issue regulations requiring preventive controls for human food and animal food, setting standards for produce safety, and requiring importers to perform certain activities to help ensure that the food they bring into the United States is produced in a manner consistent with U.S. standards.

FSMA was the first major legislative reform of FDA's food safety authorities in more than 70 years. In the **Federal Register** of January 16, 2013 (78 FR 3646), we proposed to amend our regulations for Current Good Manufacturing Practice In Manufacturing, Packing, or Holding Human Food to modernize it and to add requirements for domestic and foreign facilities that are required to register under the FD&C Act to establish and implement hazard analysis and risk-based preventive controls for human food. We also proposed to revise certain definitions in our current regulation for Registration of Food Facilities to clarify the scope of the exemption from registration requirements provided by the FD&C Act for ''farms.'' In the **Federal Register** of October 29, 2013 (78 FR 64735), we proposed regulations for domestic and foreign facilities that are required to register under the FD&C Act to establish requirements for current good manufacturing practice in manufacturing, processing, packing, and holding of animal food. We proposed to require that certain facilities establish and implement hazard analysis and risk-based preventive controls for food for animals to provide greater assurance that animal food is safe and will not cause illness or injury to animals or humans.

Based on input we received from public comments, in the **Federal Register** of September 29, 2014 (79 FR 58476 and 79 FR 58524), we proposed to amend our 2013 proposed rules for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human and Animal Food and reopened the comment period only with respect to specific issues identified in supplemental proposed rules.

In the **Federal Register** of September 17, 2015 (80 FR 55908), we issued a final rule to establish the requirements for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Base Preventive Controls for Human Food. In the **Federal Register** of September 17, 2015 (80 FR 56170), we issued a final rule to establish requirements for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals. The preventive controls final rules apply to human and animal food and require domestic and foreign facilities that are required to register under the FD&C Act to have written plans that identify hazards, specify the preventive controls that will be put in place to significantly minimize or prevent those hazards, include procedures to monitor the implementation of the preventive controls, and include corrective action procedures for use when preventive controls are not properly implemented. We also revised certain definitions in the regulation for Registration of Food Facilities to clarify the scope of the exemption from registration requirements provided for ''farms'' and, in so doing, to clarify which domestic and foreign facilities are subject to the requirements for hazard analysis and risk-based preventive controls for food. The preventive controls final rules and related fact sheets are available on FDA's FSMA Web page located at *http://www.fda.gov/FSMA*.

II. Purpose and Format of the Public Meeting

FDA is holding the public meeting on the two preventive controls final rules to address what is different from the proposals; discuss the plans for guidance documents and outstanding issues that might be addressed in guidance; provide an update on the development of implementation work plans; and answer questions.

These two preventive controls final rules are the first of several final rules that will establish the foundation of, and central framework for, the modern food safety system envisioned by Congress in FSMA. We will not use any information or data submitted during the public meeting to inform any FSMA rulemakings where the comment periods have closed.

There will be an opportunity for stakeholders who are unable to participate in person to join the meeting via webcast. (See section III of this document for more information on the webcast option.)

III. How To Participate in the Public Meeting

We are holding the public meeting on October 20, 2015, from 8:30 a.m. until 5 p.m., at Chicago Marriott Downtown Magnificent Mile, 540 North Michigan Ave, Chicago, IL 60611. Due to limited space and time, we encourage all persons who wish to attend the meeting to register in advance. There is no fee to register for the public meeting, and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Onsite registration will be accepted, as space permits, after all preregistered attendees are seated.

Table 1 of this document provides information on participation in the public meeting.

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING

	Date	Electronic address	Address	Other information
Attend public meeting.	October 20, 2015, from 8:30 a.m. to 5 p.m. CDT.	Please preregister at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	Chicago Marriott Downtown Magnificent Mile, 540 North Michigan Ave, Chicago, IL 60611.	Registration check-in begins at 8 a.m.
View webcast	October 20, 2015, from 8:30 a.m. to 5 p.m. CDT.	Individuals who wish to participate by webcast are asked to preregister at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	.....	The webcast will have closed captioning.
Preregister	Register by October 12, 2015	Individuals who wish to participate in person are asked to preregister at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	We encourage the use of electronic registration, if possible.[1] .	There is no registration fee for the public meeting.
Request special accommodations due to disability.	Request by October 6, 2015	Juanita Yates, email: *Juanita.yates@fda.hhs.gov*.	See *For Further Information Contact*.	
Submit electronic questions about the FSMA final rules.	.....	Submit questions to the FDA FSMA Technical Assistance Network at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm*.	.....	For more information about the FDA FSMA Technical Assistance Network, visit *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm*.

[1] You may also register via email, mail, or fax. Please include your name, title, firm name, address, and phone and fax numbers in your registration information and send to: Courtney Treece, Planning Professionals Ltd., 1210 West McDermott St., Suite 111, Allen, TX 75013, 704–258–4983, FAX: 469–854–6992, email: *ctreece@planningprofessionals.com*.

IV. Transcripts and Recorded Video

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov* and at FDA's FSMA Web site at: *http://www.fda.gov/FSMA*. You may also view the transcript at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov*. Additionally, we will be video recording the public meeting. Once the recorded video is available, it will be accessible at FDA's FSMA Web site at *http://www.fda.gov/FSMA*.

Dated: September 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–24027 Filed 9–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 108

[Docket No. FDA–2015–N–2819]

Emergency Permit Control Regulations; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; technical amendments.