Constituent Parts With Electronics or Software.'' Some CDER-led combination products feature a device constituent part with electronics and/or software that may be used as a platform across multiple products. An application for such a combination product may necessitate review by multiple centers, offices, and divisions within FDA. In addition, because the device constituent part may be used as a platform in multiple CDER-led combination products, the same device information may be applicable to and used to support multiple CDER submissions. For such combination products, a Type V DMF can be an efficient mechanism to provide information regarding the device constituent part when the same information is applicable to several CDER applications, and additional measures to ensure consistency are needed.

Further, because of rapid advances in technology, the device constituent part of these types of combination products could be modified frequently. Knowledge of these modifications is important in determining whether they have any impact on the safety and effectiveness of the combination product or its indications for use. Amendments to the Type V DMF provide a regulatory pathway for the DMF holder to report device modifications and for FDA to be notified of and to review device modifications.

Once FDA reviews the Type V DMF device information for one CDER application, its review may be applicable to other CDER applications if the device information remains unchanged and is pertinent to products in other CDER applications that also incorporate the DMF by reference. FDA's ability to use previously completed scientific reviews for a DMF can contribute to an efficient FDA review process and help ensure consistency across CDER applications referencing the same information.

This draft guidance applies to Type V DMF submissions as described above for CDER-led combination products. Specifically, the information in this draft guidance may be appropriate for device constituent parts with electronics and/or software that meet the statutory definition of a device and perform functions such as the following:

- Facilitate drug delivery in a manner that may include patient input or analysis (*e.g.,* an electromechanically driven pen injector with software that allows input of patient or dosing information or that analyzes dosing or device use information).
- Provide information that is used in making a decision regarding treatment, therapy, or drug delivery.
- Interface with other devices or systems to provide patient use or other information to the user or health care provider (*e.g.,* physiological parameters).
- Control or drive the features of the user interface.

This draft guidance addresses process and general content expectations for Type V DMFs for such device constituent parts. It does not address FDA premarket review standards or expectations for such constituent parts or the combination products that include them. This draft guidance is also not intended to suggest that a Type V DMF should be submitted to CDER if the sponsor has rights of reference to a device master file located in another center containing the same information.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Type V DMFs for CDER-Led Combination Products Using Device Constituent Parts With Electronics or Software.'' 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. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. 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. 3501–3520). The collections of information in 21 CFR 314.420 have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov*.

Dated: October 22, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23585 Filed 10–28–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Nurse Anesthetist Traineeship (NAT) Program Specific Data Forms, OMB Control No. 0915–0374—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR have been provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than November 29, 2019.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Nurse Anesthetist Traineeship (NAT) Program Specific Data Forms, OMB Control No. 0915–0374—Revision.

Abstract: HRSA provides advanced education nursing training grants to educational institutions to increase the numbers of Certified Registered Nurse Anesthetists through the NAT Program. The NAT Program is authorized by Section 811 of the Public Health Service (PHS) Act (42 U.S.C. 296j). The NAT Tables request information on program participants such as the number of enrollees/trainees, number of enrollees/trainees supported, number of graduates, number of graduates supported, number of projected enrollees/trainees, degree program (Master's and Doctoral), and the distribution of Nurse Anesthetists who practice in underserved, rural, and/or public health practice settings.

Need and Proposed Use of the Information: Funds appropriated for the NAT Program are distributed among eligible institutions based on a formula, as permitted by PHS Act section 806(e)(1). HRSA uses the data from the NAT Tables to determine if the Funding Factors (either the Statutory Funding Preference or Special Consideration) are met, determine the award amount, ensure compliance with programmatic and grant requirements, and provide information to the public and Congress. The NAT Tables currently collect one year of data, which allows HRSA to calculate award amounts for a single-year project period. For fiscal year 2020, HRSA is revising the forms that previously collected one year of data on prospective students to capture three years of data, thereby allowing HRSA to calculate award amounts for a multi-year project period. Table 1 will add columns to collect Year 2 and Year 3 data for the number of prospective students. While Table 2 data collection elements will not change, the header will change to provide further clarification about the data being collected.

Likely Respondents: Respondents will be applicants to HRSA's NAT Program.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Table 1—NAT: Enrollment, Traineeship Support, Graduate, Graduates Supported and Projected Data	100	1	100	3.5	350
Table 2—NAT: Graduate Data—Rural, Underserved, or Public Health	100	1	100	2.8	280
Total	*100		100		630

*The same respondents are completing Tables 1 and Table 2.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2019–23564 Filed 10–28–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Conference Support (R13) Review.

Date: November 19, 2019.

Time: 12:30 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: John P. Holden, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Boulevard, Suite 920, Bethesda, MD 20892, (301) 496–8775, *john.holden@nih.gov.*

Dated: October 23, 2019.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23553 Filed 10–28–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Immigration and Customs Enforcement

[OMB Control Number 1653–0042]

Agency Information Collection Activities: Extension of a Currently Approved Collection: Obligor Change of Address

AGENCY: U.S. Immigration and Customs Enforcement, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: In accordance with the Paperwork Reductions Act (PRA) of 1995 the Department of Homeland Security (DHS), U.S. Immigration and Customs Enforcement (ICE) will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance. This information collection was previously published in the **Federal Register** on July 24, 2019, allowing for a 60-day comment period. ICE received no comments in connection with the 60-day notice. Based on better estimates, ICE is making an adjustment from the 60-day notice to reflect a decrease in the number of respondents. The purpose of this notice