

through an application to a NOFO requiring quarterly reporting.

Annual Burden Estimates

OCS anticipates including quarterly reporting requirements in NOFOs

published in FFY 2026 and later. Because CED projects are funded for 3- to 4-year project periods, OCS anticipates that only half of active grant recipients will be required to complete

the short-form during the extension period. These assumptions are reflected in the burden estimates below.

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
CED PPR	79	2	1.5	237
CED PPR Short Form	48	2	0.5	48
Estimated Total Annual Burden Hours				285

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Section 680(a)(2), Community Services Block Grant Act, 42 U.S.C. 9921.

Mary C. Jones,
ACF/OPRE Certifying Officer.

[FR Doc. 2025–16584 Filed 8–28–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2654]

Amylyx Pharmaceuticals, Inc.; Withdrawal of Approval of New Drug Application for RELYVRIO (Sodium Phenylbutyrate and Taurursodiol) for Suspension, 3 Gram/Package and 1 Gram/Package

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of the new drug application (NDA) for RELYVRIO (sodium phenylbutyrate and taurursodiol) for suspension, 3 gram (g)/packet and 1 g/packet, held by Amylyx

Pharmaceuticals, Inc. (Amylyx), 43 Thorndike St., Cambridge, MA 02141. Amylyx has voluntarily requested that FDA withdraw approval of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of August 29, 2025.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On September 29, 2022, FDA approved NDA 216660 for RELYVRIO (sodium phenylbutyrate and taurursodiol) for suspension, 3 g/packet and 1 g/packet, for the treatment of amyotrophic lateral sclerosis (ALS) in adults.

On April 30, 2024, Amylyx reported to the Agency that a Phase 3 Trial of AMX0035 for Amyotrophic Lateral Sclerosis Treatment (Study A35–004, also known as PHOENIX), a global, 48-week, randomized, placebo-controlled clinical trial of sodium phenylbutyrate and taurursodiol in patients living with ALS, did not meet its prespecified primary and secondary endpoints. On September 30, 2024, Amylyx notified the Agency they planned to discontinue marketing of RELYVRIO as of October 31, 2024. On October 31, 2024, FDA requested that the applicant submit a letter to voluntarily request withdrawal of approval of RELYVRIO (sodium phenylbutyrate and taurursodiol) for suspension, 3 g/packet and 1 g/packet, according to § 314.150(d) (21 CFR 314.150(d)) based on the results of the Phase 3 PHOENIX trial.

On February 28, 2025, Amylyx submitted a letter asking FDA to withdraw approval of NDA 216660 for RELYVRIO (sodium phenylbutyrate and taurursodiol) for suspension, 3 g/packet and 1 g/packet, according to

§ 314.150(d) and waiving its opportunity for a hearing. In its letter requesting withdrawal of approval, Amylyx stated that it is voluntarily requesting withdrawal based on results from the Phase 3 PHOENIX trial.

For the reasons discussed above, and in accordance with the applicant’s request, approval of NDA 216660 for RELYVRIO (sodium phenylbutyrate and taurursodiol) for suspension, 3 g/packet and 1 g/packet, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of RELYVRIO (sodium phenylbutyrate and taurursodiol) for suspension, 3 g/packet and 1 g/packet, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–16646 Filed 8–28–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1330]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Submissions of Medical Device Registration and Listing

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 September 29, 2025.

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 0910–0625. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, PRAStaff@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.

Electronic Submission of Medical Device Registration and Listing—21 CFR Part 807, Subparts A Through D

OMB Control Number 0910–0625—Extension

This information collection supports FDA statutes and regulations. Under section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360) and part 807, subparts A through D (21 CFR part 807, subparts A, B, C, and D), medical device establishment owners and operators are required to electronically submit establishment registration and device listing information. Complete and accurate registration and listing information is necessary to accomplish a number of statutory and regulatory objectives, such as: (1) Identification of establishments producing marketed medical devices, (2) identification of establishments producing a specific device when that device is in short supply or is needed for national emergency, (3) facilitation of recalls for devices marketed by owners and operators of device establishments, (4) identification and cataloguing of marketed devices, (5) administering post marketing surveillance programs for devices, (6) identification of devices marketed in violation of the law, (7) identification

and control of devices imported into the country from foreign establishments, (8) and scheduling and planning inspections of registered establishments under section 704 of the FD&C Act (21 U.S.C. 374).

Respondents to this information collection are owners or operators of establishments that engage in the manufacturing, preparation, propagation, compounding, or processing of a device or devices, who must register their establishments and submit listing information for each of their devices in commercial distribution. Notwithstanding certain exceptions, foreign device establishments that manufacture, prepare, propagate, compound, or process a device that is imported or offered for import into the United States must also comply with the registration and listing requirements. The number of respondents is based on data from the FDA Unified Registration and Listing System (FURLS).

In the **Federal Register** of June 20, 2025 (90 FR 26304), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR part FDA form number	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
807.20(a)(5) ² Initial Submittal of Manufacturer Information by Initial Importers (FDA 3673)	2,219	1	2,219	1.75	3883
807.20(a)(5) ³ Annual Submittal of Manufacturer Information by Initial Importers (FDA 3673)	2,219	1	2,219	0.1	222
807.21(a) ² Creation of electronic system account (FDA 3673)	8,876	1	8,876	0.5	4,438
807.21(b) ³ Annual Request for Waiver from Electronic Registration & Listing	1	1	1	1	1
807.21(b) ² Initial Request for Waiver from Electronic Registration & Listing	1	1	1	1	1
807.22(a) ² Initial Registration & Listing (FDA 3673)	2,106	1	2,106	1	2,106
807.22(b)(1) ³ Annual Registration (FDA 3673)	30,280	1	30,280	0.5	15,140
807.22(b)(2) ³ Other updates of Registration (FDA 3673)	3,906	1	3,906	0.5	1,953
807.22(b)(3) ³ Annual Update of Listing Information (FDA 3673)	28,925	1	28,925	0.5	14,463
807.22(b)(4) Changes to listing information (outside of annual listing requirement period): Voluntary reporting of transfer of 510(k) clearance in FURLS (outside of annual listing requirement period)	4,080	1	4,080	0.25	1,020
Submission of 510(k) transfer documentation when more than one party lists the same 510(k)	2,033	1	2,033	4	8,132
807.26(e) ³ Labeling & Advertisement Submitted at FDA Request	1	1	1	1	1
807.34(a) ² Initial Registration & Listing when Electronic Filing Waiver Granted	1	1	1	1	1
807.34(a) ³ Annual Registration & Listing when Electronic Filing Waiver granted	1	1	1	1	1
807.40(b)(2) ³ Annual Update of US Agent Information (FDA 3673)	3,410	1	3,410	0.5	1,705
807.40(b)(3) ³ US Agent Responses to FDA Requests for Information (FDA 3673)	1,535	1	1,535	0.25	384

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—Continued

21 CFR part FDA form number	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
807.41(a) ³ Identification of initial importers defined in 21 CFR 807.3(g) by foreign establishments (FDA 3673)	2,955	1	2,955	0.5	1,478
807.41(b) ³ Identification of other importers (defined in 21 CFR 807.3(x) and (y) that facilitate import by foreign establishments (FDA 3673)	3,234	1	3,234	0.5	1,617
Total					56,546

¹ Totals are rounded to the nearest whole number.
² One Time Burden—Firm only provides initially.
³ Recurring Burden—Firm is required to review annually.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
807.25(d) ² List of Officers, Directors & Partners	22,338	1	22,338	.25	5,585
807.26 ² Labeling & Advertisements Available for Re- view	17,032	4	68,128	.5	34,064
Total					39,649

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.
² Recurring burden—Firm is required to keep records.

Our estimated burden for the information collection reflects an overall decrease of 17,637 hours and a corresponding decrease of 34,526 responses. Burden estimates are based on recent registration and listing information collected from establishments registering for the first time (initial registration) and establishments re-registering. We attribute this adjustment to a decrease in the number of submissions we received over the last approval period.

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: Ryan White HIV/AIDS Program (RWHAP) Parts A and B Unobligated Balances and Rebate Addendum Tables, OMB No. 0906–0047—Extension

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 October 28, 2025.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 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.

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

Information Collection Request Title: Ryan White HIV/AIDS Program Parts A and B Unobligated Balances and Rebate Addendum Tables, OMB No. 0906–0047—Extension.

Abstract: HRSA’s Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states and territories, and local clinics/community-based organizations to deliver efficient and effective HIV care, treatment, and support to low-income people diagnosed with HIV. Nearly two-thirds of RWHAP clients (patients) live at or below 100 percent of the federal poverty level (FPL). Since 1990, RWHAP has developed a comprehensive system of HIV service providers who deliver high quality direct health care and support services to over half a million people with diagnosed HIV—more than 50 percent of all people with diagnosed HIV in the United States.

Grant recipients funded under RWHAP Parts A, B, C, and D (codified under Title XXVI of the Public Health Service Act) are required to report financial data to HRSA at the beginning (Allocations Report) and at the end of each grant budget period (Expenditures Report) using the designated HRSA grant submission software which is approved by OMB under the 0915–0318 control number. HRSA collects unobligated balances (UOB) of federal funds and rebate addendum information by subprogram from their grant recipients. A UOB is the cumulative amount that is available for obligation in an unexpired account. HRSA uses the UOB and rebate addendum financial information to determine formula funding as directed by the RWHAP