4164-01-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DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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.

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