

Authority: 45 CFR 75.342; 45 CFR 75.301, Pub. L. 111–352, section 12.

Mary C. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2548]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Food and Egg Regulatory Program Standards

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: Submit written comments (including recommendations) on the collection of information by April 13, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0760. The docket number is FDA–2025–N–2548.

FOR FURTHER INFORMATION CONTACT: Patrick Clouser, Office of Operations, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20852, 240–402–5276, 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.

Animal Food and Egg Regulatory Program Standards

OMB Control Number 0910–0760—Extension

This information collection helps implement FDA’s Egg Regulatory Program Standards (ERPS) and Animal Food Regulatory Program Standards (AFRPS). The current submission seeks to revise this information collection

related to the ERPS. No revisions were made to the AFRPS.

Section 1012 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 399c) authorizes FDA to administer training and education programs for employees of State, local, Territorial, and Tribal food safety authorities relating to regulatory programs. Also, under section 205 of the FDA Safety Modernization Act (codified in 21 U.S.C. 2224), FDA, together with the Centers for Disease Control and Prevention is directed to enhance foodborne illness surveillance to improve the collection, analysis, reporting, and usefulness of data on foodborne illnesses. As part of this effort, we have initiated programs that include developing and instituting regulatory standards intended to reduce the risk of foodborne illness through coordinated efforts with our strategic partners. Regulatory program standards establish a uniform foundation for the design and management of State, local, Tribal, and Territorial programs that have the responsibility for regulating human and animal food. Partnering with other regulatory officials also helps maximize limited resources in administering FDA regulations pertaining to the manufacturing/processing, packing, or holding of food for consumption in the United States.

The ERPS identifies and includes resource and training material for the following ten standards: regulatory foundation; training program; inspection program; audit program; egg-related illness, outbreak and emergency response; compliance and enforcement program; outreach program; program planning and resources; assessment and improvement; and laboratory services. We recommend using the worksheets and forms contained in the standards, however, alternate forms that are equivalent may be used. The educational worksheets and resource materials include recordkeeping and reporting activities that help FDA verify participation and successful completion of the respective requirements. In the first year of enrollment, information is used to conduct a baseline self-assessment to determine whether the materials meet the elements of each standard. In subsequent years, we use the information to conduct a comprehensive review and evaluate program effectiveness and participation. We modify the program standards based on the ongoing assessments as well as comments and informal feedback obtained from participants. For more information, including access the program standards, we invite you to

visit our website at <https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/integrated-food-safety-system-ifss-programs-and-initiatives/regulatory-program-standards>.

In collaboration with the state governments, the FDA recently completed a revision of the egg regulatory standards that incorporated the most current knowledge and lessons learned in the application of the 2021 ERPS by state partners and program assessment by FDA. To improve program effectiveness, understanding and clarity, changes to the ERPS include those to program definitions, all 10 program standards, appendices and assessment worksheets that may be used by the states who have adopted the ERPS. Other changes include streamlining both the standards and appendices to be less prescriptive in nature. This process results in an overall reduction of appendices (most of which provided more program specific guidance or examples and therefore are not expected to change the burden) and a reformatting of the remaining appendices to be more uniform, succinct, and tabular in structure.

The ERPS is a critical component in establishing FDA’s IFSS. The ERPS, henceforth also referred to as “program standards,” establishes a uniform foundation for regulatory agencies responsible for oversight of eggs and egg products. When fully implemented, the program standards define a set of best practices of a regulatory system. The revised program standards are the result of external collaboration and coordination between FDA, the National Egg Regulatory Officials (NERO) and state governments in which we consider any formal comments received on the 2021 edition of the program standards. A copy of the revised program standards and accompanying worksheets and forms is available in the **Federal Register** docket for this notice.

In the **Federal Register** of August 22, 2025 (90 FR 41083), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received. Both comments were unrelated to the Paperwork Reduction Act.

Description of Respondents: Respondents are State Departments of Agriculture or Health regulatory officials who enroll in the AFRPS or ERPS (State or Territorial governments). Our respondent estimates are based on expected participation.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Type of respondents; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours ¹
State, local, Territorial, and/or Tribal Governments; submission of data elements to FDA consistent with ERPS	2	1	2	569	1,138
State, local, Territorial, and/or Tribal Governments; submission of data elements to FDA consistent with AFRPS	25	1	25	569	14,225
Total					15,363

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Type of respondents; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
State, local, Territorial and/or Tribal Governments; submission of data elements to FDA consistent with ERPS	2	10	20	40	800
State, local, Territorial and/or Tribal Governments; submission of data elements to FDA consistent with AFRPS	25	11	275	40	11,000
Total					11,800

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

To demonstrate conformance with the standards prior to and after enrollment in the grant programs, State and Territorial governments participating in the program standards (respondents) submit comprehensive program assessments and evaluations to their technical advisors at FDA using a dedicated email. The information required for these submissions is outlined in the provided worksheets. Additionally, the program standards require ongoing documentation to verify conformance. We base our estimates on the historical performance of these standards programs and informal consultation with the affected State and Territorial governments. We have consolidated our estimates to account for burden attributable to reporting tasks in the recordkeeping table.

Our estimated burden for the information collection reflects no change, as enrollment and participation in both programs remains steady.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-04940 Filed 3-12-26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1262]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher; EYLEA HD (afibercept)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the issuance of priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that the supplemental application (Supplement-10) for EYLEA HD (afibercept), approved November 19, 2025, meets the criteria for redeeming a priority review voucher.

FOR FURTHER INFORMATION CONTACT:

Quyên Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Room 5324, Silver Spring, MD 20993-0002, 301-796-2771, Quyên.Tran1@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the approval of a product redeeming a rare pediatric disease priority review voucher. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that the supplemental application (Supplement-10) for EYLEA HD (afibercept) meets the redemption criteria.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about EYLEA HD (afibercept), go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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