CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

210833Orig1s000

Trade Name: Sympazan Oral Film, 5mg, 10mg, and 20mg

Generic or Established: clobazam

Sponsor: Aquestive Therapeutics

Approval Date: November 1, 2018

Indication: For the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome in patients 2 years of age or older.
## CONTENTS

Reviews / Information Included in this NDA Review.

<table>
<thead>
<tr>
<th>Item</th>
<th>Included</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Letter</td>
<td>X</td>
</tr>
<tr>
<td>Other Action Letters</td>
<td>X</td>
</tr>
<tr>
<td>Labeling</td>
<td>X</td>
</tr>
<tr>
<td>REMS</td>
<td></td>
</tr>
<tr>
<td>Summary Review</td>
<td>X</td>
</tr>
<tr>
<td>Officer/Employee List</td>
<td>X</td>
</tr>
<tr>
<td>Office Director Memo</td>
<td></td>
</tr>
<tr>
<td>Cross Discipline Team Leader Review</td>
<td></td>
</tr>
<tr>
<td>Clinical Review(s)</td>
<td>X</td>
</tr>
<tr>
<td>Product Quality Review(s)</td>
<td>X</td>
</tr>
<tr>
<td>Non-Clinical Review(s)</td>
<td></td>
</tr>
<tr>
<td>Statistical Review(s)</td>
<td></td>
</tr>
<tr>
<td>Clinical Microbiology / Virology Review(s)</td>
<td></td>
</tr>
<tr>
<td>Clinical Pharmacology Review(s)</td>
<td>X</td>
</tr>
<tr>
<td>Other Reviews</td>
<td>X</td>
</tr>
<tr>
<td>Risk Assessment and Risk Mitigation Review(s)</td>
<td></td>
</tr>
<tr>
<td>Proprietary Name Review(s)</td>
<td></td>
</tr>
<tr>
<td>Administrative/Correspondence Document(s)</td>
<td></td>
</tr>
</tbody>
</table>
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210833Orig1s000

APPROVAL LETTER
Dear Dr. Mehta:

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

We acknowledge receipt of your amendment dated September 11, 2018, which constituted a response to our August 31, 2018, action letter.

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

**APPROVAL & LABELING**

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

**WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS**

We acknowledge your request to waive the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. As previously discussed with you, we are denying your request.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Instructions for Use, and Medication Guide) as well as annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in the

The SPL will be accessible via publicly available labeling repositories.

**CARTON AND CONTAINER LABELING**

Submit final printed carton and container labeling that are identical to the carton and container labeling submitted on September 21, 2018, with the expiration date format (i.e., MMMYYYY) as stated in your letter dated October 22, 2018, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (April 2017, Revision 4). For administrative purposes, designate this submission “Final Printed Carton and Container Labeling for approved NDA 210833.” Approval of this submission by FDA is not required before the labeling is used.

**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.

This product is appropriately labeled for use in pediatric patients 2 to 17 years of age for this indication. Studies for pediatric patients ages 0 to less than 2 years of age are waived. Therefore, no additional studies are needed in pediatric patients.

**PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the Prescribing Information, Medication Guide, and Patient Package Insert (as applicable) to:

OPDP Regulatory Project Manager  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft

Reference ID: 4343772

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Harold Sano, Regulatory Project Manager, at (301) 796-2429.

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

ENCLOSURES:
Content of Labeling
Prescribing Information
Medication Guide
Instructions for Use
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
11/01/2018