information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information under 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information under 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; the collections of information under 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information for the De Novo Classification Process (Evaluation of Automatic Class III Designation) have been approved under OMB control number 0910–0844; and the collections of information in the guidance document entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' have been approved under OMB control number 0910–0756. The collections of information in 21 CFR part 314 (Applications for FDA Approval to Market a New Drug) and 21 CFR part 601 (General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension) have been approved under OMB control numbers 0910–0001 and 0910–0338, respectively. The collections of information in 21 CFR parts 50 and 56 (Protection of Human Subjects: Informed Consent; Institutional Review Boards) have been approved under OMB control number 0910–0130.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov*.

Dated: December 20, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27894 Filed 12–22–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4206]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee Small Business Qualification and Certification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Form FDA 3602 and Form FDA 3602A, on which domestic and foreign applicants certify that they qualify as a small business and pay certain medical device user fees at reduced rates.

DATES: Submit either electronic or written comments on the collection of information by February 22, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 22, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 22, 2022. 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–2018–N–4206 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee Small Business Qualification and Certification.'' 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, 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.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), 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.

Medical Device User Fee Small Business Qualification and Certification

OMB Control Number 0910–0508—Extension

Medical device user fees were first established in 2002 by the Medical Device User Fee and Modernization Act (MDUFMA) (Pub. L. 107–250). User fees were renewed in 2007, with the Medical Device User Fee Amendments to the FDA Amendments Act (MDUFA II), in 2012 with the Medical Device User Fee Amendments to the FDA Safety and Innovation Act (MDUFA III), and in 2017 with the Medical Device User Fee Amendments to the FDA Reauthorization Act (MDUFA IV). MDUFA IV will be in place from October 1, 2017, until September 30, 2022.

A ''small business'' is eligible for reduced or waived fees. If an applicant does not provide information to FDA demonstrating to FDA's satisfaction that the applicant is a small business, the applicant must pay the standard (full) fee for any application it submits.

Section 738(d)(2)(A) and (e)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(d)(2)(A) and (e)(2)(A)) define a ''small business'' as an entity that reported $100 million or less of gross receipts or sales in its most recent Federal income tax return, including such returns of its affiliates, partners, and parent firms. If a firm's gross receipts or sales are no more than $30 million (including all affiliates, partners, and parent firms), they will also qualify for a waiver of the fee for their first (ever) premarket application, product development protocol, biological licensing application, or premarket report.

Forms FDA 3602 (''MDUFA Small Business Certification Request for a Business Headquartered in the United States'') and FDA 3602A (''MDUFA Foreign Small Business Certification Request for a Business Headquartered Outside the United States'') are submitted to FDA to demonstrate that an applicant qualifies as a MDUFA small business. The guidance ''Medical Device User Fee Small Business Qualification and Certification; Guidance for Industry, Food and Drug Administration Staff and Foreign Governments'' [1] describes the process by which a business may request certification as a small business and the criteria FDA will use to decide whether an entity qualifies as a MDUFA small business and is eligible for a reduction in user fees.

This estimated burden is based on the number of applications received in the last few years and includes time required to collect the required information. Based on our experience with Forms FDA 3602 and FDA 3602A, FDA believes it will take respondents 1 hour to complete either form.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3602—MDUFA Small Business Certification Request For a Business Headquartered in the United States	2,500	1	2,500	1	2,500
FDA 3602A—MDUFA Foreign Small Business Certification Request For a Business Headquartered Outside the United States	2,000	1	2,000	1	2,000

[1] The guidance ''Medical Device User Fee Small Business Qualification and Certification Guidance for Industry, Food and Drug Administration Staff and Foreign Governments'' is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-certification.*

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					4,500

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

The estimated ''No. of Respondents'' has been updated to better reflect the recent submission volume. This adjustment has resulted in a 2,500-hour decrease in the estimated ''Total Hours'' burden.

Dated: December 17, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27889 Filed 12–22–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0990–0479]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, Health and Human Service, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 24, 2022.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When requesting information, please include the document identifier 0990–0479–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Family Planning Annual Report 2.0.

Type of Collection: Revision.

OMB No. 0990–0479.

Abstract: The Office of Population Affairs (OPA), within the Office of the Assistant Secretary for Health, seeks approval for a revision of the 3-year encounter level data collection for the Family Planning Annual Report (FPAR). This annual reporting requirement is for competitively awarded grants authorized and funded by the Title X Family Planning Program. Currently approved under 0990–0479, this revision is adding the collection of two new data elements, sexual orientation and gender identity. OPA does not expect the addition of these elements to substantially change the burden.

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Grantees	70	1	102	7140
Total	70	1	102	7140

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2021–27829 Filed 12–22–21; 8:45 am]

BILLING CODE 4150–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Substance Abuse and Suicide Prevention Program: Suicide Prevention, Intervention, and Postvention; Correction

AGENCY: Indian Health Service, Department of Health and Human Services.

ACTION: Notice; correction.

SUMMARY: The Indian Health Service published a Notice of Funding Opportunity in the **Federal Register** of November 4, 2021, for the Suicide Prevention, Intervention, and Postvention grant program. The notice was missing a section in the description of the required Project Narrative that applicants must submit with their application. The Project Narrative will have a fourth section added, Statement of Need, and the page limit for the Project Narrative will increase from 15 to 17 pages.

FOR FURTHER INFORMATION CONTACT: Paul Gettys, Acting Director, Division of Grants Management, 5600 Fishers Lane, Rockville, MD 20857, Phone: (301) 443–2114.

SUPPLEMENTARY INFORMATION:

Corrections

1. In the **Federal Register** of November 4, 2021, in FR Doc 2021–24022, on page 60861, in the second column, under IV. Application and Submission Information, under 3. SF–424B, Assurances—Non-Construction Programs, correct ''Project Narrative'' to read: Project Narrative (not to exceed 17 pages).

2. In the **Federal Register** of November 4, 2021, in FR Doc 2021–24022, starting on page 60861, in the third column and continuing to page 60862, in the first column, correct ''A. Project Narrative,'' to read:

A. *Project Narrative:* This narrative should be a separate document that is no more than 17 pages and must: (1) Have consecutively numbered pages; (2) use black font 12 points or larger; (3) be