Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that SYMDEKO (tezacaftor/ivacaftor), manufactured by Vertex Pharmaceutical, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Silver Spring, MD 20993–0002, 301–796–4061, Fax: 301–796–9856, *althea.cuff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that SYMDEKO (tezacaftor/ivacaftor), manufactured by Vertex Pharmaceutical, Inc., meets the criteria for a priority review voucher. SYMDEKO (tezacaftor/ivacaftor) is indicated for the treatment of patients with cystic fibrosis aged 12 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about SYMDEKO (tezacaftor/ivacaftor), go to the ''*Drugs@FDA*'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: March 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–06138 Filed 3–28–19; 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 April 29, 2019 meeting of the Advisory Council will focus on person-centered planning for older adults including information about implementation of care plans for people living with cognitive symptoms. There will also be discussion about the use of antipsychotic medication for people with dementia and other conditions living in community settings.

DATES: The meeting will be held on April 29, 2019 from 9 a.m. to 4:30 p.m. EST.

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 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 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: 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 19 so that their names may be put on a list of expected attendees and forwarded to the security officers at the Department of Health and Human Services. 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 April 29, 2019 meeting of the Advisory Council will focus on person-centered planning for older adults including information about implementation of care plans for people living with cognitive symptoms. There will also be discussion about the use of antipsychotic medication for people with dementia and other conditions living in community settings.

Procedure and Agenda: This meeting is open to the public. Please allow 30 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 22, 2019.

Brenda Destro,

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

[FR Doc. 2019–06135 Filed 3–28–19; 8:45 am]

BILLING CODE 4150–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

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 Institute on Deafness and Other Communication

Disorders Special Emphasis Panel; NIDCD Clinical Center Application Review.

Date: April 25, 2019.

Time: 1:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Shiguang Yang, DVM, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIDCD, NIH, 6001 Executive Blvd., Room 8349, Bethesda, MD 20892, 301–496–8683, *yangshi@nidcd.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: March 25, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–06010 Filed 3–28–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

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: Center for Scientific Review Special Emphasis Panel; BRAIN Initiative: Targeted BRAIN Circuits Projects.

Date: April 16, 2019.

Time: 2:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Kirk Thompson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5184, MSC 7844, Bethesda, MD 20892, 301–435–1242, *kgt@mail.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: March 25, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–06008 Filed 3–28–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; National Cancer Institute (NCI) Generic Clearance for Application Information From Fellows, Interns, and Trainees

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Vivian Horovitch-Kelley, Program Analyst, Office of Management Policy and Compliance, National Cancer Institute, 9609 Medical Center Drive, Room 2W444, Bethesda, Maryland 20892 or call non-toll-free number (240) 276–6850 or Email your request, including your address to: *vivian.horovitch-kelley@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) 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) 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimizes 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.

Proposed Collection Title: Generic Clearance for Application Information from Fellows, Interns, and Trainees, 0925–XXXX, Exp., Date XX/XXXX, NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The ''Generic Clearance for Application Information from Fellows, Interns, and Trainees'' request supports research experiences for high school, post-baccalaureate (including post masters) individuals, graduate students, and postdoctoral fellows, interns, and trainees in a multidisciplinary environment at the National Cancer Institute (NCI). This information collection request is for applications, reference letters, letters of intent and interest, and other related documentation necessary for various Divisions, Offices, and Centers at NCI to evaluate the eligibility, merits, and quality of potential candidates. The applications will also assist in matching potential candidates to various training and internship programs. The information is for internal use to make decisions about candidates invited to visit and attend NCI fellowships, internships, and other training opportunities.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden is 12,500 hours.