NDA 211635/S-10

TENTATIVE APPROVAL

Neurelis, Inc.
c/o Pacific-Link Consulting
Attention: Richard E. Lowenthal, MS, MSA (MSEL)
President and U.S. Agent
8195 Run of the Knolls Court
San Diego, CA 92127

Dear Richard E. Lowenthal:

Please refer to your supplemental new drug application (sNDA) dated and received December 20, 2023, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for (FD&C Act) Valtoco (diazepam) nasal spray.

This supplemental NDA provides for the use of Valtoco (diazepam) nasal spray for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 2 years of age (b) (4)

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105(a); therefore, this application is not approved and will not be approved until FDA issues an approval letter after any necessary additional review of the application. Enclosed are the tentatively approved labeling (text for the Prescribing Information and Medication Guide) and the February 2022, approved Instructions for Use. This tentative approval determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

Under section 527(a) of the FD&C Act, orphan-drug exclusivity prevents FDA from approving or licensing the same drug for the same use or indication for a person who is not the holder of such approved application or of such license until the expiration of seven years from the date of approval or licensure. Aquestive Therapeutics Inc.'s product, Libervant (diazepam) buccal film, has orphan-drug exclusivity, which blocks final approval of NDA 211635/S-010 for Valtoco (diazepam) nasal spray until Libervant's orphan-drug exclusivity expires on April 26, 2031.

To obtain final approval of this application, submit an amendment two or six months prior to the date you believe that your NDA will be eligible for final approval, as

appropriate. In your cover letter, clearly identify your amendment as **"REQUEST FOR FINAL APPROVAL"**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this supplemental NDA is not approved, and the use of the enclosed tentatively approved labeling is not permitted for marketing the drug product. If you believe that there are grounds for issuing the final approval letter before the expiration of the exclusivity protection, you should amend your application accordingly.

If you have any questions, contact Harold Sano, PharmD, Regulatory Project Manager, by email at harold.sano@fda.hhs.gov or by telephone at (301) 796-2429.

Sincerely,

{See appended electronic signature page}

Paul R. Lee, MD, PhD, MA
Director (Acting)
Division of Neurology 2
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S): (tentatively approved)

- Content of Labeling
  - Prescribing Information; tentative approval
  - Medication Guide; tentative approval
  - Instructions for Use (2); last approved 2/2022

29 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

PAUL R LEE
12/18/2024 11:15:01 AM