permits Federal, State, and local governments to pre-position (e.g., stockpile, forward-deploy) MCMs in anticipation of FDA approval or clearance, authorization of an investigational use, or the issuance of an EUA. This authority is also discussed in this document.

II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on emergency use authorization of medical products and related authorities. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access


IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). This guidance refers to previously approved collections of information. These collections of information have been approved under OMB control numbers 0910–0308, 0910–0230, 0910–0471, 0910–0014, 0910–0078 and 0910–0595. The collection of information in this guidance was approved under OMB control number 0910–0595.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2017–00721 Filed 1–12–17; 8:45 am]
BILLING CODE 4164–01–P

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 theme of the February meeting will be clinical trials for Alzheimer’s disease and related dementias and recruitment challenges. Additional presentations in the afternoon will include updates on progress towards a Care and Services Summit, federal workgroup updates, and preparation for the Advisory Council’s 2017 Recommendations, due in April 2017.

DATES: The meeting will be held on Friday, February 3, 2017 from 9:00am to 5:00pm EDT.

ADDRESSES: The meeting will be held in the Great Hall 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 Khilian, 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 January 27, 2017. Those submitting comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Rohini Khilian (202) 690–5932, rohini.khilian@hhs.gov. Note: Seating may be limited. Those wishing to attend the meeting must send an email to napa@hhs.gov and put “February Meeting Attendance” in the Subject line by Friday, January 20, 2017 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 meetings theme of the February meeting will be clinical trials for Alzheimer’s disease...
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (http://vedocast.nih.gov).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Advisory Board.
Date: February 15, 2017.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging: Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Predictors and Determinants of Age-Related Reliabilities to Physical Stressors, RFA–AG–014 (UH2).
Date: February 23, 2017.
Time: 2:30 p.m. to 4:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Carmen Moten, Ph.D., MPH, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7703, cmoten@mail.nih.gov.

Name of Committee: National Institute on Aging Special Emphasis Panel; Late Onset of Alzheimer’s Disease (LOAD), PAR–16–205 (U24).
Date: March 7, 2017.
Time: 10:00 a.m. to 12:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Carmen Moten, Ph.D., MPH, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7703, cmoten@mail.nih.gov.

Name of Committee: National Institute on Aging Special Emphasis Panel; Predictors and Determinants of Age-Related Reliabilities to Physical Stressors, RFA–AG–014 (UH2).
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Agenda: To review and evaluate grant applications.
Place: National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Carmen Moten, Ph.D., MPH, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7703, cmoten@mail.nih.gov.