approval to ensure the device's continuing safety and effectiveness.

In the **Federal Register** of October 24, 2019 (84 FR 57030), 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]

Activity/21 CFR or FD&C Act section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Research conducted outside the United States (814.15(b))	25	1	25	2	50
PMA application (814.20)	46	1	46	668	30,728
Information on clinical investigations conducted outside the United States (814.20(b)(6)(ii)(C))	10	1	10	0.5 (30 minutes)	5
PMA amendments and resubmitted PMAs (814.37(a)–(c) and (e))	1,528	1	1,528	167	255,176
PMA supplements (814.39(a))	777	1	777	60	46,620
Special PMA supplement—changes being affected (814.39(d))	75	1	75	6	450
30-day notice (814.39(f))	1,722	1	1,722	16	27,552
Postapproval requirements (814.82(a)(9))	121	1	121	135	16,335
Periodic reports (814.84(b))	764	1	764	10	7,640
Agreement meeting (520(g)(7))	1	1	1	50	50
Breakthrough Devices Program (515(B) of the FD&C Act)	11	1	11	10	110
Determination Meeting (513(1)(3)(D) of the FD&C Act)	1	1	1	50	50
Panel meeting (515(c)(3) of the FD&C Act)	1	1	1	30	30
Day 100 meeting (515(d)(3) of the FD&C Act)	14	1	14	10	140
Total					384,936

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintenance of records (814.82(a)(5) and (6))	446	1	446	17	7,582

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

We made the following changes to the information collection:

- Added the burden estimate for ''Information on clinical investigations conducted outside the United States (§ 814.20(b)(6)(ii)(C)),'' which is associated with the ''Human Subject Protection; Acceptance of Data from Clinical Investigations for Medical Devices'' final rule as described previously in this document.
- Revised the burden description and table to reflect that the Expedited Access Pathway and Priority Review have been superseded by the Breakthrough Devices Program.
- Updated our burden estimate with FYs 2016 through 2018 data.

These adjustments resulted in an overall increase of 34,782 hours to the estimated burden.

Dated: January 31, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–02481 Filed 2–6–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5270]

Biosimilars and Interchangeable Biosimilars: Licensure for Fewer Than All Conditions of Use for Which the Reference Product Has Been Licensed; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Biosimilars and Interchangeable Biosimilars: Licensure for Fewer Than All Conditions of Use for Which the Reference Product Has Been Licensed.'' When finalized, this draft guidance will provide recommendations to applicants seeking licensure under the Public Health Service Act (the PHS Act) of a proposed biosimilar or proposed interchangeable biosimilar for fewer than all of the reference product's licensed conditions of use. Additionally, when finalized, this draft guidance will also provide recommendations on the submission of a supplement to a licensed biologics license application (BLA) seeking to add a condition of use that previously has been licensed for the reference product to the labeling of a licensed biosimilar or interchangeable product, including considerations related to the timing of such submissions.

DATES: Submit either electronic or written comments on the draft guidance by April 7, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include Docket No. FDA–2019–D–5270 for ''Biosimilars and Interchangeable Biosimilars: Licensure for Fewer Than All Conditions of Use for Which the Reference Product Has Been Licensed.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1132, Silver Spring, MD 20993–0002, 301–796–1042; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Biosimilars and Interchangeable Biosimilars: Licensure for Fewer Than All Conditions of Use for Which the Reference Product Has Been Licensed.'' When finalized, this draft guidance will provide recommendations to applicants seeking licensure under section 351(k) of the PHS Act (42 U.S.C. 262(k)) of a proposed biosimilar or proposed interchangeable biosimilar for fewer than all of the reference product's licensed conditions of use. Additionally, when finalized, this draft guidance will also provide recommendations on the submission of a supplement to a licensed 351(k) BLA seeking to add a condition of use that previously has been licensed for the reference product to the labeling of a licensed biosimilar or interchangeable product, including considerations related to the timing of such submissions.

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 ''Biosimilars and Interchangeable Biosimilars: Licensure for Fewer Than All Conditions of Use for Which the Reference Product Has Been Licensed.'' It does not establish any rights for any person and is not binding on FDA or the public. An alternative approach can be used if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information for BLAs submitted under section 351(k) of the PHS Act have been approved under OMB control number 0910–0719. The collections of information in 21 CFR 201.56 and 21 CFR 201.57 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/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *https://www.regulations.gov.*

Dated: February 3, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–02421 Filed 2–6–20; 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: 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 requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, 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 April 7, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, 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 ICR title for reference.

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. For program efficiency, HRSA is combining these previously separate ICRs under OMB No. 0915–0314 and will be discontinuing OMB No. 0915–0378.

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 schools must maintain 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 4-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 it has 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 collects application-related data from applicants such as the amount requested, number of students the school will fund, tuition information, and projected unused loan fund balance. Approval of the NFLP Program Specific Data Form allows HRSA to continue to 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.

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. Participating schools 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. HRSA uses the NFLP–APR Financial Data Form 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 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