Estimated Total Annual Burden Hours: 378.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), 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, 330 C Street SW., Washington, DC 20201. 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. 2016–25753 Filed 10–24–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:
Title: DRA TANF Final Rule.
OMB No.: 0970–0338.

Description: When the Deficit Reduction Act of 2005 (DRA) reauthorized the Temporary Assistance for Needy Families (TANF) program, it imposed a new data requirement that States prepare and submit data verification procedures and replaced other data requirements with new versions including: The TANF Data Report, the SSP–MOE Data Report, the Caseload Reduction Documentation Process, and the Reasonable Cause/Corrective Compliance Documentation Process. The Continuing Appropriations Act, 2014 (Pub. L. 113–46) provides federal funds to operate Temporary Assistance for Needy Families (TANF) programs in the states, DC, Guam, Puerto Rico, the U.S. Virgin Islands, and for approved federally recognized tribes and Alaskan Native Villages through January 15, 2014. We are proposing to continue these information collections without change.

Respondents: The 50 States of the United States, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Preparation and Submission of Data Verification Procedures §§ 261.60–261.63	54	1	640	34,560
Caseload Reduction Documentation Process, ACF–202 §§ 261.41 & 261.44	54	1	120	6,480
Reasonable Cause/Corrective Compliance Documentation Process §§ 262.4, 262.6, & 262.7; § 261.51	54	2	240	25,920
TANF Data Report Part 265	54	4	2,201	475,416
SSP–MOE Data Report Part 265	29	4	714	82,824

Estimated Total Annual Burden Hours: 625,200.

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 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. 2016–25775 Filed 10–24–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1380]

The Role of Hospitals in Modernizing Evidence Generation for Device Evaluation: Harnessing the Digital Revolution for Surveillance; 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 ''The Role of Hospitals in Modernizing Evidence Generation for Device Evaluation: Harnessing the Digital Revolution for Surveillance.'' Hospitals play a critical role in the development

of these national capabilities, leading to more robust evidence generation. Recently, the role of hospital reporting of device-related adverse events in device surveillance and, more generally, device evaluation, has garnered increased scrutiny. This public workshop will further explore the critical role of hospitals in the evolution of device surveillance and in creating more robust surveillance capabilities.

DATES: The public workshop will be held on December 5, 2016, 8:30 a.m. to 5 p.m. ET. Submit either electronic or written comments on the public workshop by January 6, 2017.

ADDRESSES: The public workshop will be held at Fishers Lane Conference Center, Terrace Level, 5635 Fishers Lane, Rockville, MD 20852. Parking is available for this public meeting at $7 per day (cash only). Alternatively, the location is accessible by metro via the Twinbrook metro stop (Red Line). When you leave the Metro station, make a right turn towards the east side of the parking lot. Proceed to the north east corner of the parking lot and leave through the pedestrian gate. When you exit the station you will be at the corner of Fishers Lane and Twinbrook Parkway. Cross the street and proceed down Fishers Lane to 5635 Fishers Lane. Entering through the main front entrance on Fishers Lane, you will need to take an elevator down to the Terrace Level. Follow the short hallway towards the elevators and the Conference Center glass doors are straight ahead near the elevators.

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–1380 for ''The Role of Hospitals in Modernizing Evidence Generation for Device Evaluation: Harnessing the Digital Revolution for Surveillance.'' 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.

FOR FURTHER INFORMATION CONTACT: Jill Marion, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3110, Silver Spring, MD 20993, 301–796–6128, *Jill.Marion@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In 2012, FDA issued a report, ''Strengthening Our National System for Medical Device Postmarket Surveillance,'' [1] that described limitations in current authorities and approaches to medical device postmarket surveillance and proposed a strategy for a national medical device postmarket surveillance system. The system would leverage real-world data—data developed through routine clinical practice—captured in electronic health information (such as device registries, electronic health records, and payer claims forms) that incorporated unique device identifiers to quickly identify poorly performing devices, accurately characterize and disseminate information about real-world device performance, including the clinical benefits and risks of marketed devices, and efficiently generate data to support premarket clearance or approval of new devices and new uses of currently marketed devices. Following extensive public input, FDA issued an update in 2013 [2] that outlined concrete steps the Agency would take to promote more efficient and robust national system capabilities. Two critical steps were the creation of a Planning Board and a Medical Device Registry Task Force. The Brookings Institution, under commission by FDA, convened a multistakeholder Planning Board. In February 2015, the Planning Board issued a report, ''Strengthening Patient

[1] *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM301924.pdf.*

[2] *http://www.fda.gov/downloads/MedicalDevices/Safety/CDRHPostmarketSurveillance/UCM348845.pdf.*

Care: Building a National Postmarket Medical Device Surveillance System,'' [3] that sets out the key steps towards development of a national system, including its governance, operations, and sustainability.

The system was renamed an ''evaluation system'' to reflect the broad evidence needs of stakeholders with the August 2015 release of the report, ''Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge the Clinical Care and Research,'' issued by the multistakeholder Task Force, under the auspices of the Medical Device Epidemiology Network (MDEpiNet).[4] In 2016, the Planning Board, convened by the Duke-Margolis Center for Health Policy, published ''Better Evidence on Medical Devices: A Coordinating Center for a 21st Century National Medical Device Evaluation System.'' [5] This document further clarifies the expectations, roles, and responsibilities of the coordinating center described in the Planning Board's earlier 2015 report. This additional detail provides insight into the expected business practices of an independent, transparent coordinating center that would guide the future development and implementation of the national evaluation system now referred to as the National Evaluation System for Health Technology (NEST). The Planning Board's most recent and last report titled, The National Evaluation System for health Technology (NEST): Priorities for Effective Early Implementation, was issued in September 2016. The report provides recommendations on organizational governance, development of NEST resources, and development/demonstration project areas to help begin building resources for NEST while demonstrating value to stakeholders.[6] FDA is in the process of implementing the Task Force's and Planning Board's recommendations including establishment of a Coordinating Center. FDA issued a grant in September to the Medical Device Innovation Consortium to establish the center.

The importance and challenges of hospital surveillance efforts have long been recognized. In 1997, Congress passed the Food and Drug Administration Modernization Act (Pub. L. 105–115), which amended section 519(b) of the Food, Drug and Cosmetic Act (21 U.S.C. 360i(b)). This amendment legislated the replacement of universal user facility reporting by an alternative system that is limited to a ''. . . subset of user facilities that constitutes a representative profile of user reports'' for device related deaths and serious injuries. In response, FDA developed The Medical Product Safety Network (MedSun).[7] Currently there are approximately 300 hospitals nationwide that are active, voluntary partners with FDA in the assessment and reporting of device-related events. The value of and challenges with the MedSun reporting program will be discussed at the workshop, including the limitations of passive reporting as a sole source of timely identification for the investigation and resolution of device safety issues. At this time, the digital revolution offers new opportunities to leverage information collected during routine clinical care and to build a robust national evaluation infrastructure. Therefore, the Agency believes it is an opportune time to revisit the role of hospitals in device surveillance, taking into account the limitations and challenges of traditional surveillance tools and the growing availability of new tools, methodologies, and electronic data sources. This public workshop is intended to bring together many medical device stakeholders from hospitals including clinicians, epidemiologists, healthcare risk managers, IT system managers, healthcare technology management professionals, clinical researchers, and others involved in surveillance efforts to discuss current hospital-based surveillance efforts, the role of hospitals in evidence generation and future opportunities for hospital-based surveillance, the importance of using unique device identification (UDI) to aid future development of surveillance efforts and healthcare delivery, and the partnership needed to build the future of surveillance into the infrastructure for NEST. Building the national evaluation system will bring with it changes that may support efforts in hospitals to address broader issues of improved quality of care and efficiencies.

II. Topics for Discussion at the Public Workshop

This workshop is intended to foster a dialogue about the value of, costs of, and challenges with current hospital-based reporting and surveillance, what the role of hospitals should be and reasonably could be in the evolution of device surveillance and in creating more robust surveillance capabilities in the developing national evaluation system, and how that should impact current hospital reporting requirements and future voluntary opportunities to best meet the needs of patients in receiving and hospitals in providing quality care. Topics for discussion at the public workshop include:

- An overview of the role of hospitals and potential benefits from a national evaluation system.The recent reports of the Planning Board and the work in transitioning to establishing a Coordinating Center to support development of the national system.
- The role of hospitals in evidence generation and how this fits into the national system;
- Current hospital-based surveillance efforts including participation in registries, patient safety organizations, electronic health records-based surveillance projects, and other surveillance projects.
- A review of the role of hospitals in medical device reporting activities as outlined in the Safe Medical Devices Act (Pub. L. 101–629) and current challenges hospitals face in complying with these requirements. An assessment of the current value of reporting from user facilities and identification of opportunities for process improvement.
- An exploration of FDA's MedSun, a user facility reporting program introduced in 2002 which partners with a subset of user facilities in the United States to identify and report medical device events including mandatory events under the Safe Medical Devices Act and voluntary events.
- Future surveillance opportunities for hospitals in the national system, including use of non-traditional sources of hospital data and capabilities.
- A review of the potential benefits to hospitals of the national system and Unique Device Identification implementation to modernize hospital surveillance. Additional benefits to hospitals include improvement of supply chain management, efficiency of recalls, efficiency of medical device purchasing, and quality of care.
- A discussion of how all stakeholders can work together to improve hospital-based medical device surveillance and determine the role and value of evidence generation as it is integrated into the developing national evaluation system.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending

[3] *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM435112.pdf.*

[4] *http://mdepinet.org/.*

[5] *https://healthpolicy.duke.edu/files/2016/03/med-device-report-web.pdf.*

[6] *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm.*

[7] *http://www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/.*

this public workshop must register online by November 28, 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 permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Office of Communications and Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993, 301–796–5661, FAX: 301–847–8142, *susan.monahan@fda.hhs.gov* no later than November 21, 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, and affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan to register (see special accommodations contact). 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 registration Web page after November 28, 2016. Organizations are requested to view using one connection per location.

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. 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 November 29, 2016. All requests to make oral presentations must be received by November 15, 2016. If selected for presentation, any presentation materials must be emailed to Jill Marion (see **FOR FURTHER INFORMATION CONTACT**) no later than December 2, 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 the role of hospitals in evidence generation and surveillance. 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 January 6, 2017.

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 transcript 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: October 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–25735 Filed 10–24–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0538]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animation in Direct-to-Consumer Advertising

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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: Fax written comments on the collection of information by November 25, 2016.

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 ''Animation in Direct-to-Consumer Advertising.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

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

Animation in Direct-to-Consumer Advertising

OMB Control Number 0910–NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(b)(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.

Advertisers use many techniques to increase consumer interest in their ads, including the use of animated spokes-characters. These characters may be fictional or nonfictional and human or nonhuman (Ref. 1). Despite variations in form, animated characters are often used to grab attention, increase ad memorability, and enhance persuasion to ultimately drive behavior (Refs. 2–4). Animated characters have long been used for low-involvement products (*e.g.,* food products) and have made their way into direct-to-consumer (DTC) prescription drug advertising. However, to our knowledge, one study (Ref. 5) has examined how animation affects attitudes toward products and risk perceptions in drug ads, and no studies have examined how various animation strategies (*e.g.,* symbolizing the disease vs. the benefit) and product characteristics (*e.g.,* low-risk medication vs. high-risk medication) influence these perceptions.