including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Substances Generally Recognized as Safe: Notification Procedure—21 CFR 170, Subpart E and 21 CFR 570, Subpart E

OMB Control Number 0910–0342—Extension

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that all food additives (as defined by section 201(s) (21 U.S.C. 321(s)) be approved by FDA before they are marketed. Section 409 of the FD&C Act (21 U.S.C. 349) establishes a premarket approval requirement for ''food additives.'' Section 201(s) of the FD&C Act provides an exclusion to the definition of food additive and thus from the premarket approval requirement, for uses of substances that are GRAS by qualified experts. The GRAS provision of section 201(s) of the FD&C Act is implemented in 21 CFR part 170 (part 170) and 21 CFR part 570 (part 570) for human food and animal food, respectively. Part 170, subpart E and part 570, subpart E provide a standard format for the submission of a notice. This collection utilizes a voluntary administrative procedure for notifying FDA about a conclusion that a substance is GRAS under the conditions of its intended use in human food or animal food. The information submitted to us in a GRAS notice is necessary to allow us to administer efficiently the FD&C Act's various provisions that apply to the use of substances added to food, specifically with regard to whether a substance is GRAS under the conditions of its intended use or is a food additive subject to premarket review. We use the information collected through the GRAS notification procedures to complete our evaluation within specific timelines.

Description of Respondents: The respondents to this collection of information are manufacturers of substances used in human food and animal food and feed.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
GRAS notification procedure for human food; 170.210–170.280 (part 170, subpart E)	100	1	100	170	17,000
GRAS notification procedure for animal food and animal feed; 570.210–570.280 (part 570, subpart E)	25	1	25	170	4,250
Total			75		21,250

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

Our estimated burden for the information collection reflects an overall increase of 8,500 hours, which results from an increase in the estimated number of GRAS submissions for human food from 50 to 100 per year. We attribute this adjustment to an increase in the number of submissions we received over the last 2 years.

Dated: March 6, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–04449 Filed 3–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0093]

Agency Information Collection Activities; Proposed Collection; Comment Request; Review Transparency and Communication in Reviews of 351(k) Biologics License Applications in Biosimilars User Fee Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection involving interviews of pharmaceutical manufacturers who submit 351(k) biologics license applications (BLAs) to FDA under the Program for Enhanced Review Transparency and Communication (the Program) during FYs 2018 through 2021.

DATES: Submit either electronic or written comments on the collection of information by May 13, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 13, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 13, 2019. Comments

received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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 the Docket No. FDA–2013–N–0093 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Acts and 351(k) Biologics License Applications in Biosimilars User Fee Act.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Acts and 351(k) Biologics License Applications in Biosimilars User Fee Act

OMB Control Number 0910–0746—Extension

This information collection supports the above captioned review program (''the Program''). The Program is part of our performance commitment under the fifth and sixth authorizations of the Prescription Drug User Fee Act (PDUFA), which allows us to collect user fees for the review of human drug and biologics applications for FYs 2013 through 2021, and the second authorization of the Biosimilars User Fee Act (BsUFA II), which applies to 351(k) BLAs for FYs 2018 through 2021. The Program is described in detail in FDA's Commitment Letters for PDUFA VI and BsUFA II, available at *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf* and *https://www.fda.gov/downloads/ForIndustry/*

UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf.

The Program goals are to increase the efficiency and effectiveness of the first review cycle and decrease the number of review cycles necessary for approval so that patients have timely access to safe, effective, and high-quality new drugs and biologics. A key aspect of the extension of the Program to BsUFA II is to conduct an interim and final assessment that will evaluate how well the parameters of the Program have achieved the intended goals. The BsUFA II Commitment Letter specifies that an independent contractor can conduct the assessments and specifies that they include interviews of sponsors who submit 351(k) BLAs to the Program in BsUFA II. In accordance with the PDUFA V and BsUFA II Commitment Letters, we contracted Eastern Research Group, Inc. (ERG) to conduct independent interviews of applicants after FDA issues a first-cycle action for applications reviewed under the Program. The purpose of these interviews is to collect feedback from applicants on the success of the Program in increasing transparency and communication of reviews during the review process. ERG will anonymize and aggregate sponsor responses before inclusion in the assessments and presentation materials at public meetings. We will publish in the **Federal Register** for public comment ERG's assessments with interview results and findings.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pre-test	5	1	5	1.5	7.5
Interviews	75	1	75	1.5	112.5
Total					120

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

Since last OMB approval of the information collection, we have adjusted our estimate downward by 60 survey respondents. We base our estimate on the most recent number of annual surveys. ERG interviews between one and three sponsor representatives for each 351(k) BLA first-cycle action issued for applications reviewed under the Program. ERG also conducts a pretest of the interview protocol with five respondents. Assuming it will take 1.0 to 1.5 hours to complete the pretest, we calculate a total of 7.5 annual burden hours. We estimate that up to 75 respondents will take part in the post-action interviews each year. Assuming each interview will last 1.0 to 1.5 hours, we calculate a total of 112.5 annual burden hours.

Dated: March 6, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–04429 Filed 3–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[CFDA NUMBER: 93.164]

Loan Repayment Program for Repayment of Health Professions Educational Loans; Announcement Type: Initial

Key Dates: March 15, 2019, first award cycle deadline date; August 15, 2019, last award cycle deadline date; September 15, 2019, last award cycle deadline date for supplemental loan repayment program funds; September 30, 2019, entry on duty deadline date.

I. Funding Opportunity Description

The Indian Health Service (IHS) estimated budget for fiscal year (FY) 2019 includes $27,500,000 for the IHS Loan Repayment Program (LRP) for health professional educational loans (undergraduate and graduate) in return for full-time clinical service as defined in the IHS LRP policy at *https://www.ihs.gov/loanrepayment/policiesandprocedures/* in Indian health programs.

This notice is being published early to coincide with the recruitment activity of the IHS which competes with other Government and private health management organizations to employ qualified health professionals.

This program is authorized by the Indian Health Care Improvement Act (IHCIA) Section 108, codified at 25 U.S.C. 1616a.

II. Award Information

The estimated amount available is approximately $17,750,000 to support approximately 384 competing awards averaging $46,205 per award for a two-year contract. The estimated amount available is approximately $9,750,000 to support approximately 392 competing awards averaging $24,840 per award for a one-year extension. One-year contract extensions will receive priority consideration in any award cycle. Applicants selected for participation in the FY 2019 program cycle will be expected to begin their service period no later than September 30, 2019.

III. Eligibility Information

A. Eligible Applicants

Pursuant to 25 U.S.C. 1616a(b), to be eligible to participate in the LRP, an individual must:

(1)(A) Be enrolled—

(i) In a course of study or program in an accredited institution, as determined by the Secretary, within any State and be scheduled to complete such course of study in the same year such individual applies to participate in such program; or

(ii) In an approved graduate training program in a health profession; or

(B) Have a degree in a health profession and a license to practice in a State; and

(2)(A) Be eligible for, or hold an appointment as a commissioned officer in the Regular Corps of the Public Health Service (PHS); or

(B) Be eligible for selection for service in the Regular Corps of the PHS; or

(C) Meet the professional standards for civil service employment in the IHS; or

(D) Be employed in an Indian health program without service obligation; and

(3) Submit to the Secretary an application for a contract to the LRP. The Secretary must approve the contract before the disbursement of loan repayments can be made to the participant. Participants will be required to fulfill their contract service agreements through full-time clinical practice at an Indian health program site