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]

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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–