three requests for documentation of successful completion of staff training using the CFP Training Plan and Log for a total of 1,500 annual responses. Each submission is estimated to take 0.1 hour (or 6 minutes) per response for a total of 150 hours. Thus, the total reporting burden for this information collection is 200 hours.

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: July 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14879 Filed 7–9–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–N–2434, FDA–2016–N–3535, FDA–2013–N–1619, FDA–2016–N–0736, FDA–2019–N–3885, FDA–2013–N–1423, FDA–2013–N–0804, FDA–2016–N–3995, FDA–2018–D–1592, FDA–2016–N–2066, and FDA–2017–N–0366]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Formal Meetings Between the Food and Drug Administration and Sponsors and Applicants of Prescription Drug User Fee Act Products	0910–0429	5/31/2023
Special Protocol Assessments	0910–0470	5/31/2023
Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements	0910–0606	5/31/2023
Tracking Network for PETNet, LivestockNet, and SampleNet	0910–0680	5/31/2023
Center for Tobacco Products, Food and Drug Administration Funded Trainee/Scholar Survey	0910–0887	5/31/2023
Importer's Entry Notice	0910–0046	6/30/2023
Premarket Notification Submission 510(k), Subpart E	0910–0120	6/30/2023
Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations	0910–0748	6/30/2023
Controlled Correspondence Related to Generic Drug Development	0910–0797	6/30/2023
Certification of Identity for Freedom of Information Act and Privacy Act Requests	0910–0832	6/30/2023
FDA Advisory Committee Membership Nominations	0910–0833	6/30/2023

Dated: July 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14875 Filed 7–9–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1391]

Office of Women's Health Strategic Priorities; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is opening a public docket to solicit input and comments from stakeholders interested in informing strategic priorities for the Office of Women's Health (OWH). This will help the Agency ensure that important health concerns are carefully considered in establishing OWH's scientific, educational, and outreach priorities.

DATES: Submit either electronic or written comments by September 8, 2020.

ADDRESSES: You may submit comments as follows. Please note that untimely comments will not be considered. Electronic comments must be submitted on or before September 8, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 8, 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–2020–N–1391 for ''Office of Women's Health Strategic Priorities; Establishment of a Public Docket; Request for Comments.'' 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.'' FDA 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 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 the 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.

FOR FURTHER INFORMATION CONTACT: Lisa Lineberger, Food and Drug Administration, Office of the Commissioner, Office of Women's Health, 10903 New Hampshire Ave., Bldg. 32, Rm. 2333, Silver Spring, MD 20993, 301–796–8751, *lisa.lineberger@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA's OWH was established by Congressional mandate in 1994 as part of the Office of the Commissioner. The mission of the OWH is to:

• Provide leadership and policy direction for the Agency related to women's health and coordinate efforts to establish and advance a women's health agenda for the Agency.

• promote the inclusion of women in clinical trials, the implementation of guidelines concerning the representation of women in clinical trials, and the incorporation of sex and gender considerations into clinical trial data analysis.

• identify and monitor the progress of crosscutting and multidisciplinary women's health initiatives including changing needs, areas that require study, and new challenges to the health of women as they relate to FDA's mission.

• serve as the Agency's liaison with other agencies, industry, professional associations, and advocacy groups with regards to the health of women.

OWH achieves its mission through the foundational principle that sex as a biological variable should be factored into research design, analysis, reporting, and education. To this end, OWH supports FDA's regulatory mission by funding and engaging in intramural and extramural scientific research and collaborating with stakeholders on educational and outreach projects. More information on OWH research and educational activities is available at *https://www.fda.gov/science-research/science-and-research-special-topics/womens-health-research.*

OWH recognizes the unique role FDA can play in protecting and promoting women's health and the value of considering input from consumers, health professionals, and other stakeholders as it works toward this goal. Therefore, FDA is issuing this **Federal Register** notice to open Docket No. FDA–2020–N–1391 for the public to submit comments. FDA will take the suggestions and information submitted to the docket into consideration when developing OWH scientific, educational, and outreach priorities.

II. Issues for Consideration

To maximize FDA OWH's ability to promote, protect, and advance the health of women, we are seeking input on research priorities driven by data gaps and areas of unmet need; topics for education among consumers, health professionals, and other stakeholders; and outreach to women, especially underserved and diverse populations. We are also interested in proposed methods for acting on these priorities, such as collaborations and partnerships. In particular, OWH requests comments on:

• Efforts to encourage analysis and detection of potential sex and gender differences in the safety, efficacy, and use of FDA-regulated products.

• efforts to anticipate, meet, and respond to existing and emerging issues related to women's health and FDA-regulated products.

• direct outreach to diverse groups of women to promote access to relevant information about FDA-regulated products, encourage participation in clinical trials, and maintain dialogue about critical women's health topics.

• coordination and collaboration with other Federal Agencies and external stakeholders to support research and programming on women's health topics.

• identification of regulatory decisions that can benefit from participation of women across the lifespan (*e.g.,* reproductive-age women, pregnant women, post-menopausal women, and elderly women) and women with certain health conditions.

• generation of research and programming topics, interests, and areas of focus that predominantly affect

women and/or would benefit from sex- and gender-related analyses.

Dated: July 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14878 Filed 7–9–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1066]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Annual Reporting for Custom Device Exemption

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 August 10, 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 0910–0767. 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, 10A–12M, 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.

Annual Reporting for Custom Device Exemption

OMB Control Number 0910–0767—Extension

The custom device exemption is set forth at section 520(b)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(b)(2)(B)). A custom device is in a narrow category of device that, by virtue of the rarity of the patient's medical condition or physician's special need the device is designed to treat, it would be impractical for the device to comply with premarket review regulations and performance standards.

The Food and Drug Administration Safety and Innovation Act (FDASIA) implemented changes to the custom device exemption contained in section 520(b) of the FD&C Act. The new provision amended the existing custom device exemption and introduced new concepts and procedures for custom devices, such as:

- Devices created or modified to comply with the order of an individual physician or dentist;
- the potential for multiple units of a device type (limited to no more than five units per year) qualifying for the custom device exemption; and
- annual reporting requirements by the manufacturer to FDA about devices manufactured and distributed under section 520(b) of the FD&C Act.

Under FDASIA, ''devices'' that qualify for the custom device exemption contained in section 520(b) of the FD&C Act were clarified to include no more than ''five units per year of a particular device type'' that otherwise meet all the requirements necessary to qualify for the custom device exemption.

In the **Federal Register** of September 24, 2014 (79 FR 57112), FDA announced the availability of the guidance entitled ''Custom Device Exemption.'' FDA has developed this document to provide guidance to industry and FDA staff about implementation of the custom device exemption contained in the FD&C Act. The intent of the guidance is to define terms used in the custom device exemption, explain how to interpret the ''five units per year of a particular device type'' language contained in the FD&C Act, describe information that FDA proposes manufacturers should submit in the custom device annual report, and provide recommendations on how to submit an annual report for devices distributed under the custom device exemption.

In the **Federal Register** of February 21, 2020 (85 FR 10175), we 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	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual reporting for custom devices	34	1	34	40	1,360

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