Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 330.14 have been approved under OMB control number 0910–0688. The collections of information in 21 CFR part 25 and the guidance for industry entitled ''Environmental Assessment of Human Drug and Biologics Applications,'' which are referenced in the guidance announced in this document, are approved under OMB control number 0910–0322.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: September 26, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–25118 Filed 9–28–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0690]

Center for Drug Evaluation and Research, Approach to Addressing Drug Shortage; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is opening a comment period for the notice of public workshop published in the **Federal Register** of July 28, 2011 (76 FR 45268). In that notice, FDA announced a public workshop regarding the approach of the Center for Drug Evaluation and Research to addressing drug shortages. FDA is opening a comment period in light of public interest in this topic and in order to gain additional insight about the causes and impact of drug shortages, and possible strategies for preventing or mitigating drug shortages.

DATES: Either electronic or written comments will be accepted after the workshop until December 23, 2011.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christine Moser or Lori Benner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6202, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA held a public workshop regarding CDER's current approach to addressing drug shortages. Given the increasing number of drug shortages and the attendant safety concerns for the public's health, it is important to discuss the causes of these shortages, as well as strategies to address them. This public workshop focused on collecting information and gaining perspective from professional societies, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons. The topics discussed: How CDER becomes aware of drug shortages, Reasons behind drug shortages, Determination of medically necessary products, CGMP (current good manufacturing practice) and other compliance issues, Actions taken when a drug shortage occurs, and Outcomes of mitigated drug shortages. Additional discussions included the public health impact of drug shortages and what measures can be taken to prevent the occurrence of a drug shortage. The Agency encouraged professional societies, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

II. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov,* approximately 45 days after the public workshop. It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. 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.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 26, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–25116 Filed 9–28–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Food Defense Workshop; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Office of Regulatory Affairs, Southwest Regional Office (SWRO), in cosponsorship with Oklahoma State University, Robert M. Kerr Food & Agricultural Products Center (FAPC), is announcing a public workshop entitled ''Food Defense Workshop.'' This public workshop is intended to provide information about food defense as it relates to food facilities such as farms, manufacturers, processors, distributors, retailers, and restaurants.

Date and Time: This public workshop will be held on November 2, 2011, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Robert M. Kerr Food & Agricultural Products Center, Oklahoma State University, 148 FAPC, Stillwater, OK 74078–6055.

Contact: David Arvelo, Office of Regulatory Affairs, Food and Drug Administration, Southwest Regional Office, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214–253–

4952, FAX: 214–253–4970, e-mail: *david.arvelo@fda.hhs.gov.*

For information on accommodation options, contact conference coordinator Karen Smith or Andrea Graves at the Robert M. Kerr Food & Agricultural Products Center, Oklahoma State University, 148 FAPC, Stillwater, OK 74078–6055, 405–744–6071, FAX: 405–744–6313, or e-mail: *karenl.smith@okstate.edu* or *andrea.graves@okstate.edu.* More information is also available online at *http://www.fapc.biz/fooddefense.html.* (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Registration: You are encouraged to register by October 21, 2011. The workshop has a $150 registration fee to cover the cost of facilities, materials, speakers, and breaks. Seats are limited; please submit your registration as soon as possible. The workshop will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. Registration will close after the workshop is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 8 a.m. The cost of registration at the site is $200 payable to FAPC. There is no registration fee for FDA employees.

If you need special accommodations due to a disability, please contact Karen Smith (see *Contact*) at least 7 days in advance.

Registration Form Instructions: To register, please complete the online registration form at *http://www.fapc.biz/fooddefense.html.*

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop. Course handouts may be requested after the date of the public workshop through the contact persons (see *Contact*) at cost plus shipping.

SUPPLEMENTARY INFORMATION: This public workshop is being held in response to the large volume of food defense inquiries from food manufacturers originating from the area covered by the FDA Dallas District Office. The SWRO presents this workshop to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is consistent with the purposes of the Southwest Regional Small Business Representative Program, which are in part to respond to industry inquiries, develop educational materials, and sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's regulations and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by government agencies to small businesses.

The goal of this public workshop is to present information that will enable regulated industry to better comply with the regulations authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and to better understand FDA's food defense guidance documents, especially in light of growing concerns about food protection. Information that FDA presents will be based on Agency position as articulated through regulation, guidance, and information previously made available to the public. Topics to be discussed at the workshop (both by FDA and non-FDA speakers) include: (1) Food defense awareness and definitions, (2) FDA food defense tools such as ALERT and Employees FIRST, (3) regulations issued under the Bioterrorism Act, (4) food defense guidance documents, (5) investigating food-related incidents effectively, (6) physical plant security, (7) crisis management, and other related topics. For more information, please visit *http://www.fapc.biz/fooddefense.html.* FDA expects that participation in this public workshop will provide regulated industry with greater understanding of the Agency's regulatory and policy perspectives on food protection, increase compliance with FDA regulations, and heighten food defense awareness.

Dated: September 23, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–25114 Filed 9–28–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Request for Notification From Industry Organizations Interested in Participating in the Selection Process and Request for Nominations for a Nonvoting Industry Representative on the Vaccines and Biological Products Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Vaccines and Related Biological Products Advisory Committee for the Center for Biologics Evaluation and Research (CBER) notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative to serve the Vaccines and Related Biological Products Advisory Committee. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nomination will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to the FDA by October 31, 2011, for the vacancy listed in this document. Concurrently, nomination materials for prospective candidates should be sent to FDA by October 31, 2011.

ADDRESSES: All letters of interest and nominations should be submitted in writing to Donald Jehn (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Donald Jehn, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0314, *FAX:* 301–827–0294, *e-mail: donald.jehn@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative on the CBER Advisory Committee.

I. Vaccines and Related Biological Products Advisory Committee

The Vaccines and Related Biological Products Advisory Committee (the Committee) advises the Commissioner