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]

BILLING CODE 4184–27–P

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/Packet and 1 Gram/Packet

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DATES: Approval is withdrawn as of August 29, 2025.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

BILLING CODE 4164–01–P

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