Basswood Partners, LLC, Basswood Enhanced Long Short GP, LLC, and Basswood Capital Management, LLC; all of New York, New York; to retain and acquire voting shares of American River Bankshares, Rancho Cordova, California, and thereby indirectly retain and acquire shares of American River Bank, Sacramento, California.

Ann E. Misback, Secretary of the Board.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

Proposed Data Collection Submitted for Public Comment and Recommendations

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

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled “Using Qualitative Methods to Understand Issues in HIV Prevention, Care and Treatment in the United States.” CDC’s goal for this generic information collection mechanism is to conduct qualitative studies to quickly identify barriers and facilitators to HIV prevention, care and treatment in specific regions with high HIV burden in the US.

DATES: CDC must receive written comments on or before May 14, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0022 by any of the following methods:

• Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
• Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

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.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, 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.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:
1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Using Qualitative Methods to Understand Issues in HIV Prevention, Care and Treatment in the United States (OMB Control Number 0920–1091; expires 12/31/2018)—Extension—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC).
Background and Brief Description

The CDC’s National Center on HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Division of HIV/AIDS Prevention (DHAP) seeks a three-year extension to conduct qualitative studies to quickly identify barriers and facilitators to HIV prevention, care and treatment in specific regions with high HIV burden in the US. Proposed activities remain consistent with the national HIV prevention goals, the CDC Division of HIV/AIDS Prevention (DHAP) Strategic Plan, and DHAP’s High-impact HIV Prevention approach.

The purposes for each data collection study supported under this umbrella generic information collection plan will be to understand specific barriers and facilitators to local HIV prevention, care and treatment in the United States and territories. For example, each study will seek to identify ways to improve programmatic activities along the continuum of HIV prevention, treatment and care for different populations residing in different geographic settings with greatest burden of HIV.

The target populations for the studies include, but are not limited to: (1) Persons living with HIV who are in treatment; (2) persons living with HIV who are out of treatment and who may or may not be seeking treatment at healthcare facilities; (3) persons at high risk for HIV acquisition (HIV negative) and HIV transmission (HIV positive); (4) persons from groups at high risk for HIV including gay, bisexual and other MSM, transgender persons, and injection and non-injection drug users; (5) persons from racial and ethnic minorities; and (6) healthcare providers or other professionals who provide HIV prevention, care and treatment services. Other populations may include individuals who provide non-HIV services or otherwise interact with persons living with HIV or persons at risk for HIV acquisition.

Studies will only provide local contextual information about the barriers and facilitators to HIV prevention, care, and treatment experienced by specific communities at risk for acquiring HIV infection, by HIV-positive persons across the HIV care continuum, and by organizations or individuals providing HIV prevention, care, treatment, and related support services.

Data collection methods used in any of the specific studies primarily will consist of rapid qualitative assessment methodologies, such as semi-structured and in-depth qualitative interviews, focus groups; direct observations; document reviews; and short structured surveys. Data will be analyzed using well-established qualitative analysis methods, such as coding interviews for themes about barriers and successes to HIV prevention, care, and treatment. Structured response surveys will be analyzed using descriptive statistics and other appropriate statistical methods.

CDC will use the results from each specific data collection study to help identify ways to improve local programmatic activities for specific communities along the continuum of HIV prevention, treatment and care for populations and areas with the greatest HIV burden. CDC will communicate study outcomes to local stakeholders and organizations in positions to consider and implement site-specific improvements in HIV prevention, care, and treatment for each of the study sites examined. For stakeholders, organizations, or agencies outside the local affected communities, all communications will include clear discussion of the limitations of the region-specific, qualitative methods and the non-generalizability of the study outcomes.

For a given year, each separate data collection will range from 30 (minimum) to 200 (maximum) respondents, based on the nature and scope of the research purposes. For example, if there are three data collections, the maximum combined number of expected respondents is 600. In a given year, CDC anticipates the need to screen 1,600 persons to identify 800 eligible persons, of which 600 persons will agree to participate.

CDC anticipates that screener forms will take 5 minutes to complete each, contact information forms will take 1 minute to complete each, and consent forms will take 5 minutes to complete each. CDC anticipates study eligibility for 50 percent of the targeted populations screened. Of eligible persons, 75% will agree to participate.

Brief structured surveys will take 15 minutes to complete. In-depth interviews or focus groups with respondents are expected to take 60 minutes (1 hour) to complete. In-depth interviews or focus groups with healthcare providers are expected to take 45 minutes to complete.

The total annual response burden, based on an average of 600 study respondents per year (assuming three large data collections involving 200 participants each), is 918 hours.

<table>
<thead>
<tr>
<th>Type of respondents</th>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response (in hours)</th>
<th>Total burden (in hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Public—Adults</td>
<td>Study Screener</td>
<td>1,600</td>
<td>1</td>
<td>5/60</td>
<td>133</td>
</tr>
<tr>
<td>General Public—Adults</td>
<td>Contact Information Form</td>
<td>600</td>
<td>1</td>
<td>1/60</td>
<td>10</td>
</tr>
<tr>
<td>General Public—Adults</td>
<td>Consent Form</td>
<td>600</td>
<td>1</td>
<td>5/60</td>
<td>50</td>
</tr>
<tr>
<td>General Public—Adults</td>
<td>Demographic Survey</td>
<td>500</td>
<td>1</td>
<td>15/60</td>
<td>125</td>
</tr>
<tr>
<td>General Public—Adults</td>
<td>Interview Guide</td>
<td>500</td>
<td>1</td>
<td>1</td>
<td>500</td>
</tr>
<tr>
<td>General Public—Adults</td>
<td>Provider Demographic Survey</td>
<td>100</td>
<td>1</td>
<td>15/60</td>
<td>25</td>
</tr>
<tr>
<td>General Public—Adults</td>
<td>Provider Interview Guide</td>
<td>100</td>
<td>1</td>
<td>45/60</td>
<td>75</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>918</td>
</tr>
</tbody>
</table>
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[cdc–2017–0114; docket number NIOSH–305]

Final National Occupational Research Agenda for Transportation, Warehousing and Utilities

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: NIOSH announces the availability of the final National Occupational Research Agenda for Transportation, Warehousing and Utilities.

DATES: The final document was published on March 7, 2018.

ADDRESSES: The document may be obtained at the following link: https://www.cdc.gov/niosh/nora/sectors/twu/agenda.html

FOR FURTHER INFORMATION CONTACT: Emily Novicki, M.A., M.P.H., (NORACoordinator@cdc.gov), National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Mailstop E–20, 1600 Clifton Road NE, Atlanta, GA 30329, phone (404) 498–2581 (not a toll free number).

SUPPLEMENTARY INFORMATION: On December 1, 2017, NIOSH published a request for public review in the Federal Register (82 FR 56973) of the draft version of the National Occupational Research Agenda for Transportation, Warehousing and Utilities. No comments were received.

Dated: March 8, 2018.

Frank Hearl,
Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2017–N–0493]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Utilization of Adequate Provision Among Low to Non-Internet Users

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit either electronic or written comments on the collection of information by April 12, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–New and title “Utilization of Adequate Provision Among Low to Non-internet Users.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, PRAsStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Utilization of Adequate Provision Among Low to Non-Internet Users

OMB Control Number 0910–NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300a(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

Prescription drug advertising regulations require that broadcast advertisements containing product claims present the product’s major side effects and contraindications in either audio or audio and visual parts of the advertisement (21 CFR 202.1(e)(1)); this is often called the major statement. The regulations also require that broadcast advertisements contain a brief summary of all necessary information related to side effects and contraindications or that “adequate provision” be made for dissemination of the approved package labeling in connection with the broadcast (§ 202.1(e)(1)). The requirement for adequate provision is generally fulfilled when a firm gives consumers the option of obtaining FDA-required labeling or other information via a toll-free telephone number, through print advertisements or product brochures, through information disseminated at health care provider offices or pharmacies, and through the internet (Ref. 1). The purpose of including all four elements is to ensure that most of a potentially diverse audience can access the information.

Internet accessibility is increasing, but many members of certain demographic groups (e.g., older adults, low socioeconomic status individuals) nonetheless report that the internet is inaccessible to them either as a resource or due to limited knowledge, and so a website alone may not adequately serve all potential audiences (Refs. 2 and 3). Similarly, some consumers may prefer to consult sources other than a health care provider to conduct initial research, for privacy reasons or due to limited knowledge, and so a website alone may not adequately serve all potential audiences (Refs. 1, 4, and 5). In light of these considerations, the toll-free number and print ad may provide special value to consumers who are low to non-internet users and/or those who value privacy when conducting initial research on a medication, though not necessarily unique value relative to one another. As such, a primary purpose of this research is to examine the value of including both the toll-free number and print ad as part of adequate provision in direct-to-consumer (DTC) prescription drug broadcast ads. We will also investigate the ability and willingness of low to non-internet users to make use of internet resources if other options were unavailable. These questions will be assessed using a survey methodology administered via telephone.

In addition, building on concurrent FDA research regarding drug risk...