DEPARTMENT OF HEALTH AND HUMAN SERIVCES

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 *Respdiagmtg@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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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*.

(2) *Mail or Hand delivery.* (a) DMF (M–30), DOT, West Building Ground Floor, Room W12–140, 1200 New Jersey