

20852, 301–796–5733, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the 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. “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.

**Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Dear Health Care Provider Letters: Improving Communication of Important Safety Information**

*OMB Control Number 0910–0754—Extension*

This information collection supports recommendations found in the Agency guidance document entitled, “Dear Health Care Provider Letters: Improving Communication of Important Safety Information.” The guidance provides instruction to industry and FDA staff on the content and format of DHCP letters. These letters are sent by manufacturers or distributors to health care providers to communicate an important drug warning, a change in prescribing information, or a correction of misinformation in prescription drug promotional labeling or advertising.

This guidance gives specific instruction on what should and should not be included in DHCP letters. Some DHCP letters have been too long, have contained promotional material, or otherwise have not met the goals set

forth in the applicable regulation (21 CFR 200.5). In some cases, health care providers have not been aware of important new information, and have been unable to communicate it to patients, because the letters’ content and length have made it difficult to find the relevant information. In addition, letters have sometimes been sent for the wrong reasons.

In addition to content and format recommendations for each type of DHCP letter, the guidance also includes recommendations on consulting with FDA on how to develop a DHCP letter, when to send a letter, what type of letter to send, and how to assess the letter’s impact. Based on a review of FDA’s Document Archiving, Reporting, and Regulatory Tracking System for 2016–2018, we identified 38 DHCP letters that were sent out by 24 distinct sponsors during the 3-year timeframe. We estimate that we will receive approximately 13 DHCP letters annually from approximately 8 application holders. FDA professionals familiar with DHCP letters and with the recommendations in the guidance estimate that it should take an application holder approximately 100 hours to prepare and send DHCP letters in accordance with the guidance.

We estimate the annual reporting burden of this collection of information as follows:

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

Type of activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Dear Health Care Provider Letters .....	8	1.625	13	100	1,300

<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, we have reduced our burden estimate by 17 respondents with a corresponding decrease in annual hours by 1,200. We attribute the decrease to the effectiveness of the guidance.

Dated: August 12, 2019.

**Lowell J. Schiller,**  
*Principal Associate Commissioner for Policy.*  
[FR Doc. 2019–17708 Filed 8–16–19; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA–2019–N–0001]**

**Food and Drug Administration Science Forum 2019; Public Workshop**

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

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the following public workshop entitled “FDA Science Forum 2019.” The purpose of the public workshop is to share with the public the unique scientific research and

collaborative efforts of FDA’s 11,000 scientists and researchers, who use novel science and technologies to inform FDA’s regulatory decision-making—and drive innovation.

**DATES:** The public workshop will be held on September 11, 2019, from 8:30 a.m. to 4:40 p.m., and September 12, 2019, from 9 a.m. to 4 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine

security check procedures will be performed. For parking and security information, please refer to [www.fda.gov/publicmeetinginfo](http://www.fda.gov/publicmeetinginfo).

**FOR FURTHER INFORMATION CONTACT:** Rokhsareh Shahidzadeh, Office of Scientific Professional Development, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2383, Silver Spring, MD 20993, 301-796-8740, [FDASciProDev@fda.hhs.gov](mailto:FDASciProDev@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

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

The FDA Science Forum is held biennially to share with the public the unique scientific research and collaborative efforts of our 11,000 scientists and researchers. These scientists and researchers use novel science and technologies to inform FDA's regulatory decision-making—and drive innovation. FDA scientific experts and nationally renowned scientists will speak on the eight topics of the upcoming FDA Science Forum, *Transforming Health: Innovation in FDA Science*. FDA's Science Forum welcomes the public, industry, academia, patient advocates, sister Agencies, and current and potential collaborators, to learn about the Agency's regulatory science—the type of science that is rarely undertaken by industry or academia, but that makes critical contributions to product quality and safety.

##### **II. Topics for Discussion at the Public Workshop**

Sessions in the two-day forum will highlight such areas as FDA research into new predictive tools for developing and evaluating therapeutics, advancing artificial intelligence, evaluating digital health devices, and novel methods of tackling critical public health challenges such as addiction.

##### **III. Participating in the Public Workshop**

**Registration:** To register for the public workshop, please visit the following website: <https://www.fda.gov/scienceforum>.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by September 6, 2019, at 5 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Rokhsareh Shahidzadeh (see **FOR FURTHER INFORMATION CONTACT**) no later than September 4, 2019, by 5 p.m. Eastern Time.

**Streaming Webcast of the public workshop:** This public workshop will also be webcast. To register, please visit the following website: <https://www.fda.gov/scienceforum>. Participants interested in viewing via webcast must register by September 6, 2019, at 5 p.m. Eastern Time.

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](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [https://www.adobe.com/go/connectpro\\_overview](https://www.adobe.com/go/connectpro_overview). FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Dated: August 13, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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

##### **Food and Drug Administration**

[Docket No. FDA-2013-N-0134]

##### **Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Mammography Quality Standards Act Requirements**

**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:** Fax written comments on the collection of information by September 18, 2019.

**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](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0309. Also

include the FDA docket number found in brackets in the heading of this document.

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

##### **Mammography Quality Standards Act Requirements—21 CFR Part 900**

*OMB Control Number 0910-0309—Extension*

The Mammography Quality Standards Act (Pub. L. 102-539) requires the establishment of a Federal certification and inspection program for mammography facilities; regulations and standards for accreditation and certification bodies for mammography facilities; and standards for mammography equipment, personnel, and practices, including quality assurance. The intent of these regulations is to assure safe, reliable, and accurate mammography on a nationwide level. Under the regulations, as a first step in becoming certified, mammography facilities must become accredited by an FDA-approved accreditation body (AB). This requires undergoing a review of their clinical images and providing the AB with information showing that they meet the equipment, personnel, quality assurance, and quality control standards, and have a medical reporting and recordkeeping program, a medical outcomes audit program, and a consumer complaint mechanism. On the basis of this accreditation, facilities are then certified by FDA or an FDA-approved State certification agency and must prominently display their certificate. These actions are taken to ensure safe, accurate, and reliable mammography on a nationwide basis.

The following sections of Title 21 of the Code of Federal Regulations (CFR) are not included in the burden tables because they are considered usual and customary practice and were part of the standard of care prior to the implementation of the regulations; therefore, they resulted in no additional burden: 21 CFR 900.12(c)(1) and (3) and 900.3(f)(1). 21 CFR 900.24(c) was also not included in the burden tables because if a certifying State had its approval withdrawn, FDA would take