

regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory Agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations. The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area and the World Health Organization. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions.

The current ICH process and structure can be found at the following Web site: <http://www.ich.org>. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

The agenda for the public meeting will be made available on the Internet at <http://www.fda.gov/Drugs/NewsEvents/ucm248489.htm>.

Dated: September 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-25480 Filed 10-3-11; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2011-0914]

Information Collection Request to Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of revisions to the following collection of information: 1625-0015, Bridge Permit Application Guide. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before December 5, 2011.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG-2011-0914] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT). To avoid duplicate submissions, please use only one of the following means:

- (1) *Online:* <http://www.regulations.gov>.
- (2) *Mail:* DMF (M-30), DOT, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001.
- (3) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(4) *Fax:* 202-493-2251. To ensure your comments are received in a timely manner, mark the fax, to 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>.

A copy of the ICR is 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 Street, SW., Stop 7101, Washington, DC 20593-7101.

FOR FURTHER INFORMATION CONTACT: Ms. Kenlinishia Tyler, Office of Information Management, telephone 202-475-3652, 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:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek approval of revisions of the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG-2011-0914], and must

be received by December 5, 2011. 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–2011–0914], indicate the specific section of the document to which each comment applies, providing a reason for each comment. If you submit a comment online via <http://www.regulations.gov>, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the DMF. 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 your comments and material by electronic means, mail, fax, or hand delivery to the DMF at the address under **ADDRESSES**; but please submit them by only one means. To submit your comment online, go to <http://www.regulations.gov>, and type "USCG–2011–0914" in the "Keyword" box. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and will address them accordingly.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this Notice as being available in the docket, go to <http://www.regulations.gov>, click on the "read comments" box, which will then become highlighted in blue. In the "Keyword" box insert "USCG–2011–0914" and click "Search." Click the "Open Docket Folder" in the "Actions" column. You may also visit the DMF in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act

Anyone can search the electronic form of 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 a Privacy Act statement regarding Coast Guard public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Information Collection Request

Title: Bridge Permit Application Guide.

OMB Control Number: 1625–0015.

Summary: The collection of information is a request for a bridge permit submitted as an application for approval by the Coast Guard of any proposed bridge project. An applicant must submit to the Coast Guard a letter of application along with letter-size drawings (plans) and maps showing the proposed project and its location.

Need: 33 U.S.C. 401, 491, and 525 authorize the Coast Guard to approve plans and locations for all bridges and causeways that go over navigable waters of the United States.

Forms: None.

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

Frequency: On occasion.

Burden Estimate: The estimated burden is 10,760 hours a year.

Dated: September 29, 2011.

R.E. Day,

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

[FR Doc. 2011–25543 Filed 10–3–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2011–0948]

Great Lakes Pilotage Advisory Committee

AGENCY: Coast Guard, DHS.

ACTION: Committee Management; Notice of Federal Advisory Committee Meeting.

SUMMARY: The Great Lakes Pilotage Advisory Committee (GLPAC) will meet on October 18, 2011, in Washington, District of Columbia. The meeting will be open to the public.

DATES: GLPAC will meet on Tuesday, October 18, 2011, from 9 a.m. to 4 p.m. Please note the meeting may close early

if the committee completes its business. Written material and requests to make oral presentations should reach us on or before October 14, 2011.

ADDRESSES: The meeting will be held at Coast Guard Headquarters, 2100 2nd Street Southwest, Washington, District of Columbia 20593, in conference room 51309. All visitors to Coast Guard Headquarters will have to pre-register to be admitted to the building. Please provide your name, telephone number and organization by close of business on October 14, 2011, to the contact person listed in **FOR FURTHER INFORMATION CONTACT:** below. Additionally, all visitors to Coast Guard Headquarters must produce valid photo identification for access to the facility.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the person listed in **FOR FURTHER INFORMATION CONTACT:** below as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the committee as listed in the "Agenda" section below. Comments must be submitted in writing no later than October 14, 2011, and must be identified by [USCG–2011–XXXX] and may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington DC 20590–0001.

- *Hand Delivery:* Same as mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329. To avoid duplication, please use only one of these four methods.

Instructions: All submissions received must include the words "Department of Homeland Security" and the docket number for this action. Comments received will be posted without alteration at <http://www.regulations.gov>, including any personal information provided. 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 documents or comments related to this notice, go to <http://www.regulations.gov>, and use "USCG–2011–XXXX" as your search term.