

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

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 <sup>2</sup> certain NDAs, <sup>3</sup> or certain BLAs <sup>4</sup> .	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10.115(f)(3)—submitting draft guidance proposals	1	1	1	4	4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
<b>Total</b>			<b>4,311</b>		<b>9,440</b>

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

<sup>2</sup> Abbreviated New Drug Applications.

<sup>3</sup> New Drug Applications.

<sup>4</sup> 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.*

[FR Doc. 2026–06719 Filed 4–6–26; 8:45 am]

**BILLING CODE 4164–01–P**

**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](mailto: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.*

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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](mailto: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](mailto:paperwork@hrsa.gov) or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the ICR title for reference.

*Information Collection Request Title:* Rural Health Care Services Outreach Program Measures, OMB No. 0906–0009—Revision.

*Abstract:* The Rural Health Care Services Outreach (Outreach) Program is authorized by section 330A(e) of the Public Health Service Act (42 U.S.C. 254c(e)) to “promote rural health care services outreach by improving and expanding the delivery of health care services to include new and enhanced services in rural areas.” HRSA currently collects information about Outreach grants using an OMB-approved set of performance measures and seeks to revise that approved collection. The proposed changes are a result of keeping this instrument relevant, responsive to the Outreach Program needs, and to improve clarity and ease of reporting for respondents.

The proposed changes include the consolidation of three sub-sections (Consortium/Network, Access to Care,

and Population Demographics) into two new sub-sections (Capacity/ Organizational Information and Access/ Population Demographics); the addition of nine new maternal health measures (four required measures; five optional measures) for the 11 award recipients in the Healthy Rural Hometown Initiative Track only; and adding one new question related to sustainability. Additionally, there is an increase in the estimated total burden hours compared to the previous ICR package. The increase in burden is to account for a new cohort of recipients new to this data collection. This includes 40 recipients funded under the Regular Outreach Track and 18 recipients funded under the Healthy Rural Hometown Initiative Track awarded under HRSA–25–038.

*Need and Proposed Use of the Information:* HRSA has revised the performance measures that Outreach awardees will submit to HRSA on an annual basis. The purpose of the revised data collection is to assess Outreach awardees’ progress in meeting the program goals and how well each

awardee meets their community needs. This allows HRSA to monitor and assess the impact of the Outreach program as a whole and ensure that funds are effectively used to provide services that meet the target population’s needs.

*Likely Respondents:* Respondents include all 58 Outreach award recipients.

*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 total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Rural Health Care Services Outreach Performance Measures .....	58	1	58	8.75	507.5
Total .....	58	1	58	8.75	507.5

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Maria G. Button,**

*Director, Executive Secretariat.*

[FR Doc. 2026–06671 Filed 4–6–26; 8:45 am]

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**INTERNATIONAL TRADE COMMISSION**

[Investigation Nos. 701–TA–791 and 731–TA–1779–1781 (Preliminary)]

**Oil Country Tubular Goods From Austria, Taiwan, and United Arab Emirates; Institution of Antidumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations**

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation Nos. 701–TA–791 and 731–TA–1779–1781 (Preliminary) pursuant to the Tariff Act of 1930 to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the

establishment of an industry in the United States is materially retarded, by reason of imports of oil country tubular goods from Austria, Taiwan, and United Arab Emirates, provided for in subheadings 7304.29.10, 7304.29.20, 7304.29.31, 7304.29.41, 7304.29.50, 7304.29.61, 7305.20.20, 7305.20.40, 7305.20.60, 7305.20.80, 7306.29.10, 7306.29.20, 7306.29.31, 7306.29.41, 7306.29.60, and 7306.29.81 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Government of Austria. Unless the Department of Commerce (“Commerce”) extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by May 18, 2026. The Commission’s views must be transmitted to Commerce within five business days thereafter, or by May 26, 2026.