

BLA 761269/S-011

**SUPPLEMENT APPROVAL  
FULFILLMENT OF POSTMARKETING  
REQUIREMENT**

Eisai, Inc.  
Attention: Stacie P. O'Sullivan  
Director, Global Regulatory Strategy  
200 Metro Boulevard  
Nutley, NJ 07110

Dear Stacie P. O'Sullivan:

Please refer to your supplemental biologics license application (sBLA) received June 30, 2025, and your amendments, submitted under section 351(a) of the Public Health Service Act for Legembi (lecanemab-irmb) injection for intravenous use.

This Prior Approval sBLA provides for the fulfillment of PMR 4384-3 and revisions to Subsection 12.6 (Immunogenicity) of the Prescribing Information based on the final report for PMR 4384-3.

**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, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov,<sup>1</sup> that is identical to the enclosed labeling (text for the Prescribing Information and Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements.

Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

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

<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>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] 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).

### **FULFILLMENT OF POSTMARKETING REQUIREMENT**

Your June 30, 2025, submission contains the final report for the following postmarketing requirement listed in the January 6, 2023, approval letter for BLA 761269.

4384-3      Using the improved and validated assays developed in response to PMR 4384-2, evaluate the impact of ADA and NAb on the pharmacokinetics, pharmacodynamics, safety, and efficacy of lecanemab-irmb in patients enrolled in the confirmatory study.

We have reviewed your submission and conclude that the above requirement was fulfilled.

This closes all your postmarketing requirements acknowledged in our January 6, 2023, approval letter. You are not required to report on the status of closed (released or fulfilled) PMRs/PMC in your annual report required under 21 CFR 601.70.

We remind you that there are postmarketing requirements listed in the July 6, 2023, approval letter for BLA 761269/S-001 that are still open.

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, contact Taura Holmes, PharmD, MS, Senior Regulatory Project Manager, at [Taura.Holmes@fda.hhs.gov](mailto:Taura.Holmes@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Emily Freilich, MD  
Director  
Division of Neurology 1  
Office of Neuroscience  
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide (last approved 8/2025)
  - Instructions for Use (Leqembi Iqlik, last approved 8/2025)

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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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EMILY R FREILICH  
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