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.

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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 (aflibercept)

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 (aflibercept), approved November 19, 2025, meets the criteria for redeeming a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Quyen 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, *Quyen.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 (aflibercept) 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 (aflibercept), 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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