

research serves the narrowly defined need for direct and informal public opinion on a specific topic.

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

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

Type of interview	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
In-Person Individual In-depth Interviews.	1,092	1	1,092	1 .....	1,092
In-depth Interview (IDI) Screener .....	1,800	1	1,800	0.083 (5 minutes) .....	150
Focus Group Screener .....	19,385	1	19,385	0.25 (15 minutes) .....	4,846
Focus Group Interviews .....	5,897	1	5,897	1.5 .....	8,846
Total .....					14,934

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

The number of respondents to be included in each new pretest may vary, depending on the nature of the material or message being tested and the target audience. Table 1 provides examples of the types of studies that may be administered and estimated burden levels during the 3-year period. Time to read, view, or listen to the message being tested is built into the “Hours per Response” figures. Our estimated burden for the information collection reflects an overall increase of 5,641 hours and a corresponding increase of 16,585 responses. We attribute this adjustment to the number of study responses used during the current approval and now estimated for the next 3 years.

Dated: September 18, 2020.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2020–21452 Filed 9–28–20; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2019–D–4467]

**Breast Implants—Certain Labeling Recommendations To Improve Patient Communication; Guidance for Industry and Food and Drug Administration Staff; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled “Breast Implants—Certain Labeling Recommendations to Improve Patient Communication.” This guidance contains recommendations concerning the content and format for

certain labeling information for saline and silicone gel-filled breast implants. FDA is issuing this guidance to help ensure that a patient receives and understands the benefits and risks of breast implants. These labeling recommendations are intended to enhance, but not replace, the physician-patient discussion of the benefits and risks of breast implants that uniquely pertain to individual patients.

**DATES:** The announcement of the guidance is published in the **Federal Register** on September 29, 2020.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

*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–2019–D–4467 for “Breast Implants—Certain Labeling Recommendations to Improve Patient Communication.” 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, 240–402–7500.

- **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, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Breast Implants—Certain Labeling Recommendations to Improve Patient Communication” to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Joseph Nielsen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4608, Silver Spring, MD 20993-0002, 301-796-6244.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Over the past few years, FDA has received new information pertaining to risks associated with breast implants,

including breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) and systemic symptoms commonly referred to as breast implant illness (BII) that some patients attribute to their implants. FDA has taken a number of steps to better understand and address risks associated with breast implants, including convening the General and Plastic Surgery Devices Advisory Panel on March 25 to 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 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 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. The recommendations in this guidance document supplement the recommendations in FDA’s guidance entitled “Saline, Silicone Gel, and Alternative Breast Implants.”<sup>1</sup>

A notice of availability of the draft guidance appeared in the **Federal Register** of October 24, 2019 (84 FR 57028). FDA considered comments received and revised the guidance as appropriate in response to the comments, including revisions to clarify the labeling recommendations regarding the relationship between breast

implants and systemic symptoms and certain other risks, to refine the recommendations regarding information on the patient device card to improve clarity and readability, and to provide reference to and information regarding ongoing patient registries in the patient decision checklist.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents 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.

**II. Electronic Access**

Persons interested in obtaining a copy of the 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/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. 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](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 19021 and complete title to identify the guidance you are requesting.

**III. Paperwork Reduction Act of 1995**

This 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

<sup>1</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/saline-silicone-gel-and-alternative-breast-implants>.

21 CFR part; guidance; or FDA form	Topic	OMB control No.
50, 56 .....	Protection of Human Subjects: Informed Consent; Institutional Review Boards .....	0910-0755
830 .....	Unique Device Identification System .....	0910-0720
820 .....	Quality System Regulation .....	0910-0073

Dated: September 24, 2020.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-1787]

#### Advisory Committee; Blood Products Advisory Committee; Renewal

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

**ACTION:** Notice; renewal of Federal advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the renewal of the Blood Products Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Blood Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the May 13, 2022, expiration date.

**DATES:** Authority for the Blood Products Advisory Committee will expire on May 13, 2022, unless the Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:** Christina Vert, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10993 New Hampshire Ave., Bldg. 71, Rm. 6268, Silver Spring, MD 20993-0002, 240-402-8054 *Christina.Vert@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Blood Products Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Blood Products Advisory Committee advises the Commissioner or designee in

discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee shall consist of a core of 17 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and other related professions. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members) or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize

a committee charter to specify quorum requirements.

If functioning as a medical device panel, a non-voting representative of consumer interests and a non-voting representative of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/ucm121602.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <https://www.fda.gov/advisory-committees>.

Dated: September 18, 2020.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-3091]

#### Advisory Committee; Cardiovascular and Renal Drugs Advisory Committee; Renewal

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

**ACTION:** Notice; renewal of advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the renewal of the Cardiovascular and Renal Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Cardiovascular and Renal Drugs Advisory Committee for an additional 2 years beyond the charter