

sensitive, classified, or crypto-logic materials or devices throughout CDC; (24) ensures proper destruction of classified documents that are no longer required; (25) conducts security inspections and audits of all national security information storage and processing areas; and (26) provides deployable unclassified and classified communication platforms to support high-level deploying staff to natural or manmade disaster areas in support of COOP plans.

*Occupational Health Clinic (CAJSJ).*

(1) Provides occupational health services to maintain a healthy domestic and global CDC workforce through occupational health clinics and contracted health services; (2) manages CDC occupational health services to ensure CDC compliance with Occupational Health and Safety Standards and to support the occupational requirements of CDC; (3) serves as the CDC resource for routine and emergency response occupational health services; (4) prepares CDC staff to work in hazardous conditions in response to domestic and international public health threats or concerns; (5) provides medical evaluations and consultation for personal protective equipment; (6) assures the safety and health of the CDC workforce for during deployments; (7) supports deployment processes through health screenings and physical examinations, administration of vaccinations and medications, and respiratory clearance; (8) conducts and documents ongoing medical surveillance, as needed, for post-exposures or deployed staff; (9) ensures a prepared and resilient workforce; and (10) develops and maintains procedures that support the occupational health of the CDC workforce.

**Robert R. Redfield,**

*Director, Centers for Disease Control and Prevention.*

[FR Doc. 2020-25115 Filed 11-12-20; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[CDC-2020-0082]

**Public Health Associate Program (PHAP) Alumni and Host Site Assessment; Reopening of the Comment Period**

**AGENCY:** Center for State, Tribal, Local, and Territorial Support (CSTLTS), Centers for Disease Control and

Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice and reopening of comment period.

**SUMMARY:** On July 28, 2018 the Center for State, Tribal, Local, and Territorial Support (CSTLTS), Centers for Disease Control and Prevention (CDC), published a notice in the **Federal Register** announcing the Public Health Associate Program (PHAP) Alumni and Host Site Assessment. Written comments were to be received by September 28, 2020. The Docket Number that was included in the initial publication of this 60 Day **Federal Register** Notice was incorrect. CDC is announcing the reopening of the comment period.

**DATES:** Electronic or written comments must be received by January 12, 2021.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2020-0082, by any of the following methods:

*Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.

*Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:**

*Instructions:* All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

*Please note:* Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

Dated: November 4, 2020.

**Jeffrey M. Zirger,**

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

[FR Doc. 2020-25146 Filed 11-12-20; 8:45 am]

**BILLING CODE 4163-19-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Board of Scientific Counselors, Deputy Director for Infectious Diseases (BSC, DDID)**

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

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Board of Scientific Counselors, Deputy Director for Infectious Diseases (BSC, DDID). This virtual meeting is open to the public via Zoom, limited only by the space available, which is 500 seats. Pre-registration is required by accessing the link below in the address section.

**DATES:** The meeting will be held on December 9, 2020, 1:00 p.m. to 5 p.m., EST.

**ADDRESSES:** Zoom virtual meeting. Pre-registration is required by accessing the link at [https://cdc.zoomgov.com/webinar/register/WN\\_6\\_Kuhs0ERBSX73CRak7gRQ](https://cdc.zoomgov.com/webinar/register/WN_6_Kuhs0ERBSX73CRak7gRQ). Instructions to access the meeting will be provided following registration.

**FOR FURTHER INFORMATION CONTACT:** Hilary Eiring, MPH, Designated Federal Officer, CDC, 1600 Clifton Road NE, Mailstop H24-12, Atlanta, Georgia 30329-4027, Telephone (770) 488-3901; [HEiring@cdc.gov](mailto:HEiring@cdc.gov).

**SUPPLEMENTARY INFORMATION:**

*Purpose:* The BSC, DDID, provides advice and guidance to the Secretary, Department of Health and Human Services; the Director and the Deputy Director for Infectious Diseases (DDID), CDC; and the Directors of the National Center for Emerging and Zoonotic Infectious Diseases, the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, and the National Center for Immunization and Respiratory Diseases, CDC, in the following areas: Strategies, goals, and priorities for programs and research within the national centers and monitor the overall strategic direction and focus of DDID and the national centers.

*Matters To Be Considered:* The agenda will include updates and discussions on recent outbreaks and affected populations, as well as a brief report back from the Board's Food Safety Modernization Act Surveillance Working Group. Agenda items are subject to change as priorities dictate.

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. 2020-25063 Filed 11-12-20; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2009-D-0052]

**Documenting Electronic Data Files and Statistical Analysis Programs; 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 (GFI) #197 entitled “Documenting Electronic Data Files and Statistical Analysis Programs.” This guidance is intended to inform sponsors of recommendations for documenting electronic data files and statistical analyses submitted to the Center for Veterinary Medicine (CVM) to support new animal drug applications.

**DATES:** The announcement of the guidance is published in the **Federal Register** on November 13, 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-2009-D-0052 for “Documenting Electronic Data Files and Statistical Analysis Programs.” 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 the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. 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:** Virginia Recta, Center for Veterinary Medicine (HFV-160), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0840, [virginia.recta@fda.hhs.gov](mailto:virginia.recta@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of GFI #197 entitled “Documenting Electronic Data Files and Statistical Analysis Programs.” In the **Federal Register** of May 21, 2018 (83 FR 23468), FDA published the notice of availability for a draft guidance entitled “Documenting Electronic Data Files and Statistical Analysis Programs,” giving interested persons until July 20, 2018, to comment on the draft guidance. On July 20, 2018, FDA published a notice of availability announcing the extension of the comment period to October 18, 2018 (83 FR 34595). FDA received numerous comments on the draft guidance and these comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated May 2018.

This guidance is intended to inform sponsors of recommendations for