



NDA 212028/S-006

## **SUPPLEMENT APPROVAL/ FULFILLMENT OF POSTMARKETING REQUIREMENTS**

Eisai Inc.  
Attention: Eleanor Panico, M.Eng  
Director, Regulatory Affairs  
200 Metro Boulevard  
Nutley, NJ 07110

Dear Ms. Panico:

Please refer to your supplemental new drug application (sNDA) dated and received January 11, 2022, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dayvigo (lemborexant) tablets.

This Prior Approval supplemental new drug application, submitted in response to our January 4, 2022, Prior Approval supplement request letter, provides for revisions to Highlights and Section 12.3 (Pharmacokinetics) based upon results of your postmarketing requirement studies.

### **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.

### **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 FDA.gov.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

industry *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup> The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

### **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 none of these criteria apply to your application, you are exempt from this requirement.

### **FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)**

We have received your submission dated October 28, 2020 and December 28, 2020 containing the final reports for the following postmarketing requirements listed in the December 20, 2019 approval letter.

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|--------|---|
| 3753-3 | Conduct an in vitro DDI study to assess the potential of lemborexant as a P-gp substrate at clinically relevant concentrations. Design and conduct the study in accordance with the FDA Guidance for Industry entitled "In Vitro Metabolism- and Transporter- Mediated Drug-Drug Interaction Studies."        |
| 3753-2 | Conduct an in vitro DDI study to assess the potential of lemborexant and its metabolites as an inducer for CYP2C8, CYP2C9 and CYP2C19. Design and conduct the study in accordance with the FDA Guidance for Industry entitled "In Vitro Metabolism- and Transporter- Mediated Drug-Drug Interaction Studies." |

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<sup>2</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

We have reviewed your submissions and conclude that the above requirements were fulfilled.

We remind you that there are postmarketing requirements listed in the December 20, 2019, approval letter that are still open.

### **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, contact Pawanprit (Pinky) Singh, Regulatory Project Manager, at [pawanprit.singh@fda.hhs.gov](mailto:pawanprit.singh@fda.hhs.gov) or 240-402-8866.

Sincerely,

*{See appended electronic signature page}*

Tiffany R. Farchione, MD  
Director  
Division of Psychiatry  
Office of Neuroscience  
Center for Drug Evaluation and Research

#### ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide

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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.**  
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/s/  
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