



NDA 205437/S-011

## SUPPLEMENT APPROVAL

Amgen Inc.  
Attention: Sarah Wilczynski, MS, RAC, PMP  
Manager, Regulatory Affairs  
One Amgen Drive  
Mail Stop 27-2-D  
Thousand Oaks, CA 91320-1799

Dear Ms. Wilczynski:

Please refer to your supplemental new drug application (sNDA) dated February 19, 2021, received February 19, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Otezla (apremilast) tablets.

This Prior Approval supplemental new drug application provides for changes to the Indication and Usage, and Clinical Studies sections of the labeling to include data for subjects with mild to moderate plaque psoriasis, and to allow for an expansion of the indication to include adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy. Additionally, a subsection entitled "Hypersensitivity" was added under the Warnings and Precautions section of the label.

### **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), with the addition of any labeling changes in pending "Changes Being Effectuated" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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

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>

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.

We are waiving the pediatric study requirements for patients less than 6 years of age because the necessary studies are impossible or highly impracticable.

We are deferring submission of your pediatric studies for ages 6 to 17 years of age (inclusive), because this product is ready for approval for use in adults and pediatric studies have not been completed.

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) is required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(4)(C) of the Federal Food, Drug, and Cosmetic Act. This required study is listed below.

4207-1 A Phase 3, multicenter, open-label study to assess the safety of apremilast in approximately 50 pediatric subjects (6 through 17 years of age, inclusive) with mild-to-moderate plaque psoriasis

Final Protocol Submission: 01/2024

Study Completion: 12/2026

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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>.

Final Report Submission: 09/2027

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.<sup>3</sup>

Submit the protocol(s) to your IND 070270, with a cross-reference letter to this NDA. Reports of this required pediatric postmarketing study must be submitted as an NDA or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from this study. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

### **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 Dawn Williams, Safety Regulatory Project Manager, at (301)796-5376.

Sincerely,

*{See appended electronic signature page}*

Tatiana Oussova, MD, MPH  
Deputy Director for Safety  
Division of Dermatology and Dentistry  
Office of Immunology and Inflammation  
Office of New Drugs  
Center for Drug Evaluation and Research

#### ENCLOSURE:

- Content of Labeling
  - Prescribing Information
  - Carton and Container Labeling

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<sup>3</sup> See the guidance for Industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (October 2019)*.

<https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

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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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TATIANA OUSSOVA  
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