

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

docket number for this notice. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Carol Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5437, Silver Spring, MD 20993, 301-796-3241, Carol.Krueger@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has launched an effort focused on 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. As part of this effort, FDA held a 2-day public workshop on June 8 and 9, 2011, at FDA's White Oak Conference Center in Silver Spring, MD. In the **Federal Register** of May 2, 2011 (76 FR 24495), FDA announced the workshop and provided background information. The workshop focused on medical devices that are intended for reuse after reprocessing, rather than third-party reprocessing of single-use-only medical devices. FDA has a Web cast of the workshop available for viewing at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm252205.htm>. The workshop included a public comment session.

On the workshop Web site (<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm252205.htm>), FDA stated that electronic comments regarding the public workshop could be submitted to <http://www.regulations.gov> until June 29, 2011. FDA inadvertently failed to state this in the May 2, 2011, workshop notice. Hence, <http://www.regulations.gov> was not open for submission of electronic comments. FDA is publishing this notice to provide another opportunity for public comment

on reprocessing of reusable medical devices issues.

Various types of medical devices used in health care settings, from surgical suction tips to complex endoscopes, are designed and labeled for use on multiple patients. Thousands of reusable medical devices requiring reprocessing are used every day in diagnosing and treating patients. FDA has received a number of reports of patient exposure to inadequately reprocessed medical devices and subsequent health care-associated infections (HAIs).

A definitive causal relationship between reusable device reprocessing and any patient infection is difficult to establish because inadequate reprocessing is not often investigated as a cause when an HAI is diagnosed. Several reports, however, contained evidence suggesting that inadequate reprocessing may have been a contributing factor in microbial transmission and subsequent infection. Ensuring adequate reprocessing of reusable medical devices could reduce the incidence of HAIs associated with the use of a reprocessed medical device. This will decrease the public health burden of HAIs in terms of morbidity, mortality, and cost.

The adequate reprocessing of reusable medical devices is a critically important factor in protecting patient safety. Inadequate reprocessing between patients can result in the retention of blood, tissue, and other biological debris (soil) in reusable medical devices. This soil can allow microbes to survive the high level disinfection or sterilization process, potentially resulting in HAIs or other adverse patient outcomes. FDA receives reports of problems in all steps of medical device reprocessing,¹ including cleaning, disinfecting, and sterilizing. Manufacturers, health care facilities, health care professionals, and FDA all have a role in reducing the risk of inadequately reprocessed medical devices. To help address these issues, FDA has engaged partners at the Centers for Disease Control and Prevention, the Centers for Medicaid and Medicare Services, the Veterans Health Administration, and The Joint Commission, who bring valuable expertise in disease control and health care practices to this effort.

¹ A more comprehensive description of reprocessing steps is available in FDA's draft guidance "Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/default.htm>.

II. 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.

To assist interested parties, we are asking for public comment on the following issues:

1. What are the nature, scope, and impact of reusable medical device reprocessing problems that have been observed? What are the causes of these problems?
2. What factors or criteria to facilitate reprocessing should be considered when designing reusable medical devices? How can the design process be improved to better incorporate cleanability as a design endpoint?
3. What factors or criteria should be considered when developing reprocessing instructions and validation protocols for devices to be used in various health care environments (e.g., hospital, ambulatory surgical center, physician's office), based on the draft guidance document, "Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/default.htm>?
4. What factors or criteria should be considered by a health care facility when developing reusable device reprocessing procedures and quality assurance processes?
5. How should problems with reusable medical device reprocessing be identified, reported, and acted upon by industry and users?

Dated: July 25, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

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