

**Instructions:** All submissions received must include the Docket No. FDA–2019–N–3768 for “Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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

Submit written requests for single copies of the draft document to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing

your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft document.

**FOR FURTHER INFORMATION CONTACT:** Eileen Wu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3472, Silver Spring, MD 20993–0002, 301–796–2345, [eileen.wu@fda.hhs.gov](mailto:eileen.wu@fda.hhs.gov); or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of November 7, 2019 (84 FR 60094), FDA published a notice with a 60-day comment period to request comments on the draft document entitled “Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff.” FDA is reopening the comment period until May 5, 2020. The Agency believes that an additional 60 days will allow adequate time for interested persons to submit comments without compromising the timely publication of the final version of the draft document.

##### **II. Electronic Access**

Persons with access to the internet may obtain the draft document “Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff” at <https://www.fda.gov/media/130216/download>.

Dated: March 2, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–04591 Filed 3–5–20; 8:45 am]

**BILLING CODE 4164–01–P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA–2009–N–0360]**

#### **Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Safety Communication Readership Survey**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency.

Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish 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 notice solicits comments on the Safety Communication Readership Survey.

**DATES:** Submit either electronic or written comments on the collection of information by May 5, 2020.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 5, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 5, 2020. 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–2009–N–0360 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Safety Communication Readership Survey.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3521), 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, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (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.

**FDA Safety Communication Readership Survey**

OMB Control Number 0910–0341—Extension

Section 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 375(b)) gives FDA authority to disseminate information concerning suspected or imminent danger to public health by any regulated product. Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) also authorizes FDA to conduct research relating to health information.

FDA’s Center for Devices and Radiological Health (CDRH) carries out FDA’s regulatory responsibilities regarding medical devices and radiological products. CDRH must be able to effectively communicate risk to healthcare practitioners, patients, caregivers, and consumers when there is a real or suspected threat to the public’s health. CDRH uses safety communications to transmit information concerning these risks to user communities. Safety communications are released and available to organizations such as hospitals, nursing homes, hospices, home healthcare agencies, manufacturers, retail pharmacies, and other healthcare providers, as well as patients, caregivers, consumers, and patient advocacy groups. Through a process for identifying and addressing postmarket safety issues related to regulated products, CDRH determines when to release safety communications.

FDA seeks to evaluate the clarity, timeliness, and impact of safety communications by surveying a sample of recipients and obtaining their voluntary responses to determine the impact of safety communications on the knowledge of the recipients. Understanding how the target audiences view these publications will aid in determining what, if any, changes should be considered in their content, format, and method of dissemination. The collection of this data is an important step in determining how well CDRH is communicating risk. The results from this survey will emphasize the quality of the safety communications and customer satisfaction. This will enable us to better serve the public by improving the effectiveness of safety communications.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Public Health Notification Readership Survey .....	300	3	900	0.17 (10 minutes)	153

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: March 2, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020-04563 Filed 3-5-20; 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; Information Collection Request Title: Evaluation of the Maternal and Child Health Bureau's Autism CARES Act Initiative, OMB No. 0915-0335—Revision**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, 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, provided below, or any other aspect of the ICR.

**DATES:** Comments on this ICR must be received no later than May 5, 2020.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or by mail to the HRSA Information Collection Clearance Officer, Room 14N136B, 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](mailto:paperwork@hrsa.gov) or call Lisa Wright-Solomon, HRSA Information Collection Clearance Officer at (301) 443-1984.

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

*Information Collection Request Title:* Evaluation of the Maternal and Child Health Bureau's Autism CARES Act Initiative, OMB No. 0915-0335—Revision.

*Abstract:* In response to the growing need for research and resources devoted to autism spectrum disorder and other developmental disabilities, the U.S. Congress passed the Combating Autism Act of 2006 (Pub. L. 109-416); it was reauthorized by the Combating Autism Reauthorization Act of 2011 (Pub. L. 112-32), the Autism Collaboration, Accountability, Research, Education, and Support (Autism CARES) Act of 2014 (Pub. L. 113-157) and the Autism CARES Act of 2019 (Pub. L. 116-60). Through these Autism CARES public laws, HRSA has been tasked with increasing awareness of autism spectrum disorder and developmental disabilities, reducing barriers to screening and diagnosis, promoting evidence-based interventions, and training healthcare professionals in the use of valid and reliable diagnostic tools.

*Need and Proposed Use of the Information:* The purpose of this information collection is to design and implement an impact evaluation to assess the effectiveness of HRSA's Maternal and Child Health Bureau's activities in meeting the goals and objectives of the Autism CARES Act. This ICR is a revision to an existing package; this study is the fourth

evaluation of HRSA's autism activities and employs similar data collection methodologies as the prior studies. Grantee interviews remain the primary form of data collection. Minor proposed revisions to the data collection process include (1) modifications to the interview questions based on the current legislation and HRSA's Notices of Funding Opportunity and (2) the creation of a new Grantee Survey to collect common data elements across the three program areas that focus on training, research, and state systems.

*Likely Respondents:* Grantees funded by HRSA's Autism programs will be the respondents for this data collection activity. The grantees are from the following HRSA programs: Leadership Education in Neurodevelopmental and Related Disabilities Training Program; Developmental Behavioral Pediatrics Training Program; State Innovation in Care Integration Program; State Innovation in Care Coordination Program; Research Network Program; Research Program; Interdisciplinary Technical Assistance Center; and the State Public Health Autism Center Resource Center.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. 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. The total annual burden hours estimated for this ICR are summarized in the table below.