DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Institute for Occupational Safety and Health (BSC, NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting for the aforementioned committee:

Time and Date: 8:30 a.m.–2:30 p.m., EDT, September 27, 2016.

Place: Patriots Plaza I, 395 E Street SW., Room 9000, Washington, DC 20201. The meeting is also available via webcast.

Status: This meeting is open to the public, limited only by the space available. The meeting room accommodates approximately 33 people. The public is welcome to participate during the public comment period, 12:30 p.m.–12:45 p.m. EDT, September 27, 2016.

Please note that the public comment period ends at the time indicated above or following the last call for comments, whichever is earlier. Members of the public who want to comment must sign up by providing their name by mail, email, or telephone, at the addresses provided below by September 23, 2016. Each commenter will be provided up to five minutes for comment. A limited number of time slots are available and will be assigned on a first come-first served basis. Written comments will also be accepted from those unable to attend the public session via an on-line form at the following Web site: *http://www.cdc.gov/niosh/bsc/contact.html.* The meeting is also open to the public via webcast. If you wish to attend in person or by webcast, please see the NIOSH Web site to register (*http://www.cdc.gov/niosh/bsc/*) or call (404–498–2539) at least five business days in advance of the meeting. Teleconference is available toll-free; please dial (888) 397–9578, Participant Pass Code 63257516. Adobe Connect webcast will be available at *https://odniosh.adobeconnect.com/nioshbsc/* for participants wanting to connect remotely.

Purpose: The Secretary, the Assistant Secretary for Health, and by delegation the Director, Centers for Disease Control and Prevention, are authorized under Sections 301 and 308 of the Public Health Service Act to conduct directly or by grants or contracts, research, experiments, and demonstrations relating to occupational safety and health and to mine health. The Board of Scientific Counselors provides guidance to the Director, National Institute for Occupational Safety and Health on research and prevention programs. Specifically, the Board provides guidance on the Institute's research activities related to developing and evaluating hypotheses, systematically documenting findings and disseminating results. The Board evaluates the degree to which the activities of the National Institute for Occupational Safety and Health: (1) conform to appropriate scientific standards, (2) address current, relevant needs, and (3) produce intended results.

Matters for Discussion: NIOSH Director's update; Chronic Kidney Disease and Pesticide Exposure; NIOSH Oil and Gas Sector Program; Engineering Controls for Additive (3D) Manufacturing, and Engineering Controls and Nanomaterials.

Agenda items are subject to change as priorities dictate.

An agenda is also posted on the NIOSH Web site (*http://www.cdc.gov/niosh/bsc/*). Members of the public who wish to address the NIOSH BSC are requested to contact the Executive Secretary for scheduling purposes (see contact information below). Alternatively, written comments to the BSC may be submitted via an on-line form at the following Web site: *http://www.cdc.gov/niosh/bsc/contact.html.*

Contact Person for More Information: Paul J. Middendorf, Ph.D., Executive Secretary, BSC, NIOSH, CDC, 1600 Clifton Road NE., MS–E20, Atlanta, GA 30329–4018, telephone (404) 498–2500, fax (404) 498–2526.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker, MPH, DLP,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 2016–21399 Filed 9–6–16; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, Office of Infectious Diseases (BSC, OID)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Times and Dates: 8:30 a.m.–5:00 p.m., EDT, September 27, 2016; 8:00 a.m.–12:00 p.m., EDT, September 28, 2016.

Place: CDC, Global Communications Center, 1600 Clifton Road NE., Building 19, Auditorium B3, Atlanta, Georgia 30333.

Status: The meeting is open to the public, limited only by the space available.

Purpose: The BSC, OID, provides advice and guidance to the Secretary, Department of Health and Human Services; the Director, CDC; the Director, OID; and the Directors of the National Center for Immunization and Respiratory Diseases, the National Center for Emerging and Zoonotic Infectious Diseases, and the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, CDC, in the following areas: strategies, goals, and priorities for programs; research within the national centers; and overall strategic direction and focus of OID and the national centers.

Matters for Discussion: The meeting will include updates from CDC's infectious disease national centers; a report from the Board's Food Safety Modernization Act Surveillance Working Group; and focused discussions on several program priorities, including viral hepatitis, Zika, and antimicrobial resistance.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Robin Moseley, M.A.T., Designated Federal Officer, OID, CDC, 1600 Clifton Road NE., Mailstop D10, Atlanta, Georgia 30333, Telephone: (404) 639–4461.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker, MPH, DLP,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 2016–21400 Filed 9–6–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0514]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requests for Clinical Laboratory Improvement Amendments Categorization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 7, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0607. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Requests for Clinical Laboratory Improvement Amendments of 1988 Categorization—42 CFR 493.17—OMB Control Number 0910–0607—Extension

A guidance document entitled ''Guidance for Administrative Procedures for CLIA Categorization'' was released on May 7, 2008. The document describes procedures FDA uses to assign the complexity category to a device. Typically, FDA assigns complexity categorizations to devices at the time of clearance or approval of the device. In this way, no additional burden is incurred by the manufacturer because the labeling (including operating instructions) is included in the premarket notification (510(k)) or premarket approval application (PMA). In some cases, however, a manufacturer may request Clinical Laboratory Improvement Amendments of 1998 (CLIA) categorization even if FDA is not simultaneously reviewing a 510(k) or PMA. One example is when a manufacturer requests that FDA assign CLIA categorization to a previously cleared device that has changed names since the original CLIA categorization. Another example is when a device is exempt from premarket review. In such cases, the guidance recommends that manufacturers provide FDA with a copy of the package insert for the device and a cover letter indicating why the manufacturer is requesting a categorization (*e.g.* name change, exempt from 510(k) review). The guidance recommends that in the correspondence to FDA the manufacturer should identify the product code and classification as well as reference to the original 510(k) when this is available.

In the **Federal Register** of April 27, 2016 (81 FR 24820), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Request for CLIA Categorization	60	15	900	1	900	$46,800

[1] There are no capital costs associated with this collection of information.

The number of respondents is approximately 60. On average, each respondent will request categorizations (independent of a 510(k) or PMA) 15 times per year. The cost, not including personnel, is estimated at $52 per hour ($52 \times 900$), totaling $46,800. This includes the cost of copying and mailing copies of package inserts and a cover letter, which includes a statement of the reason for the request and reference to the original 510(k) numbers, including regulation numbers and product codes. The burden hours are based on FDA familiarity with the types of documentation typically included in a sponsor's categorization requests, and costs for basic office supplies (*e.g.,* paper).

Dated: August 31, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21352 Filed 9–6–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0731]

Agency Information Collection Activities; Proposed Collection; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Eligibility Determination for Donors; and Current Good Tissue Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.