Since the last approval of this information collection, we have updated the estimated number of respondents from 20 to 10 respondents per year, based on the reduced number of notifications received in recent years. This adjustment has resulted in a 150-hour reduction to the total hour burden estimate.

Dated: November 9, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–25158 Filed 11–20–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0913]

Agency Information Collection Activities; Proposed Collection; Comment Request; 513(g) Request for Information

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 the information collection burden estimate for requests for a written statement from FDA regarding the classification and regulatory requirements that may be applicable to a particular device (513(g) requests).

DATES: Submit either electronic or written comments on the collection of information by January 22, 2018.

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 January 22, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 22, 2018. 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–2014–N–0913 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; 513(g) Request for Information.'' 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.'' 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.gpo.gov/fdsys/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: 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: Under the PRA (44 U.S.C. 3501–3520), 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.

513(g) Request for Information

OMB Control Number 0910–0705—Extension

Section 513(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(g)) provides a means for obtaining the Agency's views about the classification and regulatory requirements that may be applicable to a particular device. Section 513(g) provides that, within 60 days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act, the Secretary of Health and Human Services shall provide such person a written statement of the classification (if any) of such device and the requirements of the FD&C Act applicable to the device.

The guidance document entitled ''FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act; Guidance for Industry and Food and Drug Administration Staff'' establishes procedures for submitting, reviewing, and responding to requests for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act that are submitted in accordance with section 513(g) of the FD&C Act. FDA does not review data related to substantial equivalence or safety and effectiveness in a 513(g) request for information. FDA's responses to 513(g) requests for information are not device classification decisions and do not constitute FDA clearance or approval for marketing. Classification decisions and clearance or approval for marketing require submissions under different sections of the FD&C Act.

Additionally, the FD&C Act, as amended by the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), requires FDA to collect user fees for 513(g) requests for information. The guidance document entitled ''Guidance for Industry and Food and Drug Administration Staff; User Fees for 513(g) Requests for Information'' assists FDA staff and regulated industry by describing the user fees associated with 513(g) requests. The Medical Device User Fee Cover Sheet (Form FDA 3601), which accompanies the supplemental material described in this information collection is approved under OMB control number 0910–0511 and expires August 31, 2019.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDRH 513(g) requests	114	1	114	12	1,368
CBER 513(g) requests	4	1	4	12	48
Total					1,416

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

Respondents of this collection of information are mostly device manufacturers; however, anyone may submit a 513(g) request for information. The total number of annual responses is based on the average number of 513(g) requests received each year by the Agency.

Dated: November 9, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–25159 Filed 11–20–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Supplemental Award to the National Network for Oral Health Access

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: HRSA announces the award of a supplement in the amount of $250,000 for a HRSA-funded cooperative agreement awarded to the National Network for Oral Health Access (NNOHA). The supplement, awarded on September 25, 2017, will fund demonstration projects to increase the integration of oral health and primary care practice through the adoption of HRSA's core clinical oral health competencies for non-dental health care providers in Health Center (HC) settings, focusing on services for pregnant women and children.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: National Network for Oral Health Access.

Amount of Non-Competitive Awards: $250,000.

Budget Periods of Supplemental Funding: July 1, 2017, through June 30, 2018.

CFDA Number: 93.110.

Authority: Special Projects of Regional and National Significance program (Social Security Act, Title V, § 501(a)(2) (42 U.S.C. 701(a)(2)).

Justification: The National Network for Oral Health Access (NNOHA) supports goals to improve access to oral