

BLA 761089/S-31

SUPPLEMENT APPROVAL

Teva Pharmaceuticals USA, Inc.
Attention: Poorva Chiddarwar
Senior Manager Global Regulatory Affairs
145 Brandywine Parkway
West Chester, PA 19380

Dear Poorva Chiddarwar:

Please refer to your supplemental biologics license application (sBLA) received February 5, 2025, and your amendments, submitted under section 351(a) of the Public Health Service Act for Ajovy (fremanezumab) solution for injection.

This Prior Approval supplemental biologics license application provides for the preventive treatment of episodic migraine in pediatric patients who are 6 to 17 years of age and who weigh 45 kg or more.

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.

This supplement provides for pediatric labeling text pursuant to the Pediatric Research Equity Act (PREA). This approval is in response to a PREA PMR.

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,¹ that is identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, and Instructions for Use) 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*.²

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

² 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).

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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

As discussed further below, we note that pediatric study requirement for PMR 3485-3 for this application is partially fulfilled.

FULFILLMENT OF POSTMARKETING REQUIREMENTS

We have received your submissions dated May 29, 2018; October 14, 2022; and February 5, 2025, containing the final reports for the following postmarketing requirements listed in the September 14, 2018, approval letter.

- 3485-1 A juvenile animal toxicology study in one species.
- 3485-2 An open-label pharmacokinetic, safety, and tolerability study in pediatric migraine patients ages 6 through 11 years, with an optional open-label safety extension phase (40 weeks).

We have reviewed your submissions and conclude the above requirements have been fulfilled for PMRs 3485-1 and 3485-2.

We note that you have partially fulfilled the pediatric study requirement for PMR 3485-3 below.

- 3485-3 Deferred pediatric randomized, double-blind, placebo-controlled efficacy and safety study under PREA for the preventive treatment

of episodic migraine in children and adolescents ages 6 through 17 years. This study includes a double-blind treatment phase (12 weeks) and an open-label safety extension phase (40 weeks). This study is to be submitted as a special protocol assessment (SPA).

We remind you of your ongoing obligation with respect to pediatric patients who are 6 to 17 years of age and who weigh less than 45 kg; and we understand that you intend to develop an appropriate strength and presentation to support dosing and administration in this pediatric subpopulation.

We also remind you that in addition to PMR 3485-3, there are other postmarketing requirements listed in the September 14, 2018, approval letter that are still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.³

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 601.12(f)(4)]. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵

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).

³ For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

If you have any questions, contact Lyal Tressler, Regulatory Project Manager by email at lyal.tressler@fda.hhs.gov or by telephone at (240) 402-0434.

Sincerely,

{See appended electronic signature page}

Laura Jawidzik, MD
Director (Acting)
Division of Neurology 2
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
 - Prescribing Information
 - Patient Package Insert
 - 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/

LAURA A JAWIDZIK
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