



BLA 761097/S-001

SUPPLEMENT APPROVAL

Regeneron Pharmaceuticals, Inc.
Attention: Laura Simpson, PhD
Senior Director, Regulatory Affairs
777 Old Saw Mill River Rd
Tarrytown, NY 10591

Dear Dr. Simpson:

Please refer to your Supplemental Biologics License Application (sBLA) dated and received September 28, 2018, and your amendments, submitted under section 351(a) of the Public Health Service Act for Libtayo (cemiplimab-rwlc) injection.

This “Chang Being Effected” supplemental biologics license application provides for an update to remove the 250 mg/5 mL (50 mg/mL) dosage formulation from the Prescribing Information, container label, carton labeling, and Module 3.2.P.

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.

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).

If you have any questions, call Anh-Thy Ly, Regulatory Business Process Manager, at (240) 402 - 1001.

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:
Content of Labeling



Kathleen
Clouse Strebel

Digitally signed by Kathleen Clouse Strebel
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