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 45266). 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.

IV. Electronic Access

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

Dated: September 26, 2011.

Leslie Kux, Acting Assistant Commissioner for Policy.