The burden hours required to complete paper FDA reporting forms (Forms FDA 3500, 3500A, 1932, and 1932a) are reported under OMB control numbers 0910–0284 and 0910–0291. While FDA does not charge for the use of the ESG, the Agency requires respondents to obtain a public key infrastructure certificate to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 year to 3 years. The certificate typically costs from $20 to $30.

Our estimated burden for the information collection reflects an overall increase of 688,547 hours and a corresponding increase of 1,145,763 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: November 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26031 Filed 11–29–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Commission on Childhood Vaccines

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Advisory Commission on Childhood Vaccines (ACCV) has scheduled a public meeting. Information about the ACCV and the agenda for this meeting can be found on the ACCV website at: *http://www.hrsa.gov/advisorycommittees/childhoodvaccines/index.html.* This notice is being published less than 15 days prior to the meeting date due to unexpected administrative delays.

DATES: December 6, 2018, at 10:00 a.m. ET.

ADDRESSES: This meeting will be held by teleconference and Adobe Connect webinar. The public can join the meeting by:

1. (Audio Portion) Calling the conference phone number 800–988–0218 and providing the following information: Leader Name: Dr. Narayan Nair, Password: 9302948.

2. (Visual Portion) Connect to the ACCV Adobe Connect Meeting using the following URL: *https://hrsa.connectsolutions.com/accv/.* Participants should call and connect 15 minutes before the meeting starts for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL: *https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm* Get a quick overview at the following URL: *http://www.adobe.com/go/connectpro_overview.*

FOR FURTHER INFORMATION CONTACT: Annie Herzog, Program Analyst, Division of Injury Compensation Programs (DICP), HRSA, 5600 Fishers Lane, 08N146B, Rockville, Maryland 20857; 301–443–6593; or *aherzog@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The ACCV was established by section 2119 of the Public Health Service (PHS) Act (42 U.S.C. 300aa–19), as enacted by Public Law (Pub. L.) 99–660, and as subsequently amended, and advises the Secretary of HHS (the Secretary) on issues related to implementation of the National Vaccine Injury Compensation Program (VICP). During the December 6, 2018, meeting, agenda items will include, but are not limited to, updates from the DICP, Department of Justice (DOJ), National Vaccine Program Office (NVPO), Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health) and Center for Biologics, Evaluation and Research (Food and Drug Administration). Agenda items are subject to change as priorities dictate. Refer to the ACCV website listed above for any updated information concerning the meeting to include a draft agenda and additional meeting materials that will be posted before the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to the ACCV should be sent to Annie Herzog using the contact information above by Wednesday, December 5, 2018.

Individuals who need special assistance or another reasonable accommodation should notify Annie Herzog at the address and phone number listed above at least 3 business days before the meeting.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–26080 Filed 11–29–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meetings Announcement for the Physician-Focused Payment Model Technical Advisory Committee Required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA); Correction

ACTION: Notice of public meetings; correction.

SUMMARY: The Department of Health and Human Services published a document in the **Federal Register** of February 05, 2018 detailing the 2018 PTAC meeting dates and the link that connects to the meeting registration website. The December meeting date has been shortened to a one day meeting and the registration link has been updated.

FOR FURTHER INFORMATION CONTACT: Sarah Selenich, Designated Federal Official, at the Office of Health Policy, Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, 200 Independence Ave. SW, Washington, DC 20201, (202) 690–6870.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of February 5, 2018, in FR Doc. 2018–02211, on page 5109, in the first column, correct the ''Dates'' caption to read:

DATES: The 2018 PTAC meetings will occur on the following dates:

- Monday–Tuesday, March 26–27, 2018, from 9:00 a.m. to 5:00 p.m. ET
- Thursday–Friday, June 14–15, 2018, from 9:00 a.m. to 5:00 p.m. ET
- Thursday–Friday, September 6–7, 2018, from 9:00 a.m. to 5:00 p.m. ET
- Monday, December 10, 2018, from 12:30 p.m. to 5:00 p.m. ET

Please note that times are subject to change. If the times change, registrants will be notified directly via email.

Correction

In the **Federal Register** of February 5, 2018, in FR Doc. 2018–02211, on page 5109, in the second column, correct the ''Meeting Registration'' caption to read:

Meeting Registration:

The public may attend the meetings in-person or participate by phone via

audio teleconference. Space is limited and registration is preferred in order to attend in-person or by phone. Registration may be completed online at *http://www.cvent.com/d/gbq2tg.*

The following information is submitted when registering:

Name:

Company/organization name:

Postal address:

Email address:

Persons wishing to attend a PTAC meeting must register by following the instructions in the ''Meeting Registration'' section of this notice. A confirmation email will be sent to registrants shortly after completing the registration process.

Dated: November 14, 2018.

Brenda Destro,

Deputy Assistant Secretary for Planning and Evaluation (HSP).

[FR Doc. 2018–25992 Filed 11–29–18; 8:45 am]

BILLING CODE 4150–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for the treatment of cancer. The outcome of the evaluation will provide information to internal NCI committees that will decide whether NCI should support requests and make available contract resources for development of the potential therapeutic to improve the treatment of various forms of cancer. The research proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposed research projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, OCT2018 Cycle 30 NExT SEP Committee Meeting.

Date: December 12, 2018.

Time: 9:00 a.m. to 3:00 p.m.

Agenda: To evaluate the NCI Experimental Therapeutics Program Portfolio.

Place: National Institutes of Health, 9000 Rockville Pike, Building 1, Wilson Hall, Bethesda, MD 20892.

Contact Persons: Barbara Mroczkowski, Ph.D., Executive Secretary, Discovery Experimental Therapeutics Program, National Cancer Institute, NIH 31 Center Drive, Room 3A44, Bethesda, MD 20817, (301) 496–4291, *mroczkoskib@mail.nih.gov.*

Toby Hecht, Ph.D., Executive Secretary, Development Experimental Therapeutics Program, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 3W110, Rockville, MD 20850, (240) 276–5683, *toby.hecht2@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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: November 26, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–26015 Filed 11–29–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 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 contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Contract Review.

Date: December 14, 2018.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7353, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, *barnardm@extra.niddk.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 21, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–26017 Filed 11–29–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed 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 Vaccine Research Center Board of Scientific Counselors, NIAID.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute Of Allergy And Infectious Diseases, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Vaccine Research Center Board of Scientific Counselors, NIAID.

Date: December 12–13, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, 40 Convent Drive, Bethesda, MD 20892.

Contact Person: John R Mascola, MD, Deputy Director, Vaccine Research Center,