indicated or the offices of the Board of Governors not later than October 31, 2016.

A. Federal Reserve Bank of Boston (Prabal Chakrabarti, Senior Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02210–2204. Comments can also be sent electronically to *BOS.SRC.Applications.Comments@bos.frb.org:*

1. *TCT Holdings Inc., Teachers Insurance and Annuity Association of America and TIAA Board of Overseers,* all of New York, New York; to acquire EverBank Financial Corp and thereby indirectly acquire EverBank, both of Jacksonville, Florida.

Board of Governors of the Federal Reserve System, October 3, 2016.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2016–24221 Filed 10–5–16; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–16–0733]; [Docket No. CDC–2016–0095]

Proposed Data Collections 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 efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as requires by the Paperwork Reduction Act of 1995. This notice invites comments on Early Hearing Detection and Intervention (EDHI) Hearing and Screening Follow-up Survey.

DATES: Written comments must be received on or before December 5, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2016–0095 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instruction 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. All relevant comments received will be posted without change to *Regulation.gov*, including any personal information provided. For access to the docket to read the background documents or comments received, go to *Regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

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, and each reinstatement of previously approved information collection before submitting the collect to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited 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) ways to enhance 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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. 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.

Proposed Project

Early Hearing Detection and Intervention (EDHI) Hearing and Screening Follow-up Survey (OMB No. 0920–0733, Expiration 08/30/2016)—Reinstatement with Change—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Human Development and Disability, located within NCBDDD, promotes the health of babies, children, and adults, with a focus on preventing birth defects and developmental disabilities and optimizing the health outcomes of those with disabilities. As part of these efforts the Center is actively involved in addressing the early identification of hearing loss among newborns and infants. Congenital hearing loss is a common birth defect that affects 1 to 3 per 1,000 live births, or approximately 12,000 children across the United States annually.[1 2] Studies have shown that children with a delayed diagnosis of hearing loss can experience preventable delays in speech, language, and cognitive development.[3–5] To ensure children with hearing loss are identified as soon as possible, many states and United States (U.S.) territories have implemented Early Hearing Detection and Intervention (EHDI) programs and enacted laws related to infant hearing screening. The majority of these EHDI programs have adopted the ''1–3–6'' plan, which consists of three core goals: (1) Screening all infants for hearing loss before 1 month of age, (2) ensuring diagnostic audiologic evaluation before 3 months of age for those who do not pass the screening, and (3) enrollment in early intervention services before 6 months of age for those identified with hearing loss.

Federal support for identifying children with hearing loss began with the Children's Health Act of 2000, which authorized federal programs to support EHDI activities at the state level. Since then, funds have been distributed to states via cooperative agreements from the CDC and grants from the Health Resources and Services Administration (HRSA). States are using these federal monies to enhance EHDI programs and develop corresponding tracking and surveillance systems. These systems are intended to help EHDI programs ensure infants and children are receiving recommended

hearing screening, follow-up, and intervention services.

The CDC's NCBDDD will fund this work to obtain standardized annual jurisdictional data related to the number of children screened for hearing loss, referred for and receiving follow-up testing (*e.g.,* diagnostic audiologic evaluation). As with the original and reinstated information collection the overall purpose of this updated survey is to consistently gather the aggregate-level data required to assess progress toward the National EHDI Goals.

Proposed changes for the updated survey have been made in response to feedback from respondents and requests for additional information from state and national partners. These updates are intended to further increase the standardization and completeness of the data collected and make the survey easier to complete. These changes include adding new fields to capture data about hearing screening conducted by using one-stage, two-stage, or blended (both one-stage and two-stage) screening protocol. In addition, fields were added to be able to report the number of occurring homebirths and the number of infants not documented to have received recommended screening, diagnostic and/or intervention services, due to reasons such as the infant being adopted, no referral from the Primary Care Physician (PCP)/Ear-Nose-Throat (ENT) specialist and/or due to medical reasons. Several fields have been removed in order to improve data quality and better evaluate whether jurisdictions are meeting the nationwide benchmarks. The table for reporting type and severity of hearing loss data has been updated so that this data can be reported using only the classification system from the American Speech and Hearing Association (ASHA). The table for reporting demographics has also been updated to include fewer columns, in order to improve data quality and data standardization with the previous sections of the survey.

The collected data will continue to be used in four key ways. First, it will be used to determine annual rates of hearing screening, referral for further diagnostic testing, loss to follow-up, incidence of hearing loss in infants, and enrollment in early intervention. These data will assist in determining if infants and children are receiving recommended EHDI-related services in a timely fashion. The information is intended to be made available through presentations, articles related to EHDI programs and infant hearing loss, and online at: *www.cdc.gov/ncbddd/hearingloss/ehdi-data.html.*

Second, the data will be used to determine rates of loss to follow-up within different stages of the EHDI process. Aggregated information about maternal race, ethnicity, education, and age will be used to help determine whether rates of loss to follow-up are correlated with any of these demographic variables. As with the most recent reinstatement with change (2013), the updated survey will continue to use same set of demographic data items, which will make it possible to continue analyzing the association between factors such as maternal race and loss to follow-up, maintain comparability between previous and future data, and minimize burden on respondents by continuing to request the same data that programs are currently collecting and able to report. This information is anticipated to continue to be important in developing methods to help minimize loss to follow-up so all children receive recommended hearing-related services in a timely manner.

Third, the data will be helpful in determining to what extent jurisdictional tracking and surveillance systems are capturing essential information related to follow-up services, identification, and enrollment in early intervention. It will also be used by CDC EHDI to identify areas in jurisdictional EHDI systems that may require additional modification. This is anticipated to be helpful in providing technical support to funded jurisdictions as well as for assessing the impact of federal initiatives related to hearing loss in infants and children.

Fourth, the requested data will aid in efforts to determine the prevalence of differing degrees of hearing loss (*e.g.,* mild, severe, profound, etc.) among infants and children.

Information provided by this updated survey also has the potential to be used for other purposes. These include quality improvement activities by jurisdictional EHDI programs (*e.g.,* identifying areas within the EHDI processes that could benefit from further development) and providing requested data for Healthy People 2020, Objective ENT–VSL–1 on newborn hearing screening, evaluation, and intervention. In addition, the aggregate-level data will continue to be made available online to other state and federal agencies, organizations, and the general public.

The total burden hours is 238.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
EHDI Program State Program Coordinators Contacted	Survey Directions	59	1	10/60	10
EHDI Program State Program Coordinators who return the survey	Survey	57	1	240/60	228
Totals					238

Leroy A. Richardson

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–24132 Filed 10–5–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2896]

Public Meeting on Pre-Market Evaluation of Abuse-Deterrent Properties of Opioid Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss scientific and technical issues relating to formulation development and pre-market evaluation of opioid drug products with abuse-deterrent properties. The meeting is intended to give FDA the opportunity to discuss, and seek public input from stakeholders on, the approach to testing FDA recommended in its draft guidance ''General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products.'' The meeting will also provide an opportunity to discuss FDA's efforts to develop standardized in vitro testing methodologies for evaluating the abuse deterrence of opioid drug products. FDA is seeking input from all stakeholders, including patients, health care providers, health care payers, the pharmaceutical industry, patient advocates, academics, researchers, and other government entities.

FDA may hold one or more additional meetings in the future to discuss the risk-benefit paradigm for opioid drug products to ensure that FDA is appropriately considering the full public health impact of prescription opioid drug products and the post-market impact (''real world effects'') of abuse-deterrent opioid drug products.

DATES: The public meeting will be held on October 31, 2016, from 8:30 a.m. to 4:30 p.m. and November 1, 2016, from 8:30 a.m. to 4 p.m. The meeting may be extended or end early depending on the level of public participation. Individuals seeking to attend or to present at the meeting must register by October 17, 2016. Please register here for the meeting: *http://www.cvent.com/d/wvq0sm/4W.* Electronic or written comments regarding scientific and technical issues relating to formulation development and pre-market evaluation of abuse-deterrent properties of opioid drug products will be accepted until December 1, 2016.

ADDRESSES: The public meeting will be held at College Park Marriott Hotel and Conference Center, 3501 University Blvd. East, Hyattsville, MD 20783.

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–2896 for ''Public Meeting on Pre-Market Evaluation of Abuse-Deterrent Properties of Opioid Drug Products.'' 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.

FDA will post the agenda approximately 3 days before the public meeting at: *http://www.fda.gov/Drugs/NewsEvents/ucm509853.htm.* FDA will also post a link to the live Webcast of this public meeting on the day of the public meeting.

FOR FURTHER INFORMATION CONTACT: Michelle Eby, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6184, Silver Spring, MD 20993, 301–796–4714, *Michelle.Eby@fda.hhs.gov.*