

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2009-N-0664]

**Advancing Clinical Development of Molecular and Other Diagnostic Tests for Respiratory Tract Infections; Notice of Public Workshop****AGENCY:** Food and Drug Administration.  
**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop, co-sponsored with the Infectious Diseases Society of America (IDSA), regarding scientific issues in the development of molecular and other tests for the diagnosis of respiratory infections, entitled "Advancing Clinical Development of Molecular and Other Diagnostic Tests for Respiratory Tract Infections." The purpose of the public workshop is to provide an opportunity to share information and perspectives with health care providers, academia, and industry on various aspects of diagnostic test development for respiratory infections. Topics for discussion will include the role of emerging diagnostic tests in promoting appropriate use of antibiotics by physicians, the use of novel diagnostic tests in the study of new drugs for respiratory infections, and the possible contribution of biomarkers in the approach to treatment of respiratory infections.

**Date and Time:** The public workshop will be held on November 12, 2009, from 8 a.m. to 6 p.m. and on November 13, 2009, from 8 a.m. to 4:30 p.m.

**Location:** The public workshop will be held at the Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD 20877. Seating is limited and available only on a first-come, first-served basis.

**Contact Person:** Christine Kellerman, Center for Devices and Radiological Health, Food and Drug Administration, Office of In Vitro Diagnostic Devices, 10903 New Hampshire Ave., Building 66, rm. 5677, Silver Spring, MD 20993-0002, 301-796-5711.

**Registration:** To register electronically, e-mail registration information (including: Name, title, firm name, address, telephone, and fax numbers) to [Respdiaomt@fda.hhs.gov](mailto:Respdiaomt@fda.hhs.gov) by November 8, 2009. Persons without access to the Internet can call 301-796-5711 to register. Registration is free for the public workshop. Interested parties are encouraged to register early because space is limited. Seating will be available on a first-come, first-served

basis. Persons needing a sign language interpreter or other special accommodations should notify Christine Kellerman (see *Contact Person*) at least 7 days in advance. Additional information is also available at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm181140.htm>.

**SUPPLEMENTARY INFORMATION:****I. Background**

New diagnostic technologies offer opportunities to guide the appropriate clinical use of anti-infective agents, facilitate the study of new anti-infective agents, and aid in tracking the spread of infectious diseases. To explore issues regarding the development and adoption of emerging diagnostic tests, FDA is announcing a public workshop, co-sponsored with IDSA to address scientific issues in the development of in vitro diagnostic tests for respiratory infections.

**II. Topics for Discussion at the Public Workshop**

Topics to be discussed at the workshop include:

- Principles of clinical trial design and their application to studies of new diagnostics, or studies where new diagnostics and new drugs are investigated simultaneously;
- Test characteristics for emerging tests that would promote clinical adoption and improve antibiotic stewardship;
- Principles for including specific viral or bacterial pathogens in multiplex diagnostic test panels;
- Discussion of approaches to developing a new molecular method when there is no "gold standard" reference method; and
- The use of biomarkers in respiratory infections.

The input from this public workshop will help in developing topics for further discussion. The agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

**Transcripts:** Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, approximately 20 working days after the public workshop at a cost of 10 cents per page. A link to the transcripts will also be available on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/>

*default.htm* approximately 45 days after the workshop.

Dated: October 7, 2009.

**Jeffrey Shuren,***Acting Director, Center for Devices and Radiological Health.*

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BILLING CODE 4160-01-S

**DEPARTMENT OF HOMELAND SECURITY****Coast Guard**

[USCG-2009-0362]

**Collection of Information Under Review by Office of Management and Budget: OMB Control Numbers: 1625-0014, 1625-0038, and 1625-0069****AGENCY:** Coast Guard, DHS.**ACTION:** Thirty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, this request for comments announces that the U.S. Coast Guard is forwarding three Information Collection Requests (ICRs), abstracted below, to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB) requesting an extension of its approval for the following collections of information: (1) 1625-0014, Request for Designation and Exemption of Oceanographic Research Vessels; (2) 1625-0038, Plan Approval and Records for Tank, Passenger, Cargo and Miscellaneous Vessels, Mobile Offshore Drilling Units, Nautical School Vessels and Oceanographic Research Vessels—46 CFR Subchapters D, H, I, I-A, R and U; and (3) 1625-0069, Ballast Water Management for Vessels with Ballast Tanks Entering U.S. Waters. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

**DATES:** Please submit comments on or before November 16, 2009.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number [USCG-2009-0362] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT) or to OIRA. To avoid duplication, please submit your comments by only one of the following means:

- (1) *Electronic submission.* (a) To Coast Guard docket at <http://www.regulation.gov>. (b) To OIRA by e-mail via: [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov).
- (2) *Mail or Hand delivery.* (a) DMF (M-30), DOT, West Building Ground Floor, Room W12-140, 1200 New Jersey

Avenue, SE., Washington, DC 20590–0001. Hand deliver between the hours of 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329. (b) To OIRA, 725 17th Street, NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.

(3) Fax. (a) To DMF, 202–493–2251. (b) To OIRA at 202–395–5806. To ensure your comments are received in a timely manner, mark the fax, attention Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of the docket and will be available for inspection or copying at Room W12–140 on the West Building Ground Floor, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find the docket on the Internet at <http://www.regulations.gov>.

Copies of the ICRs are available through the docket on the Internet at <http://www.regulations.gov>. Additionally, copies are available from: Commandant (CG–611), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2100 2nd St., SW., Stop 7101, Washington, DC 20593–7101.

**FOR FURTHER INFORMATION:** Contact Mr. Arthur Requina, Office of Information Management, telephone 202–475–3523 or fax 202–475–3929, for questions on these documents. Contact Ms. Renee V. Wright, Program Manager, Docket Operations, 202–366–9826, for questions on the docket.

**SUPPLEMENTARY INFORMATION:**

The Coast Guard invites comments on whether these ICRs should be granted based on it being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the collections; (2) the accuracy of the estimated burden of the collections; (3) ways to enhance the quality, utility, and clarity of information subject to the collections; and (4) ways to minimize the burden of collections on respondents, including the use of automated collection techniques or other forms of information technology.

Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG 2009–0362]. For your comments to OIRA to be considered, it is best if they are received on or before November 16, 2009.

*Public participation and request for comments:* We encourage you to respond to this request by submitting comments and related materials. We will post all comments received, without change, to <http://www.regulations.gov>. They will include any personal information you provide. We have an agreement with DOT to use their DMF. Please see the “Privacy Act” paragraph below.

*Submitting comments:* If you submit a comment, please include the docket number [USCG–2009–0362], indicate the specific section of the document to which each comment applies, providing a reason for each comment. We recommend you include your name, mailing address, an e-mail address, or other contact information in the body of your document so that we can contact you if we have questions regarding your submission. You may submit comments and material by electronic means, mail, fax, or delivery to the DMF at the address under **ADDRESSES**; but please submit them by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. In response to your comments, we may revise the ICR or decide not to seek an extension of approval for this collection. The Coast Guard and OIRA will consider all comments and material received during the comment period.

*Viewing comments and documents:* Go to <http://www.regulations.gov> to view documents mentioned in this Notice as being available in the docket. Click on the “read comments” box, which will then become highlighted in blue. In the “Keyword” box insert “USCG–2009–0362” and click “Search.” Click the “Open Docket Folder” in the “Actions” column. You may also visit the DMF in room W12–140 on the West Building Ground Floor, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

*Privacy Act:* Anyone can search the electronic form of all comments received in dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Privacy Act statement regarding our public dockets in the January 17, 2008 issue of the **Federal Register** (73 FR 3316).

**Previous Request for Comments**

This request provides a 30-day comment period required by OIRA. The Coast Guard has published the 60-day notice (74 FR 26875, June 4, 2009) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments.

**Information Collection Request**

1. *Title:* Request for Designation and Exemption of Oceanographic Research Vessels.

*OMB Control Number:* 1625–0014.

*Type of Request:* Revision of a currently approved collection.

*Respondents:* Owners/operators of vessels.

*Abstract:* This information is necessary to ensure a vessel qualifies for the designation.

*Forms:* None.

*Burden Estimate:* The estimated burden has decreased from 51 hours to 35 hours a year.

2. *Title:* Plan Approval and Records for Tank, Passenger, Cargo and Miscellaneous Vessels, Mobile Offshore Drilling Units, Nautical School Vessels and Oceanographic Research Vessels—46 CFR Subchapters D, H, I, I–A, R and U.

*OMB Control Number:* 1625–0038.

*Type of Request:* Revision of a currently approved collection.

*Respondents:* Shipyards, designers, and manufacturers of certain vessels.

*Abstract:* Under 46 U.S.C. 3301 and 3306, the Coast Guard is responsible for enforcing regulations promoting safety of life and property in marine transportation. The Coast Guard uses this information to ensure a vessel meets the applicable standards for construction, arrangement, and equipment.

*Forms:* None.

*Burden Estimate:* The estimated burden has decreased from 13,790 hours to 2,970 hours a year.

3. *Title:* Ballast Water Management for Vessels with Ballast Tanks Entering U.S. Waters.

*OMB Control Number:* 1625–0069.

*Type of Request:* Revision of a currently approved collection.

*Respondents:* Owners and operators of certain vessels.

*Abstract:* The information is needed to ensure compliance with requirements in 33 CFR Part 151, Subparts C and D. The information will also be used for research and periodic reporting to Congress.

*Forms:* CG–5662.

*Burden Estimate:* The estimated burden has decreased from 60,769 hours to 60,727 hours a year.

**Authority:** The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: October 7, 2009.

**M.B. Lytle,**

*Captain, U.S. Coast Guard, Acting Assistant Commandant for Command, Control, Communications, Computers and Information Technology.*

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**BILLING CODE 4910-15-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2009-0934]

### National Boating Safety Advisory Council

**AGENCY:** Coast Guard, DHS.

**ACTION:** Committee management; notice of meeting.

**SUMMARY:** The National Boating Safety Advisory Council (NBSAC) and its subcommittees will meet on October 31 and November 1 and 2, 2009, in Arlington, VA. The meetings will be open to the public.

**DATES:** NBSAC will meet October 31, 2009, from 9 a.m. to 12 p.m. and on November 2, 2009, from 9 a.m. to 5 p.m. The Boats and Associated Equipment Subcommittee will meet on October 31, from 1:30 p.m. to 2:45 p.m. The Prevention Through People Subcommittee will meet on October 31, 2009, from 3 p.m. to 5 p.m., and the Recreational Boating Safety Strategic Planning Subcommittee will meet on November 1, 2009 from 9 a.m. to 5 p.m. Please note that the meetings may conclude early if the Council has completed its business.

All written materials, comments, and requests to make oral presentations at the meetings should reach Mr. Jeff Ludwig by October 26, 2009, via one of the methods described in **ADDRESSES**. Requests to have a copy of your material distributed to each member of the Council prior to the meeting should reach Mr. Ludwig by October 26, 2009.

**ADDRESSES:** The meeting will be held at the Holiday Inn Arlington, 4610 N Fairfax Drive, Arlington, VA 22203.

Please send written material, comments, and requests to make oral presentations to Mr. Jeff Ludwig by one of the submission methods described below. All materials, comments, and requests must be identified by docket number USCG-2009-0934.

**Submission Methods:** Please use only one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *E-mail:* [jeffrey.a.ludwig@uscg.mil](mailto:jeffrey.a.ludwig@uscg.mil). Include the docket number (USCG-2009-0934) in the subject line of the message.

- *Fax:* (202) 372-1932.
- *Mail:* Mr. Jeff Ludwig, COMDT (CG-54221), 2100 2nd Street, SW., Stop 7581, Washington, DC 20593.

**Instructions:** All submissions received must include the words "U.S. Coast Guard" and docket number USCG-2009-0934. All submissions received will be posted without alteration at <http://www.regulations.gov>, including any personal information provided. Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.) You may review a Privacy Act notice regarding our public dockets in the January 17, 2008 issue of the **Federal Register** (73 FR 3316).

**Docket:** For access to the docket to read background documents or submissions received by the NBSAC, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Mr. Jeff Ludwig, COMDT (CG-54221), 2100 2nd Street, SW., Stop 7581, Washington, DC 20593; (202) 372-1061; [Jeffrey.a.ludwig@uscg.mil](mailto:Jeffrey.a.ludwig@uscg.mil).

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92-463). NBSAC was established by the Federal Boat Safety Act of 1971. That law requires the Secretary of Homeland Security, and the Commandant of the Coast Guard by delegation, to consult with NBSAC in prescribing Federal regulations, and on other major matters regarding boating safety. See 46 U.S.C. 4302(c) and 13110(c).

NBSAC will meet for the purpose of discussing issues related to recreational boating safety.

#### A. Tentative Agendas of Meetings

*National Boating Safety Advisory Council (NBSAC):*

*Saturday, October 31, 2009:*

(1) Remarks—Mr. James P. Muldoon, NBSAC Chairman;

(2) Chief, Office of Auxiliary and Boating Safety Update on NBSAC Resolutions and Recreational Boating Safety Program report.

(3) Executive Secretary's report.

(4) Chairman's session.

(5) TSAC Liaison's report.

(6) NAVSAC Liaison's report.

(7) National Association of State Boating Law Administrators report.

(8) Boats and Associated Equipment Subcommittee meeting.

*Sunday, November 1, 2009:*

(9) Prevention through People Subcommittee meeting.

(10) Recreational Boating Safety Strategic Planning Subcommittee meeting.

*Monday, November 2, 2009:*

(11) Prevention through People Subcommittee report.

(12) Boats and Associated Equipment Subcommittee report.

(13) Recreational Boating Safety Strategic Planning Subcommittee report.

A more detailed agenda can be found at: <http://homeport.uscg.mil/NBSAC>, after October 26, 2009.

#### B. NBSAC Subcommittees

*Prevention Through People Subcommittee:* Discuss current regulatory projects, grants, contracts, and new issues affecting the prevention of boating accidents through outreach and education of boaters.

*Boats and Associated Equipment Subcommittee:* Discuss current regulatory projects, grants, contracts, and new issues affecting boats and associated equipment.

*Recreational Boating Safety Strategic Planning Subcommittee:* Discuss current status of the strategic planning process and any new issues or factors that could impact, or contribute to, the development of the strategic plan for the recreational boating safety program.

#### C. Meeting Procedure

This meeting is open to the public. At the discretion of the Chair, members of the public may make oral presentations during the meeting. If you would like to make an oral presentation at the meeting, please notify Mr. Jeff Ludwig as described in the **ADDRESSES** section above. If you would like a copy of your material distributed to each member of the Council in advance of the meeting, please submit thirty (30) of copies to Mr. Jeff Ludwig by October 26, 2009.

Please note that the meeting may conclude early if all business is finished.

#### D. Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Mr. Jeff Ludwig as described in the **ADDRESSES** section above as soon as possible.