U.S. FOOD & DRUG ADMINISTRATION

NDA 212641

TENTATIVE APPROVAL

Aquestive Therapeutics
Attention: Melina Cioffi, PharmD
Vice President, Regulatory Affairs
30 Technology Drive
Warren, NJ 07059

Dear Dr. Cioffi:

Please refer to your new drug application (NDA) dated November 27, 2019, received under rolling review May 31, 2019, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Libervant (diazepam) buccal film.

We also refer to the Complete Response letter dated September 25, 2020, and your resubmission dated and received on June 23, 2021, which constituted a complete response to our September 25, 2020, action letter.

This NDA provides for the use of Libervant (diazepam) buccal film (b) (4)

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed-upon enclosed labeling (text for the Prescribing Information, Instructions for Use, and Medication Guide) and submitted labeling (carton and container labeling submitted October 11, 2021, and received October 12, 2021). This 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 (cGMPs) of the facilities used in the manufacture and testing of the drug product]. This determination is subject to change on the basis of any new information that may come to our attention.

The Orphan Drug provisions of the FD&C Act, 21 U.S.C. §§ 360aa-360dd, provide for a grant of seven years of market exclusivity to which a period of pediatric exclusivity may attach. Orphan drug exclusivity blocks approval of any other application for the same drug for the same indication or use. Due to the orphan exclusivity granted to Neurelis Inc., Valtoco, your application for Libervant may not be finally approved for marketing under section 505 of the FD&C Act until the period has expired.

To obtain final approval of this application, submit an amendment two or six months prior to the: (1) expiration of the exclusivity protection or (2) 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 NDA is not approved.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

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

Sincerely,

{See appended electronic signature page}

Nick Kozauer, MD
Director
Division of Neurology 2
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):
- Content of Labeling

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/

NICHOLAS A KOZAUER
08/30/2022 11:30:10 AM