

NIH and placed in a public docket assigned by FDA.

Neonates are at risk for serious bacterial infections including meningitis, bacteremia, sepsis, and urinary tract infections. Most of these children are admitted to a hospital, where they receive antibiotics. Early onset of bacterial infection (less than 7 days of life) reflects vertical transmission, usually caused by group B streptococci (GBS), *Escherichia coli*, *Listeria monocytogenes*, or *enterococcus* species, and is a significant cause of illness and death among low birth weight infants. Late onset infections suggest nosocomial, community-acquired infections or late onset GBS; these may be caused by gram-negative organisms as well as staphylococcal species. The first line of antibiotic therapy is ampicillin in combination with gentamicin or a third-generation cephalosporin.

In the **Federal Register** of February 13, 2004 (71 FR 23931), NIH published a notice announcing the addition of several drugs, including ampicillin, to the priority list of drugs most in need of study for use by children to ensure the drugs' safety and efficacy. A written request for pediatric studies of ampicillin was issued on August 5, 2005, to the holders of applications for ampicillin. FDA did not receive a response to the written request. Accordingly, NIH issued a request for proposals to conduct the pediatric studies described in the written request in 2006, and awarded funds to Pediatric Trials Network in December 2011 to complete the studies described in the written request. Upon completion of the pediatric studies, a report of the pediatric studies of ampicillin was submitted to NIH and FDA. As required under section 409I of the PHS Act, FDA opened a public docket and NIH placed in the docket the report of pediatric studies of ampicillin that was submitted to NIH and FDA. The report includes all data generated in connection with the study, including the written request.

II. Availability of Report for Public Comment

FDA is announcing the 30-day open public comment period for the report of the pediatric studies of ampicillin that were conducted in accordance with section 409I of the PHS Act and submitted to NIH and FDA. We invite interested parties to review the Duke Clinical Research Institute report, which was posted to the docket on December 15, 2015, and submit comments to the docket (see **ADDRESSES**).

Dated: April 19, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0001]

Food and Drug Administration Small Business and Industry Assistance Regulatory Education for Industry Spring Conference; Public Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER), together with the Center for Devices and Radiological Health (CDRH), is sponsoring a 2-day public conference entitled "FDA Small Business and Industry Assistance Regulatory Education for Industry (REDI) Spring Conference." The goal of this public conference is to provide direct, relevant, and helpful information on the key aspects of drug and medical device regulations in order to increase regulatory certainty and predictability for pharmaceutical and/or medical device industry. Our primary audience is that of small manufacturers of drug and/or medical devices who want to learn about how FDA approaches the regulation of drugs and medical devices and for whom increased certainty and predictability will help to decrease the regulatory burdens that can be associated with a lack of understanding of, or familiarity with, FDA's drug and medical device regulations. However, anyone involved in the pharmaceutical and/or medical device industry may attend.

DATES: The public conference will be held May 9 and 10, 2017, from 8:30 a.m. to 4:30 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration information.

ADDRESSES: The public conference will be held in the High Ballroom, located on the Lobby Level of the Renaissance Atlanta Midtown Hotel, 866 W. Peachtree St. NW., Atlanta, GA 30308. The hotel's phone number is 678-412-2400.

FOR FURTHER INFORMATION CONTACT: Brenda Stodart, Center for Drug Evaluation and Research, Food and

Drug Administration, 10001 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-6707, email: cdersbia@fda.hhs.gov; or Elias Mallis, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-7100, email: DICE@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public conference entitled "FDA Small Business and Industry Assistance Regulatory Education for Industry Spring Conference." This public conference is intended to increase the drug and medical device industry's awareness of applicable FDA regulations. There will be an opportunity for questions and answers following each presentation.

II. Topics for Discussion at the Conference

This 2-day, FDA-led forum offers the opportunity to interact with FDA subject matter experts from across CDER and CDRH. The following information will be discussed:

- CDER Investigational New Drug Application (IND) Review Process: Types of IND; Content and Format of an IND; Chemistry Manufacturing and Controls; Pharmacology/Toxicology; Drug Inspections
- CDRH: 510(k); Biocompatibility in Premarket Submissions; Non-Conforming Product; Device Inspections

III. Participating in the Public Conference

Registration: There is no fee to attend the public conference. Space is limited, and registration will be on a first-come, first-served basis. To register, please complete registration online at: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm545309.htm>. Early registration is recommended. Registrants will receive email confirmation when they have been accepted, and reminder emails will be sent to registrants 2 days before the conference. If time and space permit, onsite registration will be available beginning at 7:30 a.m. on each day of the public conference. If you need special accommodations due to disability, please contact info@sbiaevents.com at least 7 days in advance.

Streaming Webcast of the Public Conference: This public conference will also be Webcast. Persons interested in viewing the Webcast must register to

receive a confirmation email with the Webcast link.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Transcripts: Transcripts will not be available.

Dated: April 19, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0915-0378]

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Title: Nurse Faculty Loan Program (NFLP)—Program Specific Data Form; Revision

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 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 will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than May 25, 2017.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: Nurse Faculty Loan Program (NFLP)—Program Specific Data Form, OMB No. 0915-0378—Revision.

Abstract: This clearance request is for continued approval of the Nurse Faculty Loan Program (NFLP) revised Program Specific Data Form. HRSA is streamlining the data collection form by making the following changes:

- Line Item D will be renamed “D1. NFLP Loan Fund Balance/Unused Accumulation.”
- Addition of Line Item D2 titled “NFLP Loan Fund Default Rate,” requesting information regarding the status of an institution’s default rate.
- Addition of Line Item D3 titled “Last NFLP Student Loan Award,” requesting information regarding the disbursement of NFLP loan funds within the last 2 academic years.
- Line Item E2 Column Header will be renamed “E.2 NFLP Enrollees Information by Degree—New Students Expected to Request NFLP Support.”
- Under Section B of instructions, “other attachments” will be updated to reflect the current list of NFLP Funding Opportunity Announcement attachments.

Need and Proposed Use of the Information: 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. Continued approval of the revised NFLP—Program Specific Data Form allows HRSA to efficiently capture data to generate the formula-based award and facilitates reporting on the use of funds and analysis of program outcomes.

The addition of Line Item D2, NFLP Loan Fund Default Rate, will allow HRSA to easily assess and consider an existing performance standard for those applicants with existing NFLP loan accounts. Used in combination with an existing NFLP institution’s self-reported NFLP loan balance, the addition of Line Item D3, Last NFLP Student Loan Award, will allow HRSA to assess the loan fund activity (*i.e.*, incidence of loans to students) of an existing NFLP institution applying for additional funding.

Likely Respondents: NFLP eligible applicants. This includes accredited schools of nursing offering eligible advanced masters and/or doctoral degree nursing education programs that will prepare students to serve as qualified nursing faculty.

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 burden for this revised form has decreased by 480 hours due to an estimated decrease in number of respondents. 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
NFLP—Program Specific Data Form	90	1	90	8	720
Total Burden	90	90	720