

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 hrs each. Results reporting 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. The total burden for results reporting is therefore estimated at 40,400 hours per year. There are no capital costs to report.

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.

FOR FURTHER INFORMATION CONTACT: 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 60 days of the date of this publication.

Dated: September 30, 2008.

Betsy L. Humphreys,
Deputy Director, National Library of Medicine, National Institutes of Health.
[FR Doc. E8-23790 Filed 10-7-08; 8:45 am]
BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Refugee Resettlement

Replacement Grant Award

CFDA#: 93.576.
AGENCY: Office of Refugee Resettlement, ACF, DHHS.
ACTION: Notice to award a replacement grant to Catholic Charities of Tennessee, Inc.

SUMMARY: In Fiscal Year 2005, in an effort to assist local school systems that were being strained by the arrivals of large numbers of refugee children, The Office of Refugee Resettlement (ORR) awarded, through competition, a Refugee School Impact grant to the Tennessee Department of Human Services, Nashville, TN, for a project period of August 15, 2005 through August 14, 2010. The Tennessee Department of Human Services served as the fiscal sponsor and legal entity for the project. As of June 30, 2008, the Tennessee Department of Human Services relinquished the grant. Catholic Charities of Tennessee, Inc., Nashville, TN, is now awarded a non-competitive replacement grant to continue to provide services under the Refugee School Impact project. Services provided under the grant to Catholic Charities of Tennessee, Inc., are within the scope and operation of the original award. Under the award, Catholic

Charities of Tennessee, Inc., is eligible apply for a non-competitive continuation award for the period of August 15, 2009 through August 14, 2010.

FOR FURTHER INFORMATION CONTACT: Pamela Green-Smith, Director, Division of Refugee Assistance, Office of Refugee Resettlement, 370 L'Enfant Promenade, SW., Washington, DC 20447. Telephone: 202-401-4531. E-mail: Pamela.Greensmith@acf.hhs.gov

SUPPLEMENTARY INFORMATION:

Legislative Authority: This program is authorized by Section 412 (c)(1)(A)(iii), as amended of the Immigration and Nationality Act (8 U.S.C. 1522 (c)(1)(A)(iii)) and covers the following Services: (1) English as a Second Language instruction (2) After-school tutorials focused on helping students understand and complete programs that encourage high school completion and full participation in school activities (3) After-school summer programs that support remedial work or promote school readiness (4) Parental involvement programs (5) Interpreter services for parent/teacher meetings and conferences and (6) Bi-lingual/bi-cultural counselors and aides.

Amount of Award: \$224,834.76.

Project Period: August 15, 2008—August 14, 2010.

Dated: October 1, 2008.

Pamela Green-Smith,
Director, Division of Refugee Assistance,
Office of Refugee Resettlement.
[FR Doc. E8-23774 Filed 10-7-08; 8:45 am]
BILLING CODE 4184-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2008-1006]

National Offshore Safety Advisory Committee; Meeting

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting.

SUMMARY: The National Offshore Safety Advisory Committee (NOSAC) will meet, in New Orleans, LA, to discuss various issues relating to offshore safety and security. The meeting will be open to the public.

DATES: NOSAC will meet on Thursday, November 13, 2008, from 9 a.m. to 3 p.m. The meeting may close early if all business is finished. Written material and requests to make oral presentations should reach the Coast Guard on or before October 30, 2008. Requests to

have a copy of your material distributed to each member of the committee should reach the Coast Guard on or before October 30, 2008.

ADDRESSES: NOSAC will meet in the Versailles Ballroom of the Hilton New Orleans Riverside Hotel, 2 Poydras Street, New Orleans, Louisiana. Send written material and requests to make oral presentations to Commander P.W. Clark, Designated Federal Officer, Commandant (CG-5222), U.S. Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC 20593-0001. This notice is available on our online docket, USCG-2008-0188, at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Commander P.W. Clark, Designated Federal Officer (previously referred to as Executive Director) of NOSAC, or Mr. Jim Magill, Assistant Designated Federal Officer (previously referred to as Assistant Executive Director), telephone 202-372-1414, fax 202-372-1926.

SUPPLEMENTARY INFORMATION: Notice of the meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92-463).

Agenda of Meeting

The agenda for the November 13, 2008, committee meeting includes the following:

- (1) Report on issues concerning the International Maritime Organization (IMO) and the International Organization for Standardization.
- (2) Revision of 46 CFR, Subchapter V, Subpart B—Commercial Diving Operations.
- (3) MARPOL Annex II Implementation for New and Existing Offshore Supply Vessels (OSVs).
- (4) Sandblasting standard for OCS facilities.
- (5) Evacuation of Injured Workers from remote Drilling and Production Facilities.
- (6) Transportation Worker Identification Credential (TWIC) impact on offshore facilities.
- (7) Effect of Hurricane IKE on OCS facilities.
- (8) Licensing of Large OSVs.
- (9) The LA 1 Project—New Access Road to GOM.
- (10) Information regarding notice of arrival on the U.S. Outer Continental Shelf.

Procedural

The meeting is open to the public. Please note that the meeting may close early if all business is finished. At the Chair's discretion, members of the public may make oral presentations during the meeting. If you would like to

make an oral presentation at the meeting, please notify the Designated Federal Officer no later than October 30, 2008. Written material for distribution at the meeting should reach the Coast Guard no later than October 30, 2008. If you would like a copy of your material distributed to each member of the committee in advance of the meeting, please submit 25 copies to the Designated Federal Officer no later than October 30, 2008.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the Executive Director as soon as possible.

Dated: October 2, 2008.

Howard L. Hime,

Acting Director of Commercial Regulations and Standards.

[FR Doc. E8-23772 Filed 10-7-08; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5191-N-32]

Notice of Proposed Information Collection: Comment Request; Single Family Mortgage Insurance on Hawaiian Homelands

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* December 8, 2008.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Lillian Deitzer, Departmental Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410; e-mail Lillian_L_Deitzer@HUD.gov or telephone (202) 402-8048.

FOR FURTHER INFORMATION CONTACT: Margaret E. Burns, Director, Office of Single Family Program Development,

Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410, telephone (202) 708-2121 (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions 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; (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 collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Single Family Mortgage Insurance on Hawaiian Homelands.

OMB Control Number, if applicable: 2502-0358.

Description of the need for the information and proposed use: FHA insures mortgages on single family dwellings under various provisions of the National Housing Act (12 U.S.C. 1701, et seq.). The Housing and Urban Rural Recovery Act (HURRA), Pub. L. 98-181, amended the National Housing Act to add Section 247 to permit FHA to insure mortgages for properties located on Hawaiian Homelands. Under this program, the mortgagor must be a Native Hawaiian. Section 247 requires that the Department of Hawaiian Homelands (DHHL) of the State of Hawaii (a) Will be a co-mortgagor; (b) guarantees or reimburses the Secretary for any mortgage insurance claims paid in connection with a property on Hawaiian homelands; or (c) offers other security acceptable to the Secretary. The collection of information and the regulatory origins for them are in accordance with Section 203.43i which states that the lender will: (a) Verify that the loan applicant is a native Hawaiian and that the applicant holds a lease on land in a Hawaiian Homelands area; (b) report on delinquent borrowers in