

Dated: December 23, 2005.

Betsey Dunaway,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Public Notice

AGENCY: Centers for Disease Control and Prevention (CDC), Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), National Center for Infectious Disease (NCID), Division of Bacterial and Mycotic Diseases (DBMD) and the National Immunization Program, Epidemiology and Surveillance Division through its component Branches have lead technical responsibility for research, development and evaluation of diagnostic tools for pertussis and application of these to epidemiologic studies of pertussis. CDC uses epidemiologic, laboratory, clinical, and biostatistical sciences to control and prevent vaccine preventable infectious diseases. CDC also conducts applied research in a variety of settings, and translates the findings of this research into public health practice.

CDC is seeking to evaluate commercial products, or products in development, for in vitro serological diagnosis of pertussis. Specifically these should include tests to detect anti-pertussis toxin antibodies in infected and vaccinated individuals. The tests should be based on standardized reagents commonly used in the field (such as FDA Reference Serum Standard Lot #3 or equivalents). Products will be evaluated in CDC and collaborating laboratories and if appropriate, may be used in epidemiologic validation studies. Data obtained from this comparative analysis may be used by CDC in making recommendations and decisions for diagnosis of pertussis in the public health setting.

Interested organizations that may have candidate products are invited to submit documentation for CDC to assess whether the offered product(s) are at a sufficient stage of development to be included in this comparative analysis. As a minimum, submitted information should be sufficient for CDC to determine the following for each candidate product: (a) Product package

insert or detailed instructions for use; (b) Detailed information to determine if the product is calibrated to a recognized standard; and (c) Preliminary data demonstrating suitability for validation studies.

Organizations that have products selected by CDC for this comparative analysis will be required to enter into an appropriate agreement prior to the transfer of any material to CDC. Sample agreements may be viewed at the following Web site: <http://www.cdc.gov/od/ads/techtran/forms.htm>. All information submitted to CDC will be kept confidential as allowed by relevant federal law, including the Freedom of Information Act (5 U.S.C. 552) and the Trade Secrets Act (18 U.S.C. 1905). Only information submitted within thirty days of publication of this notice will be reviewed to determine if the offered product(s) will be acceptable for possible inclusion in this comparative analysis.

Responses are preferred in electronic format and can be e-mailed to the attention of Michael J. Detmer at MDetmer@cdc.gov. Mailed responses can be sent to the following address: Michael J. Detmer, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Rd., NE., Mail Stop C-09, Atlanta, GA 30333.

FOR FURTHER INFORMATION CONTACT:

Technical: Dr. Patty Wilkins, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Rd., NE., Mail Stop D-11, Atlanta, GA 30333. Telephone (404) 639-3297, E-Mail at pwilkins@cdc.gov.

Business: Lisa Blake-DiSpigna, Technology Development Coordinator, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Rd., NE., Mail Stop A-42, Atlanta, GA 30333. Telephone (404) 639-2620, E-Mail at LBlake-DiSpigna@cdc.gov.

Dated: December 21, 2005.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Environmental Health/Agency for Toxic Substances and Disease Registry

The Program Peer Review Subcommittee of the Board of Scientific Counselors (BSC), Centers for Disease Control and Prevention (CDC), National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR): Teleconference.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), The Centers for Disease Control and Prevention, NCEH/ATSDR announces the following subcommittee meeting:

Name: Program Peer Review Subcommittee (PPRS).

Times and Dates: 12:30 p.m.–2 p.m., January 23, 2006.

Place: The teleconference will originate at the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry in Atlanta, Georgia. Please see **SUPPLEMENTARY INFORMATION** for details on accessing the teleconference.

Status: Open to the public, teleconference access limited only by availability of telephone ports.

Purpose: Under the charge of the BSC, NCEH/ATSDR the PPRS will provide the BSC, NCEH/ATSDR with advice and recommendations on NCEH/ATSDR program peer review. They will serve the function of organizing, facilitating, and providing a long-term perspective to the conduct of NCEH/ATSDR program peer review.

Matters to be Discussed: Discussion of the peer review of the Air Pollution and Respiratory Branch; discussion of the planning for the Division of Toxicology and Environmental Medicine peer review; and a discussion of the peer review process.

Agenda Items are subject to change as priorities dictate.

SUPPLEMENTARY INFORMATION: This conference call is scheduled to begin at 12:30 p.m. EST. To participate please dial (877) 315-6535 and enter conference code 383520. Public comment period is scheduled for 1:45–1:55 p.m.

FOR FURTHER INFORMATION CONTACT:

Sandra Malcom, Committee Management Specialist, Office of Science, NCEH/ATSDR, M/S E-28, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone 404/498-0003.