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.gpo.gov/fdsys/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.

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Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Anil Nayyar, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 22, Rm. 5170, Silver Spring, MD 20993–0002, 301–796–7969.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Development of Locally Applied Corticosteroid Products for the Short-Term Treatment of Symptoms Associated with Internal or External Hemorrhoids.'' This draft guidance addresses the recommended attributes of patients for enrollment, efficacy assessments, safety assessments, and additional considerations with respect to development programs and clinical trials for drugs aimed at the short-term treatment of symptoms associated with internal and external hemorrhoids.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Development of Locally Applied Corticosteroid Products for the Short-Term Treatment of Symptoms Associated with Internal and External Hemorrhoids.'' 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 that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collection of information for the protection of human subjects, informed consent, and Institutional Review Boards in 21 CFR parts 50 and 56 have been approved under OMB control numbers 0910–0755 and 0910–0130. The information collection resulting from ''GFI: Clinical Trial Data Monitoring Committees'' has been approved under OMB control number 0910–0581. The information collection in the ''Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring'' has been approved under OMB control number 0910–0733.

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* or *https://www.regulations.gov.*

Dated: December 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–26464 Filed 12–6–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Data Collection Tool for State Offices of Rural Health Grant Program, OMB No. 0915–0322—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than January 8, 2020.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Data Collection Tool for State Offices of Rural Health Grant Program, OMB No. 0915–0322—Revision.

Abstract: The mission of the Federal Office of Rural Health Policy (FORHP) is to sustain and improve access to quality care services for rural communities. In its authorizing language (Section 711 of the Social Security Act [42 U.S.C. 912]), Congress charged FORHP with administering grants, cooperative agreements, and contracts to provide technical assistance and other activities as necessary to support activities related to improving health care in rural areas. In accordance with the Public Health Service Act, Section 338J (42 U.S.C. 254r), HRSA proposes to continue the State Offices of Rural Health (SORH) Grant Program data collection process.

A 60-day notice published in the **Federal Register** on June 28, 2019, vol. 84, No. 125; pp. 31073–74. There were no public comments.

Need and Proposed Use of the Information: FORHP seeks to continue gathering information from grantees on their efforts to provide technical assistance to clients within their State. SORH grantees submit a Technical Assistance Report that includes: (1) The total number of technical assistance encounters provided directly by the grantee, and (2) the total number of unduplicated clients that received direct technical assistance from the grantee. These measures will continue with additional measures being added in the following three categories: (1) Information disseminated; (2) information created; and (3) collaborative efforts by topic area and

type of audience. These proposed new measures are being added to obtain a more accurate depiction of the breadth of SORH work and are based on recommendations from the grantees. Submission of the Technical Assistance Report is submitted via the HRSA Electronic Handbook no later than 30 days after the end of each 12 month budget period.

Likely Respondents: Fifty State Offices of Rural Health.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Technical Assistance Report	50	1	50	13.5	675
Total	50		50		675

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2019–26440 Filed 12–6–19; 8:45 am]

BILLING CODE 4165–15–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 meeting. The meeting will be open to the public. For this meeting, the TBDWG will (1) hear presentations from eight subcommittees on findings and potential actions from reports prepared for the TBDWG to consider and (2) further discuss plans for developing the next report to the HHS Secretary and Congress on federal tick-borne activities and research, taking into consideration the 2018 report. The 2020 report will address ongoing tick-borne disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, duration of illness, and intervention 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 on January 28–29, 2020, from 9:00 a.m. to 4:30 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the website for the TBDWG at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2020-1-28/index.html* when this information becomes available.

ADDRESSES: The meeting will be held at Hyatt Place Washington DC/US Capitol, 33 New York Avenue NE, Washington, DC 20002. Members of the public may also attend the meeting via webcast. Instructions for attending via webcast will be posted one week prior to the meeting at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2020-1-28/index.html.*

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: In-person attendance at the meeting is limited to space available; therefore, preregistration for public members is advisable and can be accomplished by registering at *https://www.eventbrite.com/e/tick-borne-disease-working-group-meeting-january-28-29-2020-meeting-11-tickets-81603750013.* On the day of the meeting, seating will be provided first to persons who have preregistered. People who have not preregistered will be accommodated on a first come, first served basis if additional seats are still available 10 minutes before the meeting starts. Non-U.S. citizens who plan to attend in person are required to provide additional information and must notify the Working Group support staff via email at *tickbornedisease@hhs.gov* before December 28, 2019.

The public will have an opportunity to present their views orally to the TBDWG 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/2020-1-28/index.html* and respond by midnight Tuesday, January 17, 2020, ET. Verbal comments will be limited to three minutes each to accommodate as many speakers as possible during the two 30 minute sessions. Written public comments will be accessible to the TBDWG members and made 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.