expansion of person-centered, trauma-informed (PCTI) supportive services for Holocaust survivors living in the U.S. and, (2) improve the nation's overall capacity to deliver PCTI health and human services for this population and to any older adult with a history of trauma. The administrative supplement for FY 2019 will be in the amount of $2,467,000, bringing the total award for FY 2019 to $4,935,000.

The additional funding will not be used to begin new projects, but to serve more Holocaust survivors with vital supports such as legal assistance, case management, transportation, medication management, social engagement activities designed to reduce isolation, loneliness and depression, and to provide supports for family caregivers, all of which will employ PCTI approaches. The additional funds will also be used to further expand existing technical assistance activities, under the second objective, in a variety of ways, including replicating and translating proven models of PCTI services and supports developed under this grant. Additional funds will also further the development of new training materials, curricula and partnerships to aid in the replication of PCTI practices; enhance and expand the evaluation activities currently under way; and enhance existing website capacities for improved information dissemination.

Program Name: Advancing Person-Centered, Trauma-Informed (PCTI) Supportive Services for Holocaust Survivors.

Recipient: The Jewish Federations of North America.

Period of Performance: The supplement award will be issued for the fifth (and final) year of the five-year project period of September 30, 2015 through September 29, 2020.

Total Award Amount: $4,935,000 in FY 2018.

Award Type: Cooperative Agreement Supplement.

Statutory Authority: The Older Americans Act (OAA) of 1965, as amended, Public Law 109–365—Title 4, Section 411.

Basis for Award: The Jewish Federations of North America (JFNA) is currently funded to carry out the objectives of this project, entitled *Advancing PCTI Supportive Services for Holocaust Survivors* for the period of September 30, 2015 through September 29, 2020. Since project implementation began in late 2015, the grantee has accomplished a great deal. The supplement will enable the grantee to carry their work even further, serving more Holocaust survivors and providing even more comprehensive training and technical assistance in the development of PCTI supportive services. The additional funding will not be used to begin new projects or activities.

The JFNA is uniquely positioned to complete the work called for under this project. JFNA and its project partners, including the Network of Jewish Human Services Agencies (NJHSA), and the Conference on Material Claims Against Germany (Claims Conference), have the cultural competence and long history of serving and advocating for Holocaust survivors. Additionally, JFNA is already working in collaboration with numerous partners representing a broad cross section of the Jewish human services network (*e.g.,* Selfhelp Community Services, Bet Tzedek, The Blue Card, and the Orthodox Union of America) and the ''mainstream aging services network,'' (*e.g.,* Meals on Wheels of America (MoWA), the National Association of Area Agencies on Aging (n4a), the National Council on Aging (NCOA), Leading Age and other members of the Leadership Council of Aging Organizations [LCAO]).

Establishing an entirely new grant project at this time would be potentially disruptive to the current work already well under way. More importantly, the Holocaust survivors currently being served by this project could be negatively impacted by a service disruption, thus posing the risk of re-traumatization and further negative impacts on health and wellbeing. If this supplement is not provided, the project would be less able to address the significant unmet health and social support needs of additional Holocaust survivors. Similarly, the project would be unable to expand its current technical assistance and training efforts in PCTI concepts and approaches, let alone reach beyond traditional providers of services to this population to train more ''mainstream'' providers of aging services.

For More Information Contact: For further information or comments regarding this program supplement, contact Greg Link, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Aging, Office of Supportive and Caregiver Services: telephone (202)-795–7386; email *greg.link@acl.hhs.gov.*

Dated: January 29, 2019.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2019–01121 Filed 2–4–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0071]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held on March 6, 2019, from 8 a.m. to 4:30 p.m. and March 7, 2019, from 8:30 a.m. to 4:45 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

For those unable to attend in person, the meeting will also be webcast and will be available at the following link: *https://collaboration.fda.gov/vrbpac032019/.*

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6338, Silver Spring, MD 20993–0002, 240–402–5771, *serina.hunter-thomas@fda.hhs.gov;* or Monique Hill, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6307C, Silver Spring, MD 20993–0002, 301–796–4620, *monique.hill@fda.hhs.gov;* or the FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the

Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On March 6, 2019, under Topic I, the Center for Biologics Evaluation and Research's (CBER) VRBPAC will meet in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2019 to 2020 influenza season. Also on March 6, 2019, under Topic II, the committee will meet in open session to hear an overview of the research programs in the Laboratory of Immunoregulation (LIR) and the Laboratory of Retroviruses (LR), Division of Viral Products, Office of Vaccines Research and Review, CBER, FDA.

On March 7, 2019, under Topic III, the committee will meet in open session to discuss and make recommendations on the safety and effectiveness of Dengue Tetravalent Vaccine (Live, Attenuated) (DENGVAXIA) manufactured by Sanofi Pasteur.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: On March 6, 2019, from 8 a.m. to 3:15 p.m., and on March 7, 2019, from 8:30 a.m. to 4:45 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 27, 2019. On March 6, 2019, oral presentations from the public will be scheduled between approximately 11:10 a.m. to 11:55 a.m. for the influenza strain selection portion of the meeting and 3 p.m. to 3:15 p.m. for the overview portion of the LIR/LR Site Visit. On March 7, 2019, oral presentations from the public will be scheduled between approximately 1:15 p.m. to 2:15 p.m. for the Dengue Tetravalent Vaccine (Live, Attenuated) (DENGVAXIA) manufactured by Sanofi Pasteur portion of the meeting. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 19, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 20, 2019.

Closed Committee Deliberations: On March 6, 2019, from 3:15 p.m. to 4:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The recommendations of the advisory committee regarding the progress of the investigator's research will, along with other information, be used in making personnel and staffing decisions regarding individual scientists.

We believe that public discussion of these recommendations on individual scientists would constitute an unwarranted invasion of personal privacy.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Serina Hunter-Thomas (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 15, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019–00769 Filed 2–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6644]

Fiscal Year 2019 Generic Drug Regulatory Science Initiatives; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''FY 2019 Generic Drug Regulatory Science Initiatives.'' The purpose of the public workshop is to provide an overview of the status of regulatory science initiatives for generic drugs and an opportunity for public input on these initiatives. FDA is seeking this input from a variety of stakeholders—industry, academia, patient advocates, professional societies, and other interested parties—as it fulfills its commitment under the Generic Drug User Fee Amendments of 2017 (GDUFA II) to develop an annual list of regulatory science initiatives specific to generic drugs. FDA will take the information it obtains from the public workshop into account in developing its fiscal year (FY) 2020 regulatory science initiatives.

DATES: The public workshop will be held on May 1, 2019, from 8:30 a.m. to 4:30 p.m. Submit either electronic or written comments on this public workshop by June 1, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, sections B and C), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely