investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: February 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03070 Filed 2–13–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1048]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Labeling Requirements; Unique Device Identification

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 March 16, 2023.

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 0910–0485. 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 Device Labeling Requirements; Unique Device Identification

OMB Control Number 0910–0485—Revision

This information collection supports implementation of section 519(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i(f)), requiring the establishment of a unique device identification (UDI) system by FDA. Medical device labeling requirements governed by section 502 of the FD&C Act (21 U.S.C. 352) provide that every medical device and every device package bear a unique device identifier. Implementing regulations are found in part 801, subpart B (21 CFR part 801, subpart B) (Labeling Requirements for UDI), including provisions for exceptions from UDI requirements (21 CFR 801.30). Applicable regulations are also found in part 821 (21 CFR part 821) (Medical Device Tracking Requirements); 21 CFR part 822 (Postmarket Surveillance); part 814 (21 CFR part 814) (Premarket Approval of Medical Devices); and part 820 (21 CFR part 820) (Quality System Regulations), as well as regulations pertaining to in vitro device labeling, biological device product labeling, or any article subject to the device labeling provisions in section 502 of the FD&C Act. Products not in compliance with requirements set forth in the applicable statutory and regulatory authorities may be subject to enforcement action by FDA.

For operational efficiency, we are revising the information collection to include burden that may be attributable to activities associated with provisions found in part 830 (21 CFR part 830), currently approved in OMB control number 0910–0720 and established through rulemaking on September 24, 2013 (0910–AG31). The regulations define relevant terms, identify specific data requirements, and incorporate global standards applicable to the use and discontinuation of a UDI. The regulations also provide for FDA accreditation of an issuing agency (21 CFR 830.110) and explain associated information collection activities including the establishment, maintenance, and disclosure of records. Finally, the regulations provide for administration of the Global UDI Database (GUDID) (part 830, subpart E), which specifies data that must be submitted to FDA to be made publicly available. Users of the GUDID will be able to use the device identifier portion of the UDI to query descriptive data about a specific device. The GUDID may be accessed on our website at *https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/global-unique-device-identification-database-gudid.*

In the **Federal Register** of August 24, 2022 (87 FR 51989), we published a 60-day notice soliciting comment on the proposed collection of information. No comments were received. However, upon further review and evaluation, we have made adjustments to our estimated burden for the collection of information, as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Part 801, subpart B: Labeling requirements for unique device identification	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Requirements for a unique device identifier under part 830	6,199	51	316,149	1	316,149

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

Our figures are based on economic analysis from previous Agency rulemaking. We assume most burden associated with activities applicable to satisfying UDI requirements as prescribed by part 830 is accounted for in currently approved information collections. For example, information collection associated with medical device tracking provisions in part 821 is currently approved in OMB control number 0910–0442; information collection associated with premarket approval of medical devices (part 814) is currently approved in OMB control number 0910–0231. Similarly, information collection associated with our quality system regulation (part 820)

and information collection associated with our medical device recall authority (21 CFR part 810) is approved in OMB control numbers 0910–0073 and 0910–0432, respectively. We assume burden respondents may have incurred as the result of any product relabeling, as well as one-time burden that respondents may have incurred resulting from integrating requirements into current tracking and labeling activities, has since been realized and is now accounted for among our currently approved inventory. Here, we are accounting for burden associated with UDI requirements prescribed by part 830 not otherwise included in currently approved collections and subject to general medical device labeling requirements established in part 801, subpart B. Because the PRA defines a recordkeeping requirement to include retained records, third-party notifications and disclosures, and reporting to the Federal government as well as the public, we have accounted for these activities cumulatively, characterizing them as recordkeeping activities.

Dated: February 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03071 Filed 2–13–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection; Public Comment Request; Application and Other Forms Used by the National Health Service Corps Scholarship Program, the NHSC Students to Service Loan Repayment Program, and the Native Hawaiian Health Scholarship Program

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than April 17, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the acting HRSA Information Collection Clearance Officer, at 301–594–4394.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Application and Other Forms Used by the National Health Service Corps (NHSC) Scholarship Program (SP), the NHSC Students to Service Loan Repayment Program (S2S LRP), and the Native Hawaiian Health Scholarship Program (NHHSP), OMB No. 0915–0146–Revision.

Abstract: Administered by HRSA's Bureau of Health Workforce, the NHSC SP, NHSC S2S LRP, and the NHHSP provide scholarships or loan repayment to qualified students who are pursuing primary care health professions education and training. In return, students agree to provide primary health care services in underserved communities located in federally designated Health Professional Shortage Areas once they are fully trained and licensed health professionals. Awards are made to applicants who demonstrate the greatest potential for successful completion of their education and training as well as commitment to provide primary health care services to communities of greatest need. The information from program applications, forms, and supporting documentation is used to select the best qualified candidates for these competitive awards, and to monitor program participants' enrollment in school, postgraduate training, and compliance with program requirements.

Although some program forms vary from program to program (see program-specific burden charts below), required forms generally include: a program application, academic and non-academic letters of recommendation, the authorization to release information, and the acceptance/verification of good academic standing report. The NHHSP is not seeking to change or add any forms or documentation.

Need and Proposed Use of the Information: The NHSC SP, S2S LRP, and NHHSP applications, forms, and supporting documentation are used to collect necessary information from applicants and schools that enable HRSA to make selection determinations for the competitive awards and monitor compliance (via training programs and sites) with program requirements.

Likely Respondents: Qualified students who are pursuing education and training in primary care health professions and are interested in working in health professional shortage areas and schools at which such students are enrolled.

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
NHSC Scholarship Program Application					
NHSC Scholarship Program Application	2,575	1	2,575	2.00	5150.00
Letters of Recommendation	2,575	2	5,150	1.00	5150.00
Authorization to Release Information	2,575	1	2,575	.10	257.50