

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN<sup>1</sup>—Continued

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
107.260; Revision of an infant formula recall .....	1	1	1	25	25
Total <sup>2</sup> .....	.....	.....	.....	.....	.....

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2 reports FDA's third-party disclosure burden estimates for §§ 107.230 and 107.260. The estimated burden hours per disclosure is an average based on FDA's experience. The third-party disclosure burden in § 107.230 is the requirement to promptly notify each affected direct account (customer) about the recall, and if the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post a notice of the recall at the point of purchase. FDA estimates that two respondents will conduct infant formula recalls under § 107.230 and that it will take a respondent 50 hours to comply with the third-party disclosure requirements of that section, for a total of 100 hours. The third-party disclosure burden in § 107.260 is the requirement to issue additional notifications where the recall strategy or implementation is determined to be deficient. FDA estimates that one respondent will issue additional notifications under § 107.260 and that it will take a respondent 25 hours to comply with the third-party disclosure requirements of that section, for a total of 25 hours.

Dated: June 12, 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-2011-N-0655]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Generic Drug User Fee Act Cover Sheet

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by July 17, 2017.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0632. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed

collection of information to OMB for review and clearance.

#### Form FDA 3728, Animal Generic User Fee Act Cover Sheet—21 U.S.C. 379j-21—OMB Control Number 0910-0632—Extension

Section 741 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j-21) establishes three different kinds of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j-21(a)). Because concurrent submission of user fees with applications is required, the review of an application cannot begin until the fee is submitted. Form FDA 3728 is the Animal Generic Drug User Fee Act (AGDUGA) Cover Sheet, which is designed to collect the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form, when completed electronically, will result in the generation of a unique payment identification number used by FDA to track the payment. It will be used by FDA's Center for Veterinary Medicine and FDA's Office of Financial Management to initiate the administrative screening of new generic animal drug applications to determine if payment has been received.

In the **Federal Register** of September 2, 2016 (81 FR 60707), 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 <sup>1</sup>

Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3728 .....	20	2	40	.08 (5 minutes) .....	3.2

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents to this collection of information are new generic animal drug applicants. Based on Agency data for the past 3 years, FDA estimates there are approximately 40 submissions annually and a total of 3.2 burden hours. The burden for this information collection has not changed since the last OMB approval.

Dated: June 12, 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

**Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Application and Other Forms Utilized by the National Health Service Corps (NHSC) Scholarship Program (SP), the NHSC Students To Service Loan Repayment Program (S2S LRP), and the Native Hawaiian Health Scholarship Program (NHHSP), OMB No. 0915-0146—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 July 17, 2017.

**ADDRESSES:** Submit your comments, including the ICR 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:* Application and Other Forms Utilized by the National Health Service Corps (NHSC) Scholarship Program (SP), the NHSC Students to Service Loan Repayment Program (S2S LRP), and the Native Hawaiian Health Scholarship Program (NHHSP), OMB No. 0915-0146—Revision

*Abstract:* Administered by HRSA's Bureau of Health Workforce (BHW), the NHSC SP, NHSC S2S LRP, and the NHHSP provide scholarships or loan repayment to qualified students who are pursuing primary care health professions education and training. In return, students agree to provide primary health care services in medically underserved communities located in federally designated Health Professional Shortage Areas once they are fully trained and licensed health professionals. Awards are made to applicants who demonstrate the greatest potential for successful completion of their education and training as well as commitment to provide primary health care services to communities of greatest need. The information from program applications, forms, and supporting documentation is used to select the best qualified candidates for these competitive awards, and to monitor program participants' enrollment in school, postgraduate training, and compliance with program requirements. The revisions to this information collection request include the removal of two forms for the NHSC S2S LRP application section.

Although some program forms vary from program to program (see program-specific burden charts below), required

forms generally include: A program application, academic and non-academic letters of recommendation, the authorization to release information, and the acceptance/verification of good standing report. Additional forms for the NHSC SP include the data collection worksheet, which is completed by the educational institutions of program participants; the post graduate training verification form (also applicable for NHSC S2S LRP participants), which is completed by program participants and their residency director; and the enrollment verification form, which is completed by program participants and the educational institution for each academic term.

*Need and Proposed Use of the Information:* The NHSC SP, S2S LRP, and NHHSP applications, forms, and supporting documentation are used to collect necessary information from applicants that will enable BHW to make selection determinations for the competitive awards, and to monitor compliance with program requirements.

*Likely Respondents:* Qualified students who are pursuing education and training in primary care health professions education and training, and are interested in working in health professional shortage areas.

*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 revision contributes to a reduction of burden of approximately 100 hours. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden—Hours