a list of guidance documents that CDRH is considering for development and providing stakeholders an opportunity to provide comments and/or draft language for those topics, or suggestions for new or different guidances. This notice announces the Web site location of the list of guidances on which CDRH is intending to work over the next fiscal year (FY). We note that the Agency is not required to issue every guidance on the list, nor is it precluded from issuing guidance documents that are not on the list. The list includes topics that currently have no guidance associated with them, topics where updated guidance may be helpful, and topics for which CDRH has already issued level 1 drafts that may be finalized following review of public comments. We will consider stakeholder comments as we prioritize our guidance efforts.

FDA and CDRH priorities are subject to change at any time. Topics on this and past guidance priority lists may be removed or modified based on current priorities. We also note that CDRH's experience over the years has shown that there are many reasons CDRH staff does not complete the entire annual agenda of guidances it undertakes. Staff are frequently diverted from guidance development to other activities, including review of premarket submissions or postmarket problems. In addition, the center is required each year to issue a number of guidances that it cannot anticipate at the time the annual list is generated. These may involve newly identified public health issues as well as special control guidance documents for de novo classifications of devices. It will be helpful, therefore, to receive comments that indicate the relative priority of different guidance topics to interested stakeholders.

Through feedback from stakeholders, including draft language for guidance documents, CDRH expects to be able to better prioritize and more efficiently draft guidances that will be useful to industry and other stakeholders. This will be the fifth annual list CDRH has posted. FDA intends to update the list each year.

FDA invites interested persons to submit comments on any or all of the guidance documents on the list. FDA has established a docket where comments about the FY 2012 list, draft language for guidance documents on those topics, and suggestions for new or different guidances may be submitted (see **ADDRESSES**). FDA believes this docket is an important tool for receiving information from interested parties and for sharing this information with the public. Similar information about planned guidance development is included in the annual Agency-wide notice issued by FDA under its good guidance practices (21 CFR 10.115(f)(5)). This CDRH list, however, will be focused exclusively on device-related guidances and will be made available on FDA's Web site prior to the beginning of each FY from 2008 to 2012. To access the list of the guidance documents CDRH is considering for development in FY 2012, visit FDA's Web site *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109196.htm*.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: September 29, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–25507 Filed 10–3–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Preparation for International Conference on Harmonization Steering Committee and Expert Working Group Meetings in Seville, Spain; Regional Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Preparation for ICH Steering Committee and Expert Working Group Meetings in Seville, Spain'' to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Seville, Spain. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Group meetings in Seville, Spain, scheduled on November 5 through 10, 2011, at which discussion of the topics underway and the future of ICH will continue.

Date and Time: The public meeting will be held on October 25, 2011, from 2 p.m. to 4 p.m.

Location: The public meeting will be held at the Washington Theater room at the Hilton Washington DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: All participants must register with Kimberly Franklin, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, e-mail: *Kimberly.Franklin@fda.hhs.gov,* or FAX: 301–595–7937.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), written material, and requests to make oral presentations to the contact person (see *Contact Person*) by October 21, 2011.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Public oral presentations will be scheduled between approximately 3:30 p.m. and 4 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person (see *Contact Person*) by October 21, 2011, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, telephone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

If you need special accommodations due to a disability, please contact Kimberly Franklin (see *Contact Person*) at least 7 days in advance.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: The ICH was established in 1990 as a joint

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 Manufactures 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]

BILLING CODE 4160–01–P

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