DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop regarding the approach of the Center for Drug Evaluation and Research (CDER) to addressing drug shortages. This public workshop is intended to provide information for, and to gain additional insight from, professional societies, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons about the causes and impact of drug shortages, and possible strategies for preventing or mitigating drug shortages. The input from this public workshop will help in developing topics for further discussion with industry and professional societies, and other stakeholders and may help the Agency to better address drug shortage issues.

Date and Time: The public workshop will be held on September 26, 2011, from 8:30 a.m. to 4:30 p.m.

Location: The public workshop will be held at 10903 New Hampshire Ave., Bldg. 31, rm. 1503 B and C (Great Room), Silver Spring, MD 20993. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings.'' Please note that visitors to the White Oak Campus must enter through Building 1. (*http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*).

Contact Persons: 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 or 301–796–1600.

Registration: To register electronically, e-mail registration information (including name, title, firm name, address, telephone, and fax number) to *dsworkshop@fda.hhs.gov* by September 19, 2011. Persons without access to the Internet can call Christine Moser at 301–796–1300 or Lori Benner at 301–796–1300 to register. Registration is free for the public workshop. Seating will be available on a first-come, first-served basis. Persons needing a sign language interpreter or other special accommodations should notify Christine Moser or Lori Benner (see Contact) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing 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 will focus on providing information and gaining perspective from professional societies, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons. The following topics will be 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 discussion will include the public health impact of drug shortages and what measures can be taken to prevent the occurrence of a drug shortage. The Agency encourages professional societies, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* 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 (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, Rm. 6–30, Rockville, MD 20857.

Dated: July 22, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0294]

Reprocessing of Reusable Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is considering factors affecting the reprocessing of reusable medical devices, including reprocessing quality, device design as it relates to the reprocessing of reusable medical devices, reprocessing methodologies, validation methodologies, and health care facility best practices. This is part of an ongoing effort to address patient exposure to inadequately reprocessed reusable medical devices. FDA would like to provide another opportunity for public comment by establishing a docket to receive information and comments from the public on factors affecting the reprocessing of reusable medical devices.

DATES: Submit either electronic or written comments by September 26, 2011.

ADDRESSES: You may submit comments, identified with the FDA docket number found in brackets in the heading of this document, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and