BLA 125156/S-128

SUPPLEMENT APPROVAL

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

Dear Dr. Vonasek:

Please refer to your supplemental biologics license application (sBLA), dated and received January 19, 2024, and your amendments, submitted under section 351(a) of the Public Health Service Act for LUCENTIS® (ranibizumab injection). This Prior Approval sBLA provides for the addition of a new warning for retinal vasculitis with or without occlusion in the WARNINGS AND PRECAUTIONS and PATIENT COUNSELING INFORMATION sections of the Prescribing Information.

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,[1] that is identical to the enclosed labeling (text for the Prescribing Information) 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]

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).

[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.

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.

If you have any questions, call Lois Almoza, Senior Regulatory Project Manager at (240) 402-5146.

Sincerely,

{See appended electronic signature page}

William M. Boyd, MD
Deputy Director
Division of Ophthalmology
Office of Specialty Medicine
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
    - Prescribing Information

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/

WILLIAM M BOYD
02/15/2024 12:37:52 PM