technical assistance is needed to help recipients improve their program implementation if necessary. In addition, the findings continue to allow CDC to determine the potential impact of currently recommended strategies and make changes to those recommendations if necessary. DASH was able to refine and target the technical assistance provided to recipient agencies to better ensure they completed their work plans and spent funds according to the original Notice of Funding Opportunity. The reporting template will include sections on the following topics: sexual health education (SHE), sexual health services (SHS), safe and supportive environments (SSE) required and additional activities. No personally identifiable information will be collected.

The estimated burden per response ranges from eight hours for Component 1 to 14 hours for Component 2. Recipients will complete the reporting templates every six months and the work plan templates once a year under this approval. Annualizing the collection over one year results in an estimated annualized burden of 3,320 burden hours for respondents. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Surveillance Recipients (Program Managers).	Promoting Adolescent Health through School-Based HIV/STD Prevention Component 1 Reporting Template and Work Plan.	80	3	8	1,920
Local education agency HIV prevention recipients (Program Managers).	Promoting Adolescent Health through School-Based HIV/STD Prevention Component 2 Reporting Template and Work Plans (required programmatic activities work plan and professional development work plan).	25	4	14	1,400
Total					3,320

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-24–1289]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Sealant Efficiency Assessment for Locals and States (SEALS)'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on June 5, 2023 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Sealant Efficiency Assessment for Locals and States (SEALS) (OMB Control No. 0920–1289)—Reinstatement—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

By age 19, 67% of U.S. adolescents living in poverty have experienced tooth decay and 27% have at least one decayed tooth needing treatment. School sealant programs provide dental sealants, which protect against 80% of cavities for two years, and continue to protect against 50% of cavities for up to

four years. CDC requests information from states regarding children's cavity risk, one-year sealant retention rate, sealant program services delivered, and school sealant program cost and quantity of resources used at each school event. This data will allow CDC and states to monitor the performance and efficiency of their school sealant programs, which will improve and extend program delivery to more children.

CDC requests OMB approval for a Reinstatement of a previously approved data collection. The total estimated annualized burden hours requested are 1,388. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State Sealant Administrator	Add Program and Add User	18	1	45/60
SSP Local Administrator	Add User and Add School	162	1	43/60
SSP Local Administrator	Program Options and Cost Options	162	1	46/60
SSP Local Administrator	Add Event	162	20	21/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4488]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2024

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the fee rates and payment procedures for fiscal year (FY) 2024 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Drug User Fee Amendments of 2023 (ADUFA V), authorizes FDA to collect user fees for certain animal drug applications and supplemental animal drug applications, for certain animal drug products, for certain establishments where such products are made, and for certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2024.

DATES: The application fee rates are effective for applications submitted on or after October 1, 2023, and will remain in effect through September 30, 2024.

FOR FURTHER INFORMATION CONTACT: Visit FDA's website at *https://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm* or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6888, *Lisa.Kable@fda.hhs.gov.* For general questions, you may also email FDA's Center for Veterinary Medicine (CVM) at: *cvmadufa@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 740 of the FD&C Act (21 U.S.C. 379j–12), as amended by ADUFA V, establishes four different types of user fees: (1) fees for certain types of animal drug applications and supplemental animal drug applications; (2) annual fees for certain animal drug products; (3) annual fees for certain establishments where such products are made; and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions (21 U.S.C. 379j–12(a)). When certain conditions are met, FDA will waive or reduce fees (21 U.S.C. 379j–12(d)).

For FYs 2024 through 2028, the FD&C Act establishes the base revenue amount for each fiscal year (21 U.S.C. 379j–12(b)(1)). Beginning in FY 2025, the base revenue amount is subject to adjustment for inflation and workload (21 U.S.C. 379j–12(c)(2) and (3)). Also beginning in FY 2025, ADUFA V provides for an operating reserve adjustment to allow FDA to adjust the fee revenue amount to maintain a specified operating reserve of carryover user fees (21 U.S.C. 379j–12(c)(4)). FDA may increase the fee revenue amount to maintain a 12-week minimum. If FDA has an excess operating reserve, FDA will decrease the fee revenue amount so that FDA has 22 weeks of operating reserve for FY 2025, 20 weeks for FY 2026, 18 weeks for FY 2027, and 16 weeks for FY 2028.

Fees for applications, establishments, products, and sponsors are to be established each year by FDA so that the percentages of the total revenue that are derived from each type of user fee will be as follows: (1) revenue from application fees shall be 20 percent of total fee revenue; (2) revenue from product fees shall be 27 percent of total fee revenue; (3) revenue from establishment fees shall be 26 percent of total fee revenue; and (4) revenue from sponsor fees shall be 27 percent of total fee revenue (21 U.S.C. 379jndash;12(b)(2)). The fee revenue amount for FY 2024 is $33,500,000 (21 U.S.C. 379j–12(b)(1)). The target revenue amounts for each fee category for FY 2024 are as follows: for application fees, the target revenue amount is $6,700,000; for product fees, the target revenue amount is $9,045,000; for establishment fees, the target revenue amount is $8,710,000; and for sponsor fees, the target revenue amount is $9,045,000.

For FY 2024, the animal drug user fee rates are: $683,673 for an animal drug application; $341,837 for a supplemental animal drug application for which safety or effectiveness data are required, for an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)), and for an application for conditional approval under section 571 of the FD&C Act (21 U.S.C. 360ccc) for which an animal drug application submitted under section 512(b)(1) of the FD&C Act has been previously approved under section 512(d)(1) of the FD&C Act for another intended use; $12,459 for the annual product fee; $174,200 for the annual establishment fee; and $153,305 for the annual sponsor fee. FDA will issue invoices for FY 2024 product, establishment, and sponsor fees by December 31, 2023, and payment will be due by January 31, 2024. The application fee rates are effective for applications submitted on or after October 1, 2023, and will remain in effect through September 30, 2024.