with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Brian Booth, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2186, Silver Spring, MD 20993, 301–796–1508.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Pharmacokinetic-Based Criteria for Supporting Alternative Dosing Regimens of Programmed Cell Death Receptor-1 (PD–1) or Programmed Cell Death-Ligand 1 (PD–L1) Blocking Antibodies for Treatment of Patients with Cancer.'' This draft guidance provides recommendations for sponsors of INDs and BLAs on the use of PK-based criteria to support the approval of alternative dosing regimens for PD–1 or PD–L1 blocking antibodies. The draft guidance is based on accumulated scientific and regulatory experience for PD–1 and PD–L1 drugs and, as such, does not address development of alternative dosing regimens for any other drugs or biologics, changes in route of administration, or novel formulations of previously approved PD–1/PD–L1 products.

Sponsors may seek approval of alternative intravenous (IV) dosing regimens that are different from those tested in clinical efficacy and safety trials. These alternative IV dosing regimens are typically designed to change doses (*e.g.,* body weight adjusted doses to flat doses) and/or dosing intervals (*e.g.,* once every 3 weeks to once every 6 weeks). Longer dosing interval periods can minimize patient burden and reduce risks associated with more frequent administration (*e.g.,* infusion reactions), as well as exposure to communicable diseases (*e.g.,* SARS–CoV–2) associated with visits to hospitals or infusion centers. The draft guidance describes the criteria for using the PK-based approach and the documents that should be included in the submissions seeking approval.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Pharmacokinetic-Based Criteria for Supporting Alternative Dosing Regimens of Programmed Cell Death Receptor-1 (PD–1) or Programmed Cell Death-Ligand 1 (PD–L1) Blocking Antibodies for Treatment of Patients with Cancer.'' 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections 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 for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014 and the collections of information in 21 CFR part 601 have been approved under 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov.*

Dated: August 17, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–18317 Filed 8–25–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Infant Mortality

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Infant Mortality (ACIM or Committee) has scheduled a public meeting. Information about ACIM and the agenda for this meeting can be found on the ACIM website at *https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

DATES: September 21, 2021, 12:00 p.m.–4:00 p.m. Eastern Time and September 22, 2021, 12:00 p.m.–4:00 p.m. Eastern Time.

ADDRESSES: This meeting will be held via webinar. *The webinar link and log-in information will be available at ACIM's website before the meeting: https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

FOR FURTHER INFORMATION CONTACT: Vanessa Lee, MPH, Designated Federal Official, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18N84, Rockville, Maryland 20857; (301) 443–0543; or *SACIM@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACIM is authorized by section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended. The Committee is governed

by provisions of Public Law 92–463, as amended, (5 U.S.C. app. 2), which sets forth standards for the formation and use of Advisory Committees.

ACIM advises the Secretary of Health and Human Services on department activities and programs directed at reducing infant mortality and improving the health status of pregnant women and infants. ACIM represents a public-private partnership at the highest level to provide guidance and focus attention on the policies and resources required to address the reduction of infant mortality and the improvement of the health status of pregnant women and infants. With a focus on life course, the ACIM addresses disparities in maternal health to improve maternal health outcomes, including preventing and reducing maternal mortality and severe maternal morbidity. ACIM provides advice on how best to coordinate myriad federal, state, local, and private programs and efforts that are designed to deal with the health and social problems impacting infant mortality and maternal health, including implementation of the Healthy Start program and maternal and infant health objectives from the National Health Promotion and Disease Prevention Objectives (*i.e.,* Healthy People 2030).

The agenda for the September 21–22, 2021, meeting is being finalized and may include the following topics: Federal program updates; discussion of recommendations by ACIM to the Secretary; fatality review programs; health of indigenous mothers and infants; financing of care; and patient-physician racial concordance in health care. Refer to the ACIM website for any updated information concerning the meeting.

Members of the public will have the opportunity to provide written or oral comments. Requests to submit a written statement or make oral comments to the ACIM should be sent to Vanessa Lee, using the email address above at least three business days prior to the meeting. Public participants may submit written statements in advance of the scheduled meeting by emailing *SACIM@hrsa.gov.* Oral comments will be honored in the order they are requested and may be limited as time allows.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Vanessa Lee at the contact information listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–18378 Filed 8–25–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Dental and Craniofacial Research Council, September 9, 2021, 10:00 a.m. to September 9, 2021, 4:00 p.m., National Institutes of Health, National Institute of Dental and Craniofacial Res., 6701 Democracy Blvd., Bethesda, MD 20892 which was published in the **Federal Register** on August 13, 2021, FR Doc. 2021–17302, 86 FR 44736.

This meeting is being amended to change the times of the Open and Closed sessions. The Open session will be from 9:00 a.m. to 2:30 p.m. and will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*). The Closed session will be from 2:45 p.m. to 3:30 p.m. The meeting is partially Closed to the public.

Dated: August 23, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–18401 Filed 8–25–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Electronic Individual Development Plan (eIDP) (National Eye Institute)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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: Dr. Cesar E. Perez-Gonzalez, Training Director, Office of the Scientific Director, National Eye Institute, NIH, Building 31, Room 6A22, MSC 0250, Bethesda, Maryland 20892 or call non-toll-free number (301) 451–6763 or Email your request, including your address to: *cesarp@nei.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on May 24, 2021, page 27856–27857 (86 FR 27856) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

The National Eye Institute (NEI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Electronic Individual Development Plans, 0925–NEW, XX/XX/XXXX, National Eye Institute (NEI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Eye Institute's (NEI) Office of the Scientific Director (OSD) goal is to train the next generation of vision researchers and ophthalmologists. Trainees who participate in NEI research come with different levels of education (student, postbaccalaureate, predoctoral including graduate and medical students, postdoctoral fellows) and for different amounts of time (6 months to 5 years). Training at the NEI focuses on scientific and professional skill development. To enhance their chances of obtaining their ideal career, completing an annual Individual