emergency, FDA intends to revise and replace this guidance with any appropriate changes based on comments received on this guidance and the Agency's experience with implementation.

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 ''Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID–19 Public Health Emergency.'' 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

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information relating to the protection of human subjects and IRBs have been approved under OMB control number 0910–0130; and the collections of information in FDA's guidance for industry on ''Individual Patient Expanded Access Applications: Form FDA 3926'' have been approved under OMB control number 0910–0814.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics, https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders*, or *https://www.regulations.gov.*

Dated: June 3, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–12429 Filed 6–8–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Tick-Borne Disease Working Group

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As required by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the Tick-Borne Disease Working Group (TBDWG) will hold a virtual meeting. The meeting will be open to the public. For this meeting, the TBDWG will review the draft 2020 report to the HHS Secretary and Congress and review and approve graphics and images for the report. The 2020 report will address ongoing tick-borne disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, and interventions for individuals with tick-borne diseases; advances made pursuant to such research; federal activities related to tick-borne diseases; and gaps in tick-borne disease research.

DATES: The meeting will be held online via webcast on July 8, 2020, from 9:00 a.m. to 5:30 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the TBDWG webpage at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2020-7-8/index.html* when this information becomes available.

FOR FURTHER INFORMATION CONTACT: James Berger, Designated Federal Officer for the TBDWG; Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Mary E. Switzer Building, 330 C Street SW, Suite L600, Washington, DC 20024. Email: *tickbornedisease@hhs.gov;* Phone: 202–795–7608.

SUPPLEMENTARY INFORMATION: Please register for the virtual meeting at *https://kauffmaninc.adobeconnect.com/tbdwg_july2020/event/event_info.html.* After registering, you will receive an email confirmation with a personalized link to access the webcast on July 8.

The public will have an opportunity to present their views to the TBDWG orally during the meeting's public comment session or by submitting a written public comment. Comments should be pertinent to the meeting discussion. Persons who wish to provide verbal or written public comment should review instructions at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2020-7-8/index.html* and respond by midnight June 24, 2020, ET. Verbal comments will be limited to three minutes each to accommodate as many speakers as possible during the 30 minute session. Written public comments will be accessible to the public on the TBDWG web page prior to the meeting.

Background and Authority: The Tick-Borne Disease Working Group was established on August 10, 2017, in accordance with Section 2062 of the 21st Century Cures Act, and the Federal Advisory Committee Act, 5 U.S.C. App., as amended, to provide expertise and review federal efforts related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities. The TBDWG is required to submit a report to the HHS Secretary and Congress on their findings and any recommendations for the federal response to tick-borne disease every two years.

Dated: May 20, 2020.

James J. Berger,

Designated Federal Officer, Tick-Borne Disease Working Group, Office of Infectious Disease and HIV/AIDS Policy.

[FR Doc. 2020–12432 Filed 6–8–20; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–4040–0018]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before July 9, 2020.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Ed Calimag, *ed.calimag@hhs.gov* or (202) 690–7569. When submitting comments or requesting information, please include the document identifier 4040–0018–30D and project title for reference.