password protected platforms. Respondents will include educational developers requesting accreditation for their trainings and public health and healthcare professionals who seek training. No statistical methods will be used to analyze the information collected. CDC will use identifiable information in TCEO to track participant completion of educational activities to facilitate required reporting to earn continuing education credits, hours, or units. Aggregate and non-aggregate data from the evaluations in TCEO and CDC TRAIN will be used to improve educational activities and assess learning outcomes.

CDC requests approval for an estimated 412,600 annual burden hours. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden time per response (in hours)	Total Response Burden (in hours)
Educational Developers (Health Educators).	TCEO Proposal	120	1	5	600
Public Health and Health Care Professionals (Learners).	TCEO New Participant Registration	300,000	1	5/60	25,000
Public Health and Health Care Professionals (Learners).	TCEO Post-Course Evaluation	300,000	3	10/60	150,000
Public Health and Health Care Professionals (Learners).	TCEO Follow-Up Evaluation	30,000	3	3/60	4,500
TCEO Sub-Total					180,100
Public Health and Health Care Professionals (Learners).	CDC TRAIN Immediate Post-Course Evaluation Tool.	300,000	3	15/60	225,000
Public Health and Health Care Professionals (Learners).	CDC TRAIN Delayed Follow-Up Evaluation Tool.	30,000	3	5/60	7,500
0.33TRAIN Sub-Total					232,500
Total					412,600

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–15794 Filed 7–23–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2021–0075]

Advisory Committee on Immunization Practices (ACIP)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), announces the following meeting of the Advisory Committee on Immunization Practices (ACIP). This meeting is open to the public. Time will be available for public comment. The meeting will be webcast live via the World Wide Web. For more information on ACIP please visit the ACIP website: *http://www.cdc.gov/vaccines/acip/index.html.*

DATES: The meeting will be held on September 29, 2021, from 10:00 a.m. to 5:05 p.m., EDT, and September 30, 2021, from 10:00 a.m. to 1:10 p.m., EDT (times subject to change), see the ACIP website for updates: *http://www.cdc.gov/vaccines/acip/index.html.* The public may submit written comments from July 26, 2021 through September 30, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2021–0075 by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H24–8, Atlanta, Georgia 30329–4027, Attn: ACIP Meeting.

Instructions: All submissions received must include the Agency name and Docket Number. All relevant comments received in conformance with the *https://www.regulations.gov* suitability policy will be posted without change to *https://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.* Written public comments submitted 72 hours prior to the ACIP meeting will be provided to ACIP members before the meeting.

FOR FURTHER INFORMATION CONTACT: Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road NE, MS–H24–8, Atlanta, Georgia 30329–4027; Telephone: (404) 639–8367; Email: *ACIP@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The committee is charged with advising the Director, CDC, on the use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the Director of the Centers for Disease Control and Prevention and appear on CDC immunization schedules must be covered by applicable health plans.

Matters To Be Considered: The agenda will include discussions on cholera vaccine, hepatitis vaccines, herpes zoster vaccines, orthopoxvirus vaccine, pneumococcal vaccine, and tickborne

encephalitis vaccine. No recommendation votes are scheduled. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda visit *https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html.*

Meeting Information: The meeting will be webcast live via the World Wide Web; for more information on ACIP please visit the ACIP website: *http://www.cdc.gov/vaccines/acip/index.html.*

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Written Public Comment: The docket will be opened to receive written comments on September 1, 2021. Written comments must be received on or before September 30, 2021.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the September 29–30, 2021, ACIP meeting must submit a request at *http://www.cdc.gov/vaccines/acip/meetings/* no later than 11:59 p.m., EDT, September 24, 2021, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email September 28, 2021. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may only speak once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–15799 Filed 7–23–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0651]

Cellular, Tissue and Gene Therapies Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Cellular, Tissue and Gene Therapies Advisory Committee (CTGTAC). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. Matters considered at the meeting will include discussion of the toxicity risks of adeno-associated virus (AAV) vector-based gene therapy products. The discussion topics include oncogenicity risks due to vector genome integration and safety issues identified during preclinical and/or clinical evaluation. The meeting will be open to the public on both days. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on September 2 and 3, 2021, from 10 a.m. to 6 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/advisory-committees/about-advisory-committees/common-questions-and-answers-about-fda-advisory-committee-meetings.* The online web conference meeting will be available at the following links on the day of the meeting: Day 1 *https://youtu.be/58KjL9_p9Tw* and Day 2 *https://youtu.be/yLggQF0XUUY.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2021–N–0651. The docket will close on September 1, 2021. Submit either electronic or written comments on this public meeting on or before September 1, 2021. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 1, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before August 26, 2021, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact