who wishes to provide comments to the Committee utilizing electronic data projection submit the necessary material to the Designated Federal Officer prior to the close of business on November 10, 2014.

Dated: September 17, 2014.

James J. Berger,
Designated Federal Officer and Senior Advisor for Blood and Tissue Safety Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee (CLIAC)

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., November 5, 2014; 8:30 a.m.–12:00 p.m., November 6, 2014.

Place: CDC, Century Center, 2500 Century Parkway NE., Room 1200/1201, Atlanta, Georgia 30345.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people. This meeting will also be Webcast, please see information below.

Purpose: This Committee is charged with providing scientific and technical advice and guidance to the Secretary of Health and Human Services (HHS); the Assistant Secretary for Health; the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration (FDA); and the Administrator, Centers for Medicare and Medicaid Services (CMS). The advice and guidance pertain to general issues related to improvement in clinical laboratory quality and laboratory medicine practice and specific questions related to possible revision of the Clinical Laboratory Improvement Amendment (CLIA) standards. Examples include providing guidance on studies designed to improve safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods and the electronic transmission of laboratory information.

Matters for Discussion: The agenda will include agency updates from CDC, CMS, and FDA. Presentations and discussions will include the FDA Draft Guidance on Laboratory Developed Tests; CLIA-waived testing, including the process and criteria for waiver approval; a report from the workgroup charged with providing input to CLIAC regarding the acceptability and application of virtual cross-matching in lieu of serologic cross-matching for transplantation; and issues related to laboratory biosafety in the United States.

Agenda items are subject to change as priorities dictate.

Webcast: This meeting will also be Webcast. Persons interested in viewing the Webcast can access information at: http://www.cdc.gov/cliac/default.aspx

Online Registration Required: All people attending the CLIAC meeting in-person are required to register for meeting online at least 5 business days in advance for U.S. citizens and at least 10 business days in advance for international registrants. Register at http://www.cdc.gov/cliac/default.aspx by scrolling down and clicking the link under “Meeting Registration” and completing all forms according to the instructions given. Please complete the required fields before submitting your registration and submit no later than October 29, 2014 for U.S. registrants and October 22, 2014 for international registrants.

Providing Oral or Written Comments: It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments whenever possible.

Oral Comments: In general, each individual or group requesting to make oral comments will be limited to a total time of five minutes (unless otherwise indicated).

Written Comments: For individuals or groups unable to attend the meeting, CLIAC accepts written comments on the day of the meeting (unless otherwise stated). However, it is requested that comments be submitted at least one week prior to the meeting date. Written Comments: For individuals or groups unable to attend the meeting, CLIAC accepts written comments on the day of the meeting (unless otherwise stated).

Availability of Meeting Materials:

Summary Report. To assure adequate time is scheduled for public comments, speakers should notify the contact person below at least one week prior to the meeting date.

Written Comments: For individuals or groups unable to attend the meeting, CLIAC accepts written comments on the day of the meeting (unless otherwise stated).

The Centers for Disease Control and Prevention (CDC) Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

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Contact Person for More Information: Catherine Ramadei, Acting Chief, Federal Advisory Committee Management Branch, Management Branch.