



NDA 210493/S-002

APPROVAL LETTER

Helsinn Healthcare SA
c/o Helsinn Therapeutics Us Inc
Attention: Jason Najdzinowicz
170 Wood Avenue South, 5th Floor
Iselin, NJ 08830

Dear Mr. Najdzinowicz:

Please refer to your Supplemental New Drug Application (sNDA) dated November 28, 2019, received November 29, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Akynzeo (fosnetupitant and palonosetron) Injection.

This Prior Approval supplemental new drug application provides for:

- Addition of a new dosage form (AKYNZEO injection), which is a solution in a single dose 20 mL vial for intravenous infusion.
- Addition of a new site of manufacture for the new formulation, Baxter Oncology GmbH (Baxter), Halle/Westfalen, Germany [FEI: 3002806419].
- Changes to the drug product specifications:
 - Change in appearance from lyophilized cake to solution
 - Change in the Assay specification from 90.0 – 110.0% at time of release to 95.0 – 105.0%.

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 agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>.

Content of labeling must be identical to the enclosed labeling (text for the prescribing information, and text for the patient package insert) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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/DrugsGuidanceComplianceRegulatoryInformation/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 NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to enclosed carton and immediate container labels and carton and immediate container labels submitted on March 27, 2020, 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 NDA 210493/S-002.**” Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Grecia C. Edwards, Regulatory Business Process Manager, at (240) 402 - 1773.

Sincerely,

{See appended electronic signature page}

David Lewis, PhD.
Branch Chief, BII
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:

Content of Labeling
Carton and Container Labeling