

BLA 761197/S-002

## SUPPLEMENT APPROVAL

Genentech, Inc.  
Attention: Meike Lorenz-Candlin, PhD  
Regulatory Program Management  
1 DNA Way  
South San Francisco, CA 94080-4990

Dear Dr. Lorenz-Candlin:

Please refer to your supplemental biologics license application (sBLA), dated and received April 6, 2022, submitted under section 351(a) of the Public Health Service Act for SUSVIMO™ (ranibizumab injection). This Prior Approval supplemental biologics application provides for updates to the SUSVIMO Prescribing Information regarding the risk of septum dislodgement.

### **APPROVAL & LABELING**

We have completed our review of this application. 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, Instructions for Use, 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>

The SPL will be accessible via publicly available labeling repositories.

### **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).

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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>.

If you have any questions regarding this supplement, call Derek Alberding, Clinical Analyst, at (240) 402-0963.

Sincerely,

*{See appended electronic signature page}*

Wiley A. Chambers, MD  
Director  
Division of Ophthalmology  
Office of Specialty Medicine  
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use

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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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