BLA 125387/S-060

APPROVAL LETTER

Regeneron Pharmaceuticals, Inc.
Attention: Candace Drumma
Senior Manager Cmc Regulatory Affairs
81 Columbia Turnpike, Bldg 85
Rensselaer, NY 12144

Dear Ms. Drumma:

Please refer to your Supplemental Biologics License Application (sBLA) dated and received April 12, 2019, and your amendments, submitted under section 351(a) of the Public Health Service Act for Eylea (aflibercept) injection, 2 mg/0.05 mL.

We acknowledge receipt of your amendment dated April 12, 2019, which constituted a complete response to our October 15, 2018, action letter.

This Prior Approval supplemental biologics license application provides for the addition of a new sterile 2 mg/0.05 mL single-dose pre-filled syringe (PFS) presentation for aflibercept drug product. [redacted]

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, 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 titled *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

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 MS Word format that includes the changes approved in this supplemental application.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels submitted on October 9, 2018 and trade carton labeling submitted on July 24, 2019 as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved BLA 125387/S-060.**" Approval of this submission by FDA is not required before the labeling is used.

This information will be included in your biologics license application file.

If you have any questions, call Andrew Shiber, Regulatory Business Process Manager, at (301) 796 - 4798.

Sincerely,

{See appended electronic signature page}

Kathleen A. Clouse, Ph.D.
Director
Division of Biotechnology Review and Research I
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling
Carton and Container Labeling