3606(a)(1) of the Food and Drug Omnibus Reform Act (FDORA). The content described in section 3606(b) of FDORA is further addressed through this guidance's reference to FDA's draft guidance for industry, investigators, and other stakeholders entitled ''Digital Health Technologies for Remote Data Acquisition in Clinical Investigations'' (December 2021). In this draft guidance, a DCT refers to a clinical trial where some or all of the trial-related activities occur at locations other than traditional clinical trial sites. These trial-related activities may take place at the location of trial participants or in local healthcare facilities that are close to trial participants' locations.

DCTs may involve different levels of decentralization. In fully decentralized clinical trials, all activities take place at locations other than traditional trial sites. In hybrid DCTs, some activities involve in-person visits by trial participants to traditional clinical trial sites, and other visits or activities are conducted at locations other than traditional clinical trial sites. FDA's regulatory requirements are the same for DCTs and traditional site-based clinical trials.

DCTs may include the use of local healthcare providers and local clinical laboratory facilities in the management of trial participants and the use of telehealth and digital health technologies to remotely acquire data. By allowing remote participation and reducing the need to travel for face-to-face visits, DCTs may enhance convenience for study participants, facilitate research on diseases affecting populations with limited mobility, and reduce the burden on caregivers.

The investigator in a DCT is responsible for the conduct of the DCT and oversight of individuals delegated to perform trial-related activities. In a DCT, the investigator still ensures that appropriate informed consent is obtained, the investigational product is appropriately administered in accordance with the protocol, and other required safety and efficacy assessments are done with appropriate documentation. Specific issues related to the feasibility, design, implementation, or analysis of a DCT should be discussed with the relevant FDA review division.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Decentralized Clinical Trials for Drugs, Biological Products, and Devices.'' 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 11 have been approved under OMB control number 0910–0303; the collections of information in 21 CFR part 312, including Form FDA 1572, have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 812 and 812.140 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR parts 50 and 56 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/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09399 Filed 5–2–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–2060]

Determination That Levitra (Vardenafil Hydrochloride) Oral Tablets, 5 Milligrams, 10 Milligrams, and 20 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that Levitra (vardenafil hydrochloride) oral tablets, 5 milligrams (mg), 10 mg, and 20 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to these products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Daniel Ritterbeck, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6219, Silver Spring, MD 20993–0002, 301–796–4673, *Daniel.Ritterbeck@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Levitra (vardenafil hydrochloride) oral tablets, 5 mg, 10 mg and 20 mg, are

the subject of NDA 021400, held by Bayer HealthCare Pharmaceuticals, Inc., and initially approved on August 19, 2003. Levitra is a phosphodiesterase 5 inhibitor indicated for the treatment of erectile dysfunction.

In letters dated September 26, 2019, September 24, 2020, and September 20, 2021, Bayer HealthCare Pharmaceuticals, Inc. notified FDA that Levitra (vardenafil hydrochloride) oral tablets, 5 mg, 10 mg and 20 mg, respectively, were being discontinued, and FDA moved the drug products to the ''Discontinued Drug Product List'' section of the Orange Book.

Respira Therapeutics, Inc. submitted a citizen petition dated August 29, 2022 (Docket No. FDA–2022–P–2060), under 21 CFR 10.30, requesting that the Agency determine whether Levitra (vardenafil hydrochloride) oral tablets, 20 mg, were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 5 mg and 10 mg strengths, those strengths have also been discontinued. On our own initiative, we have also determined whether those strengths were withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that Levitra (vardenafil hydrochloride) oral tablets, 5 mg, 10 mg, and 20 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of Levitra (vardenafil hydrochloride) oral tablets, 5 mg, 10 mg, and 20 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list Levitra (vardenafil hydrochloride) oral tablets, 5 mg, 10 mg, and 20 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to these drug products. Additional ANDAs for these drug products may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09365 Filed 5–2–23; 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 Paperwork Reduction Act of 1995, HRSA 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 will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than June 2, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *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.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the Acting HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call 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.

A 60-day notice published in the **Federal Register** on February 14, 2023, 88 FR 9525–26. There were no public comments.

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.