

Commissioner to authorize the emergency use of an unapproved medical product or an unapproved use of an approved medical product for certain emergency circumstances after the Department of Health and Human Services (HHS) Secretary has made a declaration of an emergency or threat justifying emergency use. That declaration by the HHS Secretary must in turn be based on a determination of an emergency or potential emergency or material threat associated with the CBRN agent by, respectively, the Secretary of Homeland Security, the Secretary of Defense, or the HHS Secretary. The Commissioner may issue an EUA to allow an MCM to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a CBRN agent, or by a product used to diagnose, treat, or prevent such diseases or conditions, when available data meet specified criteria to support such uses and there are no adequate, approved, and available alternatives.

Section 564A, as added by PAHPRA, establishes streamlined mechanisms to facilitate preparedness and response activities involving certain FDA-approved MCMs without FDA issuing EUAs, which can be a resource-intensive process. These authorities, which apply only to eligible FDA-approved medical products intended for use during a CBRN emergency, include provisions that:

- Empower FDA to extend the expiration date of an eligible FDA-approved MCM stockpiled for use in a CBRN emergency, and establish appropriate conditions relating to such extensions, such as appropriate storage, sampling, and labeling;
- Permit FDA to waive otherwise applicable current good manufacturing practice requirements (e.g., storage or handling) to accommodate emergency response needs;
- Allow emergency dispensing of MCMs during an actual CBRN emergency event without requiring an individual prescription, or all of the information otherwise required, for each recipient of the MCM; and
- Permit the Centers for Disease Control and Prevention to create and issue “emergency use instructions” concerning the FDA-approved conditions of use for eligible products. These authorities, and the definition of eligible products to which they apply, are discussed in this guidance.

To enable stakeholders to prepare for potential rapid deployment of MCMs during an actual CBRN emergency, section 564B (also added by PAHPRA)

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

Persons with access to the Internet may obtain the guidance at <http://www.fda.gov/regulatoryinformation/Guidances/default.htm>, <http://www.regulations.gov>, or <http://www.fda.gov/medicalcountermeasures>.

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.

Dated: January 10, 2017.

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 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 January 27, 2017. 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 “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 Meeting: 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.

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: January 5, 2017.

Kathryn E. Martin,

Acting Assistant Secretary for Planning and Evaluation.

[FR Doc. 2017-00606 Filed 1-12-17; 8:45 am]

BILLING CODE P

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://videocast.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.

Open: 1:00 p.m. to 2:00 p.m.
Agenda: Program reports and presentations; business of the Board.

Closed: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove 9609 Medical Center Drive, Room TE406 Rockville, MD 20850 (Virtual Meeting).

Contact Person: Paulette S. Gray, Ph.D., Executive Secretary, Division of Extramural Activities, National Cancer Institute—Shady Grove National Institutes of Health, 9609 Medical Center Drive, Room 7W444, Bethesda, MD 20892, 240-276-6340, graypp@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: <http://deainfo.nci.nih.gov/advisory/ncab/ncab.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 9, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017-00579 Filed 1-12-17; 8:45 am]

BILLING CODE 4140-01-P

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 Resiliencies 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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 10, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017-00733 Filed 1-12-17; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Action Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

AGENCY: National Institutes of Health (NIH), HHS.

ACTION: Notice of action under the *NIH Guidelines*.

SUMMARY: The National Institutes of Health (NIH) considered a proposal to conduct research involving the deliberate transfer of a chloramphenicol resistance trait to *Rickettsia typhi*, *conorii*, *rickettsii*, and *felis*. The acquisition of this antibiotic resistance trait could possibly compromise the use of a class of antibiotics for the treatment of Rickettsia infections in humans. Under the *NIH Guidelines* (<http://www.osp.od.nih.gov/sites/default/files/>