

owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 10, 2019.

A. Federal Reserve Bank of Atlanta (Kathryn Haney, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to Applications.Comments@atl.frb.org:

1. *Community Bancshares of Mississippi, Inc. Employee Stock Ownership Plan, Brandon, Mississippi*, to acquire additional voting shares, for a total of 18.82 percent, of Community Bancshares of Mississippi, Inc., Brandon, Mississippi, and thereby indirectly acquire shares of Community Bank of Mississippi, Forest, Mississippi.

Board of Governors of the Federal Reserve System, March 8, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

[OMB No. 0985-0007]

Agency Information Collection Activities; Proposed Collection; Public Comment Request; Annual Reporting Requirements for the Older Americans Act Title VI Grant Program

AGENCY: Administration for Community Living, HHS.

ACTION: Notice

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice.

This Extension without Change (ICR Ext) solicits comments on the information collection requirements related to the Program Performance Reports for Title VI grants under the Older Americans Act.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by May 13, 2019.

ADDRESSES: Submit electronic comments on the collection of information to: Cynthia LaCounte, Cynthia.LaCounte@acl.hhs.gov. Submit written comments on the collection of information to Administration for Community Living, Washington, DC 20201, Attention: Cynthia LaCounte.

FOR FURTHER INFORMATION CONTACT: Cynthia LaCounte, Director, Office of American Indian, Alaskan Native and Native Hawaiian Programs, Administration for Community Living, Washington, DC 20416, 202-795-7380, Cynthia.LaCounte@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The purpose of the Program Performance Report data collection provides a data base for ACL to: (1) Monitor program achievement of performance objective; (2) establish program policy and direction; and (3) prepare responses to Congress, the OMB, the General Accounting Office, other Federal Departments, and public and private agencies as required by the OAA Title II sections 202(f)(1) and 207. This data collection will also support ACL in tracking performance outcomes and efficiency measures with respect to the annual and long-term performance targets established in compliance with the Government Performance Results Modernization Act (GPRAMA). If ACL did not collect the program data herein requested, it would not be able to monitor and manage total program progress as expected, nor develop program policy options directed toward assuring the most effective use of limited Title VI funds.

The proposed data collection tools may be found on the ACL website for review at <https://www.acl.gov/about-acl/public-input>.

Estimated Program Burden

ACL estimates the burden associated with this collection of information as follows: 274 tribal grantees respond annually and it will take 2.5 hours to complete the Title VI report for each grantee for a total of 685 hours for all tribal grantees to complete the form.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Title VI Part A, B and C	274	1	2.5	685
Total	274	1	2.5	685

Dated: March 5, 2019.

Mary Lazare,

Principal Deputy Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-4002]

Electronic Submission of Adverse Event Reports to the Food and Drug Administration Adverse Event Reporting System Using International Council for Harmonisation E2B(R3) Standards; Public Meetings; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meetings; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is re-announcing three public meetings entitled “Electronic Submission of Adverse Event Reports to FDA Adverse Event Reporting System (FAERS) Using International Council for Harmonisation (ICH) E2B(R3) Standards.” The purpose of these public meetings is to provide the pharmaceutical industry and other interested parties with information on the plans, progress, and technical specifications to upgrade electronic submission standards for drug, biological, and drug/biologic-led combination products for the premarket and postmarket safety surveillance programs managed by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). These meetings will focus on enhancements to electronic submission of Individual Case Safety Reports (ICSRs) in FAERS using ICH E2B(R3) standards.

FDA is seeking input from stakeholders as it fulfills its commitment to implement ICH E2B(R3) standards by holding three public meetings. FDA will use the information provided by the public to inform the enhancements to FAERS required for the implementation of ICH E2B(R3)

standards and relevant regional variations.

DATES: The first public meeting is being rescheduled due to a previous lapse in appropriations. The rescheduled first public meeting will be held on March 25, 2019, from 9 a.m. to 4 p.m. The second public meeting will be held on July 17, 2019, from 9 a.m. to 4 p.m. The third public meeting will be held on February 19, 2020, from 9 a.m. to 4 p.m. Submit either electronic or written comments on these public meetings by April 25, 2019, for the first public meeting; by August 16, 2019, for the second public meeting, and by March 20, 2020, for the third public meeting. See the **SUPPLEMENTARY INFORMATION** section for registration dates and information.

ADDRESSES: The first public meeting will be held at the Silver Spring Civic Building at Veterans Plaza, The Buffalo Soldiers Great Hall, 1 Veterans Pl., Silver Spring, MD 20910. The second and third public meetings will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/default.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. For timely consideration, we request that electronic comments be submitted before or within 30 days after each public meeting (*i.e.*, comments submitted by or before April 25, 2019, for the first public meeting; August 16, 2019, for the second public meeting; and March 20, 2020, for the third public meeting. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 25, 2019, August 16, 2019, and March 20, 2020, after the first, second, and the third meeting, respectively. 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.

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-N-4002 for “Electronic Submission of Adverse Event Reports to FAERS Using ICH E2B(R3) Standards.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be