Dated: April 5, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–08153 Filed 4–8–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0536]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device User Fee Cover Sheet, Form FDA 3601

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 11, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0511. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device User Fee Cover Sheet, Form FDA 3601—OMB Control Number 0910–0511—Extension

The Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), and the Medical Device User Fee Amendments of 2007 (Title II of the Food and Drug Administration Amendments Act of 2007), authorizes FDA to collect user fees for certain medical device applications. Under this authority, companies pay a fee for certain new medical device applications or supplements submitted to the Agency for review. Because the submission of user fees concurrently with applications and supplements is required, the review of an application cannot begin until the fee is submitted. Form FDA 3601, the Medical Device User Fee Cover Sheet, is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference between the fees submitted for an application with the actual submitted application by using a unique number tracking system. The information collected is used by FDA's Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research to initiate the administrative screening of new medical device applications and supplemental applications.

The total number of annual responses is based on the average number of cover sheet submissions received by FDA in recent years. The number of received annual responses includes cover sheets for applications that were qualified for small businesses and fee waivers or reductions. The estimated hours per response are based on past FDA experience with the various cover sheet submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates (18 minutes).

In the **Federal Register** of October 21, 2015 (80 FR 63793), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3601	5,214	1	5,214	0.30 (18 minutes).	1,564

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 5, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–08154 Filed 4–8–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council on Alzheimer's Research, Care, and Services provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. The Advisory Council will spend the majority of the April meeting considering recommendations made by each of the three subcommittees for updates to the 2016 National Plan. Additional presentations in the afternoon will include an update on the Dementia Friendly America campaign, planning progress towards a Care and Services Summit, and federal workgroup updates.

DATES: The meeting will be held on April 29, 2016 from 9 a.m. to 5 p.m. EDT.

ADDRESSES: The meeting will be held in Room 800 in the Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

Comments: Time is allocated in the afternoon on the agenda to hear public comments. The time for oral comments will be limited to two (2) minutes per individual. In lieu of oral comments,

formal written comments may be submitted for the record to Rohini Khillan, ASPE, 200 Independence Avenue SW., Room 424E, Washington, DC 20201. All comments should be submitted to *napa@hhs.gov* for the record and to share with the Advisory Council by April 20, 2016. Those submitting comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Rohini Khillan (202) 690–5932, *rohini.khillan@hhs.gov.* Note: Seating may be limited. Those wishing to attend the meeting must send an email to *napa@hhs.gov* and put ''April 29 Meeting Attendance'' in the Subject line by Friday, April 15, 2016 so that their names may be put on a list of expected attendees and forwarded to the security officers the Humphrey Building. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and the entrance to federal buildings may change without notice. If you wish to make a public comment, you must note that within your email.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: The Advisory Council will spend the majority of the April meeting considering recommendations made by each of the three subcommittees for updates to the 2016 National Plan. Additional presentations in the afternoon will include an update on progress made by the Dementia Friendly America campaign, and update on planning towards a Care and Services Summit, and federal workgroup updates.

Procedure and Agenda: This meeting is open to the public. Please allow 45 minutes to go through security and walk to the meeting room. The meeting will also be webcast at *www.hhs.gov/live* .

Authority: 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: March 23, 2016.

Richard G. Frank,

Assistant Secretary for Planning and Evaluation.

[FR Doc. 2016–08170 Filed 4–8–16; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Delegation of Authority

Notice is hereby given that I have delegated to the Administrator, Centers for Medicare & Medicaid Services (CMS) with authority to re-delegate, the authority under Title 31, Section 313(d)(1) and (2) of the United States Code (U.S.C.), as amended, to implement the coordination with the Secretary of the Treasury, and establish an arrangement with the Secretary of the Treasury, regarding the appropriate functions that the Federal Insurance Office (FIO) may perform relating to health insurance, as determined based on Section 2791 of the Public Health Service Act [42 U.S.C. 300gg–91], or relating to long-term care insurance.

I hereby affirm and ratify any actions taken by the Administrator, CMS, or other CMS officials, which involve the exercise of this authority prior to the effective date of this delegation.

This delegation of authority is effective immediately.

This delegation of authority may be re-delegated.

Authority: 31 U.S.C. 313

Dated: March 24, 2016.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2016–08171 Filed 4–8–16; 8:45 am]

BILLING CODE 4150–03–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–0193]

Certificates of Alternative Compliance, First Coast Guard District

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The Coast Guard announces that the First Coast Guard District's Prevention Department has issued certificates of alternative compliance with the International Regulations for Preventing Collisions at Sea (72 COLREGS), to vessels of special construction or purpose that cannot fully comply with the light, shape, and sound signal provisions of 72 COLREGS without interfering with their special function. This notice promotes the Coast Guard's maritime safety and stewardship missions.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email Mr. Kevin Miller, First Coast Guard District's Towing Vessel and Barge Safety Specialist at (617) 223–8272 or [*Kevin.L.Miller2@uscg.mil*].

SUPPLEMENTARY INFORMATION:

Discussion

The United States is signatory to the International Maritime Organization's International Regulations for Preventing Collisions at Sea, 1972, as amended. The special construction or purpose of some vessels makes them unable to comply with the light, shape, and sound signal provisions of 72 COLREGS. Under statutory law [1] and Coast Guard regulation,[2] a vessel may instead meet alternative requirements and the vessel's owner, builder, operator, or agent may apply for a certificate of alternative compliance (COAC). The Chief of the Inspections and Investigations Branch in each Coast Guard District office determines whether the vessel for which the COAC is sought complies as closely as possible with 72 COLREGS, and decides whether to issue the COAC. Once issued, a COAC remains valid until information supplied in the application for the COAC, or the terms of the COAC, become inapplicable to the vessel. Under the governing statute [3] and regulation,[4] the Coast Guard must publish notice of each COAC issued by the District office.

The First Coast Guard District issued COACs to the following vessels between 2012 and 2015:

Year	Vessel name	Details
2012	MARK MORAN	This certificate authorizes the placement of the vessel's sidelights in a position 12′ 8.5″ from the vessel's side, mounted to the deckhouse.

[1] 33 U.S.C. 1605.

[2] 33 CFR 81.3.

[3] 33 U.S.C. 1605(c).

[4] 33 CFR 81.18.