Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance'' dated April 1996.

This final guidance contains the addition of ''Appendix E: Devices for which a 510(k) Should Contain Data to Validate Reprocessing Instructions,'' which includes a subset of medical devices that FDA has identified that pose a greater likelihood of microbial transmission and represent a high risk of infection if they are not adequately reprocessed. Because of this greater public health risk, 510(k) submissions for these devices should include protocols and complete test reports of the validation of the reprocessing instructions so that FDA has the information it needs to evaluate substantial equivalence.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on reprocessing validation methods and 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 guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1748 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 parts 801 and 809 have been approved under OMB control number 0910–0485 (medical device labeling); the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120 (premarket notification); the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078 (investigational device exemption); the collections of information in 21 CFR part 814, subparts A through E have been approved under OMB control number 0910–0231 (premarket approval); the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910–0332 (humanitarian use devices); and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073 (quality system regulation).

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at *http://www.regulations.gov.*

Dated: March 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–06029 Filed 3–16–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request Surveys To Support an Evaluation of the National Human Genome Research Institute (NHGRI) Summer Workshop in Genomics (Short Course)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Human Genome Research Institute (NHGRI), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments And For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Carla L. Easter, Ph.D., Chief, Education and Community Involvement Branch, NHGRI, Building 31, Room B1B55, 31 Center Drive, MSC 2070, Bethesda, MD 20892 or call non-toll-free number (301) 594–1364 or Email your request, including your address to: *easterc@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Surveys to Support an Evaluation of the NHGRI Summer Workshop in Genomics (Short Course), 0925–NEW, National Human Genome Research Institute (NHGRI), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of the proposed data collection activity is to complete a full-scale outcome evaluation of NHGRI's Summer Workshop in Genomics (a.k.a., the ''Short Course'') focusing on program participants between 2004 and 2012. This training program is an intensive multi-day course that updates instructors and researchers of biology and nursing (and other related disciplines) on the latest research trends and topics in genomic science. The course focuses on the continuing effort to find the genetic basis of various diseases and disorders, and current topics on the ethical, legal and social implications of genomics.

The Education and Community Involvement Branch (ECIB) designed the program to accomplish the following goals, which align with elements of both the NIH and NHGRI missions:

- Expand NIH and NHGRI's professional network to reach out to diverse communities, and to create new partnership opportunities.
- Prepare the next generation of genomics professionals for an era of genomic medicine.
- Train and diversify the pipeline of genome professionals in alignment with the NIH and US Department of Health and Human Services diversity efforts.

The ECIB has systematically collected feedback annually after the program from participants since inception of the Short Course in 2003, and then used the data to tweak the program, but it has not conducted a long-term, cumulative and substantive outcome evaluation. NHGRI and the ECIB propose to conduct such an outcome evaluation, focusing on three main objectives:

(1) To understand the degree of genetic and genomic curriculum integration by faculty participants;

(2) To explore the barriers and supports faculty experience and changes when integrating curriculum; and

(3) To investigate the influence of the program on the participants' career path.

Survey findings will provide valuable information about the various methods and pathways instructors use to disseminate new knowledge (and the associated timelines), the barriers and supports experienced by faculty as they integrate new knowledge into their teaching, and insights about additional avenues of support that NHGRI could provide teaching faculty from the types of institutions identified. Key indicators will also provide evidence about the degree to which the Short Course is meeting its goals. Collectively, the outcome evaluation will inform future program design and budget allocations.

OMB approval is requested for 2 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 155.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Short Course Survey—Students	Students	110	1	30/60	55
Short Course Survey—Faculty	Faculty	200	1	30/60	100
Totals		310			155

Dated: March 11, 2015.

Gloria Butler,

NHGRI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2015–06086 Filed 3–16–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 12, 2015, from 8:30 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.* For those unable to attend in person, the meeting will also be Web cast and will be available at the following link: *https://collaboration.fda.gov/vrbpac0515/.*

Contact Person: Sujata Vijh, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6128, Silver Spring, MD 209930–0002, 240–402–7107; or Denise Royster, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6134, Silver Spring, MD 209930–0002, 240–402–8158; or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On May 12, 2015, from 8:30 a.m. to 5 p.m., the committee will meet in open session to discuss the development and licensure of Ebola vaccines.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 5, 2015. Oral presentations from the public will be scheduled between 1:15 p.m. and 2:15 p.m. Those individuals interested in making formal oral presentations should