Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Susan Storey, Center for Veterinary Medicine (HFV–131), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0578, *susan.storey@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of draft GFI #268 entitled ''Adaptive and Other Innovative Designs for Effectiveness Studies of New Animal Drugs.'' Section 305 of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018 (Pub. L. 115–234), among other things, directed FDA to hold a public meeting for interested parties to discuss innovative animal drug investigation designs and to issue guidance addressing the incorporation of the use of such elements of investigations as complex adaptive and other novel investigation designs, data from foreign countries, real-world evidence (including ongoing surveillance activities, observational studies, and registry data), biomarkers, and surrogate endpoints into proposed clinical investigation protocols and applications for new animal drugs.

In the **Federal Register** of July 9, 2019 (84 FR 32749), FDA's Center for Veterinary Medicine (CVM) published a notice of a public meeting entitled ''Incorporating Alternative Approaches in Clinical Investigations for New Animal Drugs'' giving interested persons until August 17, 2019, to comment on the topics discussed at the public meeting and the questions published in the meeting notice (84 FR 32749 at 32750–32751).[1] On August 13, 2019, we published a notice announcing the extension of the comment period to September 16, 2019 (84 FR 40071). CVM received numerous comments on the topics discussed at the public meeting and the questions published in the meeting notice and those comments were considered as the draft GFI #268 entitled ''Adaptive and Other Innovative Designs for Effectiveness Studies of New Animal Drugs'' was developed.

This draft guidance describes principles for designing, conducting, and reporting the results for investigations or studies, including adaptive design features, when they are incorporated into clinical investigations submitted to CVM to demonstrate substantial evidence of effectiveness for new animal drug applications or a reasonable expectation of effectiveness for applications for conditional approval of a new animal drug. It also provides information about how sponsors may obtain feedback from CVM on technical issues related to the use of adaptive and innovative designs before the submission of an application.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, if finalized, will represent the current thinking of FDA regarding the use of complex adaptive and other novel investigation designs to support the effectiveness of new animal drugs. 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.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required.

However, this draft guidance refers to previously approved FDA collections of information found in FDA regulations. These collections of information are subject to review by the OMB under the PRA. The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry* or *https://www.regulations.gov.*

Dated: July 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15239 Filed 7–14–20; 8:45 am]

BILLING CODE 4164–01–P

[1] *https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/public-meeting-incorporating-alternative-approaches-clinical-investigations-new-animal-drugs.*

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 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. During the July 20, 2020 meeting, an invited panel will present on emergency preparedness for people with dementia with a special focus on the COVID–19 pandemic. The chairs of the subcommittees (Research, Clinical Care, and Long-Term Services and Supports) will present recommendations for adoption by the full Advisory Council.

DATES: The meeting will be held on July 20, 2020 from 1:00 p.m. to 4:30 p.m. EST.

ADDRESSES: The meeting will be virtual, streaming at *http://www.hhs.gov/live.*

Comments: Time is allocated on the agenda to hear public comments from 4:00 p.m. to 4:30 p.m. The time for oral comments will be limited to two (2) minutes per individual. In order to provide a public comment, please register by emailing your name to *napa@hhs.gov* by Thursday, July 16. Registered commenters will receive both a dial-in number and a link to join the meeting virtually; individuals will have the choice to either join virtually via the link, or to call in only by using the dial-in number. *Note:* There may be a 30–45 second delay in the livestream video presentation of the conference. For this reason, if you have pre-registered to submit a public comment, it is important to connect to the meeting by 3:45 p.m. to ensure that you do not miss your name and allotted time when called. If you miss your name and allotted time to speak, you may not be able to make your public comment. All participant audio lines will be muted for the duration of the meeting and only

unmuted by the Host at the time of the participant's public comment. Should you have questions during the session email *napa@hhs.gov* and someone will respond to your message as quickly as possible.

In order to ensure accuracy, please submit a written copy of oral comments for the record by emailing *napa@hhs.gov* by Tuesday, July 21. These comments will be shared on the website and reflected in the meeting minutes.

In lieu of oral comments, formal written comments may be submitted for the record by Tuesday, July 21 to Helen Lamont, Ph.D., OASPE, 200 Independence Avenue SW, Room 424E, Washington, DC 20201. Comments may also be sent to *napa@hhs.gov.* Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Helen Lamont, 202–260–6075, *helen.lamont@hhs.gov.* Note: The meeting will be available to the public live at *www.hhs.gov/live*.

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: An invited panel will present on emergency preparedness for people with dementia with a special focus on the COVID–19 pandemic. The chairs of the subcommittees (Research, Clinical Care, and Long-Term Services and Supports) will present recommendations for adoption by the full Advisory Council.

Procedure and Agenda: The meeting will be webcast at *www.hhs.gov/live* and video recordings will be added to the National Alzheimer's Project Act website when available, after the meeting.

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: June 16, 2020.

Brenda Destro,

Deputy Assistant Secretary for Planning and Evaluation, Office of Human Services Policy.

[FR Doc. 2020–15196 Filed 7–14–20; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Calcium Channels, GPCRs, and Proteins of Neurodegeneration.

Date: July 28, 2020.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Geoffrey G Schofield, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040–A, MSC 7850, Bethesda, MD 20892, 301–435–1235, *geoffreys@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; ORIP Training (Training in Veterinary and Comparative Medicine).

Date: August 10, 2020.

Time: 10:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: John Harold Laity, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–402–8254, *john.laity@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 9, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–15193 Filed 7–14–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting; NIH Human Fetal Tissue Research Ethics Advisory Board—FY2020

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a virtual meeting of the NIH Human Fetal Tissue Research Ethics Advisory Board—FY2020.

The meeting will be open to the public as indicated below. Individuals who need special assistance with virtual attendance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public, as indicated below, 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 and cooperative agreement applications and R&D contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant and cooperative agreement applications and R&D contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: NIH Human Fetal Tissue Research Ethics Advisory Board—FY2020.

Date: July 31, 2020.

Open: 10:00 a.m.–11:05 a.m.

Agenda: Welcome and Charge to the Ethics Advisory Board; Introduction of Committee Members; Confidentiality and Conflict of Interest Procedures; Meeting Procedures; and Public Comment Period.

Place: Virtual Meeting/Webcast (link for the meeting will be available at *https://osp.od.nih.gov/biotechnology/nih*).

Closed: 11:15 a.m.–4:15 p.m.

Agenda: To make recommendations regarding the ethics of research involving human fetal tissue (HFT) proposed in NIH grant and cooperative agreement applications and R&D contract proposals, as set forth in the NIH Guide Notice NOT–OD–19–128.

Contact Person: Cari Young, ScM, Health Science Policy Analyst, Office of Science Policy, Office of the Director, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301–496–9838, *SciencePolicy@od.nih.gov*.

''*This notice is being published less than 15 days prior to the meeting due to the unforeseen circumstances of COVID–19 which required the Department's full response and caused a delay in moving this committee and meeting forward.*''