

data on the number of manufacturers that would be covered by the draft guidance, we estimate that approximately 70 manufacturers will develop an Emergency Plan as recommended by the draft guidance (i.e., 1 Plan per manufacturer to include all manufacturing facilities, sites, and drug products), and that each Plan will take approximately 500 hours to develop, maintain, and update.

The draft guidance also encourages manufacturers to include a procedure in their Plan for notifying CDER when the Plan is activated and when returning to normal operations. The draft guidance recommends that these notifications occur within 1 day of a Plan's activation and within 1 day of a Plan's deactivation. The draft guidance specifies the information that should be included in these notifications, such as which drug products will be manufactured under altered procedures, which products will have manufacturing temporarily delayed, and any anticipated or potential drug shortages. We expect that approximately

two notifications (for purposes of this analysis, we consider an activation and a deactivation notification to equal one notification) will be sent to CDER by approximately two manufacturers each year, and that each notification will take approximately 16 hours to prepare and submit.

This draft guidance also refers to previously approved collections of information found in FDA regulations. Under the draft guidance, if a manufacturer obtains information after releasing a MNP under its Plan leading to suspicion that the product might be defective, CDER should be contacted immediately ([drugshortages@fda.hhs.gov](mailto:drugshortages@fda.hhs.gov)) in adherence to existing recall reporting regulations (21 CFR 7.40) (OMB control number 0910-0249) or defect reporting requirements for drug application products (21 CFR 314.81(b)(1)) and therapeutic biological products regulated by CDER (21 CFR 600.14) (OMB control numbers 0910-0001 and 0910-0458, respectively).

The following collections of information found in FDA current good manufacturing practice (CGMP) regulations in part 211 (21 CFR part 211) are approved under OMB control number 0190-0139. The draft guidance encourages manufacturers to maintain records, in accordance with the CGMP requirements (see, e.g., § 211.180), that support decisions to carry out changes to approved procedures for manufacturing and release of products under the Plan. The draft guidance states: A Plan should be developed, written, reviewed, and approved within the site's change control quality system in accordance with the requirements in §§ 211.100(a) and 211.160(a); execution of the Plan should be documented in accordance with the requirements described in § 211.100(b); and standard operating procedures should be reviewed and revised or supplementary procedures developed and approved to enable execution of the Plan.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

	Number of Respondents	Number of Responses per Respondent	Total Responses	Hours per Response	Total Hours
Notify FDA of Plan activation and deactivation	2	1	2	16	32
<b>Total</b>					<b>32</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this information collection.

TABLE 2.—ESTIMATED RECORDKEEPING BURDEN<sup>1</sup>

	Number of Recordkeepers	Number of Records per Recordkeeping	Total Records	Hours per Record	Total Hours
Develop initial Plan	70	1	70	500	35,000
<b>Total</b>					<b>35,000</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this information collection.

**IV. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: January 4, 2010.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Board of Scientific Counselors, National Center for Injury Prevention and Control, (BSC, NCIPC)**

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:

*Time and Date:* 8:30 a.m.–5:30 p.m., January 22, 2010.

*Place:* CDC, 4770 Buford Hwy., NE., Building 106, First Floor, Rooms 1B, Atlanta, Georgia 30341.

*Status:* Open: 8:30 a.m.–11:30 a.m., January 22, 2010. Closed: 11:30 a.m.–5:30 p.m., January 22, 2010.

*Purpose:* The board makes recommendations regarding policies, strategies, objectives, and priorities, and reviews progress toward injury prevention goals and provides evidence in injury prevention-related research and programs. The board provides advice on the appropriate balance of intramural and extramural research, and provides advice on the structure, progress and performance of intramural programs. The Board of Scientific Counselors is also designed to provide guidance on extramural scientific program matters, including the: (1) Review of extramural research concepts for funding

opportunity announcements; (2) conduct of Secondary Peer Review of extramural research grants, cooperative agreements, and contracts applications received in response to the funding opportunity announcements as it relates to the Center's programmatic balance and mission; (3) submission of secondary review recommendations to the Center Director of applications to be considered for funding support; (4) review of research portfolios; and (5) review of program proposals. The board shall provide guidance on the National Center of Injury Prevention and Control's programs and research activities by conducting scientific peer review of intramural research and programs within the National Center for Injury Prevention and Control; by ensuring adherence to Office of Management and Budget requirements for intramural peer review; and by monitoring the overall direction, focus, and success of the National Center for Injury Prevention and Control.

**Matters to be Discussed:** As this meeting of the Board of Scientific Counselors, the board will be discussing the upcoming portfolio topics, activities promoting the Injury Research Agenda, and other scientific matters.

Agenda items are subject to change as priorities dictate.

**Contact Person for More Information:** Dr. Gwendolyn Cattledge, PhD, MSEH, Deputy Associate Director for Science and the Designated Federal Officer for the Board of Scientific Counselors, NCIPC, CDC, 4770 Buford Highway, NE., Mailstop F-63, Atlanta, Georgia 30341, Telephone (770) 488-1430.

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 CDC and the Agency for Toxic Substances and Disease Registry.

**Gary J. Johnson,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2010-22 Filed 1-7-10; 8:45 am]

**BILLING CODE 4163-18-P**

**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 committee meeting:

**Times and Dates:**

8:30 a.m.–5 p.m., February 9, 2010.

8:30 a.m.–3 p.m., February 10, 2010.

**Place:** CDC, 1600 Clifton Road, NE., Tom Harkin Global Communications

Center, Building 19, Room 232, Auditorium B, Atlanta, Georgia 30333.

**Online Registration Required:** In order to expedite the security clearance process at the CDC Roybal Campus located on Clifton Road, all CLIAC attendees are required to register for the meeting online at least 14 days in advance at <http://wwwn.cdc.gov/cliac/default.aspx> by clicking the "Register for a Meeting" link and completing all forms according to the instructions given. Please complete all the required fields before submitting your registration and submit no later than January 26, 2010.

**Status:** Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

**Purpose:** This Committee is charged with providing scientific and technical advice and guidance to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the need for, and the nature of, revisions to the standards under which clinical laboratories are regulated; the impact on medical and laboratory practice of proposed revisions to the standards; and the modification of the standards to accommodate technological advances.

**Matters To Be Discussed:** The agenda will include updates from the CDC, the Centers for Medicare & Medicaid Services, and the Food and Drug Administration; a report from the CLIAC Biochemical Genetic Testing Workgroup and discussion of the Workgroup's proposals related to good laboratory practices for biochemical genetic testing; and presentations and discussions related to electronic health records and electronic transmission of laboratory information.

Agenda items are subject to change as priorities dictate.

**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 an oral presentation will be limited to a total time of five minutes (unless otherwise indicated). Speakers must also submit their comments in writing for inclusion in the meeting's Summary Report. To assure adequate time is scheduled for public comments, individuals or groups planning to make an oral presentation should, when possible, 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 until the date of the meeting (unless otherwise stated). However, the comments should be received at least one week prior to the meeting date so that the comments may be made available to the Committee for their consideration and public distribution. Written comments, one hard copy with original signature, should be provided to the contact person below. Written comments will be included in the meeting's Summary Report.

**Contact Person for Additional Information:** Nancy Anderson, Chief, Laboratory Practice Standards Branch, Division of Laboratory Systems, National Center for Preparedness, Detection, and Control of Infectious Diseases, CDC, 1600 Clifton Road, NE., Mailstop F-11, Atlanta, Georgia 30333; telephone (404) 498-2741; fax (404) 498-2219; or via e-mail at [Nancy.Anderson@cdc.hhs.gov](mailto:Nancy.Anderson@cdc.hhs.gov).

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: December 30, 2009.

**Gary J. Johnson,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Dental & Craniofacial Research; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.