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: Submit written comments (including recommendations) on the collection of information by September 21, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0497. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10:00 a.m.–12:00 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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.

Focus Groups as Used by the Food and Drug Administration (All FDA-Regulated Products)

OMB Control Number 0910–0497—Extension

FDA conducts focus group interviews on a variety of topics involving FDA-regulated products, including drugs, biologics, devices, food, tobacco, and veterinary medicine.

Focus groups provide an important role in gathering information because they allow for a more indepth understanding of consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies. Focus groups serve the narrowly defined need for direct and informal opinion on a specific topic and as a qualitative research tool have three major purposes:

- To obtain consumer information that is useful for developing variables and measures for quantitative studies,
- to better understand consumers' attitudes and emotions in response to topics and concepts, and
- to further explore findings obtained from quantitative studies.

FDA will use focus group findings to test and refine their ideas but will generally conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

Respondents to this collection of information will include members of the general public, healthcare professionals, the industry, and other stakeholders who are related to a product under FDA's jurisdiction. Inclusion and exclusion criteria will vary depending on the research topic.

In the **Federal Register** of January 8, 2020 (85 FR 916), we published a 60-day notice requesting public comment on the proposed collection of information. FDA received three comments. FDA thanks the commenters for their comments and provides our response below. The first and second comments strongly support the proposed information collection related to focus groups used by the FDA. The third comment was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Focus Group Interviews	8,800	1	8,800	1.75	15,400

[1] 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: August 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–18243 Filed 8–19–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4620]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Reports of Corrections and Removals

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: Submit written comments (including recommendations) on the collection of information by September 21, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0359. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD

20852, 301–796–5733, *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.

Medical Devices; Reports of Corrections and Removals—21 CFR part 806

OMB Control Number 0910–0359—Extension

FDA is requesting approval for the collection of information pertaining to reports of corrections and removals required under part 806 (21 CFR part 806), which implements section 519(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i(g)), as amended by the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115).

Under § 806.10 (21 CFR 806.10), within 10 working days of initiating any action to correct or remove a device to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act caused by the device that may present a risk to health, device manufacturers or importers must submit a written report to FDA of the correction or removal.

Under § 806.20(a) (21 CFR 806.20(a)), device manufacturers or importers that initiate a correction or removal that is not required to be reported to FDA must keep a record of the correction or removal.

In the **Federal Register** of December 20, 2016 (81 FR 92603), FDA published a final rule titled ''Postmarketing Safety Reporting for Combination Products.'' This final rule describes the postmarketing safety reporting requirements that apply when two or more different types of regulated medical products (drugs, devices, and/or biological products, which are referred to as ''constituent parts'' of a combination product) comprise a combination product and the combination product or its constituent parts have received FDA marketing authorization. PMSR is approved under OMB control number 0910–0834.

Under § 4.102(c)(1)(iii) (21 CFR 4.102(c)(1)(iii)), combination product applicants whose combination products received marketing authorization under a BLA, NDA, or ANDA and include a device constituent part must also submit correction or removal reports as described in § 806.10 and comply with recordkeeping requirements as described in § 806.20.

Under § 4.105(b) (21 CFR 4.105(b)), combination product applicants must maintain records relating to their postmarketing safety reports for whichever is the longest required recordkeeping period under the PMSR requirements applicable to the combination product applicant under § 4.102.

The information collected in the reports of corrections and removals will be used by FDA to identify marketed devices that have serious problems and to ensure that defective devices are removed from the market. This will assure that FDA has current and complete information regarding these corrections and removals to determine whether recall action is adequate. Failure to collect this information would prevent FDA from receiving timely information about devices that may have a serious effect on the health of users of the devices.

Reports of corrections and removals may be submitted to FDA via mail or using FDA's Electronic Submission Gateway (ESG). We estimate that approximately 50 percent of submitters will use the ESG. Our estimate of the reporting and recordkeeping burden is based on Agency records and our experience with this program, as well as similar programs that utilize FDA's ESG.

For respondents who submit corrections and removals using the electronic process, the operating and maintenance costs associated with this information collection are approximately $50 per year to purchase a digital verification certificate (certificate must be valid for 1 to 3 years). This burden may be minimized if the respondent has already purchased a verification certificate for other electronic submissions to FDA. However, FDA is assuming that all respondents who submit corrections and removals using the electronic process will be establishing a new WebTrader account and purchasing a digital verification certificate. We therefore estimate the total operating and maintenance costs to be $25,850 annually (517 respondents × $50).

In the **Federal Register** of February 21, 2020 (85 FR 10168), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity (21 CFR part)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]	Total operating and maintenance costs
Electronic process setup [3]	517	1	517	3.08	1,592	$25,850
Submission of corrections and removals (part 806)	1,033	1	1,033	10	10,330	
4.102(c)(1)(iii) Submitting correction or removal reports	20	1	20	10	200	

[1] There are no capital costs associated with this collection of information.

[2] Totals may not sum due to rounding.

[3] We estimate that approximately 50 percent of respondents will submit corrections and removals using the electronic process. The actual burden hours for setup of the electronic process listed in the reporting burden table are divided by 3 to avoid double counting in the Office of Information and Regulatory Affairs Consolidated Information System. However, the one-time Average Burden per Response is 9.25 hours, resulting in a total one-time burden of 4,782 hours for the setup of the electronic process.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity (21 CFR Part)	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [2]
Records of corrections and removals (part 806)	93	1	93	10	930

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Activity (21 CFR Part)	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [2]
4.105(b) additional recordkeeping by device-led combination products	279	0.45	126	0.5	63

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals may not sum due to rounding.

New information technology applications have allowed us to more accurately calculate the number of registrants of medical device facilities that submit information electronically. Therefore, there is a 50 percent reduction in the number of respondents who will submit corrections and removals using the electronic process.

In addition, under OMB control number 0910–0834 (''Postmarketing Safety Reporting for Combination Products''), an additional 200 hours have been added to the annual reporting burden and an additional 63 hours have been added to the annual recordkeeping burden to comply with the PMSR requirements.

We have therefore revised the number of respondents to the information collection. This adjustment has resulted in a 1,293-hour decrease of the estimated burden.

Dated: August 14, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–18269 Filed 8–19–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0008]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will take place virtually on October 7, 2020, from 9 a.m. Eastern Time to 6 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993–0002, *aden.asefa@fda.hhs.gov,* 301–796–0400, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION: *Agenda:* The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On October 7, 2020, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the TransMedics Organ Care System (OCS)—Heart, by TransMedics, Inc. The proposed Indication for Use for the TransMedics OCS—Heart, as stated in the PMA, is as follows:

The TransMedics OCS Heart System is a portable *ex-vivo* organ perfusion and monitoring system indicated for the resuscitation, preservation, and assessment of donor hearts with one or more of the following characteristics for transplantation into a potential recipient in a near-physiologic, normothermic, and beating state:

- Expected cross-clamp or ischemic time ≥4 hours due to donor or recipient characteristics (*e.g.,* donor-recipient geographical distance, expected recipient surgical time)
- Donor Age ≥55 years
- Donors with history cardiac arrest and downtime ≥20 minutes
- Donor history of alcohol use
- Donor LV Ejection Fraction ≤50 percent but ≥40 percent
- Donor history of Left Ventricular Hypertrophy (septal or posterior wall thickness of >12 and ≤16 millimeters)

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/advisory-committees/circulatory-system-devices-panel/2020-meeting-materials-circulatory-system-devices-panel.* Select the link for the 2020 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 1, 2020. Oral presentations from the public will be scheduled on October 7, 2020, between approximately 1 p.m. Eastern Time and 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed