Carryover and Reallotment Report for one fiscal year be submitted to HHS by the grantee before the allotment for the next fiscal year may be awarded. The Administration for Children and Families is requesting no changes in the collection of data with the Carryover and Reallotment Report, a form for the collection of data, and the Simplified Instructions for Timely Obligations of LIHEAP Funds and Reporting Funds for Carryover and Reallotment. The form clarifies the information being requested and ensures the submission of all the required information. The form facilitates our response to numerous queries each year concerning the amounts of obligated funds. Use of the form is voluntary. Grantees have the option to use another format.

Respondents:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Carryover and Reallotment Report	192	1	3	576

Estimated Total Annual Burden Hours: 576.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–10458 Filed 4–29–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0293]

Draft Guidance for Industry and FDA Staff: Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled "Draft Guidance for Industry and FDA Staff: Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." The recommendations in this guidance are intended to improve the safety and effectiveness of devices with processing or reprocessing labeling. This draft guidance is not final; nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see § 10.115 (21 CFR 10.115(g)(5))), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by August 1, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Draft Guidance for Industry and FDA Staff: Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send a fax request to 301–847–8149 to receive a hard copy. Alternatively, you may submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852. Send one self-addressed adhesive label to the office that you are ordering from to assist in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Steven Turtil, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1570, Silver Spring, MD 20993–0002, 301–796–6305; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, there has been a significant advance in knowledge and technology involved in reprocessing reusable medical devices. Additionally, there has been an evolution towards more complex reusable medical device designs that are more difficult to clean and disinfect or sterilize. The revision of this guidance, originally published in 1996, reflects scientific advances in this area. Under FDA labeling regulations (part 801 (21 CFR part 801)), a device must have adequate directions for use, which include instructions on preparing a device for use. Instructions on how to

reprocess (i.e., clean and disinfect or sterilize) a reusable device are critical to ensuring a reusable device is appropriately prepared for its next use.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on processing and reprocessing labeling for medical devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability is available for all CDRH guidance documents at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm,* and for CBER guidance documents at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* To receive "Draft Guidance for Industry and FDA Staff: Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1748 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E are approved under OMB control number 0910–0120; the collections of information in part 801 are approved under OMB control number 0910–0485; and the collections of information in 21 CFR part 812 are approved under OMB control number 0910–0078.

V. 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: April 26, 2011.

Nancy K. Stade,

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

[FR Doc. 2011–10516 Filed 4–29–11; 8:45 am]

BILLING CODE 4160–01–P

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.*

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* 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* (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: