



BLA 125320/S-221

SUPPLEMENT APPROVAL

Amgen Inc
Attention: Asif Tejpar
Senior Manager, Regulatory Affairs CMC
One Amgen Center Drive
Mail Stop: 27-2-D
Thousand Oaks, CA 91320-1799

Dear Asif Tejpar:

Please refer to your supplemental biologics license application (sBLA) dated and received December 2, 2024, and your amendments, submitted under section 351(a) of the Public Health Service Act for Xgeva and Prolia (denosumab) injection.

This Prior Approval supplemental biologics license application provides for:

- Modified drug substance and drug product stability protocols with reduced testing frequency
- Extension of the Prolia and Xgeva drug product shelf life from 36 months to 48 months per stability protocol
- Extension of the room temperature storage period from 14 to 30 days (with corresponding changes to labeling) for Prolia and Xgeva

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 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 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.

If you have any questions, contact Anita Brown, Sr. Regulatory Business Process Manager, at Anita.Brown@fda.hhs.gov or (301) 796 - 2066.

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(s):

Content of Labeling

- Prescribing Information
- Medication Guide



Rapti
Madurawe

Digitally signed by Rapti Madurawe

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