

applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of June 11, 2020.

**FOR FURTHER INFORMATION CONTACT:** Martha Nguyen, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, [Martha.Nguyen@fda.hhs.gov](mailto:Martha.Nguyen@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval

of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 065232 .....	Ceftriaxone Sodium for Injection, Equivalent to (EQ) 10 grams (g) base/vial.	Hospira Inc., 275 North Field Dr., Building H1, Lake Forest, IL 60045.
ANDA 088697 .....	Amitriptyline Hydrochloride (HCl) Tablets, 10 milligrams (mg).	Par Pharmaceutical Inc., One Ram Ridge Rd., Spring Valley, NY 10977.
ANDA 088698 .....	Amitriptyline HCl Tablets, 25 mg .....	Par Pharmaceutical Inc.
ANDA 088699 .....	Amitriptyline HCl Tablets, 50 mg .....	Do.
ANDA 088700 .....	Amitriptyline HCl Tablets, 75 mg .....	Do.
ANDA 088701 .....	Amitriptyline HCl Tablets, 100 mg .....	Do.
ANDA 088702 .....	Amitriptyline HCl Tablets, 150 mg .....	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of June 11, 2020. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on June 11, 2020, may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: May 6, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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**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 and Annual Performance Report Financial Data 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 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. 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 11, 2020.

**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](http://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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-1984.

**SUPPLEMENTARY INFORMATION:**

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

*Abstract:* This clearance request is for approval of both the Nurse Faculty Loan Program (NFLP) Program Specific Data Form and the Annual Performance Report (APR) Financial Data Form. The APR Financial Data Form is currently approved under OMB Approval No. 0915-0314 and the Program Specific Data Form is currently approved under OMB Approval No. 0915-0378, both with the expiration date of July 31, 2020. The APR Form was previously titled as the Nurse Faculty Loan Program, Annual Operating Report. For program efficiency, HRSA is combining these previously separate ICRs under OMB No. 0915-0314 and will be discontinuing OMB No. 0915-0378.

A 60-day notice published in the **Federal Register** on February 7, 2020, vol. 85, No. 26; pp. 7315-7316. 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 an agreement with schools of nursing for the establishment and

operation of a student loan fund to increase the number of qualified nurse faculty.

Under the agreement, HRSA makes awards to the school for the NFLP loan fund, which must be maintained in a distinct account. The school of nursing makes loans from the NFLP account to students enrolled full-time or, at the discretion of the Secretary, part-time, in a master's or doctoral nursing education program that will prepare them to become qualified nursing faculty. Following graduation from the NFLP lending school, loan recipients may receive up to 85 percent NFLP loan cancellation over a four-year period in exchange for service as full-time faculty at a school of nursing. The NFLP lending school collects any portion of the loan that is not cancelled and any loans that go into repayment due to default, 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 will collect application related data from applicants such as the amount requested, number of students to be funded, tuition information, and projected unused loan fund balance. Approval of the NFLP—Program Specific Data Form will allow HRSA to

continue to efficiently capture data to generate the formula-based awards for the NFLP program. 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.

HRSA is also seeking public comment on the NFLP—APR Financial Data Form. The NFLP—APR Financial Data Form is an online form that exists in the HRSA Electronic Handbooks (EHBs) Performance Report module. The NFLP—APR Financial Data Form will collect 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. Participating 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.

The school of nursing 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). Participating 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. Approval of the NFLP—APR Financial Data Form extension will allow HRSA to continue to monitor program performance and program outcome.

*Likely Respondents:* Participating NFLP 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 respondents 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 .....	260	1	260	6	1,560
Total Burden .....	350	.....	350	.....	2,280

**Maria G. Button,**

*Director, Executive Secretariat.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

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:* Vascular and Hematology Integrated Review Group; Hemostasis and Thrombosis Study Section.

*Date:* June 12, 2020.

*Time:* 8:00 a.m. to 6:00 p.m.