TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
10.19—request for waiver, suspension, or modification of requirements	2	1	2	1	2
10.30 and 10.31—citizen petitions and petitions related to ANDAs [2] certain NDAs,[3] or certain BLAs [4].	330	1	330	24	7,920
10.33—administrative reconsideration of action	13	1	13	10	130
10.35—administrative stay of action	28	1	28	10	280
10.65—meetings and correspondence	18	1	18	5	90
10.85—requests for Advisory opinions	3	1	3	16	48
10.115(f)(3)—submitting draft guidance proposals	1	1	1	4	4
12.22—Filing objections and requests for a hearing on a regulation or order.	15	1	15	20	300
12.45—Notice of participation	1	1	1	3	3
External requests for FDA speakers	3,900	1	3,900	0.17 (10 minutes)	663
Total			4,311		9,440

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Abbreviated New Drug Applications.
[3] New Drug Applications.
[4] Biologics License Applications.

Based on submissions to FDA's Division of Dockets Management since our last evaluation of the information collection, we have adjusted burden estimates associated with the individual activities that correspond to the applicable provisions. As a result, the information collection reflects an increase of 3,080 annual burden hours.

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

[FDA–2026–N–3058]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; LOARGYS (pegzilarginase-nbln)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. 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 award of the priority review voucher. FDA has determined that LOARGYS (pegzilarginase-nbln), approved February 23, 2026, manufactured by Immedica Pharma AB, meets the criteria for 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 issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined LOARGYS (pegzilarginase-nbln), manufactured by Immedica Pharma AB, meets the criteria for a priority review voucher. LOARGYS (pegzilarginase-nbln) injection is indicated for the treatment of hyperargininemia in adult and pediatric patients 2 years of age and older with Arginase 1 Deficiency (ARG1–D), in conjunction with dietary protein restriction.

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 LOARGYS (pegzilarginase-nbln), 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.

[FR Doc. 2026–06722 Filed 4–6–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Rural Health Care Services Outreach Program Measures, OMB No. 0906–0009—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than June 8, 2026.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 13N82, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–3983.