ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|---|---|---|---|---|
| Individuals (male and female) aged 18 years and older | Study Screener | 30,880 | 1 | 2/60 |
| | Survey Module | 5,445 | 1 | 30/60 |

**Jeffrey M. Zirger,**

*Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.*

[FR Doc. 2023–10957 Filed 5–22–23; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2023–N–0687]**

### Abbott Laboratories Pharmaceutical Products Division; Withdrawal of Approval of New Drug Applications for CYLERT (Pemoline) Tablets, 18.75 Milligrams, 37.5 Milligrams, and 75 Milligrams, and CYLERT (Pemoline) Chewable Tablets, 37.5 Milligrams

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of new drug application (NDA) 016832 for CYCLERT (pemoline) tablets, 18.75 milligrams (mg), 37.5 mg, and 75 mg, as well as NDA 017703 for CYCLERT (pemoline) chewable tablets, 37.5 mg, held by Abbott Laboratories Pharmaceutical Products Division, c/o G&L Scientific, 25 Independence Blvd., 4th Floor, Warren, NJ 07059 (Abbott). Abbott requested that approval of these applications be withdrawn and has waived its opportunity for a hearing.

**DATES:** Approval is withdrawn as of May 23, 2023.

**FOR FURTHER INFORMATION CONTACT:** Kimberly Lehrfeld, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** On January 27, 1975, FDA approved NDA 016832 for CYLERT (pemoline) tablets, 18.75 mg, 37.5 mg, and 75 mg, for use in the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD). On January 30, 1976, the Agency approved NDA 017703 for CYLERT (pemoline) chewable tablets, 37.5 mg, for use in the treatment of ADHD. On October 24, 2005, FDA issued a Postmarket Drug Safety Information for Patients and Providers communication entitled ''Information for Healthcare Professionals: Pemoline Tablets and Chewable Tablets (Marketed as CYLERT)'' which concluded the overall liver toxicity risk of CYLERT (pemoline) (NDAs 016832 and 017703) and generic pemoline products outweighed the benefits of these products (*https://wayback.archive-it.org/7993/20171114124349/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126461.htm*).

All holders of approved applications for pemoline products, including Abbott, ceased marketing the products at that time. On April 12, 2021, FDA contacted Abbott and requested the company submit a request for FDA to withdraw approval of NDAs 016832 and 017703 for CYLERT tablets and CYLERT chewable tablets, respectively, pursuant to § 314.150(d) (21 CFR 314.150(d)) due to the risk of liver toxicity. On September 2, 2021, Abbott requested that FDA withdraw approval of CYLERT (pemoline) tablets and CYLERT (pemoline) chewable tablets, NDAs 016832 and 017703, respectively, under § 314.150(d) and waived its opportunity for a hearing.

For the reasons discussed above, and in accordance with the applicant's request, approval of NDAs 016832 and 017703 for CYLERT (pemoline) tablets, 18.75 mg, 37.5 mg, and 75 mg, and CYLERT (pemoline) chewable tablets, 37.5 mg, respectively, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of CYLERT (pemoline) tablets, 18.75 mg, 37.5 mg, and 75 mg, and CYLERT (pemoline) chewable tablets, 37.5 mg, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(a) and 331(d))).

Dated: May 17, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–10924 Filed 5–22–23; 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; Public Comment Request; Nurse Faculty Loan Program—Program Specific Data Form, Annual Performance Report Financial Data Form and NFLP Due Diligence Form; OMB No. 0915–0314–Revision

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

**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 22, 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 HRSA Information

Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–1984.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* Nurse Faculty Loan Program—Program Specific Data Form, Annual Performance Report Financial Data Form and NFLP Due Diligence Form OMB No. 0915–0314–Revision

*Abstract:* This clearance request is for approval of the Nurse Faculty Loan Program (NFLP)—Program Specific Data Form, NFLP—Annual Performance Report (APR) Financial Data Form, and the NFLP Due Diligence Form. The Program Specific Data Form and the NFLP—APR Financial Data Form are currently approved under OMB Approval No. 0915–0314, with the expiration date of August 31, 2023. The NFLP Due Diligence Form is a new form. HRSA seeks to use the NFLP Due Diligence Form for recipients to formally notify HRSA of any write-off amounts due to uncollectible debt and loan cancellation due to death and permanent/total disability. For program efficiency, HRSA is adding the new NFLP Due Diligence Form to the current NFLP ICR under OMB No. 0915–0314.

A 60-day notice published in the **Federal Register** on March 8, 2023, vol. 88, No. 45; pp. 14378–79. There were no public comments.

*Need and Proposed Use of the Information:* Section 846A of the Public Health Service Act provides the Secretary of HHS with the authority to enter into agreements with accredited schools of nursing for the establishment and operation of student loan funds to increase the number of qualified nurse faculty. Under the agreements, HRSA makes awards to accredited schools of nursing and the schools provide loans to students enrolled in advanced education nursing degree programs who are committed to becoming nurse faculty. Following graduation from the NFLP grant recipient school, NFLP borrowers may receive up to 85 percent of loan cancellation over a 4-year period in exchange for service as full-time faculty at a school of nursing. The NFLP grant recipient school collects any portion of the loan that is not cancelled and any loans that go into repayment and deposits these monies into the NFLP loan fund to make additional NFLP loans.

The NFLP—Program Specific Data Form is a required electronic attachment within the NFLP application materials. The data provided in the form is essential for the formula-based criteria used to determine the award amount to the applicant schools. The form collects application related data from applicants such as the amount requested, number of students to be funded, tuition information, and projected unused loan fund balance. This data collection assists HRSA in streamlining the application submission process, enabling an efficient award determination process, and facilitating reporting on the use of funds and analysis of program outcomes. There have been no changes to this form.

The NFLP—APR Financial Data Form is an online form that exists in the HRSA Electronic Handbooks Performance Report module. The NFLP—APR Financial Data Form collects outcome and financial data to capture the NFLP loan fund account activity related to financial receivables, disbursements, and borrower account data related to employment status, loan cancellation, loan repayment and collections. NFLP grant recipient schools will provide HHS with current and cumulative information on (1) NFLP loan funds received, (2) number and amount of NFLP loans made, (3) number and amount of loans cancelled, (4) number and amount of loans in repayment, (5) loan default rate percent, (6) number of NFLP graduates employed as nurse faculty, and (7) other related loan fund costs and activities. NFLP grant recipient schools must keep records of all NFLP loan fund transactions. The NFLP—APR Financial Data Form is used to monitor grantee performance by collecting information related to the NFLP loan fund operations and financial activities for a specified reporting period (July 1 through June 30 of the academic year). NFLP grant recipient schools are required to complete and submit the NFLP—APR Financial Data Form annually. The data provided in the form is essential for HRSA to effectively monitor the school's use of NFLP funds in accordance with the statute and program guidelines. There have been no changes to this form.

The NFLP Due Diligence Form will be a required form to be completed and submitted electronically by NFLP grant recipient schools. This form indicates that due diligence has been exercised in the cancellation of any remaining loan funds for NFLP borrowers due to permanent/total disability, death, and uncollectible/bad debt write-offs. The data collected on the due diligence form will include the student borrower's unique ID number, reason for cancellation, the amount of principal loaned, the total amount of principal loan funds and corresponding interest canceled, and the outstanding amount of principal/interest being canceled or written-off. The NFLP Due Diligence Form is essential for monitoring performance measure outcomes and to verify and validate accuracy of information submitted on the NFLP Annual Performance Reports.

*Likely Respondents:* NFLP grant recipient schools and applicants to the NFLP 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 |
|---|---|---|---|---|---|
| Nurse Faculty Loan Program—Program Specific Data Form | 90 | 1 | 90 | 8 | 720 |
| Nurse Faculty Loan Program—Annual Performance Report Financial Data Form | 207 | 1 | 207 | 6 | 1242 |
| Nurse Faculty Loan Program—Due—Diligence Form | 20 | 1 | 20 | 1 | 20 |

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

| Form name | Number of respondents | Number of responses per respondent | Total responses | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|---|
| Total Burden | 317 | 3 | 317 | 15 | 1982 |

**Maria G. Button,**

*Director, Executive Secretariat.*

[FR Doc. 2023–10929 Filed 5–22–23; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[Document Identifier: OS–0937–0198]**

## Agency Information Collection Request. 30-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before June 22, 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 30-day Review—Open for Public Comments'' or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 264–0041, or *PRA@HHS.GOV.*

When submitting comments or requesting information, please include the document identifier 0937–0198–30D and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* Public Health Service Policies on Research Misconduct (42 CFR part 93).

*Type of Collection:* Extension.

*OMB No.:* OS–0937–0198.

*Abstract:* The Office of Research Integrity is requesting an extension on a currently approved collection. The purpose of the Institutional Assurance and Annual Report on Possible Research Misconduct form PHS–6349 is to provide data on the amount of research misconduct activity occurring in institutions conducting PHS-supported research. The purpose of the Assurance of Compliance by Sub-Award Recipients forms PHS–6315 is to establish an assurance of compliance for a sub-awardee institution. Forms PHS 6349 and PHS–6315 are also used to provide an annual assurance that the institution has established and will follow administrative policies and procedures for responding to allegations of research misconduct that comply with the Public Health Service (PHS) Policies on Research Misconduct (42 CFR part 93).

Research misconduct is defined as receipt of an allegation of research misconduct and/or the conduct of an inquiry and/or investigation into such allegations. These data enable the ORI to monitor institutional compliance with the PHS regulation.

There were minor revisions made on forms PHS–6349 and PHS–6315. The revisions will not alter the data collection.

*Need and Proposed Use:* The information is needed to fulfill section 493 of the Public Health Service Act (42 U.S.C. 289b), which requires assurances from institutions that apply for financial assistance under the Public Health Service Act for any project or program that involves the conduct of biomedical or behavioral research. In addition, the information is also required to fulfill the assurance and annual reporting requirements of 42 CFR part 93. ORI uses the information to monitor institutional compliance with the regulation. Lastly, the information may be used to respond to congressional requests for information to prevent misuse of Federal funds and to protect the public interest.

ESTIMATED ANNUALIZED BURDEN HOUR TABLE

| Forms (if necessary) | Respondents (if necessary) | Number of respondents | Number of responses per respondents | Average burden per response | Total burden hours |
|---|---|---|---|---|---|
| PHS–6349 | Awardee Institutions | 5,770 | 1 | 10/60 | 961 |
| PHS–6315 | Sub-Awardee Institutions | 156 | 1 | 5/60 | 13 |
| Total | | 5,926 | 2 | | 974 |

**Sherrette A. Funn,**

*Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.*

[FR Doc. 2023–10938 Filed 5–22–23; 8:45 am]

**BILLING CODE 4150–31–P**