

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention****Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Public Health Burden of Antimicrobial Resistant Streptococcus Pneumoniae, Panel 1, Potential Extramural Project (PEP), R02**

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:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Public Health Burden of Antimicrobial Resistant Streptococcus Pneumoniae, Panel 1, Potential Extramural Project (PEP), R02.

Times and Dates: 1:30 p.m.–3 p.m., July 11, 2005 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to: Public Health Burden of Antimicrobial Resistant Streptococcus Pneumoniae, Panel 1, Potential Extramural Project (PEP), R02.

Contact Person for More Information: J. Felix Rogers, Ph.D., M.P.H., Scientific Program Administrator, National Immunization Program, CDC, 1600 Clifton Road NE., Mailstop E-05, Atlanta, GA 30333, Telephone 404.639.6101.

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.

Dated: June 13, 2005.

Alvin Hall,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention****The National Institute for Occupational Safety and Health (NIOSH)**

Name: Discussion of Concepts for Standards for Approval of Respirators for Use against Chemical, Biological, Radiological and Nuclear Agents (CBRN) and Guidelines for their Use; and Concepts for Standards for a Multi-Function Powered Air Purifying Respirator (PAPR).

Dates and Times: July 19, 2005; 10 a.m.–4 p.m. July 20, 2005; 8:30 a.m.–3 p.m.

The Meeting on July 19 will address concepts for standards for CBRN Closed Circuit, Self Contained Breathing Apparatus (SCBA) and guidelines for use of NIOSH approved CBRN respirators. The Meeting on July 20 will address concepts for standards for a CBRN Powered Air Purifying Respirator and a Multi-Function PAPR.

Place: Holiday Inn Select Pittsburgh South, 164 Fort Couch Road, Pittsburgh, Pennsylvania.

Purpose: NIOSH will continue discussions of concepts for standards and testing processes for PAPR and Closed Circuit, SCBA suitable for respiratory protection against CBRN agents. NIOSH will also introduce concepts for establishing multi-function PAPR requirements and guidelines for use of NIOSH-approved CBRN respirators. NIOSH, along with the U.S. Army Research, Development and Engineering Command (RDECOM) and the National Institute for Standards and Technology (NIST), will present information to attendees concerning the concept development for the CBRN PAPR standard and the CBRN Closed Circuit, SCBA standard. Participants will be given an opportunity to ask questions on these topics and to present individual comments for consideration. Interested participants may obtain a copy of the CBRN PAPR, the Multi-Function PAPR concept paper, the CBRN Closed Circuit, Self Contained Breathing Apparatus concept paper, and concepts for the guidance documents, as well as earlier versions of other concept papers used during the standard development effort, from the NIOSH National Personnel Protective Technology Laboratory (NPPTL) web site, address: <http://www.cdc.gov/niosh/npptl>. The June 20, 2005, concept papers will be used as the basis for discussion at the public meeting. Municipal, state, and federal responder

groups, particularly in locations considered potential terrorism targets, have been developing and modifying response and consequence management plans for domestic security and preparedness issues. Since the World Trade Center and anthrax incidents, most emergency response agencies have operated with a heightened appreciation of the potential scope and sustained resource requirements for coping with such events. The federal Interagency Board for Equipment Standardization and Interoperability (IAB) has worked to identify personal protective equipment that is already available on the market for responders' use. The IAB has identified the development of standards or guidelines for respiratory protection equipment as a top priority. NIOSH, NIST, the National Fire Protection Association (NFPA), and the Occupational Safety and Health Administration have entered into a Memorandum of Understanding defining each agency or organization's role in developing, establishing, and enforcing standards or guidelines for responders' respiratory protective devices. NIST has initiated Interagency Agreements with NIOSH and RDECOM to aid in the development of appropriate protection standards or guidelines. NIOSH has the lead in developing standards or guidelines to test, evaluate, and approve respirators. NIOSH, RDECOM, and NIST hosted public meetings on April 17 and 18, 2001; June 18 and 19, 2002; October 16 and 17, 2002; April 29, 2003; June 25, 2003; October 16, 2003; May 4, 2004; and December 15, 2004; presenting their progress in assessing respiratory protection needs of responders to CBRN incidents. The methods or models for developing hazard and exposure estimates and the status in evaluating test methods and performance standards that may be applicable as future CBRN respirator standards or guidelines were discussed at these meetings. Three NIOSH CBRN respirator standards and several NFPA standards for ensembles, SCBA, and protective clothing were the first adopted by the U.S. Department of Homeland Security (DHS). On February 26, 2004, DHS adopted, as DHS standards, three NIOSH criteria for testing and certifying respirators for protection against CBRN exposures. NIOSH uses the criteria to test (1) SCBA for use by emergency responders against CBRN, (2) PAPR for use by emergency responders against CBRN exposures, and (3) escape respirators for protection against CBRN.

Status: This meeting is hosted by NIOSH and will be open to the public,

limited only by the space available. The meeting room will accommodate approximately 150 people. Interested parties should make hotel reservations directly with the Holiday Inn Select Pittsburgh South (412-833-5300 or 1-800-HOLIDAY) before the cut-off date of June 27, 2005. A special group rate of \$94 per night for meeting guests has been negotiated for this meeting. The NIOSH/NPPTL Public Meeting must be referenced to receive this rate. Interested parties should confirm their attendance to this meeting by completing a registration form and forwarding it by e-mail (npptlevents@cdc.gov) or fax (304-225-2003) to the NPPTL Event Management Office. A registration form may be obtained from the NIOSH Homepage (<http://www.cdc.gov/niosh>) by selecting conferences and then the event.

An opportunity to make presentations regarding the discussions of concepts for standards and testing processes for PAPR standards and for Closed Circuit, SCBA Breathing Apparatus standards suitable for respiratory protection against CBRN agents, multi-function PAPRs for industrial applications, and guidelines for use of NIOSH-approved CBRN respirators will be given.

Requests to make such presentations at the public meeting should be made by e-mail to the NPPTL Event Management Office (npptlevents@cdc.gov). All requests to present should include the name, address, telephone number, relevant business affiliations of the presenter, a brief summary of the presentation, and the approximate time requested for the presentation. Oral presentations should be limited to 15 minutes. After reviewing the requests for presentation, NPPTL Event Management will notify each presenter of the approximate time that their presentation is scheduled to begin. If a participant is not present when their presentation is scheduled to begin, the remaining participants will be heard in order. At the conclusion of the meeting, an attempt will be made to allow presentations by any scheduled participants who missed their assigned times. Attendees who wish to speak but did not submit a request for the opportunity to make a presentation may be given this opportunity at the conclusion of the meeting, at the discretion of the presiding officer.

Comments on the topics presented in this notice and at the meeting should be mailed to: NIOSH Docket Office, Robert

A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, Telephone 513-533-8303, Fax 513-533-8285. Comments may also be submitted by e-mail to

niocindocket@cdc.gov. E-mail attachments should be formatted in Microsoft Word. Comments should be submitted to NIOSH no later than August 19, 2005. Comments regarding the Multi-Function PAPR should reference Docket Number NIOSH-008 in the subject heading. Comments regarding CBRN PAPR should reference Docket Number NIOSH-010 in the subject heading. Comments regarding the CBRN Closed Circuit, SCBA should reference Docket Number NIOSH-039.

Contact for Additional Information: NPPTL Event Management, 3604 Collins Ferry Road, Suite 100, Morgantown, West Virginia 26505-2353, Telephone 304-599-5941 x138, Fax 304-225-2003, E-mail npptlevents@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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: June 14, 2005.

Alvin Hall,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0186]

Agency Information Collection Activities; Proposed Collection; Comment Request; State Enforcement Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements contained in existing FDA regulations governing State enforcement notifications.

DATES: Submit written or electronic comments on the collection of information by August 19, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.