25–26, 2019, to discuss the long-term benefits and risks of breast implants indicated for breast augmentation and reconstruction. FDA learned from presentations at the March 2019 panel meeting, and through comments submitted to the associated public docket, that some patients may not be receiving or understanding important information regarding the benefits and risks of breast implants in a format that allows them to make a well-informed decision about whether or not to have a breast implantation.

For these reasons, FDA is now providing recommendations concerning the content and format of certain labeling information for these devices. Specifically, FDA is recommending that manufacturers incorporate a boxed warning and a patient decision checklist into the labeling for these devices to better ensure certain information is received and understood by patients. This draft guidance also recommends updated and additional labeling information, including updates to the silicone gel-filled breast implant rupture screening recommendations, inclusion of an easy-to-find description of materials, and provision of patient device cards that were recommended at the March 2019 panel meeting.

This draft guidance is not intended to include a complete listing of all labeling components for breast implants. When finalized, the recommendations in this draft guidance will supplement or in some cases replace recommendations in FDA's guidance entitled ''Saline, Silicone Gel, and Alternative Breast Implants'' (November 2006) (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/saline-silicone-gel-and-alternative-breast-implants*).

Based on the information presented at the March 2019 panel meeting, FDA continues to gather available information regarding the benefits and risks associated with different types of breast implants, and consider appropriate labeling and regulatory requirements for them. FDA will continue to analyze all available information regarding the risks associated with breast implants and take additional actions as determined necessary or appropriate. FDA invites comments on the benefits and risks of smooth and textured breast implants, respectively, as well as the labeling recommendations for these implants.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Breast Implants—Certain Labeling Recommendations to Improve Patient Communication.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Breast Implants—Certain Labeling Recommendations to Improve Patient Communication'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 19021 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR Part; guidance; or FDA form	Topic	OMB control No.
814, subparts A through E	Premarket approval	0910–0231
812	Investigational Device Exemption	0910–0078
801	Medical Device Labeling Regulations	0910–0485
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards	0910–0755
830	Unique Device Identification System	0910–0720
820	Current Good Manufacturing Practice (CGMP); Quality System Regulation	0910–0073

Dated: October 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23197 Filed 10–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0557]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarket Surveillance of Medical Devices

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 November 25, 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.* All comments should be identified with the OMB control number 0910–0449. 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, *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.

Postmarket Surveillance of Medical Devices—21 CFR part 822

OMB Control Number 0910–0449—Extension

Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360*l*) authorizes FDA to require a manufacturer to conduct postmarket surveillance (PS) of any device that meets the criteria set forth in the statute. The PS regulation establishes procedures that FDA uses to approve and disapprove PS plans. The regulation provides instructions to manufacturers, so they know what information is required in a PS plan submission. FDA reviews PS plan submissions in accordance with §§ 822.15 through 822.19 of the regulation, which describe the grounds for approving or disapproving a PS plan. In addition, the PS regulation provides instructions to manufacturers to submit interim and final reports in accordance with § 822.38. Respondents to this collection of information are those manufacturers that require PS of their products.

In the **Federal Register** of June 19, 2019 (84 FR 28554), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
PS submission (822.9 and 822.10)	25	1	25	120	3,000
Changes to PS plan after approval (822.21)	9	1	9	40	360
Changes to PS plan for a device that is no longer marketed (822.28)	6	1	6	8	48
Waiver (822.29)	1	1	1	40	40
Exemption request (822.30)	16	1	16	40	640
Periodic reports (822.38)	25	3	75	40	3,000
Total					7,088

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Explanation of Reporting Burden Estimate: The burden captured in table 1 is based on the data from FDA's internal tracking system. Sections 822.26, 822.27, and 822.34 do not constitute information collection subject to review under the PRA because it entails no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument (see 5 CFR 1320.3(h)(1)).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Manufacturer records (822.31)	25	1	25	20	500
Investigator records (822.32)	75	1	75	5	375
Total					875

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Explanation of Recordkeeping Burden Estimate: FDA expects that at least some of the manufacturers will be able to satisfy the PS requirement using information or data they already have. For purposes of calculating burden, however, FDA has assumed that each PS order can only be satisfied by a 3-year clinically based surveillance plan, using three investigators. These estimates are based on FDA's knowledge and experience with PS.

Our estimated burden for the information collection reflects a decrease of 29,982 hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years.

Dated: October 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23205 Filed 10–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0825]

Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Approval of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.