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 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 the 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.

FOR FURTHER INFORMATION CONTACT: LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *PCNS@fda.hhs.gov,* or 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 FDA'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: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On November 6, 2020, the committee will discuss biologics license application (BLA) 761178, for aducanumab solution for intravenous infusion, submitted by Biogen Inc., for the treatment of Alzheimer's disease.

FDA intends to make the meeting's background material and pre-recorded presentations available to the public no later than 2 business days before the meeting. The pre-recorded presentations will be viewed by the committee prior to the meeting and will not be replayed on meeting day. If FDA is unable to post the background material and/or pre-recorded presentations on its website prior to the meeting, the background material and/or pre-recorded presentations will be made publicly available on FDA's website at the time of the advisory committee meeting. The meeting will include brief summaries of the pre-recorded presentations. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before October 23, 2020, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 October 15, 2020. 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 October 16, 2020.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

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 LaToya Bonner (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: September 22, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21448 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4726]

Abbreviated New Drug Application Submissions—Amendments and Requests for Final Approval To Tentatively Approved Abbreviated New Drug Applications; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''ANDA Submissions—Amendments and Requests for Final Approval to Tentatively Approved ANDAs.'' This guidance is intended to assist applicants in preparing and submitting amendments to tentatively approved abbreviated new drug applications (ANDAs), including requests for final approval. This guidance provides recommendations on the timing and content of amendments to tentatively approved ANDAs to facilitate submission in a timely fashion to enable final approval on the earliest date on which the ANDA may lawfully be approved based on patent and/or exclusivity protections (earliest lawful approval date). This guidance finalizes the draft guidance of the same title issued on February 1, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on September 29, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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 information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–4726 for ''ANDA Submissions—Amendments and Requests for Final Approval to Tentatively Approved ANDAs.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential 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 this 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 requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1670, Silver Spring, MD 20993–0002, 240–402–7930, *elizabeth.giaquinto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''ANDA Submissions—Amendments and Requests for Final Approval to Tentatively Approved ANDAs.'' This guidance is intended to assist applicants in preparing and submitting amendments to tentatively approved ANDAs, including requests for final approval. This guidance provides recommendations on the timing and content of amendments to tentatively approved ANDAs to facilitate submission in a timely fashion to enable final approval on the earliest date on which the ANDA may lawfully be approved based on patent and/or exclusivity protections (earliest lawful approval date).

If an ANDA meets the substantive requirements for approval but cannot be finally approved by FDA because of unexpired patents or exclusivities, FDA will tentatively approve the ANDA. Under section 505 of the Federal Food, Drug, and Cosmetic Act) (21 U.S.C. 355), a drug product that is the subject of a tentatively approved ANDA is not an approved drug and does not have an effective approval until FDA issues an approval after any necessary additional review of the application.

An ANDA applicant may submit amendments to a tentatively approved application that propose changes to the application, request final approval, or propose changes and request final approval. As described in the guidance, an amendment proposing changes to the application may delay FDA's final approval of the ANDA, depending on the timing of submission of the amendment and the nature of the changes proposed and any related deficiencies identified upon review. The guidance is intended to assist applicants in preparing an amendment for submission in a timely fashion to enable final approval on the earliest lawful approval date. In particular, applicants that wish to request final approval should determine whether changes are necessary before requesting this final approval, review any changes that have been made to their application since the tentative approval was granted, and consider the possible review goal dates that may be assigned to the request for final approval to request final approval in a timely fashion.

In the **Federal Register** of February 1, 2019 (84 FR 1164), FDA announced the availability of the draft guidance of the same title dated January 2019. The draft guidance was posted on FDA's website on January 16, 2019, during the lapse in appropriations to provide advance notice of the document to the public. The comment period opened upon publication in the **Federal Register**. FDA received five comments on the draft guidance and those comments were considered as the guidance was finalized. The final guidance contains minor clarifications to the draft guidance. The guidance announced in

this notice finalizes the draft guidance dated January 2019.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''ANDA Submissions—Amendments and Requests for Final Approval to Tentatively Approved ANDAs.'' 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. Electronic Access

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

Dated: September 22, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21470 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice To Announce Supplemental Award To Support Training and Technical Assistance To Address Clinical Workforce Development

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

ACTION: Announcing supplemental award to support training and technical assistance to address clinical workforce development.

SUMMARY: HRSA provided supplemental funding to Community Health Center, Inc. (CHCI), a currently-funded National Training and Technical Assistance Partner (NTTAP) award recipient. CHCI will expand training and technical assistance (T/TA) to health centers and HRSA-funded State and Regional Primary Care Associations (PCAs) to support implementation of a tool developed for health centers to assess and improve their readiness to engage in health professional training programs and address national health care workforce shortages.

FOR FURTHER INFORMATION CONTACT: Tracey Orloff, Director, HRSA, Strategic Partnerships Division, Office of Quality Improvement, at *TOrloff@hrsa.gov* or (301) 443–3197.

SUPPLEMENTARY INFORMATION:

Recipient of the Award: Community Health Center, Inc.

Amount of Non-Competitive Award: $320,000.

Period of Supplemental Funding: August 2020 to June 2022.

CFDA Number: 93.129.

Authority: Section 330(l) of the Public Health Service Act, 42 U.S.C. 254b(l).

Justification: The National Center for Health Workforce Analysis estimates a shortage of over 23,000 primary care physician positions by 2025. Residency programs are needed for health centers to address health care workforce shortages that limit their ability to deliver comprehensive, culturally competent, high quality primary health care services.

CHCI created the Readiness to Train Assessment Tool (RTAT™) for health centers to assess their own readiness to engage in health professional training programs and use the results to manage their workforce shortages. Supplemental funding is necessary to ensure timely implementation of the RTAT™ in order to complete the data collection, analysis, and results dissemination needed for health centers to address critical workforce shortages. As the organization that developed the RTAT™, and the only NTTAP currently funded to provide enhanced T/TA on clinical workforce development to health centers, CHCI has the necessary expertise, organizational systems, and structure in place to immediately expand T/TA efforts in this area.

Thomas J. Engels,

Administrator.

[FR Doc. 2020–21514 Filed 9–28–20; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Centers for Disease Control and Prevention (CDC)/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) has scheduled a public meeting.

DATES: November 5, 2020, 2:00 p.m.–5:15 p.m. Eastern Time (ET) and November 6, 2020, 2:00 p.m.–5:15 p.m. ET. The deadline for online registration is 12:00 p.m. ET on November 2, 2020.

ADDRESSES: This meeting will be held virtually. Please visit the meeting information page to register: *https://chacfall2020.org.*

FOR FURTHER INFORMATION CONTACT: Theresa Jumento, Senior Public Health Advisor, HIV/AIDS Bureau, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–443–5807; or *CHACAdvisoryComm@hrsa.gov.*

SUPPLEMENTARY INFORMATION: CHAC was established under section 222 of the Public Health Service Act, [42 U.S.C. 217a], as amended.

The purpose of CHAC is to advise the Secretary, HHS; the Director, CDC; and the Administrator, HRSA regarding objectives, strategies, policies, and priorities for HIV, viral hepatitis, and other STDs; prevention and treatment efforts including surveillance of HIV infection, viral hepatitis, and other STDs, and related behaviors; epidemiologic, behavioral, health services, and laboratory research on HIV, viral hepatitis, and other STDs; identification of policy issues related to HIV/viral hepatitis/STD professional eduction, patient healthcare delivery, and prevention services; agency policies about prevention of HIV, viral hepatitis and other STDs; treatment, healthcare delivery, and research and training; strategic issues influencing the ability of CDC and HRSA to fulfill their missions of providing prevention and treatment services; programmatic efforts to prevent and treat HIV, viral hepatitis, and other STDs; and support to the agencies in their developoment of responses to emerging health needs related to HIV, viral hepatitis, and other STDs.

During the November 5–6, 2020, meeting, CHAC will discuss community engagement activities related to the President's initiative on ''Ending the HIV Epidemic: A Plan for America'' and the COVID–19 pandemic. CHAC will also discuss the needs and challenges of HIV prevention and care for women. Agenda items are subject to change as priorities dictate. Refer to the CHAC meeting information page for any updated information concerning the meeting.

While this meeting is open to the public, advance registration is required. Members of the public will have the opportunity to provide comments. Requests to offer oral comments will be accepted in the order they are received and may be limited as time allows.