the grantees may be experiencing in implementing their projects on a timely manner, and, for writing Annual Report to Congress.

Respondents: Refugee Microenterprise Development Program 22.

Refugee Home-Based Child Care Microenterprise Development Program 23

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondents	Average burden hours per respondents	Total burden hours
Refugee Microenterprise Development Program	22	8	4	88
Refugee Home-Based Child Care Microenterprise Development Program	23	7	4	92
Total Burden				180

Estimated Total Annual Burden Hours: 180

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–02625 Filed 2–9–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0343]

Advancing the Development of Biomarkers in Traumatic Brain Injury; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled, ''Advancing the Development of Biomarkers in Traumatic Brain Injury.'' This workshop aims to examine potential biomarkers, discuss the challenges and solutions related to biomarker development methodologies, and establish strategies for data standardization, sharing and analysis of big data sets for traumatic brain injury (TBI). By convening the relevant stakeholders, the goal is to obtain input on the scientific, clinical, patient, and regulatory considerations associated with TBI biomarker development to improve diagnosis and clinical utility for TBI.

DATES: The public workshop will be held on March 3, 2016, from 8 a.m. to 5 p.m. Submit either electronic or written comments on the public workshop by May 3, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2016–N–0343 for ''Advancing the Development of Biomarkers in Traumatic Brain Injury.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31, Rm. 1503 (the Great Room, sections B and C), Silver Spring, MD 20993. 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 *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Allison Kumar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5408, Silver Spring, MD 20993, 301–796–6369, email: *Allison.Kumar@fda.hhs.gov;* or Lakshmi Kannan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5402, Silver Spring, MD 20993, 240–402–7735, email: *Lakshmi.Kannan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Each year, TBI contribute to a substantial number of deaths and cases of permanent disability; yet both accurate diagnostics and effective treatments remain stubbornly elusive. Diagnosis of TBI in the acute setting remains a major obstacle, as ''gold standard'' diagnostic criteria for TBI have not yet been established, despite the availability of several published diagnostic criteria. Many of these criteria determine the severity of the injury and classify TBI as mild, moderate, and severe. Recently, the importance of apparently mild injuries has been recognized as a major public health crisis for people including military personnel, children and young adults in sport activities throughout their normal life. This group of mild TBI (mTBI) patients represents the greatest challenges to accurately diagnose and to predict outcome because neuroimaging tools such as computed tomography (CT) are not sensitive enough for detection beyond identifying structural abnormalities. The use of CT can only detect the presence of structural lesions (*i.e.,* hematomas) which require immediate medical attention or to rule out head injury complications from more severe trauma. Unlike other organ-based diseases such as myocardial infarction, prostate cancer, and polycystic kidney disease where biomarkers are clinically essential to guide diagnosis, prognosis, and treatment, there are no definitive biomarkers tests available for TBI. Over the last decade there have been a myriad of studies exploring many promising biomarkers including neuroimaging and bio fluid-based for all forms of TBI severity; however, none have become part of the standard protocols for diagnosis of TBI. In addition, there are currently no FDA qualified biomarkers for clinical use in TBI. Therefore, there is an unmet need for TBI biomarkers in the clinical setting to: (1) Aid in early diagnosis and stratify the severity of injury, (2) improve prognosis, (3) monitor ongoing pathological processes, and (4) evaluate the efficacy of treatments.

II. Topics for Discussion at the Public Workshop

The public workshop seeks to engage stakeholders from academia, industry, government agencies, heath care, and patient care groups to discuss the scientific, clinical, patient, and regulatory considerations associated with potential and emerging biomarkers in TBI to improve diagnosis, clinical trial design, and outcome measures. This discussion is essential for encouraging and expediting the development of biomarker tests as scientifically validated tools for clinical utility particularly in mTBI, as well as in the full spectrum of TBI.

This public workshop consists of brief presentations and interactive discussions through several panel sessions. Following the presentations, we plan to hold moderated discussions where participants and additional panelists can provide their individual perspectives. Specifically, this workshop is designed to address the following topics:

• Examine potential candidate biomarkers for TBI-neuroimaging, biofluid-based, and other emerging biomarkers such as electroencephalogram.

○ Strength of current scientific evidence;

○ different contexts of use; and

○ correlation to clinical outcome assessments.

• Challenges and recommendations related to TBI biomarker development.

○ Intent of use;

○ device output-including variations with technology, qualitative v. quantitative, individual v. composite score;

○ analytical performance- including quality of the measurement (precision, linearity);

○ clinical reference standard;

○ clinical and functional validation; and

○ appropriate statistical approaches/methods.

• Strategies for improving data standardization, sharing, and application of big data analytics methods in the field of biomarker development.

○ Explore existing and potential big datasets and registries for TBI (*e.g.* TBI Endpoints Development Initiative Meta Dataset, National Institute of Neurological Disorders and Stroke Common Data Elements, Federal Interagency Traumatic Brain Injury Research);

○ platforms and methods used to build big data infrastructure;

○ barriers to broader biomarker data aggregation, dissemination, and application; and

○ possible strategies to address these barriers.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. (EST), February 22, 2016. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Office of Communication and Education, Center for Devices and Radiological Health, Food and Drug Administration, 301–796–5661, email: *susan.monahan@fda.hhs.gov* no later than February 16, 2016.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this meeting/public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. The webcast link will be available on the workshop Web page after February 25, 2016. Please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Requests for Oral Presentations: This public workshop includes a public comment session and topic-focused sessions. During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comments and participate in the focused sessions. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by February 25, 2016. All requests to make oral presentations must be received by the close of registration on February 22, 2016, by 4 p.m. (EST). If selected for presentation, any presentation materials must be emailed to Lakshmi Kannan (see **FOR FURTHER INFORMATION CONTACT**) no later than February 25, 2016. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

FDA is holding this public workshop to obtain information on development of TBI biomarkers and data standardization. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is May 3, 2016.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.* A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

Dated: February 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–02592 Filed 2–9–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than April 11, 2016.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N–39, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Rural Opioid Overdose Reversal Grant Program OMB No. 0906–xxxx–New.

Abstract: This program is authorized by Section 711(b) of the Social Security Act (U.S.C. 912(b), as amended and the Consolidated and Further Continuing Appropriations Act (Pub. L. 114–113). The purpose of this grant program is to reduce the incidences of morbidity and mortality related to opioid overdoses in rural communities through the purchase and placement of emergency devices