4-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-5852]

Sage Therapeutics, Inc.; Withdrawal of Approval of a New Drug Application for ZULRESSO (Brexanolone) Solution, 100 Milligrams/20 Milliliters

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of a new drug application (NDA) for ZULRESSO (brexanolone) solution, 100 milligrams (mg)/20 milliliters (mL), held by Sage Therapeutics, Inc., 55 Cambridge Parkway, Cambridge, MA 02142 (Sage). Sage notified the Agency in writing that the drug product was no longer marketed and requested that the approval of the application be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Sage has informed FDA that ZULRESSO (brexanolone) solution, 100 mg/20 mL, is no longer marketed and has requested that FDA withdraw approval of NDA 211371 under the process in § 314.150(c) (21 CFR 314.150(c)). Sage has also, by its request, waived its opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Therefore, approval of NDA 211371, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Approval of the entire application is withdrawn, including any

strengths and dosage forms included in the application but inadvertently missing from this notice. Introduction or delivery for introduction into interstate commerce of ZULRESSO (brexanolone) solution, 100 mg/20 mL, without an approved NDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Any ZULRESSO (brexanolone) solution, 100 mg/20 mL, that is in inventory on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: March 7, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

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