

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**210833Orig1s000**

**OTHER ACTION LETTERS**



NDA 210833

**TENTATIVE APPROVAL**

Aquestive Therapeutics  
Attention: Rikin Mehta, PharmD, JD, LLM  
Head of Regulatory Affairs  
30 Technology Drive  
Warren, NJ 07059

Dear Dr. Mehta:

Please refer to your New Drug Application (NDA) dated October 31, 2017, received October 31, 2017, and to your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Sympazan (clobazam) oral film, 5 mg, 10 mg, and 20 mg.

This NDA provides for the use of Sympazan (clobazam) oral film for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients 2 years of age or older.

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 and Medication Guide) and submitted labeling (carton and immediate container labels submitted July 27, 2018). 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 Federal Food, Drug, and Cosmetic 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. Due to the orphan exclusivity granted to Lundbeck Pharmaceuticals' products, Onfi (clobazam) tablets and oral suspension, your application for Sympazan (clobazam) oral film may not be finally approved for marketing under Section 505 of the 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 deemed approved.

Please note that this drug product may not be marketed in the United States without final agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d).

### **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.

We note that if this application is ultimately approved, you will need to meet these requirements.

If you have any questions, call E. Andrew Papanastasiou, Regulatory Project Manager, at (301) 796-1930.

Sincerely,

*{See appended electronic signature page}*

Eric Bastings, MD  
Deputy Director  
Division of Neurology Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

ENCLOSURE:  
Content of Labeling

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

-----  
**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/  
-----

ERIC P BASTINGS  
08/31/2018