This draft guidance also refers to previously approved collections of information found in FDA regulations with respect to submitting supplements to approved applications. These collections of information are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3502). The collection of information in 21 CFR 201.56(a)(2) has been approved under OMB control number 0910-0572; in 21 CFR 314.70 has been approved under OMB control number 0910–0001; in 21 CFR 601.12 has been approved under OMB control number 0910-0338; and in 21 CFR 514.8(c) has been approved under OMB control number 0910-0032.

# **III. Comments**

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http:// www.regulations.gov.* 

# **IV. Electronic Access**

Persons with access to the Internet may obtain the document at http:// www.fda.gov/Drugs/Guidance ComplianceRegulatoryInformation/ Guidances/default.htm, http:// www.fda.gov/BiologicsBloodVaccines/ GuidanceComplianceRegulatory Information/default.htm, http:// www.fda.gov/AnimalVeterinary/ GuidanceComplianceEnforcement/ GuidanceforIndustry/default.htm, or http://www.regulations.gov.

Dated: June 6, 2014.

### Leslie Kux,

Assistant Commissioner for Policy. [FR Doc. 2014–13569 Filed 6–10–14; 8:45 am] BILLING CODE 4164–01–P

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

# Health Resources and Services Administration

# Advisory Committee on Infant Mortality; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting: *Name:* Advisory Committee on Infant Mortality (ACIM).

*Dates and Times:* July 9, 2014, 8:30 a.m.–5:30 p.m., July 10, 2014, 8:30 a.m.– 3:30 p.m.

*Place:* To be determined. (The most current information, including the agenda, will be posted at: *http://www.hrsa.gov/advisorycommittees/mchbadvisory/InfantMortality/index.html*).

*Status:* The meeting is open to the public with attendance limited to space availability.

Purpose: The Committee provides advice and recommendations to the Secretary of Health and Human Services on the following: Department of Health and Human Services' programs that focus on reducing infant mortality and improving the health status of infants and pregnant women and factors affecting the continuum of care with respect to maternal and child health care. It includes outcomes following childbirth; strategies to coordinate myriad federal, state, local, and private programs and efforts that are designed to deal with the health and social problems impacting on infant mortality; and the implementation of the Healthy Start Program and Healthy People 2020 infant mortality objectives.

*Agenda:* Topics that will be discussed include the following: Health Resources and Services Administration (HRSA) Update; MCHB Update; Healthy Start Program Update; Updates from Partnering Agencies and Organizations; and ACIM's recommendations for the HHS National Strategy to Address Infant Mortality, specifically Strategy 2: The continuum of high-quality, patientcentered care.

Proposed agenda items are subject to change as priorities dictate. Time will be provided for public comments limited to 5 minutes each. Comments are to be submitted in writing no later than 5 p.m. ET on July 1, 2014.

FOR FURTHER INFORMATION CONTACT: Anyone requiring information regarding the Committee should contact Michael C. Lu, M.D., M.P.H., Executive Secretary, ACIM, Health Resources and Services Administration, Room 18 W, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, Telephone: (301) 443–2170. Individuals who are submitting public comments or who have questions regarding the meeting and location should contact David S. de la Cruz, Ph.D., M.P.H., ACIM Designated Federal Official, Health Resources and Services Administration, Maternal and Child Health Bureau, Telephone: (301) 443–0543, email: David.delaCruz@ hrsa.hhs.gov.

Dated: June 4, 2014. Jackie Painter, Deputy Director, Division of Policy and Information Coordination. [FR Doc. 2014–13527 Filed 6–10–14; 8:45 am] BILLING CODE

# DEPARTMENT OF HOMELAND SECURITY

# **Coast Guard**

[USCG-2014-0154]

## 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 (ICRs) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of a revision to the following collection of information: 1625–0005, Application and Permit to Handle Hazardous Materials. 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 August 11, 2014.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number [USCG-2014-0154] 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.

Copies of the ICR(s) are available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–612), ATTN PAPERWORK REDUCTION ACT MANAGER, US COAST GUARD, 2703 MARTIN LUTHER KING JR AVE SE STOP 7710, WASHINGTON DC 20593– 7710.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents. Contact Ms. Cheryl Collins, 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 these ICRs should be granted based on the Collections 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 the Collections on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise these ICRs or decide not to seek approval of revisions of the Collections. 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-2014-0154], and must be received by August 11, 2014. 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-2014–0154], indicate the specific section of the document to which each comment applies, providing a reason for each comment. You may submit your comments and material online (via http://www.regulations.gov), by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via 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 email 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 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-2014–0154" in the "Search" box. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 81/2 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 "Search" box insert "USCG-2014-0154" 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**

1. *Title:* Application and Permit to Handle Hazardous Materials.

*OMB Control Number:* 1625–0005. *Summary:* The information sought by this collection, which includes form CG–4260, ensures the safe handling of explosives and other hazardous materials around ports and aboard vessels.

*Need:* Sections 1225 and 1231 of 33 U.S.C. authorize the Coast Guard to establish standards for the handling, storage, and movement of hazardous materials on a vessel and waterfront facility. Regulations in 33 CFR 126.17, 49 CFR 176.100, and 176.415 prescribe the rules for facilities and vessels.

Forms: CG-4260.

*Respondents:* Shipping agents and terminal operators that handle hazardous materials.

*Frequency:* On occasion.

*Burden Estimate:* The estimated burden has decreased from 205 hours to 182 hours a year due to a decrease in the estimated number of responses.

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

Dated: June 3, 2014.

## Marshall B. Lytle,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Command, Control, Communications, Computers and Information Technology. [FR Doc. 2014–13548 Filed 6–10–14; 8:45 am]

BILLING CODE 9110-04-P

## DEPARTMENT OF HOMELAND SECURITY

## **Coast Guard**

[USCG-2014-0107]

# Information Collection Request to Office of Management and Budget

**AGENCY:** Coast Guard, DHS. **ACTION:** Sixty-day notice requesting comments.