



BLA 761099/S-012

SUPPLEMENT APPROVAL

Pfizer Inc.
Attention: Melissa Nguyen
Senior Manager, Pfizer Global Regulatory Sciences
275 North Field Drive, Bldg. H1
Lake Forest, IL 60045

Dear Melissa Nguyen:

Please refer to your supplemental biologics license application (sBLA) dated and received February 29, 2024, and your amendment, submitted under section 351(k) of the Public Health Service Act for Zirabev (bevacizumab-bvzr) injection.

This Prior Approval sBLA provides for a change to the USPI to extend the in-use storage time for the diluted Zirabev in 0.9% sodium chloride solution from 8 hours to 16 days at 2-8°C.

APPROVAL & LABELING

We have completed our review of this sBLA, 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](https://www.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 Effectuated" (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 Effectuated" (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, contact Kristine Leahy, Sr. Regulatory Business Process Manager, at Kristine.Leahy@fda.hhs.gov or call (240) 402 – 5834.

Sincerely,

{See appended electronic signature page}

Rapti Madurawe, Ph.D.
Director
Division of Product Quality Assessment XVI
Office of Product Quality Assessment III
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:

- Content of Labeling
 - Prescribing Information



Rapti
Madurawe

Digitally signed by Rapti Madurawe

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