BLA 125293/S-116

SUPPLEMENT APPROVAL

Horizon Therapeutics Ireland DAC
Attention: Bharath Perumandla
Senior Manager, Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Dear Bharath Perumandla:

Please refer to your supplemental biologics license application (sBLA) dated and received June 29, 2026, submitted under section 351(a) of the Public Health Service Act for Krystexxa (pegloticase) injection.

This "Changes Being Effected" supplemental biologics license application provides for the submission of the revised Medication Guide.

APPROVAL & LABELING

We have completed our review of this sBLA. 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 (Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

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.*[2]

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

[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

[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 Kristi De Lisle, MS, BSN, RN, Regulatory Business Process Manager, at Kristi.Delisle@fda.hhs.gov or (301) 796 – 8013.

Sincerely,

{See appended electronic signature page}

Patrick Lynch, PhD for
Joel Welch, PhD
Director
Office of Product Quality Assessment III
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

- Content of Labeling
    - Medication Guide

Patrick Lynch

Digitally signed by Patrick Lynch
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