Hampshire Ave., Bldg. 22, Rm. 2169, Silver Spring, MD 20993–0002, 240–402–2628.

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Advanced Prostate Cancer: Developing Gonadotropin-Releasing Hormone Analogues.'' This draft guidance describes the FDA's current recommendations regarding the overall development program and clinical trial designs for developing GnRH analogues to treat advanced prostate cancer.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Advanced Prostate Cancer: Developing Gonadotropin-Releasing Hormone Analogues.'' 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. This guidance is not subject to Executive Order 12866.

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This draft guidance refers to previously approved collections of information found in FDA regulations.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 collection of information in 21 CFR part 312 has been approved under OMB control number 0910–0014. 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 0910–0755. The collections of information in 21 CFR parts 201.56 and 201.57 (Prescription Drug Labeling) have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: July 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15268 Filed 7–17–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0427]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Inspection by Accredited Persons Program

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: Fax written comments on the collection of information by August 19, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0510. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007; Accreditation Criteria

OMB Control Number 0910–0510—Extension

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250) was signed into law on October 26, 2002. Section 201 of MDUFMA added a new paragraph (g) to section 704 of the Federal, Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons) to conduct inspections of eligible manufacturers of class II or class III devices. FDA's guidance document entitled ''Inspection by Accredited Persons Under The Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007; Accreditation Criteria'' [1] provides information for those interested in participating in this voluntary program.

In the **Federal Register** of March 14, 2019 (84 FR 9352), FDA 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]

Section of the FD&C Act; Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
704(g); Request for Accreditation	1	1	1	80	80

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

[1] *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm089721.pdf.*

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 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15269 Filed 7–17–19; 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 Information Collection Request Title: The National Health Service Corps Loan Repayment Program, OMB No. 0915–0127—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, 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 September 16, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail them to HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: The National Health Service Corps Loan Repayment Program, OMB No. 0915–0127—Revision.

Abstract: The National Health Service Corps (NHSC) Loan Repayment Program (LRP) was established to assure an adequate supply of trained primary care health professionals to provide services in the neediest Health Professional Shortage Areas (HPSAs) of the United States. The NHSC Substance Use Disorder (SUD) Workforce LRP and the NHSC Rural Community LRP were established to recruit and retain a health professional workforce with specific training and credentials to provide evidence-based SUD treatment in HPSAs. Under these programs, HHS agrees to repay the qualifying educational loans of selected primary care health professionals. In return, the health professionals agree to serve for a specified period of time in a NHSC-approved site located in a federally-designated HPSA approved by the Secretary for LRP participants. The forms utilized by each LRP include the following: (1) The NHSC LRP Application, the Authorization for Disclosure of Loan Information form, (2) the Privacy Act Release Authorization form, and, if applicable, (3) the Verification of Disadvantaged Background form, and (4) the Private Practice Option form. The first three of the aforementioned NHSC LRP forms collect information that is needed for selecting participants and repaying qualifying educational loans. The last referenced form, the Private Practice Option Form, is needed to collect information for all participants who have applied for that service option.

NHSC-approved sites are health care facilities that provide comprehensive outpatient, ambulatory, primary health care services to populations residing in HPSAs. Related in-patient services may be provided by NHSC-approved Critical Access Hospitals and Indian Health Service hospitals. In order to become an NHSC-approved site, new sites must submit a Site Application for review and approval. Existing NHSC-approved sites are required to complete a Site Recertification Application every 3 years in order to maintain their NHSC-approved status. Both the NHSC Site Application and Site Recertification Application request information on the clinical service site, sponsoring agency, recruitment contact, staffing levels, service users, charges for services, employment policies, and fiscal management capabilities. Assistance in completing these applications may be obtained through the appropriate State Primary Care Office and the NHSC. The information collected on the applications is used for determining the eligibility of sites for the assignment of NHSC health professionals and to verify the need for NHSC clinicians. NHSC service site approval is valid for 3 years.

Need and Proposed Use of the Information: The need and purpose of this information collection is to assess an LRP applicant's eligibility and qualifications for the LRP, and to obtain information for NHSC site applicants. The NHSC LRP application asks for personal, professional, and financial/loan information.

The proposed revisions in this ICR include asking applicants to provide their educational information on the completion of advanced training such as the Primary Care Training and Enhancement (PCTE) Champion fellowship. To identify the PCTE Champions, the NHSC will require applicants to respond to the following additional questions and submit their National Practitioner Identifier (NPI):

(1) Have you completed a fellowship?

(2) Applicants who selected ''yes'' to the question above are required to submit the NPI number.

NHSC policy requires behavioral health providers to practice in a community-based setting that provides access to comprehensive behavioral health services. Accordingly, for those sites seeking to be assigned behavioral health NHSC participants, additional site information will be collected from an NHSC Comprehensive Behavioral Health Services Checklist. NHSC sites that do not directly offer all required behavioral health services must demonstrate a formal affiliation with a comprehensive, community-based primary behavioral health setting or facility to provide these services.

Likely Respondents: Likely respondents include: (1) Licensed primary care medical, dental, and mental and behavioral health providers who are employed or seeking employment, and are interested in serving underserved populations; (2) health care facilities interested in participating in the NHSC and becoming an NHSC-approved service site; and (3) NHSC sites providing behavioral health care services directly, or through a formal affiliation with a comprehensive community-based primary behavioral health setting or facility providing comprehensive behavioral health services.

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