DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 16

[Docket Nos. FDA–2011–N–0143 and FDA–2011–N–0146]

Food and Drug Administration Food Safety Modernization Act: Proposed Rules on Foreign Supplier Verification Programs and the Accreditation of Third-Party Auditors/Certification Bodies; 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 to discuss two proposed rules aimed at strengthening assurances that imported food meets the same safety standards as food produced domestically. The Foreign Supplier Verification Programs (FSVP) proposal establishes requirements for importers to verify that their foreign suppliers are implementing the modern, prevention-oriented food safety practices called for by the Food Safety Modernization Act (FSMA) and achieving the same level of food safety as domestic growers and processors. The second proposed rule on the Accreditation of Third-Party Auditors/Certification Bodies would strengthen the quality, objectivity, and transparency of foreign food safety audits on which many U.S. food companies and importers currently rely to help manage the safety of their global food supply chains. The purpose of the public meeting is to solicit oral stakeholder and public comments on the proposed rules and to inform the public about the rulemaking process (including how to submit comments, data, and other information to the rulemaking dockets), and to respond to questions about the proposed rules.

DATES: See section II, ''How to Participate in the Public Meetings'' in the **SUPPLEMENTARY INFORMATION** section for dates and times of the public meeting, closing dates for advance registration, and information on deadlines for submitting either electronic or written comments to FDA's Division of Dockets Management.

ADDRESSES: See section II, ''How to Participate in the Public Meetings'' in the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: *For questions about registering for the meeting, to register by phone, or to submit a notice of participation by mail, fax, or email:* Peggy Walker, Planning Professionals, Ltd., 1210 West McDermott Dr., Suite 111, Allen, TX 75013, telephone: 469–854–6991, FAX: 469–854–6992, email: *pwalker@planningprofessionals.com.*

For general questions about the meeting, to request an opportunity to make an oral presentation at the public meeting, to submit the full text, comprehensive outline, or summary of an oral presentation, or for special accommodations due to a disability, contact: Juanita Yates, Center for Food Safety and Applied Nutrition (HFS–009), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, telephone: 240–402–1731, email: *Juanita.yates@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FSMA (Pub. L. 111–353), was signed into law by President Obama on January 4, 2011, 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, set standards for produce safety, and require importers to have a program to verify that the food products they bring into the United States are 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, even though FDA has increased the focus of its food safety efforts on prevention over the past several years. In the **Federal Register** of January 16, 2013 (78 FR 3503 and 78 FR 3646), FDA announced the establishment of two dockets so that the public can review the produce safety proposed rule and the preventive controls proposed rule for human food and submit comments to the Agency. These proposed rulemakings were the first of several key proposals in furtherance of FSMA's food safety mandate. For information on the produce safety proposed rule, the preventive controls proposed rule and related fact sheets see FDA's FSMA Web page located at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm.*

In the **Federal Register** of July 29, 2013 (78 FR 45729 and 78 FR 45781) FDA announced the second set of FSMA proposed rules and the establishment of two additional dockets so that the public can review the proposals on FSVP and the Accreditation of Third-Party Auditors/Certification Bodies and submit comments to the Agency. Under the proposed FSVP rule, those importing FDA-regulated food into the United States will be held accountable for verifying that their suppliers produce food in a manner consistent with U.S. standards. Under the proposed rule that would establish the Accreditation of Third-Party Auditors/Certification Bodies program, FDA would recognize accreditation bodies based on certain criteria such as competency and impartiality. The accreditation bodies, which could be foreign governments or their agencies or private companies, would in turn accredit third-party auditors to audit and issue certifications for foreign food facilities and food.

FDA is announcing a series of public meetings entitled ''The Food Safety Modernization Act Public Meeting on Proposed Rules for Foreign Supplier Verification Programs (FSVP) and for the Accreditation of Third-Party Auditors/Certification Bodies for Imported Food Public Meeting'' so that the food industry, consumers, foreign governments, and other stakeholders can better evaluate and comment on the proposals. The Washington, DC public meeting is the first of three that the Agency plans to hold during the proposed rules' comment period. We intend to hold the additional public meetings in diverse geographical regions of the United States. Specific locations, dates, and registration information for these meetings will appear in a separate **Federal Register** notice to publish shortly. All three public meetings will have the same agenda and are intended to facilitate and support the proposed rules' evaluation and commenting process.

II. How To Participate in the Public Meetings

FDA is holding the public meetings on the FSVP and the Accreditation of Third-Party Auditors/Certification Bodies proposed rules to inform the public about the rulemaking process, including how to submit comments, data, and other information to the rulemaking docket; to respond to questions about the proposed rules; and to provide an opportunity for interested persons to make oral presentations. Due to limited space and time, FDA encourages all persons who wish to attend the meetings to register in advance. There is no fee to register for the public meetings, 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.

Those requesting an opportunity to make an oral presentation during the time allotted for public comment at the meeting are asked to submit a request and to provide the specific topic or issue to be addressed. Due to the anticipated high level of interest in presenting public comment and limited time available, FDA is allocating 3 minutes to each speaker to make an oral presentation. Speakers will be limited to making oral remarks; there will not be an opportunity to display materials such as slide shows, videos, or other media during the meeting. If time permits, individuals or organizations that did not register in advance may be granted the opportunity to make an oral presentation. FDA would like to maximize the number of individuals who make a presentation at the meeting and will do our best to accommodate all persons who wish to make a presentation or express their opinions at the meeting.

FDA encourages persons and groups who have similar interests to consolidate their information for presentation by a single representative. After reviewing the presentation requests, FDA will notify each participant before the meeting of the approximate time their presentation is scheduled to begin and remind them of the presentation format (i.e., 3-minute oral presentation without visual media).

While oral presentations from specific individuals and organizations will be necessarily limited due to time constraints during the public meeting, stakeholders may submit electronic or written comments discussing any issues of concern to the administrative record (the docket) for the rulemaking. All relevant data and documentation should be submitted with the comments to the relevant docket, i.e., FSVP, Docket No. FDA–2011–N–0143, or accreditation of third-party auditors, Docket No. FDA–2011–N–0146.

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

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING AND ON SUBMITTING COMMENTS TO THE RULEMAKING DOCKETS

	Date	Electronic address	Address	Other information
Public meeting ...	September 19, 2013, from 8:30 a.m. to 5 p.m. and September 20, 2013, from 8:30 a.m. to 12:30 p.m.		Omni Shoreham Hotel, 2500 Calvert St. NW. (at Connecticut Ave.), Washington, DC 20008.	Onsite registration both days from 8 a.m. to 8:30 a.m.
Advance registration.	By September 10, 2013.	Individuals who wish to participate in person are asked to preregister at *http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	We encourage you to use electronic registration if possible.[1]	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.
Request to make an oral presentation.	By August 29, 2013.	http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.[2]	.....	Requests made on the day of the meeting to make an oral presentation will be granted as time permits. Information on requests to make an oral presentation may be posted without change to *http://www.regulations.gov,* including any personal information provided.
Request special accommodations due to a disability.	By August 29, 2013.	Juanita Yates, email: *Juanita.yates@fda.hhs.gov*.	See **FOR FURTHER INFORMATION CONTACT**.	
Submit electronic or written comments.	By November 26, 2013.	Docket Nos. FDA–2011–N–0143 and FDA–2011–N–0146.		

[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: Peggy Walker, Planning Professionals, Ltd., 1210 West McDermott Dr., suite 111, Allen, TX 75013, telephone: 469–854–6991, FAX: 469–854–6992, e-mail: *pwalker@planningprofessionals.com.* Onsite registration will also be available.

[2] You may also request to make an oral presentation at the public meetingv via email. Please include your name, title, firm name, address, and phone and FAX numbers as well as the full text, comprehensive outline, or summary of your oral presentation and send to: Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740, telephone: 240–402–1731, email: *Juanita.yates@fda.hhs.gov.*

III. Comments, Transcripts, and Recorded Video

Information and data submitted voluntarily to FDA during the public meeting will become part of the administrative record for the relevant rulemaking and will be accessible to the public at *http://www.regulations.gov.* The transcript of the proceedings from the public meeting will become part of the administrative record for each of the rulemakings. 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/Food/GuidanceRegulation/FSMA/default.htm.* It may also be viewed 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. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Additionally, FDA 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/Food/GuidanceRegulation/FSMA/default.htm.*

Dated: *August 13, 2013.*

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–19961 Filed 8–15–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA–2013–N–0888]

Dean Foods Company and WhiteWave Foods Company; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition submitted by the Dean Foods Company and the WhiteWave Foods Company proposing that the food additive regulations be amended to provide for the expanded safe uses of vitamin D_2 and vitamin D_3 as nutrient supplements in food.

DATES: The food additive petition was filed on June 27, 2013.

FOR FURTHER INFORMATION CONTACT: Judith Kidwell, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1071.

SUPPLEMENTARY INFORMATION: Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 3A4801), submitted by the Dean Foods Company and the WhiteWave Foods Company, c/o Hogan Lovells US LLP, Columbia Square, 555 Thirteenth Street NW., Washington, DC 20004. The petition proposes to amend 21 CFR 172.379 to provide for the safe use of vitamin D_2 as a nutrient supplement in edible plant-based food products intended for use as alternatives to milk and milk products and to amend 21 CFR 172.380 to provide for the safe use of vitamin D_3 as a nutrient supplement in milk at levels higher than those currently permitted.

We have determined under 21 CFR 25.32(k) 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.

Dated: August 12, 2013.

Dennis M. Keefe,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 2013–19915 Filed 8–15–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 151

[K00103 12/13 A3A10; 134D0102DR–DS5A300000–DR.5A311.IA000113; Docket ID: BIA–2013–0005]

RIN 1076–AF15

Land Acquisitions: Appeals of Land Acquisition Decisions

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Proposed rule; Reopening of comment period.

SUMMARY: In May, the Bureau of Indian Affairs (BIA) published a proposed rule revising a section of regulations governing decisions by the Secretary to approve or deny applications to acquire land in trust. The public comment period for that rule closed in July. This notice reopens the comment period for 15 days.

DATES: Comments on the proposed rule published May 29, 2013 (78 FR 32214) must be received by September 3, 2013.

ADDRESSES: You may submit comments by any of the following methods, though the Federal rulemaking portal or email are the preferred methods:

—*Federal rulemaking portal: http://www.regulations.gov.* The rule is listed under the agency name ''Bureau of Indian Affairs.'' The rule has been assigned Docket ID: BIA–2013–0005.

—*Email: consultation@bia.gov.* Include the number 1076–AF15 in the subject line of the message.

—*Mail* or *hand delivery:* Elizabeth Appel, Office of Regulatory Affairs & Collaborative Action, U.S. Department of the Interior, 1849 C Street NW., MS–4141, Washington, DC 20240. Include the number 1076–AF15 in the submission.

We cannot ensure that comments received after the close of the comment period (see **DATES**) will be included in the docket for this rulemaking and considered. Comments sent to an address other than those listed above will not be included in the docket for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Elizabeth Appel, Office of Regulatory Affairs & Collaborative Action, (202) 273–4680; *elizabeth.appel@bia.gov.*

SUPPLEMENTARY INFORMATION:

On May 29, 2013, BIA published a proposed rule revising 25 CFR 151.12 (78 FR 32214). The proposed rule would remove procedural requirements that are no longer necessary in light of the *Patchak* Supreme Court decision and increase transparency by better articulating the process for issuing decisions to acquire land in trust under 25 CFR part 151. The comment period for the proposed rule closed July 29, 2013. With this notice, BIA is reopening the comment period for an additional 15 days, in response to requests it received from commenters for additional time.

BIA will also consider any comments that it received between the close of the orginial comment period on July 29, 2013 and the reopening of the comment period on August 16, 2013. If you submitted comments during this period, there is no need to resubmit them.

Dated: August 9, 2013.

Kevin K. Washburn,

Assistant Secretary—Indian Affairs.

[FR Doc. 2013–19947 Filed 8–15–13; 8:45 am]

BILLING CODE 4310–6W–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2013–0455; FRL–9900–12-Region 4]

Approval and Promulgation of Implementation Plans; Tennessee; Revisions to the Knox County Portion of the Tennessee State Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a revision to the Knox County portion of the Tennessee State Implementation Plan (SIP), submitted by the State of Tennessee, through the Tennessee Department of Environment and Conservation (TDEC) on December 13,