Federal Register: Reprocessing of Reusable Medical Devices; Public Workshop

U.S. Food & Drug Administration

[Federal Register: May 2, 2011 (Volume 76, Number 84)] [Notices] [Page 24495-24496] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr02my11-85]
---------- DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration [Docket No. FDA-2011-N-0294] Reprocessing of Reusable Medical Devices; Public Workshop AGENCY: Food and Drug Administration, HHS. ACTION: Notice of public workshop; request for comments. ---------- The Food and Drug Administration (FDA) is announcing a public workshop entitled: ``Reprocessing of Reusable Medical Devices Workshop.'' The purpose of the workshop is to discuss factors affecting the reprocessing of reusable medical devices and FDA's plans to address the identified issues. This workshop is part of an ongoing FDA effort to address patient exposure to inadequately reprocessed reusable medical devices with the overall goal to reduce the risk of infection. The topics to be discussed are: Factors affecting reprocessing quality, device design as it relates to reprocessing reusable medical devices, reprocessing methodologies, validation methodologies, and healthcare facility best practices. Date and Time: The public workshop will be held on June 8, 2011, from 8:30 a.m. to 5:30 p.m. and June 9, 2011, from 8:30 a.m. to 5 p.m. Location: The public workshop will be held in the Great Room at the FDA White Oak Conference Center, Bldg. 31, Rm. 1503, 10903 New Hampshire Ave., Silver Spring, MD 20993. Contact Person: Carol Krueger, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5437, Silver Spring, MD 20993, 301- 796-3241, FAX: 301-847-8510, or e-mail: Carol.Krueger@fda.hhs.gov [1]. Registration and Requests for Oral Presentations: Registration is free and on a first-come, first-served basis. Persons interested in attending this workshop must register online by 5 p.m. on June 1, 2011. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, on-site registration on the day of the public workshop will be provided beginning at 7:30 a.m. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible. If you need special accommodations due to a disability, please contact Susan Monahan (e-mail: Susan.Monahan@fda.hhs.gov [2] or phone: 301-796-5661) no later than June 1, 2011. This workshop will also be Web cast. Persons interested in participating by Web cast must register online by 5 p.m. on June 1, 2011. Early registration is recommended because Web cast connections are limited. Organizations are requested to register all participants, but view using one connection per location. Web cast participants will be sent connection requirements. To register for the public workshop, please visit the following Web site: http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm [3] (or go to the FDA Medical Devices News & Events--Workshops & Conferences calendar and select this public workshop from

the posted events list). Please provide complete contact information for each attendee, including: Name, title, affiliation, address, email, telephone and FAX number. For those without Internet access, please call the contact person to register. Registrants will receive confirmation once they have been accepted. You will be notified if you are on a waitlist. This workshop includes a public comment session. During online registration you may indicate if you wish to make an oral presentation during a public comment session at the public workshop, and which topic you wish to address in your presentation. FDA has included general topics for comment in this document. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin. All requests to make oral presentations, as well as presentation materials, must be sent to the contact person by June 1, 2011. SUPPLEMENTARY INFORMATION: I. Background Various types of medical devices used in healthcare settings, from surgical suction tips to complex endoscopes, are designed and labeled for use on multiple patients. The workshop will focus on medical devices that are intended for reuse after reprocessing, rather than third-party reprocessing of single-use-only medical devices. 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 healthcare-associated infections (HAIs). Several reports contained evidence suggesting that inadequate reprocessing may have been a contributing factor in microbial transmission and subsequent infection. 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. 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, healthcare facilities, healthcare professionals, and the FDA all have a role in reducing the risk of inadequately reprocessed medical devices.
---------- 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/reprocessingreusabledevices [4].
---------- Because of the critical importance of adequate reprocessing of medical devices, the FDA has launched an initiative to focus on improvements in device design, reprocessing procedures and validation methodologies, and healthcare facility quality assurance practices. To help address these issues, the FDA has engaged partners at the Centers for Disease Control and Prevention (CDC), the Centers for Medicaid and Medicare Services

(CMS), the Veterans Health Administration (VHA), and The Joint Commission (JC), who bring valuable expertise in disease control and healthcare practices to this initiative. II. Topics for Discussion at the Public Workshop The public workshop will be organized to discuss the following topic areas: 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 healthcare 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'' at http://www.fda.gov/ reprocessingreusabledevices [4]. 4. What factors or criteria should be considered by a healthcare 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? III. Transcripts Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov [5]. 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 Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857. A link to the transcripts will also be available on the Internet at http://www.fda.gov/MedicalDevices/ NewsEvents/WorkshopsConferences/default.htm [3] (select this public workshop from the posted events list), approximately 45 days after the public workshop. Dated April 26, 2011. Nancy K. Stade, Deputy Director for Policy, Center for Devices and Radiological Health. [FR Doc. 2011-10532 Filed 4-29-11; 8:45 am] BILLING CODE 4160-01-P

SOURCE [6]

Source URL (retrieved on *09/16/2014 - 7:55pm*):
http://www.mdtmag.com/news/2011/05/federal-register-reprocessing-reusable-medical-devices-public-workshop

Links:
[1] mailto://edocket.access.gpo.gov/2011/Carol.Krueger@fda.hhs.gov
[2] mailto://edocket.access.gpo.gov/2011/Susan.Monahan@fda.hhs.gov
[3] http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm
[4] http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.fda.gov/reprocessingreusabledevices
[5] http://frwebgate.access.gpo.gov/cgi-

bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.regulations.gov
[6] http://edocket.access.gpo.gov/2011/2011-10532.htm