registration information will be required for 3,000 trials of drugs and biologics and 445 trials of medical devices each year.

Each initial registration is estimated to take 7 hours and each of the subsequent 8 updates to the record are estimated to take 2 hours, resulting in an annual burden of 79,235 hours. It is estimated that there will be voluntary submissions of registration information for 6,000 trials of drugs and biologics, 545 trials of devices, and 5,280 trials of other types of medical interventions. Using the same hour estimates as for mandatory registration, the burden associated with voluntary registrations is estimated at 271,975 hours, bringing the total registration burden to 351,210 hours. In the first year of operation, it is estimated that there will be an additional burden of 84,150 hours associated with the updating of information for 7,000 trials of drugs and biologics and 650 trials of medical devices that were previously registered in the databank and ongoing as of December 26, 2007 (90 days after enactment). It is estimated that such trials will require one update of 3 hours to bring them into compliance with the new law (FDAAA) and 4 subsequent updates of 2 hours each. Submisson of results information is required only for those applicable clinical trials of drugs, biologics, and devices that are subject to the mandatory registration requirements of FDAAA and for which the product(s) under study have been approved or cleared by the FDA. It is estimated that results reporting will be required for 1,645 trials of drugs and biologics and 375 trials of medical devices each year. Initial submission of results information is estimated to require 10 hours, and each result submission is expected to require two updates that take 5 hours each. It is estimated that 2,345 trials per year will submit certifications for delayed reporting of results information or a request for an extension of the reporting deadline. Preparation and submission of such information is estimated to take 1 hour. The total burden for results reporting is therefore estimated at 42,745 hours per year. There are no capital costs to report. The operating and maintenance budget for the Clinical Trials Registry Databank in FY2009 is projected to be approximately $3 million.

Request For Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: David Sharlip, National Library of Medicine, Building 38A, Room B2N12, 8600 Rockville Pike, Bethesda, MD 20894, or call non-toll free number 301–402–9680 or e-mail your request to *sharlipd@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: December 17, 2008.

Betsy L. Humphreys,

Deputy Director, National Library of Medicine, National Institutes of Health.

[FR Doc. E8–31448 Filed 1–5–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Library of Medicine, Special Emphasis Panel, G08/K99/R01/R13 SEP.

Date: February 11, 2009.

Time: 12 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Zoe E. Huang, MD, Scientific Review Officer, Division of Extramural Programs, National Library of Medicine, National Institutes of Health, 6705 Rockledge Drive, Suite 301, MSC 7968, Bethesda, MD 20892–7968, 301–594–4937, *huangz@mail.nih.gov.*

Name of Committee: National Library of Medicine Special Emphasis Panel; G13 SEP.

Date: February 20, 2009.

Time: 8:30 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Zoe E. Huang, MD, Scientific Review Officer, Division of Extramural Programs, National Library of Medicine, National Institutes of Health, 6705 Rockledge Drive, Suite 301, MSC 7968, Bethesda, MD 20892–7968, (301) 594–4937, *huangz@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: December 22, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–31379 Filed 1–5–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2008–0961]

Collection of Information Under Review by Office of Management and Budget: OMB Control Number: 1625–0073

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 an Information Collection Request (ICR), 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 collection of information: 1625–0073, Alteration of Unreasonable Obstructive Bridges. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Please submit comments on or before February 5, 2009.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2008–0961] 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 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, to the attention of the Desk Officer for the Coast Guard.

(3) *Fax.* (a) To DMF, 202–493–2251. (b) To OIRA at 202–395–6566. To ensure your comments are received in time, mark the fax to the attention of the 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 this 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 this docket on the Internet at *http://www.regulations.gov.*

A copy of the ICR is available through this docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from Commandant (CG–611), U.S. Coast Guard Headquarters, (Attn: Mr. Arthur Requina), 2100 2nd Street, SW., Washington, DC 20593–0001. The telephone number is 202–475–3523.

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 this ICR 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. Comments to Coast Guard must contain the docket number of this request, [USCG 2008–0961]. For your comments to OIRA to be considered, it is best if they are received on or before the February 5, 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 paragraph on DOT's ''Privacy Act Policy'' below.

Submitting comments: If you submit a comment, please include the docket number [USCG–2008–0961], 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. Enter the docket number [USCG–2008–0961] in the Search box, and click, ''Go>>.'' 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 (73 FR 54842, September 23, 2008) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments.

Information Collection Request

Title: Alteration of Unreasonable Obstructive Bridges.

OMB Control Number: 1625–0073.

Type Of Request: Extension of a currently approved collection.

Affected Public: Public and private owners of bridges over navigable waters of the United States.

Abstract: Sections 494, 502, 511, 513, 514, 516, 517, 521, 522, and 523 of 33 U.S.C. authorize the Coast Guard to alter bridges and causeways that go over navigable waters of the United States and are deemed to be unreasonably obstructive. Coast Guard regulations on the alteration of unreasonably obstructive bridges are located in 33 CFR part 116.

Forms: None.

Burden Estimate: The estimated burden has increased from 200 hours to 240 hours per year.

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

Dated: December 29, 2008.

D.T. Glenn,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Command, Control, Communications, Computers and Information Technology.

[FR Doc. E8–31416 Filed 1–5–09; 8:45 am]

BILLING CODE 4910–15–P