DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee (CLIA)

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.

Name: Clinical Laboratory Improvement Advisory Committee (CLIA).

Time and Dates: 8:30 a.m.–5 p.m.; September 17, 2003; 8:30 a.m.–3:30 p.m.; September 18, 2003.

Place: Sheraton Colony Square Hotel, 185 14th Street NE., Atlanta, Georgia 30361.

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 CDC, the Centers for Medicare & Medicaid Services, and the Food and Drug Administration; a report on the results of the General Services Administration’s Office of Government-wide Policy Federal Advisory Committee Stakeholder Engagement Survey; presentations and discussion on the CLIA waiver criteria and process; previous CLIA recommendations related to such, and Advamed’s CLIA waiver criteria proposal; a report on the Coordinating Council for Clinical Laboratory Workforce’s June 2003 meeting; a report on the April 2003 Quality Institute; a summary of the March 2003 CLIA meeting on direct access testing; a presentation on Lab Tests Online; a report on the first meeting of the Secretary’s Advisory Committee on Genetics, Health and Society; and several presentations on CDC’s various genetic testing activities.

Agenda items are subject to change as priorities dictate. Providing Oral or Written Comments: It is the policy of CLIA 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 meetings Summary Report. Written Comments: For individuals or groups unable to attend the meeting, CLIA 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 meetings Summary Report.

Contact Person for Additional Information: Rhonda Whalen, Chief, Laboratory Practice Standards Branch, Division of Laboratory Systems, Public Health Practice Program Office, CDC, 4770 Buford Highway, NE, Mailstop F-11, Atlanta, Georgia 30341-3717; telephone (770) 486-8042; fax (770) 488-8279; or via e-mail at RWhalen@cdc.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 both CDC and the Agency for Toxic Substances and Disease Registry.


Alvin Hall,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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BILLING CODE 4153-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Information Relevant to Toluene Exposure

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).
ACTION: Notice of request for comments and information relevant to occupational exposure to toluene.

SUMMARY: NIOSH is reviewing the recommendations in its document “Criteria for a Recommended Standard: Occupational Exposure to Toluene” [NIOSH 1973] (http://www.cdc.gov/niosh/13-11023.html). A review of recent literature indicates that the NIOSH recommended exposure limit (REL) of 100 ppm as an 8-hr time-weighted average (TWA) does not sufficiently protect workers from the adverse effects of exposure to toluene. NIOSH is requesting (1) comments and information relevant to the evaluation of the health risks associated with occupational exposure to toluene, (2) reports or other data that demonstrate adverse health effects in workers exposed to toluene at or below the NIOSH REL, and (3) information pertinent to establishing a more protective REL for toluene.

Comments concerning this notice must be received within 60 days after date of publication.

ADDRESSES: Comments may be transmitted either electronically to ntiocindocket@cdc.gov, by facsimile to 513/533-8230, or by regular mail or hand delivery to NIOSH Docket Office, M/S C–34, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226. E-mail attachments should be formatted as WordPerfect 7/8/9 or Microsoft Word.

FOR FURTHER INFORMATION CONTACT: Henryka Nagy, M/S C–34, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226, 513/533-6369.

SUPPLEMENTARY INFORMATION: In the document “Criteria for a Recommended Standard: Occupational Exposure to Toluene” [NIOSH 1973] (http://www.cdc.gov/niosh/13-11023.html), NIOSH recommended that exposure to toluene be limited to 100 ppm as an 8-hr TWA. This exposure limit was expected to prevent acute and chronic effects on the central and peripheral nervous system from exposures to toluene. NIOSH has conducted a literature review of the health effects data on toluene exposure and finds evidence that adverse effects on the central and peripheral nervous systems and reproductive system, as well as irritation of the eye and respiratory tract may occur in workers exposed to concentrations at and below the current NIOSH REL of 100 ppm [Andersen et al. 1983; Larsen and Leira 1980; Røbek and Nise 1988; Foo et al. 1990; Ng et al. 1992; ATSDDR 2000; NERG 2000]. NIOSH seeks to obtain materials, including published and unpublished reports and research findings, to evaluate the possible health risks of occupational exposure to toluene at concentrations below 100 ppm.

Examples of requested information include, but are not to be limited to, the following:

1. Identification of industries or occupations in which exposures to toluene may occur.
2. Trends in production, use, and import of toluene over the past 10 years.
3. Description of work tasks and scenarios with a potential for exposure to toluene.
4. Current occupational exposure concentrations in various types of industries and jobs and, if available, data to document these concentrations.
5. Case reports or other health data that demonstrate adverse health effects in workers exposed to toluene, or animal data (published or peer-reviewed data are preferred).
6. Description of work practices and engineering controls used to reduce or prevent workplace exposure.
7. Educational materials for worker safety or training on the safe handling of toluene.
8. Data pertaining to the technical feasibility of establishing a more protective REL for toluene.

NIOSH will use this information to determine the need for developing new recommendations for reducing occupational exposure to toluene. All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

References

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.

Alvin Hall,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.
[FR Doc. 03-22102 Filed 8-26-03; 10:03 am]
BILLING CODE 4150-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
(Docket No. 2003N–0199)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Importer’s Entry Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by September 26, 2003.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on