BLA 022210/S-024 **CORRECTED SUPPLEMENT APPROVAL**

Zenpep, LLC
Attention: Vandana Garikipati, PhD
Vice President, Regulatory Affairs
8000 Marina Boulevard, Suite 300
Brisbane, CA 94005

Dear Dr. Garikipati:

Please refer to your supplemental biologics license application (sBLA), dated and received March 23, 2022, and your amendments, submitted under section 351(a) of the Public Health Service Act for Zenpep (pancrelipase) delayed-release capsules. We also refer to the approval letter dated September 28, 2022, which contained the following errors:

- Incorrect applicant name on the approval letter
- Incorrect "manufactured by" name and address in the Prescribing Information, Medication Guide, and carton and container labeling

This corrected action letter incorporates the correction of the errors. The effective action date will remain September 28, 2022, the date of the original letter.

This Prior Approval supplemental biologics application provides for revisions to the Zenpep labeling to conform to the labeling requirements for biological products regulated under section 351 of the PHS act.

APPROVAL & LABELING

We acknowledge your November 15, 2022, submission containing corrected Prescribing Information and Medication Guide.

We have completed our review of this application. It is approved, effective September 28, 2022, 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 (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 *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 [21 CFR 601.12(f)] in Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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 CONTAINER LABELING

We acknowledge your September 9, 2022, submission containing printed carton and container labeling. We also acknowledge your November 15, 2022, submission containing corrected printed carton and container labeling.

For information on FDA's compliance policy for requirements related to BLA-specific labeling revisions, see guidance for industry, *The "Deemed to be a License" Provision of the BPCI Act: Questions and Answers*.[3]

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

[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.

[3] Available at: https://www.fda.gov/media/119274/download. For the most recent version of a guidance, check the FDA Guidance Documents Database at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

Because none of these criteria apply to your application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[4]

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.[5] Information and Instructions for completing the form can be found at FDA.gov.[6]

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 Anum Shami, PharmD, Regulatory Project Manager, at 301-837-7103 or anum.shami@fda.hhs.gov

Sincerely,

{See appended electronic signature page}

Juli Tomaino, MD, MS
Deputy Director
Division of Gastroenterology
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide
- Carton and Container Labeling

[4] For the most recent version of a guidance, check the FDA guidance web page athttps://www.fda.gov/media/128163/download.
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[6] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JULI A TOMAINO
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